

2016

THE MASTER OF PHARMACY (M. PHARM.) COURSE REGULATION 2014

(BASED ON NOTIFICATION IN THE GAZETTE OF INDIA No. 362, DATED DECEMBER 11, 2014)

SCHEME AND SYLLABUS



PHARMACY COUNCIL OF INDIA

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भारत का राजपत्र The Gazette of India

असाधारण

EXTRAORDINARY

भाग III—खण्ड 4

PART III—Section 4

प्राधिकार से प्रकाशित

PUBLISHED BY AUTHORITY

सं. 362]

नई दिल्ली, बृहस्पतिवार, दिसम्बर 11, 2014/अग्रहायण 20, 1936

No. 362]

NEW DELHI, THURSDAY, DECEMBER 11, 2014/AGRAHAYANA 20, 1936

PHARMACY COUNCIL OF INDIA

NOTIFICATION

New Delhi, the 10th December, 2014

The Master of Pharmacy (M.Pharm) Course Regulations, 2014

No. 14-136/ 2014-PCI.—In exercise of the powers conferred by Sections 10 and 18 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government hereby makes the following regulations; namely—

CHAPTER – I: REGULATIONS

1. Short Title and Commencement

These regulations shall be called as “The Revised Regulations for the Master of Pharmacy (M. Pharm.) Degree Program - Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi”. They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by the authorities of the university.

2. Minimum qualification for admission

A Pass in the following examinations

- a) B. Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B.Pharm.)
- b) Every student, selected for admission to post graduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

Note: It is mandatory to submit a migration certificate obtained from the respective university where the candidate had passed his/her qualifying degree (B.Pharm.)

3. Duration of the program

The program of study for M.Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Pharmacy Council of India, New Delhi.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

Each semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from the month of December/January to May/June in every calendar year.

6. Attendance and progress

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly the credit associated with any of the other academic, co/extra-curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

7.1. Credit assignment

7.1.1. Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

7.2. Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits

are distributed semester-wise as shown in Table 14. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

8. Academic work

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective courses.

9. Course of study

The specializations in M.Pharm program is given in Table 1.

Table – 1: List of M.Pharm. Specializations and their Code

S. No.	Specialization	Code
1.	Pharmaceutics	MPH
2.	Industrial Pharmacy	MIP
3.	Pharmaceutical Chemistry	MPC
4.	Pharmaceutical Analysis	MPA
5.	Pharmaceutical Quality Assurance	MQA
6.	Pharmaceutical Regulatory Affairs	MRA
7.	Pharmaceutical Biotechnology	MPB
8.	Pharmacy Practice	MPP
9.	Pharmacology	MPL
10.	Pharmacognosy	MPG

The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Table – 2 to 11. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table – 2 to 11.

Table – 2: Course of study for M. Pharm. (Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./week	Marks
Semester I					
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH102T	Drug Delivery System	4	4	4	100
MPH103T	Modern Pharmaceutics	4	4	4	100
MPH104T	Regulatory Affair	4	4	4	100
MPH105P	Pharmaceutics Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH203T	Computer Aided Drug Delivery System	4	4	4	100
MPH204T	Cosmetic and Cosmeceuticals	4	4	4	100
MPH205P	Pharmaceutics Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 3: Course of study for M. Pharm. (Industrial Pharmacy)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MIP101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MIP102T	Pharmaceutical Formulation Development	4	4	4	100
MIP103T	Novel drug delivery systems	4	4	4	100
MIP104T	Intellectual Property Rights	4	4	4	100
MIP105P	Industrial Pharmacy Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MIP201T	Advanced Biopharmaceutics and Pharmacokinetics	4	4	4	100
MIP202T	Scale up and Technology Transfer	4	4	4	100
MIP203T	Pharmaceutical Production Technology	4	4	4	100
MIP204T	Entrepreneurship Management	4	4	4	100
MIP205P	Industrial Pharmacy Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 4: Course of study for M. Pharm. (Pharmaceutical Chemistry)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPC101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPC1012T	Advanced Organic Chemistry -I	4	4	4	100
MPC103T	Advanced Medicinal chemistry	4	4	4	100
MPC104T	Chemistry of Natural Products	4	4	4	100
MPC105P	Pharmaceutical Chemistry Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPC201T	Advanced Spectral Analysis	4	4	4	100
MPC202T	Advanced Organic Chemistry -II	4	4	4	100
MPC203T	Computer Aided Drug Design	4	4	4	100
MPC204T	Pharmaceutical Process Chemistry	4	4	4	100
MPC205P	Pharmaceutical Chemistry Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 5: Course of study for M. Pharm. (Pharmaceutical Analysis)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPA102T	Advanced Pharmaceutical Analysis	4	4	4	100
MPA103T	Pharmaceutical Validation	4	4	4	100
MPA104T	Food Analysis	4	4	4	100
MPA105P	Pharmaceutical Analysis Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPA201T	Advanced Instrumental Analysis	4	4	4	100
MPA202T	Modern Bio-Analytical Techniques	4	4	4	100
MPA203T	Quality Control and Quality Assurance	4	4	4	100
MPA204T	Herbal and Cosmetic Analysis	4	4	4	100
MPA205P	Pharmaceutical Analysis Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 6: Course of study for M. Pharm. (Pharmaceutical Quality Assurance)

Course Code	Course	Credit Hours	Credit Points	Hrs./week	Marks
Semester I					
MQA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MQA102T	Quality Management System	4	4	4	100
MQA103T	Quality Control and Quality Assurance	4	4	4	100
MQA104T	Product Development and Technology Transfer	4	4	4	100
MQA105P	Pharmaceutical Quality Assurance Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MQA201T	Hazards and Safety Management	4	4	4	100
MQA202T	Pharmaceutical Validation	4	4	4	100
MQA203T	Audits and Regulatory Compliance	4	4	4	100
MQA204T	Pharmaceutical Manufacturing Technology	4	4	4	100
MQA205P	Pharmaceutical Quality Assurance Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 7: Course of study for M. Pharm. (Regulatory Affairs)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MRA 101T	Good Regulatory Practices	4	4	4	100
MRA 102T	Documentation and Regulatory Writing	4	4	4	100
MRA 103T	Clinical Research Regulations	4	4	4	100
MRA 104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights	4	4	4	100
MRA 105P	Regulatory Affairs Practical I	12	6	12	150
	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
MRA 201T	Regulatory Aspects of Drugs & Cosmetics	4	4	4	100
MRA 202T	Regulatory Aspects of Herbal & Biologicals	4	4	4	100
MRA 203T	Regulatory Aspects of Medical Devices	4	4	4	100
MRA 204T	Regulatory Aspects of Food & Nutraceuticals	4	4	4	100
MRA 205P	Regulatory Affairs Practical II	12	6	12	150
	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Table – 8: Course of study for M. Pharm. (Pharmaceutical Biotechnology)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPB 101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPB 102T	Microbial And Cellular Biology	4	4	4	100
MPB 103T	Bioprocess Engineering and Technology	4	4	4	100
MPB 104T	Advanced Pharmaceutical Biotechnology	4	4	4	100
MPB 105P	Pharmaceutical Biotechnology Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPB 201T	Proteins and protein Formulation	4	4	4	100
MPB 202T	Immunotechnology	4	4	4	100
MPB 203T	Bioinformatics and Computer Technology	4	4	4	100
MPB 204T	Biological Evaluation of Drug Therapy	4	4	4	100
MPB 205P	Pharmaceutical Biotechnology Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Table – 9: Course of study for M. Pharm. (Pharmacy Practice)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPP 101T	Clinical Pharmacy Practice	4	4	4	100
MPP 102T	Pharmacotherapeutics-I	4	4	4	100
MPP 103T	Hospital & Community Pharmacy	4	4	4	100
MPP 104T	Clinical Research	4	4	4	100
MPP 105P	Pharmacy Practice Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPP 201T	Principles of Quality Use of Medicines	4	4	4	100
MPP 102T	Pharmacotherapeutics II	4	4	4	100
MPP 203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	4	4	100
MPP 204T	Pharmacoepidemiology & Pharmacoeconomics	4	4	4	100
MPP 205P	Pharmacy Practice Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 10: Course of study for (Pharmacology)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPL 101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPL 102T	Advanced Pharmacology-I	4	4	4	100
MPL 103T	Pharmacological and Toxicological Screening Methods-I	4	4	4	100
MPL 104T	Cellular and Molecular Pharmacology	4	4	4	100
MPL 105P	Pharmacology Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPL 201T	Advanced Pharmacology II	4	4	4	100
MPL 102T	Pharmacological and Toxicological Screening Methods-II	4	4	4	100
MPL 203T	Principles of Drug Discovery	4	4	4	100
MPL 204T	Experimental Pharmacology practical- II	4	4	4	100
MPL 205P	Pharmacology Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 11: Course of study for M. Pharm. (Pharmacognosy)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPG101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPG102T	Advanced Pharmacognosy-1	4	4	4	100
MPG103T	Phytochemistry	4	4	4	100
MPG104T	Industrial Pharmacognostical Technology	4	4	4	100
MPG105P	Pharmacognosy Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPG201T	Medicinal Plant biotechnology	4	4	4	100
MPG102T	Advanced Pharmacognosy-II	4	4	4	100
MPG203T	Indian system of medicine	4	4	4	100
MPG204T	Herbal cosmetics	4	4	4	100
MPG205P	Pharmacognosy Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 12: Course of study for M. Pharm. III Semester
(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
MRM 301T	Research Methodology and Biostatistics*	4	4
-	Journal club	1	1
-	Discussion / Presentation (Proposal Presentation)	2	2
-	Research Work	28	14
Total		35	21

* Non University Exam

Table – 13: Course of study for M. Pharm. IV Semester
(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
-	Journal Club	1	1
-	Research Work	31	16
-	Discussion/Final Presentation	3	3
Total		35	20

Table – 14: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	Minimum=02 Maximum=07*
Total Credit Points	Minimum=95 Maximum=100*

*Credit Points for Co-curricular Activities

Table – 15: Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	Maximum Credit Points Eligible / Activity
Participation in National Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	01
Participation in international Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	02
Academic Award/Research Award from State Level/National Agencies	01
Academic Award/Research Award from International Agencies	02
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	01
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)	02

Note: International Conference: Held Outside India

International Journal: The Editorial Board Outside India

*The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

10. Program Committee

1. The M. Pharm. programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.
2. The composition of the Programme Committee shall be as follows:
A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M.Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.
3. Duties of the Programme Committee:
 - i. Periodically reviewing the progress of the classes.
 - ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
 - iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.

- iv. Communicating its recommendation to the Head of the institution on academic matters.
- v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessionalexam and before the end semester exam.

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table – 16.

11.1. End semester examinations

The End Semester Examinations for each theory and practical coursethrough semesters I to IVshall beconducted by the respective university except for the subject with asterix symbol (*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Tables – 16: Schemes for internal assessments and end semester examinations
(Pharmaceutics- MPH)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPH 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPH 102T	Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH 103T	Modern Pharmaceutics	10	15	1 Hr	25	75	3 Hrs	100
MPH 104T	Regulatory Affair	10	15	1 Hr	25	75	3 Hrs	100
MPH 105P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPH 201T	Molecular Pharmaceutics(Nano Tech and Targeted DDS)	10	15	1 Hr	25	75	3 Hrs	100
MPH 202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100
MPH 203T	Computer Aided Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH	Cosmetic	10	15	1 Hr	25	75	3 Hrs	100

204T	and Cosmeceutic als							
MPH 205P	Pharmaceuti cs Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 17: Schemes for internal assessments and end semester examinations
(Industrial Pharmacy- MIP)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MIP101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MIP102T	Pharmaceutical Formulation Development	10	15	1 Hr	25	75	3 Hrs	100
MIP103T	Novel drug delivery systems	10	15	1 Hr	25	75	3 Hrs	100
MIP104T	Intellectual Property Rights	10	15	1 Hr	25	75	3 Hrs	100
MIP105P	Industrial Pharmacy Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MIP201T	Advanced Biopharmaceutics and Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100
MIP202T	Scale up and Technology Transfer	10	15	1 Hr	25	75	3 Hrs	100
MIP203T	Pharmaceutical Production Technology	10	15	1 Hr	25	75	3 Hrs	100
MIP204T	Entrepreneurship Management	10	15	1 Hr	25	75	3 Hrs	100

MIP205P	Industrial Pharmacy Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 18: Schemes for internal assessments and end semester examinations
(Pharmaceutical Chemistry-MPC)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continu- ous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPC101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPC102T	Advanced Organic Chemistry -I	10	15	1 Hr	25	75	3 Hrs	100
MPC103T	Advanced Medicinal chemistry	10	15	1 Hr	25	75	3 Hrs	100
MPC104T	Chemistry of Natural Products	10	15	1 Hr	25	75	3 Hrs	100
MPC105P	Pharmaceutical Chemistry Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPC201T	Advanced Spectral Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPC202T	Advanced Organic Chemistry -II	10	15	1 Hr	25	75	3 Hrs	100
MPC203T	Computer Aided Drug Design	10	15	1 Hr	25	75	3 Hrs	100
MPC204T	Pharmaceutical Process Chemistry	10	15	1 Hr	25	75	3 Hrs	100
MPC205P	Pharmaceutic	20	30	6 Hrs	50	100	6	150

	al Chemistry Practical II						Hrs	
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 19: Schemes for internal assessments and end semester examinations
(Pharmaceutical Analysis-MPA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continu- ous Mode	Sessional Exams		Tot al	Mark s	Dura- tion	
			Mark s	Durati- on				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA102T	Advanced Pharmaceutical Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA103T	Pharmaceuti- cal Validation	10	15	1 Hr	25	75	3 Hrs	100
MPA104T	Food Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA105P	Pharmaceuti- cal Analysis-I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPA201T	Advanced Instrumental Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA202T	Modern Bio- Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPA203T	Quality Control and Quality	10	15	1 Hr	25	75	3 Hrs	100

	Assurance							
MPA204T	Herbal and Cosmetic analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA205P	Pharmaceuti cal Analysis- II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 20: Schemes for internal assessments and end semester examinations
(Pharmaceutical Quality Assurance-MQA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MQA1 01T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MQA1 02T	Quality Management System	10	15	1 Hr	25	75	3 Hrs	100
MQA1 03T	Quality Control and Quality Assurance	10	15	1 Hr	25	75	3 Hrs	100
MQA1 04T	Product Development and Technology Transfer	10	15	1 Hr	25	75	3 Hrs	100
MQA1 05P	Pharmaceutical Quality Assurance Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MQA2 01T	Hazards and Safety Management	10	15	1 Hr	25	75	3 Hrs	100
MQA2 02T	Pharmaceutical Validation	10	15	1 Hr	25	75	3 Hrs	100
MQA2 03T	Audits and Regulatory Compliance	10	15	1 Hr	25	75	3 Hrs	100
MQA2 04T	Pharmaceutical Manufacturing Technology	10	15	1 Hr	25	75	3 Hrs	100
MQA2 05P	Pharmaceutical Quality Assurance Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 21: Schemes for internal assessments and end semester examinations
(Pharmaceutical Regulatory Affairs-MRA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuo us Mod e	Sessional Exams		Tot al	Mar ks	Dura tion	
			Mar ks	Durati on				
SEMESTER I								
MRA10 1T	Good Pharmaceutical Practices	10	15	1 Hr	25	75	3 Hrs	100
MRA10 2T	Documentation and Regulatory Writing	10	15	1 Hr	25	75	3 Hrs	100
MRA10 3T	Clinical Research Regulations	10	15	1 Hr	25	75	3 Hrs	100
MRA10 4T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights	10	15	1 Hr	25	75	3 Hrs	100
MRA10 5T	Pharmaceutical Regulatory Affairs Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MRA20 1T	Regulatory Aspects of Drugs & Cosmetics	10	15	1 Hr	25	75	3 Hrs	100

MRA20 2T	Regulatory Aspects of Herbal & Biologicals	10	15	1 Hr	25	75	3 Hrs	100
MRA20 3T	Regulatory Aspects of Medical Devices	10	15	1 Hr	25	75	3 Hrs	100
MRA20 4T	Regulatory Aspects of Food & Nutraceuticals	10	15	1 Hr	25	75	3 Hrs	100
MRA20 5P	Pharmaceutical Regulatory Affairs Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 22: Schemes for internal assessments and end semester examinations
(Pharmaceutical Biotechnology-MPB)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPB10 1T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPB10 2T	Microbial And Cellular Biology	10	15	1 Hr	25	75	3 Hrs	100
MPB10 3T	Bioprocess Engineering and Technology	10	15	1 Hr	25	75	3 Hrs	100
MPB10 4T	Advanced Pharmaceutical Biotechnology	10	15	1 Hr	25	75	3 Hrs	100
MPB10 5P	Pharmaceutical Biotechnology Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPB20 1T	Proteins and protein Formulation	10	15	1 Hr	25	75	3 Hrs	100
MPB20 2T	Immunotechnology	10	15	1 Hr	25	75	3 Hrs	100
MPB20 3T	Bioinformatics and Computer Technology	10	15	1 Hr	25	75	3 Hrs	100
MPB20 4T	Biological Evaluation of Drug Therapy	10	15	1 Hr	25	75	3 Hrs	100
MPB20 5P	Pharmaceutical Biotechnology Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 23: Schemes for internal assessments and end semester examinations
(Pharmacy Practice-MPP)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPP10 1T	Clinical Pharmacy Practice	10	15	1 Hr	25	75	3 Hrs	100
MPP10 2T	Pharmacotherapeutics-I	10	15	1 Hr	25	75	3 Hrs	100
MPP10 3T	Hospital & Community Pharmacy	10	15	1 Hr	25	75	3 Hrs	100
MPP10 4T	Clinical Research	10	15	1 Hr	25	75	3 Hrs	100
MPP10 5P	Pharmacy Practice Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPP20 1T	Principles of Quality Use of Medicines	10	15	1 Hr	25	75	3 Hrs	100
MPP10 2T	Pharmacotherapeutics II	10	15	1 Hr	25	75	3 Hrs	100
MPP20 3T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	10	15	1 Hr	25	75	3 Hrs	100
MPP20 4T	Pharmacoepidemiology & Pharmacoeconomics	10	15	1 Hr	25	75	3 Hrs	100
MPP20 5P	Pharmacy Practice Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 24: Schemes for internal assessments and end semester examinations
(Pharmacology-MPL)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPL10 1T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPL10 2T	Advanced Pharmacology-I	10	15	1 Hr	25	75	3 Hrs	100
MPL10 3T	Pharmacological and Toxicological Screening Methods-I	10	15	1 Hr	25	75	3 Hrs	100
MPL10 4T	Cellular and Molecular Pharmacology	10	15	1 Hr	25	75	3 Hrs	100
MPL10 5P	Experimental Pharmacology - I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPL20 1T	Advanced Pharmacology II	10	15	1 Hr	25	75	3 Hrs	100
MPL10 2T	Pharmacological and Toxicological Screening Methods-II	10	15	1 Hr	25	75	3 Hrs	100
MPL20 3T	Principles of Drug Discovery	10	15	1 Hr	25	75	3 Hrs	100
MPL20 4T	Clinical research and pharmacovigilance	10	15	1 Hr	25	75	3 Hrs	100
MPL20 5P	Experimental Pharmacology - II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 25: Schemes for internal assessments and end semester examinations
(Pharmacognosy-MPG)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPG10 1T	Modern Pharmaceutics I Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPG10 2T	Advanced Pharmacognosy-I	10	15	1 Hr	25	75	3 Hrs	100
MPG10 3T	Phytochemistry	10	15	1 Hr	25	75	3 Hrs	100
MPG10 4T	Industrial Pharmacognostical Technology	10	15	1 Hr	25	75	3 Hrs	100
MPG10 5P	Pharmacognosy Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPG20 1T	Medicinal Plant biotechnology	10	15	1 Hr	25	75	3 Hrs	100
MPG10 2T	Advanced Pharmacognosy-II	10	15	1 Hr	25	75	3 Hrs	100
MPG20 3T	Indian system of medicine	10	15	1 Hr	25	75	3 Hrs	100
MPG20 4T	Herbal cosmetics	10	15	1 Hr	25	75	3 Hrs	100
MPG20 5P	Pharmacognosy Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 26: Schemes for internal assessments and end semester examinations
(Semester III& IV)

Course Code	Course	Internal Assessment			End Semester Exams			Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
MRM301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
-	Research work*	-	-	-	-	350	1 Hr	350
Total								525
SEMESTER IV								
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75
-	Research work and Colloquium	-	-	-	-	400	1 Hr	400
Total								500

***Non University Examination**

11.2. Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table – 27: Scheme for awarding internal assessment: Continuous mode

Theory	
Criteria	Maximum Marks
Attendance (Refer Table – 28)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – 28)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

Table – 28: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95 – 100	8	10
90 – 94	6	7.5
85 – 89	4	5
80 – 84	2	2.5
Less than 80	0	0

11.2.1. Sessional Exams

Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical sessional examinations is given in the table. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables.

12. Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of M.Pharm. programme if he/she secures at least 50% marks in that particular course including internal assessment.

13. Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 12, then he/she shall reappear for the end semester examination of that course. However his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

14. Improvement of internal assessment

A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end semester theory examinations.

15. Reexamination of end semester examinations

Reexamination of end semester examination shall be conducted as per the schedule given in table 29. The exact dates of examinations shall be notified from time to time.

Table – 29: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I and III	November / December	May / June
II and IV	May / June	November / December

16. Allowed to keep terms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in 6. ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I and II semesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

17. Grading of performances

17.1. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – 30.

**Table – 30: Letter grades and grade points equivalent to
Percentage of marks and performances**

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

18. The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C₁, C₂, C₃ and C₄ and the student's grade points in these courses are G₁, G₂, G₃ and G₄, respectively, and then students' SGPA is equal to:

$$\text{SGPA} = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4}{C_1 + C_2 + C_3 + C_4}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and ABS grade awarded in that semester. For example if a learner has a F or ABS grade in course 4, the SGPA shall then be computed as:

$$\text{SGPA} = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4 \text{ ZERO}}{C_1 + C_2 + C_3 + C_4}$$

19. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA

shall only reflect the new grade and not the fail grades earned earlier. The CGPA is calculated as:

$$\text{CGPA} = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4}{C_1 + C_2 + C_3 + C_4}$$

where $C_1, C_2, C_3, \dots$ is the total number of credits for semester I, II, III, ... and $S_1, S_2, S_3, \dots$ is the SGPA of semester I, II, III, ...

20. Declaration of class

The class shall be awarded on the basis of CGPA as follows:

First Class with Distinction	= CGPA of 7.50 and above
First Class	= CGPA of 6.00 to 7.49
Second Class	= CGPA of 5.00 to 5.99

21. Project work

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

Objective(s) of the work done	50 Marks
Methodology adopted	150 Marks
Results and Discussions	250 Marks
Conclusions and Outcomes	50 Marks
Total	500 Marks

Evaluation of Presentation:

Presentation of work	100 Marks
Communication skills	50 Marks
Question and answer skills	100 Marks
Total	250 Marks

22. Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the M.Pharm program shall not be eligible for award of ranks. Moreover, the candidates should have completed the M. Pharm program in minimum prescribed number of years, (two years) for the award of Ranks.

23. Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

24. Duration for completion of the program of study

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

25. Revaluation / Retotaling of answer papers

There is no provision for revaluation of the answer papers in any examination. However, the candidates can apply for retotaling by paying prescribed fee.

26. Re-admission after break of study

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying a condonation fee.

PHARMACEUTICS (MPH)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY

60 HOURS

1. a. **UV-Visible spectroscopy:** Introduction, Theory, Laws, 11
Instrumentation associated with UV-Visible spectroscopy, Hrs
Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.
- b. **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy
- c. **Spectrofluorimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
- d. **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.
2. **NMR spectroscopy:** Quantum numbers and their role in NMR, 11
Principle, Instrumentation, Solvent requirement in NMR, Hrs
Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy.

3	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy	11 Hrs
4	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography	11 Hrs
5	a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	11 Hrs
6	Immunological assays : RIA (Radio immuno assay), ELISA, Bioluminescence assays.	5 Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

DRUG DELIVERY SYSTEMS (MPH 102T)

SCOPE

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

OBJECTIVES

Upon completion of the course, student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of delivering system
- The formulation and evaluation of Novel drug delivery systems..

THEORY

60 Hrs

1.	Sustained Release(SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.	10 Hrs
2	Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.	10 Hrs
3	Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.	10 Hrs
4	Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.	06 Hrs

5	Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.	10 Hrs
6	Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	08 Hrs
7	Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	06 Hrs

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

JOURNALS

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

MODERN PHARMACEUTICS (MPH 103T)

Scope

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

Objectives

Upon completion of the course, student shall be able to understand

- The elements of preformulation studies.
- The Active Pharmaceutical Ingredients and Generic drug Product development
- Industrial Management and GMP Considerations.
- Optimization Techniques & Pilot Plant Scale Up Techniques
- Stability Testing, sterilization process & packaging of dosage forms.

THEORY

60 HRS

1. a. **Preformation Concepts** – Drug Excipient interactions - 10 Hrs
different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.
- b. **Optimization techniques in Pharmaceutical Formulation:** 10 Hrs
Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation
2. **Validation** : Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities. 10 Hrs
3. **cGMP & Industrial Management:** Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management. 10 Hrs

- 4 **Compression and compaction:** Physics of tablet compression, 10
compression, consolidation, effect of friction, distribution of Hrs
forces, compaction profiles. Solubility.
- 5 **Study of consolidation parameters;** Diffusion parameters, 10
Dissolution parameters and Pharmacokinetic parameters, Heckel Hrs
plots, Similarity factors – f_2 and f_1 , Higuchi and Peppas plot,
Linearity Concept of significance, Standard deviation , Chi square
test, students T-test , ANOVA test.

REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H. Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P. Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.

REGULATORY AFFAIRS (MPH 104T)

Scope

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents : filing process of IND, NDA and ANDA

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance and

Objectives:

Upon completion of the course, it is expected that the students will be able to understand

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilance and process of monitoring in clinical trials.

THEORY

60 Hrs

1. a. **Documentation in Pharmaceutical industry:** Master formula record, DMF (Drug Master File), distribution records. 12 Hrs
Generic drugs product development Introduction , Hatch-Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.
- b. **Regulatory requirement for product approval:** API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs

2	CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.	12 Hrs
3	Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	12 Hrs
4	Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.	12 Hrs

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. <https://www.tga.gov.au/tga-basics>

PHARMACEUTICS PRACTICALS - I

(MPH 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. To perform *In-vitro* dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Muco adhesive tablets.
12. Formulation and evaluation of trans dermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS) (MPH 201T)

Scope

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Objectives

Upon completion of the course student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of NTDS
- The formulation and evaluation of novel drug delivery systems.

THEORY

60 Hrs

1.	Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.	12 Hrs
2	Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.	12 Hrs
3	Micro Capsules / Micro Spheres: Types, preparation and evaluation , Monoclonal Antibodies ; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.	12 Hrs
4	Pulmonary Drug Delivery Systems : Aerosols, propellents, ContainersTypes, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.	12 Hrs
5	Nucleic acid based therapeutic delivery system : Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future.	12 Hrs

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, VallabhPrakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 2001).

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 202T)

Scope

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

Objectives

Upon completion of this course it is expected that students will be able understand,

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

THEORY

60 Hrs

1. **Drug Absorption from the Gastrointestinal Tract:** 12 Hrs
Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH-partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.

- 2 **Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance:** Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, *in vitro*: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. *In vitro–in vivo* correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product. 12 Hrs

- 3 **Pharmacokinetics:** Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of k_{max} and v_{max} . Drug interactions: introduction, the effect of protein-binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters. 12 Hrs

- 4 **Drug Product Performance, In Vivo: Bioavailability and Bioequivalence:** drug product performance, purpose of bioavailability studies, relative and absolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution. 12 Hrs

- 5 **Application of Pharmacokinetics:** Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies. 12 Hrs

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmarkar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thomas N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pamarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics, 1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.

COMPUTER AIDED DRUG DEVELOPMENT (MPH 203T)

Scope

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

Objectives

Upon completion of this course it is expected that students will be able to understand,

- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition
- Computers in Preclinical Development
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics(CFD)

THEORY

60 Hrs

1.	a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling b. Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.	12 Hrs
2	Computational Modeling Of Drug Disposition: Introduction ,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.	12 Hrs

- 3 **Computer-aided formulation development::** Concept of 12
optimization, Optimization parameters, Factorial design, Hrs
Optimization technology & Screening design. Computers in
Pharmaceutical Formulation: Development of pharmaceutical
emulsions, microemulsion drug carriers Legal Protection of
Innovative Uses of Computers in R&D, The Ethics of Computing
in Pharmaceutical Research, Computers in Market analysis
- 4 a. **Computer-aided biopharmaceutical characterization:** 12
Gastrointestinal absorption simulation. Introduction, Theoretical Hrs
background, Model construction, Parameter sensitivity analysis,
Virtual trial, Fed vs. fasted state, In vitro dissolution and *in vitro*-
in vivo correlation, Biowaiver considerations
b. **Computer Simulations in Pharmacokinetics and**
Pharmacodynamics: Introduction, Computer Simulation: Whole
Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.
c. **Computers in Clinical Development:** Clinical Data Collection
and Management, Regulation of Computer Systems
- 5 **Artificial Intelligence (AI), Robotics and Computational fluid** 12
dynamics: General overview, Pharmaceutical Automation, Hrs
Pharmaceutical applications, Advantages and Disadvantages.
Current Challenges and Future Directions.

REFERENCES

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

COSMETICS AND COSMECEUTICALS (MPH 204T)

Scope

This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.

Objectives

Upon completion of the course, the students shall be able to understand

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

THEORY

60 Hrs

1. **Cosmetics – Regulatory** : Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics., Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties. 12 Hrs
2. **Cosmetics - Biological aspects** : Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm. 12 Hrs
3. **Formulation Building blocks**: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars. 12 Hrs
Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.

- Controversial ingredients:** Parabens, formaldehyde liberators, dioxane.
- 4 **Design of cosmeceutical products:** Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations. 12 Hrs
- 5 **Herbal Cosmetics :** Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics. 12 Hrs

REFERENCES

1. Harry's Cosmeticology. 8th edition.
2. Poucher'sperfumecosmeticsandSoaps,10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3rd edition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.

PHARMACEUTICS PRACTICALS - II

(MPH 205P)

1. To study the effect of temperature change , non solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by Winnoline[®] software
11. *In vitro* cell studies for permeability and metabolism
12. DoE Using Design Expert[®] Software
13. Formulation data analysis Using Design Expert[®] Software
14. Quality-by-Design in Pharmaceutical Development
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Computational Modeling Of Drug Disposition
17. To develop Clinical Data Collection manual
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpaste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

INDUSTRIAL PHARMACY (MIP)
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(MIP 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know,

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY

60 HOURS

1. **UV-Visible spectroscopy:** Introduction, Theory, Laws, 11 Hrs
Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.

IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy

Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

2. **NMR spectroscopy:** Quantum numbers and their role in NMR, 11 Hrs
Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy.

- 3 **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy 11 Hrs

- 4 **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: 11 Hrs
 - a) Paper chromatography b) Thin Layer chromatography
 - c) Ion exchange chromatography d) Column chromatography
 - e) Gas chromatography f) High Performance Liquid chromatography
 - g) Affinity chromatography

- 5 **Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: 11 Hrs
 - a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

- X ray Crystallography:** Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

6. **Immunological Assays:** Radioimmunity assay (RIA), ELISA (Theory & practical) and knowledge on Bioluminescence assays. 5 Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

PHARMACEUTICAL FORMULATION DEVELOPMENT (MIP 102T)

Scope

This course is designed to impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D.

Objectives

On completion of this course it is expected that students will be able to understand-

- *The scheduled activities in a Pharmaceutical firm.*
- *The pre formulation studies of pilot batches of pharmaceutical industry.*
- *The significance of dissolution and product stability*

THEORY

60 Hrs

1. **Preformulation Studies:** Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination. 12 Hrs
2. **Formulation Additives:** Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. Design of experiments – factorial design for product and process development. 12 Hrs
3. **Solubility:** Importance, experimental determination, phase-solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy. 12 Hrs
4. **Dissolution:** Theories, mechanisms of dissolution, *in-vitro* dissolution testing models – sink and non-sink. Factors influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Biorelevant media, *in-vitro* and *in-vivo* correlations, levels of correlations. 12 Hrs

- 5 **Product Stability:** Degradation kinetics, mechanisms, stability 12
 testing of drugs and pharmaceuticals, factors influencing-media Hrs
 effects and pH effects, accelerated stability studies, interpretation
 of kinetic data (API & tablets). Solid state stability and shelf life
 assignment. Stability protocols, reports and ICH guidelines.

REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice Of Industrial Pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Connors KA. A Text book of pharmaceutical analysis Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
5. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. Marcel Dekker Inc., New York, 1981
6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer Pvt. Ltd., New Delhi, 2005.
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3rd ed., CBS publications, New Delhi, 2008.
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3rd ed., CBS Publishers & distributors, New Delhi, 2005.
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
11. W. Grimm - Stability testing of drug products.
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999.
13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I & II., 4th ed., CBS Publishers & distributors, New Delhi, 2004.
14. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
15. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
16. United States Pharmacopoeia. United States Pharmacopoeial Convention, Inc, USA, 2003.
17. Encyclopaedia of Pharm. Technology, Vol I – III.
18. Wells J. I. Pharmaceutical Preformulation : The physicochemical properties of drug substances, Ellis Horwood Ltd. England, 1988.

NOVEL DRUG DELIVERY SYSTEMS (MIP 103T)

Scope

This course is designed to impart knowledge and skills necessary to train the students in the area of novel drug delivery systems.

Objective

On completion of this course it is expected that students will be able to understand,

- The need, concept, design and evaluation of various customized, sustained and controlled release dosage forms.
- To formulate and evaluate various novel drug delivery systems

THEORY

60 Hrs

1.	Concept & Models for NDDS: Classification of rate controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release.	12 Hrs
Carriers for Drug Delivery: Polymers / co-polymers-introduction, classification, characterization, polymerization techniques, application in CDDS / NDDS, biodegradable & natural polymers.		
2	Study of Various DDS: Concepts, design, formulation & evaluation of controlled release oral DDS, Mucoadhesive DDS (buccal, nasal, pulmonary) Pulsatile, colon specific, liquid sustained release systems, Ocular delivery systems	12 Hrs
3	Transdermal Drug Delivery Systems: Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems.	08 Hrs
4	Sub Micron Cosmeceuticals: Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, eye etc and it's regulatory aspects.	04 Hrs

- 5 **Targeted Drug Delivery Systems:** Importance, concept, 12
biological process and events involved in drug targeting, design, Hrs
formulation & evaluation, methods in drug targeting –
nanoparticles, liposomes, niosomes, pharmacosomes, resealed
erythrocytes, microspheres, magnetic microspheres. Specialized
pharmaceutical emulsions – multiple emulsions, micro-emulsions.

- 6 **Protein / Peptide Drug Delivery Systems:** Concepts, delivery
techniques, formulation, stability testing, causes of protein
destabilization, stabilization methods.

- 7 **Biotechnology in Drug Delivery Systems:** Brief review of 06
major areas-recombinant DNA technology, monoclonal Hrs
antibodies, gene therapy.

- 8 **New trends for Personalized Medicine:** Introduction, Definition, 06
Pharmacogenetics, Categories of Patients for Personalized Hrs
Medicines: Customized drug delivery systems, Bioelectronic
Medicines, 3D printing of pharmaceuticals, Telepharmacy.

REFERENCES

1. Novel Drug Delivery System, Y.W. Chein, Vol 50, Marcel Dekker, NY.
2. Controlled Drug Delivery Systems, Robinson, Vol 29, Marcel Dekker, NY.
3. Transdermal Controlled Systemic Medications, YW Chein, Vol 31, Marcel Dekker, NY.
4. Bioadhesive DDS, E. Mathiowitz, Vol 98, Marcel Dekker, NY.
5. Nasal System Drug Delivery, K.S.E. Su, Vol 39, Marcel Dekker, NY.
6. Drug Delivery Devices, Vol 32, P Tyle Marcel Dekker, NY.
7. Polymers for Controlled Drug Delivery, P.J. Tarcha, CRC Press.
8. Pharmaceutical Biotechnology, Vyas, CBS, Delhi.
9. Biotechnology of Industrial Antibiotics, E.J. Vandamme, Marcel Dekker, NY.
10. Protein Formulation & Delivery, E.J. McNally, Vol 99, Marcel Dekker, NY.
11. Drug Targeting, M.H. Rubinstein, John Wiley, NY.

INTELLECTUAL PROPERTY RIGHTS (MIP 104T)

Scope

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in drug regulatory affairs

Objectives

On completion of this course it is expected that students will be able to understand,

- Assist in Regulatory Audit process.
- Establish regulatory guidelines for drug and drug products
- The Regulatory requirements for contract research organization

THEORY

60 Hrs

1.	Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filling of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in Patent.	12 Hrs
2	Role of GATT, TRIPS, and WIPO	12 Hrs
3	Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating Indian Pharmaceutical sector.	12 Hrs
4	Brief introduction to CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA	12 Hrs
5	Regulatory requirements for contract research organization. Regulations for Biosimilars.	12 Hrs

REFERENCES :

1. Pharmaceutical Process Validation: By Fra R. Berry and Robert A. Nash, Vol 57, 2nd Edition
2. Applied Production and Operation Management By Evans, Anderson and Williams
3. GMP for pharmaceuticals Material Management by K.K. Ahuja Published by CBS publishers
4. ISO 9000-Norms and explanations
5. GMP for pharmaceuticals- Willing S.H. Marcel and Dekker

INDUSTRIAL PHARMACY PRACTICAL - I

(MIP 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC / GC
4. Estimation of riboflavin/quinine sulphate by fluorimetry
5. Estimation of sodium/potassium by flame photometry
6. Effect of surfactants on the solubility of drugs.
7. Effect of pH on the solubility of drugs.
8. Stability testing of solution and solid dosage forms for photo degradation..
9. Stability studies of drugs in dosage forms at 25 °C, 60% RH and 40 °C, 75% RH.
10. Compatibility evaluation of drugs and excipients (DSC & FTIR).
11. Preparation and evaluation of different polymeric membranes.
12. Formulation and evaluation of sustained release oral matrix tablet/ oral reservoir system.
13. Formulation and evaluation of microspheres / microcapsules.
14. Formulation and evaluation of transdermal drug delivery systems.
15. Design and evaluation of face wash, body- wash, creams, lotions, shampoo, toothpaste, lipstick.
16. Electrophoresis of protein solution.
17. Preparation and evaluation of Liposome delivery system.

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MIP 201T)

Scope

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply Biopharmaceutics theories in practical problem solving.

Objectives

On completion of this course it is expected that students will be able to understand,

- The basic concepts in Biopharmaceutics and pharmacokinetics.
- The use of raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- To critically evaluate Biopharmaceutics studies involving drug product equivalency.
- To design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

THEORY

60 Hrs

- 1. Drug Absorption From The Gastrointestinal Tract:** 12 Hrs
Gastrointestinal tract, Mechanism of drug absorption, Factors affecting, pH-partition theory, Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.
- 2 Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance:** 12 Hrs
Introduction, Biopharmaceutic Factors Affecting Drug Bioavailability, Rate-Limiting Steps in Drug Absorption, Physicochemical Nature of the

- Drug Formulation Factors Affecting Drug Product Performance, *In Vitro*: Dissolution and Drug Release Testing, Compendial Methods of Dissolution, Alternative Methods of Dissolution Testing, Meeting Dissolution Requirements, Problems of Variable Control in Dissolution Testing Performance of Drug Products: *In Vitro–In Vivo* Correlation, Dissolution Profile Comparisons, Drug Product Stability, Considerations in the Design of a Drug Product.
- 3 **Pharmacokinetics:** Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model- IV bolus, IV infusion, Extra-vascular; Multi Compartment model: Two compartment - model in brief, Non-Linear Pharmacokinetics: Cause of non-linearity, Michaelis – Menten equation, Estimation K_{max} and V_{max}. Drug interactions: Introduction, The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. 12 Hrs

 - 4 **Drug Product Performance, In Vivo: Bioavailability and Bioequivalence:** Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability, , Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Evaluation of the Data, Bioequivalence Example, Study Submission and Drug Review Process, The Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution. 12 Hrs

 - 5 **Application of Pharmacokinetics:** Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Relationship between Pharmacokinetics including Pharmacodynamics: Generation of a pharmacokinetic–pharmacodynamic (PKPD) equation, Pharmacokinetic and pharmacodynamic, interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs: Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies. 12 Hrs

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmarkar and Sunil B.J aishwal., Vallab Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics, 1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.

SCALE UP AND TECHNOLOGY TRANSFER (MIP 202T)

Scope

This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

Objectives:

On completion of this course it is expected that students will be able to understand,

- Manage the scale up process in pharmaceutical industry.
- Assist in technology transfer.
- To establish safety guidelines, which prevent industrial hazards.

THEORY

60 Hrs

1. **Pilot plant design:** Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parentral and semisolid preparations. 12 Hrs
- Scale up:** Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parentral, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology
- 2 **Validation:** General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vendor qualification. 12 Hrs
- 3 **Equipment Qualification:** Importance, IQ, OQ, PQ for equipments – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine. Aseptic room validation. 12 Hrs
- 4 **Process validation:** Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control. 12 Hrs

- 5 **Industrial safety:** Hazards – fire, mechanical, electrical, 12 chemical and pharmaceutical, Monitoring & prevention systems, Hrs industrial effluent testing & treatment. Control of environmental pollution.

REFERENCES

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T.Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L.Lachman, H.A.Lieberman, Varghese Publ. Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parenteral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan,Dehli.

PHARMACEUTICAL PRODUCTION TECHNOLOGY (MIP 203T)

Scope

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in Production

Objectives

On completion of this course it is expected that students will be able to understand,

- Handle the scheduled activities in a Pharmaceutical firm.
- Manage the production of large batches of pharmaceutical formulations.

THEORY

60 Hrs

	Improved Tablet Production: Tablet production process, unit operation improvements, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.	12 Hrs
1.		
	Coating Technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.	
2	Parenteral Production: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.	12 Hrs
3	Lyophilization & Spray drying Technology: Principles, process, freeze-drying and spray drying equipments.	12 Hrs
4	Capsule Production: Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered. Disperse Systems Production: Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion, problems encountered.	12 Hrs

Packaging Technology: Types of packaging materials, machinery, labeling, package printing for different dosage forms.

- 5 **Air Handling Systems:** Study of AHUs, humidity & temperature control, air filtration systems, dust collectors. **Water Treatment Process:** Techniques and maintenance – RO, DM, ultra – filtration, WFI. 12 Hrs

REFERENCES

1. The Theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publ, Bombay.
2. Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.
3. Pharmaceutical Dosage Forms, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
4. Pharmaceutical Dosage Forms, Parenteral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
5. Pharmaceutical Production Facilities, design and applications, by G.C. Cole, Taylor and Francis.
6. Dispersed System Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Product design and testing of polymeric materials by N.P. Cheremisinoff.
8. Pharmaceutical Project Management, T.Kennedy, Vol 86, Marcel Dekker, NY.
9. Packaging Pharmaceutical and Health Care, H.Lockhard.
10. Quality Control of Packaging Materials in Pharmaceutical Industry, .Kharburn, Marcel Dekker, NY.
11. Freeze drying / Lyophilization of Pharmaceuticals & Biological Products, L. Ray, Vol 96, Marcel Dekker, NY.
12. Tablet Machine Instrumentation In Pharmaceuticals, PR Watt, Ellis Horwoods, UK.

ENTREPRENEURSHIP MANAGEMENT (MIP 204T)

Scope

This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

Objectives:

On completion of this course it is expected that students will be able to understand,

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies And Networking

THEORY

60 Hrs

1.	Conceptual Frame Work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management.	12 Hrs
2	Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency –Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.	12 Hrs
3	Launching And Organising An Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilisation - finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.	12 Hrs
4	Growth Strategies And Networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study.	12 Hrs

5	Preparing Project Proposal To Start On New Enterprise	12
	Project work – Feasibility report; Planning, resource mobilisation and implementation.	Hrs

REFERENCES

1. Akhauri, M.M.P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R.D & Brush, C.G.(1996) The Women Entrepreneurs, D.C. Health & Co., Toronto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.

INDUSTRIAL PHARMACY PRACTICAL - II

(MIP 205P)

1. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
2. Comparison of dissolution of two different marketed products /brands
3. Protein binding studies of a highly protein bound drug & poorly protein bound drug
4. Bioavailability studies of Paracetamol (Animal).
5. Pharmacokinetic and IVIVC data analysis by WinnolineR software
6. In vitro cell studies for permeability and metabolism
7. Formulation and evaluation of tablets
8. Formulation and evaluation of capsules
9. Formulation and evaluation of injections
10. Formulation and evaluation of emulsion
11. Formulation and evaluation of suspension.
12. Formulation and evaluation of enteric coating tablets.
13. Preparation and evaluation of a freeze dried formulation.
14. Preparation and evaluation of a spray dried formulation.

PHARMACEUTICAL CHEMISTRY (MPC)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPC 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know about chemicals and excipients

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY

60 Hrs

1. a. **UV-Visible spectroscopy:** Introduction, Theory, Laws, 10
Instrumentation associated with UV-Visible spectroscopy, Choice Hrs
of solvents and solvent effect and Applications of UV-Visible
spectroscopy, Difference/ Derivative spectroscopy.
b. **IR spectroscopy:** Theory, Modes of Molecular vibrations,
Sample handling, Instrumentation of Dispersive and Fourier -
Transform IR Spectrometer, Factors affecting vibrational
frequencies and Applications of IR spectroscopy, Data
Interpretation.
c. **Spectrofluorimetry:** Theory of Fluorescence, Factors affecting
fluorescence (Characteristics of drugs that can be analysed by
fluorimetry), Quenchers, Instrumentation and Applications of
fluorescence spectrophotometer.
d. **Flame emission spectroscopy and Atomic absorption
spectroscopy:** Principle, Instrumentation, Interferences and
Applications.
2. **NMR spectroscopy:** Quantum numbers and their role in NMR, 10
Principle, Instrumentation, Solvent requirement in NMR, Hrs
Relaxation process, NMR signals in various compounds,
Chemical shift, Factors influencing chemical shift, Spin-Spin
coupling, Coupling constant, Nuclear magnetic double resonance,
Brief outline of principles of FT-NMR and ¹³C NMR. Applications
of NMR spectroscopy.

3	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	10 Hrs
4	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a) Thin Layer chromatography b) High Performance Thin Layer Chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Ultra High Performance Liquid chromatography h) Affinity chromatography i) Gel Chromatography	10 Hrs
5	a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	10 Hrs
6	a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation	10 Hrs

and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

ADVANCED ORGANIC CHEMISTRY - I (MPC 102T)

Scope

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Objectives

Upon completion of course, the student shall be to understand

- The principles and applications of retrosynthesis
- The mechanism & applications of various named reactions
- The concept of disconnection to develop synthetic routes for small target molecule.
- The various catalysts used in organic reactions
- The chemistry of heterocyclic compounds

THEORY

60 Hrs

1. Basic Aspects of Organic Chemistry:

12

1. Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications.
2. Types of reaction mechanisms and methods of determining them,
3. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations.

Hrs

Addition reactions

- a) Nucleophilic uni- and bimolecular reactions (SN1 and SN2)
- b) Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule)
- c) Rearrangement reaction

2 Study of mechanism and synthetic applications of following named Reactions:

12

Hrs

Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner-Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeier-Haack Reaction, Sharpless asymmetric epoxidation, Baeyer-Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction

- 3 **Synthetic Reagents & Applications:** 12 Hrs
 Aluminiumisopropoxide, N-bromosuccinamide, diazomethane, dicyclohexylcarbodiimide, Wilkinson reagent, Witting reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, Triphenylphosphine, Benzotriazol-1-yloxy) tris (dimethylamino) phosphonium hexafluoro-phosphate (BOP).
- Protecting groups**
- Role of protection in organic synthesis
 - Protection for the hydroxyl group, including 1,2-and 1,3-diols: ethers, esters, carbonates, cyclic acetals & ketals
 - Protection for the Carbonyl Group: Acetals and Ketals
 - Protection for the Carboxyl Group: amides and hydrazides, esters
 - Protection for the Amino Group and Amino acids: carbamates and amides
- 4 **Heterocyclic Chemistry:** 12 Hrs
 Organic Name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six membered and fused heterocyclics such as Debus-Radziszewski imidazole synthesis, Knorr Pyrazole Synthesis Pinner Pyrimidine Synthesis, Combes Quinoline Synthesis, Berntsen Acridine Synthesis, Smiles rearrangement and Traube purine synthesis.
- Synthesis of few representative drugs containing these heterocyclic nucleus such as Ketoconazole, Metronidazole, Miconazole, celecoxib, antipyrin, Metamizole sodium, Terconazole, Alprazolam, Triamterene, Sulfamerazine, Trimethoprim, Hydroxychloroquine, Quinine, Chloroquine, Quinacrine, Amsacrine, Prochlorperazine, Promazine, Chlorpromazine, Theophylline, Mercaptopurine and Thioguanine.
- 5 **Synthon approach and retrosynthesis applications** 12 Hrs
- Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconversion and addition (FGI and FGA)
 - C-X disconnections; C-C disconnections – alcohols and carbonyl compounds; 1,2-, 1,3-, 1,4-, 1,5-, 1,6-difunctionalized compounds
 - Strategies for synthesis of three, four, five and six-membered ring.

REFERENCES

1. "Advanced Organic chemistry, Reaction, Mechanisms and Structure", J March, John Wiley and Sons, New York.
2. "Mechanism and Structure in Organic Chemistry", ES Gould, Hold Rinchart and Winston, New York.
3. "Organic Chemistry" Clayden, Greeves, Warren and Wothers., Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Pearson Education Ltd, Dorling Kindersley (India) Pvt. Ltd.,.
5. A guide to mechanisms in Organic Chemistry, Peter Skyes (Orient Longman, New Delhi).
6. Reactive Intermediates in Organic Chemistry, Tandon and Gowell, Oxford & IBH Publishers.
7. Combinational Chemistry – Synthesis and applications – Stephen R Wilson & Anthony W Czarnik, Wiley – Blackwell.
8. Carey, Organic Chemistry, 5th Edition (Viva Books Pvt. Ltd.)
9. Organic Synthesis - The Disconnection Approach, S. Warren, Wiley India
10. Principles of Organic Synthesis, ROC Norman and JM Coxan, Nelson Thorns.
11. Organic Synthesis - Special Techniques. VK Ahluwalia and R Agarwal, Narosa Publishers.
12. Organic Reaction Mechanisms IVth Edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.

ADVANCED MEDICINAL CHEMISTRY (MPC 103T)

Scope

The subject is designed to impart knowledge about recent advances in the field of medicinal chemistry at the molecular level including different techniques for the rational drug design.

Objectives

At completion of this course it is expected that students will be able to understand

- Different stages of drug discovery
- Role of medicinal chemistry in drug research
- Different techniques for drug discovery
- Various strategies to design and develop new drug like molecules for biological targets
- Peptidomimetics

THEORY

60 Hrs

1. **Drug discovery:** Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets. 12 Hrs

Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs antagonists, artificial enzymes.

- 2 **Prodrug Design and Analog design:** 12 Hrs
 - a) **Prodrug design:** Basic concept, Carrier linked prodrugs/ Bioprecursors, Prodrugs of functional group, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.
 - b) **Combating drug resistance:** Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance.
 - c) **Analog Design:** Introduction, Classical & Non classical, Bioisosteric replacement strategies, rigid analogs,

alteration of chain branching, changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.

3	a) Medicinal chemistry aspects of the following class of drugs	12 Hrs
	Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs:	
	a) Anti-hypertensive drugs, Psychoactive drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors, Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents.	
	b) Stereochemistry and Drug action: Realization that stereo selectivity is a pre-requisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug adsorption, metabolism, distribution and elimination.	
4	Rational Design of Enzyme Inhibitors	12 Hrs
	Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.	
5	Peptidomimetics	12 Hrs
	Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally. Chemistry of prostaglandins, leukotrienes and thromboxones.	

REFERENCES

1. Medicinal Chemistry by Burger, Vol I –VI.
2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 12th Edition, Lppincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
3. Comprehensive Medicinal Chemistry – Corwin and Hansch.
4. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

5. Introduction to Quantitative Drug Design by Y.C. Martin.
6. Principles of Medicinal Chemistry by William Foye, 7th Edition, Ippincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
7. Drug Design Volumes by Arienes, Academic Press, Elsevier Publishers, Noida, Uttar Pradesh..
8. Principles of Drug Design by Smith.
9. The Organic Chemistry of the Drug Design and Drug action by Richard B.Silverman, II Edition, Elsevier Publishers, New Delhi.
10. An Introduction to Medicinal Chemistry, Graham L.Patrick, III Edition, Oxford University Press, USA.
11. Biopharmaceutics and pharmacokinetics, DM.Brahmankar, Sunil B. Jaiswal II Edition, 2014, Vallabh Prakashan, New Delhi.
12. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, First edition, Wiley publishers.

CHEMISTRY OF NATURAL PRODUCTS (MPC 104T)

Scope

The subject is designed to provide detail knowledge about chemistry of medicinal compounds from natural origin and general methods of structural elucidation of such compounds. It also emphasizes on isolation, purification and characterization of medicinal compounds from natural origin.

Objectives

At completion of this course it is expected that students will be able to understand-

- Different types of natural compounds and their chemistry and medicinal importance
- The importance of natural compounds as lead molecules for new drug discovery
- The concept of rDNA technology tool for new drug discovery
- General methods of structural elucidation of compounds of natural origin
- Isolation, purification and characterization of simple chemical constituents from natural source

THEORY

60 Hrs

1. **Study of Natural products as leads for new pharmaceuticals for the following class of drugs** 12 Hrs
 - a) Drugs Affecting the Central Nervous System: Morphine Alkaloids
 - b) Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide
 - c) Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol
 - d) Neuromuscular Blocking Drugs: Curare alkaloids
 - e) Anti-malarial drugs and Analogues
 - f) Chemistry of macrolid antibiotics (Erythromycin, Azithromycin, Roxithromycin, and Clarithromycin) and β - Lactam antibiotics (Cephalosporins and Carbapenem)
2. **a) Alkaloids** 12 Hrs

General introduction, classification, isolation, purification, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation and stereochemistry of ephedrine, morphine, ergot, emetine and reserpine.

b) Flavonoids

Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin.

c) Steroids

General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, chemistry of contraceptive agents male & female sex hormones (Testosterone, Estradiol, Progesterone), adrenocorticoids (Cortisone), contraceptive agents and steroids (Vit – D).

- 3 **a) Terpenoids** 12 Hrs

Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono (citral, menthol, camphor), di (retinol, Phytol, taxol) and tri terpenoids (Squalene, Ginsenoside) carotinoids (β carotene).

b) Vitamins

Chemistry and Physiological significance of Vitamin A, B1, B2, B12, C, E, Folic acid and Niacin.

- 4 **a). Recombinant DNA technology and drug discovery** 12 Hrs

rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation

b). Active constituent of certain crude drugs used in Indigenous system Diabetic therapy – *Gymnema sylvestre*, *Salacia reticulata*, *Pterocarpus marsupium*, *Swertia chirata*, *Trigonella foenum graecum*; Liver dysfunction – *Phyllanthus niruri*; Antitumor – *Curcuma longa* Linn.

- 5 **Structural Characterization of natural compounds** 12 Hrs

Structural characterization of natural compounds using IR, ¹HNMR, ¹³CNMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit-D, Quercetin and Digitalis glycosides.

REFERENCES

1. Modern Methods of Plant Analysis, Peech and M.V.Tracey, Springer – Verlag, Berlin, Heidelberg.
2. Phytochemistry Vol. I and II by Miller, Jan Nostrant Rein Hld.
3. Recent advances in Phytochemistry Vol. I to IV – Scikel Runeckles, Springer Science & Business Media.
4. Chemistry of natural products Vol I onwards IWPAC.
5. Natural Product Chemistry Nakanishi Gggolo, University Science Books, California.
6. Natural Product Chemistry “A laboratory guide” – Rapheal Khan.
7. The Alkaloid Chemistry and Physiology by RHF Manske, Academic Press.
8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmannstall.
9. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall, Himalaya Publishing House.
10. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal, Krishan Prakashan.
11. Organic Chemistry Vol I and II by I.L. Finar, Pearson education.
12. Elements of Biotechnology by P.K. Gupta, Rastogi Publishers.
13. Pharmaceutical Biotechnology by S.P.Vyas and V.K.Dixit, CBS Publishers.
14. Biotechnology by Purohit and Mathur, Agro-Bios, 13th edition.
15. Phytochemical methods of Harborne, Springer, Netherlands.
16. Burger's Medicinal Chemistry.

PHARMACEUTICAL CHEMISTRY PRACTICAL - I

(MPC 105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer, RNA & DNA estimation
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on Column chromatography
4. Experiments based on HPLC
5. Experiments based on Gas Chromatography
6. Estimation of riboflavin/quinine sulphate by fluorimetry
7. Estimation of sodium/potassium by flame photometry

To perform the following reactions of synthetic importance

1. Purification of organic solvents, column chromatography
2. Claisen-schmidt reaction.
3. Benzyllic acid rearrangement.
4. Beckmann rearrangement.
5. Hoffmann rearrangement
6. Mannich reaction
7. Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4 experiments)
8. Estimation of elements and functional groups in organic natural compounds
9. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, co-chromatographic technique for identification of isolated compounds and interpretation of UV and IR data.
10. Some typical degradation reactions to be carried on selected plant constituents

ADVANCED SPECTRAL ANALYSIS (MPC 201T)

Scope

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, ATR-IR, DSC etc.

Objectives

At completion of this course it is expected that students will be able to understand-

- Interpretation of the NMR, Mass and IR spectra of various organic compounds
- Theoretical and practical skills of the hyphenated instruments
- Identification of organic compounds

THEORY

60Hrs

1.	UV and IR spectroscopy: Wood ward – Fieser rule for 1,3- butadienes, cyclic dienes and α , β -carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds.	12 Hrs
2	NMR spectroscopy: 1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds.	12 Hrs
3	Mass Spectroscopy Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds.	12 Hrs
4	Chromatography: Principle, Instrumentation and Applications of the following : a) GC-MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CE-MS g) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I-EC (Ion-Exclusion Chromatography) k) Flash chromatography	12 Hrs

- 5 **a). Thermal methods of analysis** 12
Introduction, principle, instrumentation and application of DSC, Hrs
DTA and TGA.
- b). Raman Spectroscopy**
Introduction, Principle, Instrumentation and Applications.
- c). Radio immuno assay**
Biological standardization , bioassay, ELISA, Radioimmuno
assay of digitalis and insulin.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

ADVANCED ORGANIC CHEMISTRY - II (MPC 202T)

Scope

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Objectives

Upon completion of course, the student shall be able to understand

- The principles and applications of Green chemistry
- The concept of peptide chemistry.
- The various catalysts used in organic reactions
- The concept of stereochemistry and asymmetric synthesis.

THEORY

60 Hrs

1. Green Chemistry:

12

- a. Introduction, principles of green chemistry
- b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis
- c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications
- d. Continuous flow reactors: Working principle, advantages and synthetic applications.

Hrs

2 Chemistry of peptides

12

- a. Coupling reactions in peptide synthesis
- b. Principles of solid phase peptide synthesis, t-BOC and Fmoc protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides
- c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies
- d. Side reactions in peptide synthesis: Deletion peptides, side

Hrs

reactions initiated by proton abstraction, protonation, over-activation and side reactions of individual amino acids.

3	Photochemical Reactions Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation.	12 Hrs
Pericyclic reactions Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatropic rearrangement reactions with examples		
4	Catalysis: a. Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages b. Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs. c. Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs d. Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions e. Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction. f. Phase transfer catalysis - theory and applications	12 Hrs
5	Stereochemistry & Asymmetric Synthesis a. Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis-trans isomerism, E and Z notation. b. Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.	12 Hrs

REFERENCES

1. "Advanced Organic chemistry, Reaction, mechanisms and structure", J March, John Wiley and sons, New York.
2. "Mechanism and structure in organic chemistry", ES Gould, Hold Rinchart and Winston, New York.
3. "Organic Chemistry" Clayden, Greeves, Warren and Wothers., Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
6. Organic synthesis-the disconnection approach, S. Warren, Wiley India
7. Principles of organic synthesis, R.C. Norman and J.M. Coxon, Nelson Thornes
8. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal, Narosa Publishers.
9. Organic reaction mechanisms IV edn, VK Ahluwalia and RK Parashar, Narosa Publishers.

COMPUTER AIDED DRUG DESIGN (MPC 203T)

Scope

The subject is designed to impart knowledge on the current state of the art techniques involved in computer assisted drug design.

Objectives

At completion of this course it is expected that students will be able to understand

- Role of CADD in drug discovery
- Different CADD techniques and their applications
- Various strategies to design and develop new drug like molecules.
- Working with molecular modeling softwares to design new drug molecules
- The *in silico* virtual screening protocols

Theory

60 Hrs

1. Introduction to Computer Aided Drug Design (CADD)

12
Hrs

History, different techniques and applications.

Quantitative Structure Activity Relationships: Basics

History and development of QSAR: Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equation and electronic parameters (σ), lipophilicity effects and parameters ($\log P$, π -substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters.

2 **Quantitative Structure Activity Relationships: Applications**

12
Hrs

Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations.

3D-QSAR approaches and contour map analysis.

Statistical methods used in QSAR analysis and importance of statistical parameters.

3 **Molecular Modeling and Docking**

12
Hrs

a) Molecular and Quantum Mechanics in drug design.

b) Energy Minimization Methods: comparison between global

minimum conformation and bioactive conformation

- c) Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, choline esterase (AchE & BchE)

- 4 **Molecular Properties and Drug Design** 12
a) Prediction and analysis of ADMET properties of new molecules and its importance in drug design. Hrs
b) *De novo* drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design.
c) Homology modeling and generation of 3D-structure of protein.
- 5 **Pharmacophore Mapping and Virtual Screening** 12
Concept of pharmacophore, pharmacophore mapping, Hrs
identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping.

In Silico Drug Design and Virtual Screening Techniques

Similarity based methods and Pharmacophore based screening, structure based *In-silico* virtual screening protocols.

REFERENCES

1. Computational and structural approaches to drug discovery, Robert M Stroud and Janet. F Moore, RCS Publishers.
2. Introduction to Quantitative Drug Design by Y.C. Martin, CRC Press, Taylor & Francis group..
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975, Elsevier Publishers.
4. Principles of Drug Design by Smith and Williams, CRC Press, Taylor & Francis.
5. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman, Elsevier Publishers.
6. Medicinal Chemistry by Burger, Wiley Publishing Co.

7. An Introduction to Medicinal Chemistry –Graham L. Patrick, Oxford University Press.
8. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, Ippincott Williams & Wilkins.
9. Comprehensive Medicinal Chemistry – Corwin and Hansch, Pergamon Publishers.
10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

PHARMACEUTICAL PROCESS CHEMISTRY (MPC 204T)

Scope

Process chemistry is often described as scale up reactions, taking them from small quantities created in the research lab to the larger quantities that are needed for further testing and then to even larger quantities required for commercial production. The goal of a process chemist is to develop synthetic routes that are safe, cost-effective, environmentally friendly, and efficient. The subject is designed to impart knowledge on the development and optimization of a synthetic route/s and the pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients (APIs) and new chemical entities (NCEs) for the drug development phase.

Objectives

At completion of this course it is expected that students will be able to understand

- The strategies of scale up process of APIs and intermediates
- The various unit operations and various reactions in process chemistry

THEORY

60 Hrs

1. Process chemistry

12

Introduction, Synthetic strategy

Hrs

Stages of scale up process: Bench, pilot and large scale process.

In-process control and validation of large scale process.

Case studies of some scale up process of APIs.

Impurities in API, types and their sources including genotoxic impurities

2 Unit operations

12

a) *Extraction*: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.

b) *Filtration*: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,

c) *Distillation*: azeotropic and steam distillation

d) *Evaporation*: Types of evaporators, factors affecting evaporation.

e) *Crystallization*: Crystallization from aqueous, non-aqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.

3	Unit Processes - I	12 Hrs
	a) Nitration: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration, b) Halogenation: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process. c) Oxidation: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H_2O_2, sodium hypochlorite, Oxygen gas, ozonolysis.	
4	Unit Processes - II	12 Hrs
	a) Reduction: Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process. b) Fermentation: Aerobic and anaerobic fermentation. Production of i. Antibiotics; Penicillin and Streptomycin, ii. Vitamins: B2 and B12 iii. Statins: Lovastatin, Simvastatin c) Reaction progress kinetic analysis i. Streamlining reaction steps, route selection, ii. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.	
5	Industrial Safety	12 Hrs
	a) MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE) b) Fire hazards, types of fire & fire extinguishers c) Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001 (Environmental Management System), Effluents and its management	

REFERENCES

1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever-Changing Climate-An Overview; K. Gadamasetti, CRC Press.
2. Pharmaceutical Manufacturing Encyclopedia, 3rd edition, Volume 2.
3. Medicinal Chemistry by Burger, 6th edition, Volume 1-8.
4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7th edition, McGraw Hill
5. Polymorphism in Pharmaceutical Solids .Dekker Series Volume 95 Ed: H G Brittain (1999)
6. Regina M. Murphy: Introduction to Chemical Processes: Principles, Analysis, Synthesis
7. Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up
8. P.H.Groggins: Unit processes in organic synthesis (MGH)
9. F.A.Henglein: Chemical Technology (Pergamon)
10. M.Gopal: Dryden's Outlines of Chemical Technology, WEP East-West Press
11. Clausen,Mattson: Principle of Industrial Chemistry, Wiley Publishing Co.,
12. Lowenheim & M.K. Moran: Industrial Chemicals
13. S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II, Vikas Publishing House
14. J.K. Stille: Industrial Organic Chemistry (PH)
15. Shreve: Chemical Process, Mc Grawhill.
16. B.K.Sharma: Industrial Chemistry, Goel Publishing House
17. ICH Guidelines
18. United States Food and Drug Administration official website www.fda.gov

PHARMACEUTICAL CHEMISTRY PRACTICALS – II

(MPC 205P)

1. Synthesis of organic compounds by adapting different approaches involving (3 experiments)
 - a) Oxidation
 - b) Reduction/hydrogenation
 - c) Nitration
2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)
3. Assignments on regulatory requirements in API (2 experiments)
4. Comparison of absorption spectra by UV and Wood ward – Fieser rule
5. Interpretation of organic compounds by FT-IR
6. Interpretation of organic compounds by NMR
7. Interpretation of organic compounds by MS
8. Determination of purity by DSC in pharmaceuticals
9. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
10. To carry out the preparation of following organic compounds
11. Preparation of 4-chlorobenzhydrylpiperazine. (an intermediate for cetirizine HCl).
12. Preparation of 4-iodotoluene from p-toluidine.
13. NaBH₄ reduction of vanillin to vanillyl alcohol
14. Preparation of umbelliferone by Pechhman reaction
15. Preparation of triphenyl imidazole
16. To perform the Microwave irradiated reactions of synthetic importance (Any two)
17. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using softwares
18. Calculation of ADMET properties of drug molecules and its analysis using softwares
Pharmacophore modeling
19. 2D-QSAR based experiments
20. 3D-QSAR based experiments
21. Docking study based experiment
22. Virtual screening based experiment

PHARMACEUTICAL ANALYSIS (MPA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know about chemicals and excipients

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY

60 Hrs

1. a. **UV-Visible spectroscopy:** Introduction, Theory, Laws, 10
Instrumentation associated with UV-Visible spectroscopy, Choice Hrs
of solvents and solvent effect and Applications of UV-Visible
spectroscopy, Difference/ Derivative spectroscopy.
b. **IR spectroscopy:** Theory, Modes of Molecular vibrations,
Sample handling, Instrumentation of Dispersive and Fourier -
Transform IR Spectrometer, Factors affecting vibrational
frequencies and Applications of IR spectroscopy, Data
Interpretation.
c. **Spectrofluorimetry:** Theory of Fluorescence, Factors affecting
fluorescence (Characteristics of drugs that can be analysed by
fluorimetry), Quenchers, Instrumentation and Applications of
fluorescence spectrophotometer.
d. **Flame emission spectroscopy and Atomic absorption
spectroscopy:** Principle, Instrumentation, Interferences and
Applications.
2. **NMR spectroscopy:** Quantum numbers and their role in NMR, 10
Principle, Instrumentation, Solvent requirement in NMR, Hrs
Relaxation process, NMR signals in various compounds,
Chemical shift, Factors influencing chemical shift, Spin-Spin
coupling, Coupling constant, Nuclear magnetic double resonance,
Brief outline of principles of FT-NMR and ¹³C NMR. Applications
of NMR spectroscopy.
3. **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass 10

- Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. Hrs
- 4 **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: 10 Hrs
- Thin Layer chromatography
 - High Performance Thin Layer Chromatography
 - Ion exchange chromatography
 - Column chromatography
 - Gas chromatography
 - High Performance Liquid chromatography
 - Ultra High Performance Liquid chromatography
 - Affinity chromatography
 - Gel Chromatography
- 5 a. **Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: 10 Hrs
- Paper electrophoresis
 - Gel electrophoresis
 - Capillary electrophoresis
 - Zone electrophoresis
 - Moving boundary electrophoresis
 - Iso electric focusing
- b. **X ray Crystallography:** Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction
- 6 **Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry. 10 Hrs
- Thermal Techniques:** Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation

and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

ADVANCED PHARMACEUTICAL ANALYSIS (MPA 102T)

Scope

This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradants, Stability testing of phytopharmaceuticals and their protocol preparation. It also covers the biological testing of various vaccines and their principle and procedure.

Objective

After completion of the course students shall able to know,

- Appropriate analytical skills required for the analytical method development.
- Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.
- Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products

THEORY

60 Hrs

1.	Impurity and stability studies: Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines Impurities in new drug products: Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products Impurities in residual solvents: General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents	10 Hrs
2	Elemental impurities: Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis	10 Hrs

Stability testing protocols:

Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates. With practical considerations.

3	Impurity profiling and degradent characterization: Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradent characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products	10 Hrs
4	Stability testing of phytopharmaceuticals: Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.	10 Hrs
5	Biological tests and assays of the following: a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)	10 Hrs
6	Immunoassays (IA) Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.	10 Hrs

REFERENCES

1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th Edition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, John Wiley & Sons, 1982.

4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers New Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, NewDelhi, 1964.
8. Indian Pharmacopoeia Vol I , II & III 2007, 2010, 2014.
9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005
12. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.
13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

PHARMACEUTICAL VALIDATION (MPA 103T)

Scope

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Objectives

Upon completion of the subject student shall be able to

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments
- Validate the manufacturing facilities

THEORY

60 Hrs

1.	Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan. Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status-Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments.	12 Hrs
2	Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.	12 Hrs
3	Validation of Utility systems: Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen. Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).	12 Hrs
4	Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.	12 Hrs

Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP 5.

- 5 **General Principles of Intellectual Property:** Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices. 12 Hrs

REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

FOOD ANALYSIS (MPA 104T)

Scope

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products.

Objectives

At completion of this course student shall be able to understand various analytical techniques in the determination of

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- And also student shall have the knowledge on food regulations and legislations

THEORY

60 Hrs

1. **Carbohydrates:** classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, Crude fibre and application of food carbohydrates
Proteins: Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins. 12 Hrs
2. **Lipids:** Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fats and fatty foods. 12 Hrs
Vitamins: classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series.
3. **Food additives:** Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents. 12 Hrs
Pigments and synthetic dyes: Natural pigments, their occurrence and characteristic properties, permitted synthetic

dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes.

- 4 **General Analytical methods** for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk. 12 Hrs
 Analysis of fermentation products like wine, spirits, beer and vinegar.
- 5 **Pesticide analysis:** Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products. 12 Hrs
 Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA.

REFERENCES

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Analysis of Food constituents – Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005.

PHARMACEUTICAL ANALYSIS PRACTICALS - II

(MPA 105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Assay of official compounds by different titrations
8. Assay of official compounds by instrumental techniques.
9. Quantitative determination of hydroxyl group.
10. Quantitative determination of amino group
11. Colorimetric determination of drugs by using different reagents
12. Impurity profiling of drugs
13. Calibration of glasswares
14. Calibration of pH meter
15. Calibration of UV-Visible spectrophotometer
16. Calibration of FTIR spectrophotometer
17. Calibration of GC instrument
18. Calibration of HPLC instrument
19. Cleaning validation of any one equipment
20. Determination of total reducing sugar
21. Determination of proteins
22. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
23. Determination of fat content and rancidity in food products
24. Analysis of natural and synthetic colors in food
25. Determination of preservatives in food
26. Determination of pesticide residue in food products
27. Analysis of vitamin content in food products
28. Determination of density and specific gravity of foods
29. Determination of food additives

ADVANCED INSTRUMENTAL ANALYSIS (MPA 201T)

Scope

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, and hyphenated techniques.

Objectives

After completion of course student is able to know,

- interpretation of the NMR, Mass and IR spectra of various organic compounds
- theoretical and practical skills of the hyphenated instruments
- identification of organic compounds

THEORY

60 Hrs

1. **HPLC:** Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC-role and principles of ultra, nano liquid chromatography in pharmaceutical analysis. Immobilized polysaccharide CSP's: Advancement in enantiomeric separations, revised phase Chiral method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC. 12 Hrs
2. **Biochromatography:** Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases. 12 Hrs
Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification.
High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications.
3. **Super critical fluid chromatography:** Principles, instrumentation, pharmaceutical applications. 12 Hrs
Capillary electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method

development in CE, Crown ethers as buffer additives in capillary electrophoresis. CE-MS hyphenation.

- 4 **Mass spectrometry:** Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrpole, Time of flight, FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF; Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap). 12 Hrs

- 5 **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR with reference to ¹³CNMR: Spin spin and spin lattice relaxation phenomenon. ¹³C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations. 12 Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.
8. Organic Spectroscopy by Donald L. Paviya, 5th Edition.

MODERN BIO-ANALYTICAL TECHNIQUES (MPA 202T)

Scope

This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

Objectives

Upon completion of the course, the student shall be able to understand

- Extraction of drugs from biological samples
- Separation of drugs from biological samples using different techniques
- Guidelines for BA/BE studies.

THEORY

60 Hrs

1. **Extraction of drugs and metabolites from biological matrices:** 12 Hrs
General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid - Liquid extraction and Solid phase extraction and other novel sample preparation approach.
Bioanalytical method validation: USFDA and EMEA guidelines.
2. **Biopharmaceutical Consideration:** 12 Hrs
Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, *In Vitro*: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: *In-vitro*, *in-situ* and *In-vivo* methods.
3. **Pharmacokinetics and Toxicokinetics:** 12 Hrs
Basic consideration, Drug interaction (PK-PD interactions), The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics-Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics.
4. **Cell culture techniques** 12 Hrs
Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of

cells and their applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry.

5	Metabolite identification: In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met –ID. Regulatory perspectives. <i>In-vitro</i> assay of drug metabolites & drug metabolizing enzymes.	12 Hrs

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence:

Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies.

REFERENCES

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition. CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercey. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, Newyork, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercey, USA. 2007.
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
10. ICH, USFDA & CDSCO Guidelines.
11. Palmer

QUALITY CONTROL AND QUALITY ASSURANCE (MPA 203T)

Scope

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Objectives

At the completion of this subject it is expected that the student shall be able to know

- the cGMP aspects in a pharmaceutical industry
- to appreciate the importance of documentation
- to understand the scope of quality certifications applicable to Pharmaceutical industries
- to understand the responsibilities of QA & QC departments

THEORY

60 hrs

1. Concept and Evolution of Quality Control and Quality Assurance	12 Hrs
Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines.	
Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation.	
2. cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guidelines.	12 Hrs
3. Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3)	12 Hrs

Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials.

4. **Documentation in pharmaceutical industry:** Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data. **12 Hrs**
5. **Manufacturing operations and controls:** Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging. **12 Hrs**

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management

9. The drugs and cosmetics act 1940 – Deshpande, Nileshe Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.

HERBAL AND COSMETIC ANALYSIS (MPA 204T)

Scope

This course is designed to impart knowledge on analysis of herbal products. Regulatory requirements, herbal drug interaction with monographs. Performance evaluation of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.

Objectives

At completion of this course student shall be able to understand

- Determination of herbal remedies and regulations
- Analysis of natural products and monographs
- Determination of Herbal drug-drug interaction
- Principles of performance evaluation of cosmetic products.

THEORY

60 Hrs

1. **Herbal remedies- Toxicity and Regulations:** Herbals vs 12
Conventional drugs, Efficacy of herbal medicine products, Hrs
Validation of Herbal Therapies, Pharmacodynamic and
Pharmacokinetic issues. Herbal drug standardization: WHO and
AYUSH guidelines.
2. **Adulteration and Deterioration:** Introduction, types of 12
adulteration/substitution of herbal drugs, Causes and Measure of Hrs
adulteration, Sampling Procedures, Determination of Foreign
Matter, DNA Finger printing techniques in identification of drugs of
natural origin, heavy metals, pesticide residues, phototoxin and
microbial contamination in herbal formulations.
Regulatory requirements for setting herbal drug industry:
Global marketing management, Indian and international patent
law as applicable herbal drugs and natural products and its
protocol.
3. **Testing of natural products and drugs:** Effect of herbal 12
medicine on clinical laboratory testing, Adulterant Screening using Hrs
modern analytical instruments, Regulation and dispensing of
herbal drugs, Stability testing of natural products, protocol.

Monographs of Herbal drugs: Study of monographs of herbal
drugs and comparative study in IP, USP, Ayurvedic

Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

- 4 **Herbal drug-drug interaction:** WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines. 12 Hrs

- 5 **Evaluation of cosmetic products:** Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS. 12 Hrs
 Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards.

REFERENCES

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Quality Control Methods for Medicinal Plant, WHO, Geneva
4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar
5. Essential of Pharmacognosy by Dr.S.H.Ansari
6. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi
7. Indian Standard specification, for raw materials, BIS, New Delhi.
8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
9. Harry's Cosmeticology 8th edition
10. Suppliers catalogue on specialized cosmetic excipients
11. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition,

PHARMACEUTICAL ANALYSIS PRACTICALS - I

(MPA 205P)

1. Comparison of absorption spectra by UV and Wood ward – Fiesure rule
2. Interpretation of organic compounds by FT-IR
3. Interpretation of organic compounds by NMR
4. Interpretation of organic compounds by MS
5. Determination of purity by DSC in pharmaceuticals
6. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
7. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis.
8. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques.
9. Isolation of analgesics from biological fluids (Blood serum and urine).
10. Protocol preparation and performance of analytical/Bioanalytical method validation.
11. Protocol preparation for the conduct of BA/BE studies according to guidelines.
12. In process and finished product quality control tests for tablets, capsules, parenterals and creams
13. Quality control tests for Primary and secondary packing materials
14. Assay of raw materials as per official monographs
15. Testing of related and foreign substances in drugs and raw materials
16. Preparation of Master Formula Record.
17. Preparation of Batch Manufacturing Record.
18. Quantitative analysis of rancidity in lipsticks and hair oil
19. Determination of aryl amine content and Developer in hair dye
20. Determination of foam height and SLS content of Shampoo.
21. Determination of total fatty matter in creams (Soap, skin and hair creams)
22. Determination of acid value and saponification value.
23. Determination of calcium thioglycolate in depilatories

PHARMACEUTICAL QUALITY ASSURANCE (MQA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MQA 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know about chemicals and excipients

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY

60 Hrs

1. a. **UV-Visible spectroscopy:** Introduction, Theory, Laws, 12
Instrumentation associated with UV-Visible spectroscopy, Choice Hrs
of solvents and solvent effect and Applications of UV-Visible
spectroscopy, Difference/ Derivative spectroscopy.
b. **IR spectroscopy:** Theory, Modes of Molecular vibrations,
Sample handling, Instrumentation of Dispersive and Fourier -
Transform IR Spectrometer, Factors affecting vibrational
frequencies and Applications of IR spectroscopy, Data
Interpretation.
c. **Spectrofluorimetry:** Theory of Fluorescence, Factors
affecting fluorescence (Characteristics of drugs that can be
analysed by fluorimetry), Quenchers, Instrumentation and
Applications of fluorescence spectrophotometer.
d. **Flame emission spectroscopy and Atomic absorption
spectroscopy:** Principle, Instrumentation, Interferences and
Applications.
2. **NMR spectroscopy:** Quantum numbers and their role in NMR, 12
Principle, Instrumentation, Solvent requirement in NMR, Hrs
Relaxation process, NMR signals in various compounds,
Chemical shift, Factors influencing chemical shift, Spin-Spin
coupling, Coupling constant, Nuclear magnetic double resonance,
Brief outline of principles of FT-NMR and ¹³C NMR. Applications
of NMR spectroscopy.

3	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	12 Hrs
4	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: • Thin Layer chromatography • High Performance Thin Layer Chromatography • Ion exchange chromatography • Column chromatography • Gas chromatography • High Performance Liquid chromatography • Ultra High Performance Liquid chromatography • Affinity chromatography • Gel Chromatography	12 Hrs
5	a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	12 Hrs
6	a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation	12 Hrs

and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.
10. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

QUALITY MANAGEMENT SYSTEMS (MQA 102T)

Scope

This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.

Objectives

At completion of this course it is expected that students will be able to understand-

- The importance of quality
- ISO management systems
- Tools for quality improvement
- Analysis of issues in quality
- Quality evaluation of pharmaceuticals
- Stability testing of drug and drug substances
- Statistical approaches for quality

THEORY

60 Hrs

1. **Introduction to Quality:** Evolution of Quality, Definition of Quality, Dimensions of Quality 12 Hrs
Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality
Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behavior, concept of internal and external customers. Case studies.
Cost of Quality: Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, Preventing cost of quality.

- 2 **Pharmaceutical quality Management:** Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements. 12 Hrs

- 3 **Six System Inspection model:** Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system. Concept of self inspection. 12 Hrs
Quality systems: Change Management/ Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.

- 4 **Drug Stability:** ICH guidelines for stability testing of drug substances and drug products. 12 Hrs
Study of ICH Q8, Quality by Design and Process development report
Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.

- 5 **Statistical Process control (SPC):** Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability. 8 Hrs

- 6 Regulatory Compliance through Quality Management and development of Quality Culture 4 Hrs
Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.

REFERENCES

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
3. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
4. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001
5. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
6. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
7. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
8. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.

QUALITY CONTROL AND QUALITY ASSURANCE (MQA 103T)

Scope

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Objectives

Upon completion of this course the student should be able to

- Understand the cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable to Pharmaceutical industries
- To understand the responsibilities of QA & QC departments.

THEORY

60 Hrs

1. **Introduction:** Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines. 12 Hrs
Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.
2. cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. 12 Hrs
3. Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. 12 Hrs

In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).

- 4 **Documentation in pharmaceutical industry:** Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents.
Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non regulated markets. 12 Hrs

- 5 **Manufacturing operations and controls:** Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal. 12 Hrs
Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.

5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
14. Packaging of Pharmaceuticals.
15. Schedule M and Schedule N.

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (MQA 104T)

Scope

This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and analytical tests and methods, required following candidate drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in manufacturing places.

Objectives

Upon completion of this course the student should be able to

- To understand the new product development process
- To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D
- To elucidate necessary information to transfer technology of existing products between various manufacturing places

THEORY

60 Hrs

1. **Principles of Drug discovery and development:** Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA. 12 Hrs
2. **Pre-formulation studies:** Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol, Stability testing during product development. 12 Hrs
3. **Pilot plant scale up:** Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges. 12 Hrs

4	Pharmaceutical packaging: Pharmaceutical dosage form and their packaging requirements, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials. Quality control test: Containers, closures and secondary packing materials.	12 Hrs
5	Technology transfer: Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models. Documentation in technology transfer: Development report, technology transfer plan and Exhibit.	12 Hrs

REFERENCES

1. The process of new drug discovery and development. I and II Edition (2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis.
2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
4. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.
5. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rd Edn, Lea & Febriger, Philadelphia.
6. Pharmaceutical product development. Vandana V. Patrevala. John I. Disouza. Maharukh T.Rustomji. CRC Press, Group of Taylor and Francis.
7. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania.
8. Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19th Edn.(1995)O.O2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
9. The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt. Ltd.
10. Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1st Edition(Reprint 2006). Taylor and Francis. London and New York.

QUALITY ASSURANCE PRACTICAL - I

(MQA 105P)

PRACTICALS

1. Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet/ capsules/ semisolids) by UV Vis spectrophotometer
2. Simultaneous estimation of multi-drug component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry or AAS
7. Case studies on
 - Total Quality Management
 - Six Sigma
 - Change Management/ Change control. Deviations,
 - Out of Specifications (OOS)
 - Out of Trend (OOT)
 - Corrective & Preventive Actions (CAPA)
 - Deviations
8. Development of Stability study protocol
9. Estimation of process capability
10. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
11. Assay of raw materials as per official monographs
12. Testing of related and foreign substances in drugs and raw materials
13. To carry out pre formulation study for tablets, parenterals (2 experiment).
14. To study the effect of pH on the solubility of drugs, (1 experiment)
15. Quality control tests for Primary and secondary packaging materials
16. Accelerated stability studies (1 experiment)
17. Improved solubility of drugs using surfactant systems (1 experiment)
18. Improved solubility of drugs using co-solvency method (1 experiment)
19. Determination of P_{ka} and $\log p$ of drugs.

HAZARDS AND SAFETY MANAGEMENT (MQA 201T)

Scope

This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle based approach to solve the complex tribulations.

Objectives

At completion of this course it is expected that students will be able to

- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an ideas to clear mechanism and management in different kinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

THEORY

60Hrs

1.	Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.	12 Hrs
2	Air based hazards: Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.	12 Hrs
3	Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards,	12 Hrs

Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.

- 4 **Fire and Explosion:** Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion-electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers. 12 Hrs

- 5 **Hazard and risk management:** Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools 12 Hrs
 Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services.

REFERENCES

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. "Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

PHARMACEUTICAL VALIDATION (MQA 202T)

Scope

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Objectives

At completion of this course, it is expected that students will be able to understand

- The concepts of calibration, qualification and validation
- The qualification of various equipments and instruments
- Process validation of different dosage forms
- Validation of analytical method for estimation of drugs
- Cleaning validation of equipments employed in the manufacture of pharmaceuticals

THEORY

60 Hrs

1. **Introduction to validation:** Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan.
Qualification: User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status-Calibration Preventive Maintenance, Change management). 10 Hrs
2. **Qualification of manufacturing equipment:** Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine. 10 Hrs
Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.

- 3 **Qualification of laboratory equipments:** Hardness tester, 10
Friability test apparatus, tap density tester, Disintegration tester, Hrs
Dissolution test apparatus
Validation of Utility systems: Pharmaceutical water system &
pure steam, HVAC system, Compressed air and nitrogen.

- 4 **Process Validation:** Concept, Process and documentation of 10
Process Validation. Prospective, Concurrent & Retrospective Hrs
Validation, Re validation criteria, Process Validation of various
formulations (Coated tablets, Capsules, Ointment/Creams, Liquid
Orals and aerosols.), Aseptic filling: Media fill validation, USFDA
guidelines on Process Validation- A life cycle approach.
Analytical method validation: General principles, Validation of
analytical method as per ICH guidelines and USP.

- 5 **Cleaning Validation:** Cleaning Method development, Validation 10
of analytical method used in cleaning, Cleaning of Equipment, Hrs
Cleaning of Facilities. Cleaning in place (CIP).
Validation of facilities in sterile and non-sterile plant.
Computerized system validation: Electronic records and digital
signature - 21 CFR Part 11 and GAMP

- 6 **General Principles of Intellectual Property:** Concepts of 10
Intellectual Property (IP), Intellectual Property Protection (IPP), Hrs
Intellectual Property Rights (IPR); Economic importance,
mechanism for protection of Intellectual Property –patents,
Copyright, Trademark; Factors affecting choice of IP protection;
Penalties for violation; Role of IP in pharmaceutical industry;
Global ramification and financial implications. Filing a patent
applications; patent application forms and guidelines. Types
patent applications-provisional and non provisional, PCT and
convention patent applications; International patenting
requirement procedures and costs; Rights and responsibilities of
a patentee; Practical aspects regarding maintaining of a Patent
file; Patent infringement meaning and scope. Significance of
transfer technology (TOT), IP and ethics-positive and negative
aspects of IPP; Societal responsibility, avoiding unethical
practices.

REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
6. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
7. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
8. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
9. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker
10. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.
11. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
12. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press
13. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press

AUDITS AND REGULATORY COMPLIANCE (MPA 203T)

Scope

This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Objectives

Upon completion of this course the student should be able to

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

THEORY

60 Hrs

1.	Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies	12 Hrs
2	Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.	12 Hrs
3	Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.	12 Hrs
4	Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.	12 Hrs

- 5 **Auditing of Quality Assurance and engineering department:** 12
Quality Assurance Maintenance, Critical systems: HVAC, Water, Hrs
Water for Injection systems, ETP.

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).

PHARMACEUTICAL MANUFACTURING TECHNOLOGY (MQA 204T)

Scope

This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.

Objectives

At completion of this course it is expected that students will be able to understand,

- The common practice in the pharmaceutical industry developments, plant layout and production planning
- Will be familiar with the principles and practices of aseptic process technology, non sterile manufacturing technology and packaging technology.
- Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing

THEORY

60 Hrs

1. **Pharmaceutical industry developments:** Legal requirements and Licenses for API and formulation industry, Plant location- Factors influencing. 12 Hrs
Plant layout: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout.
Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.
2. **Aseptic process technology:** Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume). 12 Hrs
Advanced sterile product manufacturing technology : Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.
Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP),

Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS).

Lyophilization technology: Principles, process, equipment.

- 3 **Non sterile manufacturing process technology:** 12 Hrs
Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft).
Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.
Coating technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.
- 4 **Containers and closures for pharmaceuticals:** Types, 12 Hrs
performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material.
- 5 **Quality by design (QbD) and process analytical technology (PAT):** 12 Hrs
Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP, CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.

REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
6. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
8. United States Pharmacopoeia. United States Pharmacopoeial Convention, Inc, USA, 2003.
9. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor & Francis, 1st Edition. UK.
10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA Inc. New york.
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey, 2008.

QUALITY ASSURANCE PRACTICAL – II PRACTICALS (MQA 205P)

1. Organic contaminants residue analysis by HPLC
2. Estimation of Metallic contaminants by Flame photometer
3. Identification of antibiotic residue by TLC
4. Estimation of Hydrogen Sulphide in Air.
5. Estimation of Chlorine in Work Environment.
6. Sampling and analysis of SO₂ using Colorimetric method
7. Qualification of following Pharma equipment
 - a. Autoclave
 - b. Hot air oven
 - c. Powder Mixer (Dry)
 - d. Tablet Compression Machine
8. Validation of an analytical method for a drug
9. Validation of a processing area
10. Qualification of at least two analytical instruments
11. Cleaning validation of one equipment
12. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
13. Check list for Bulk Pharmaceutical Chemicals vendors
14. Check list for tableting production.
15. Check list for sterile production area
16. Check list for Water for injection.
17. Design of plant layout: Sterile and non-sterile
18. Case study on application of QbD
19. Case study on application of PAT

PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

GOOD REGULATORY PRACTICES (MRA 101T)

Scope

This course is designed to impart fundamental knowledge on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP for Pharmaceuticals, Cosmetics, Food & Nutraceuticals, Medical devices, *In-vitro* Diagnostic Medical Devices (IVDs) and biological products and understand the rationale behind these requirements and will propose ways and means of complying with them.

Objectives

At completion of this course it is expected that students will be able to understand,

- The key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices.
- Prepare and implement the check lists and SOPs for various Good Regulatory Practices
- Implement Good Regulatory Practices in the Healthcare and related Industries
- Prepare for the readiness and conduct of audits and inspections.

THEORY

60 Hrs

1.	Current Good Manufacturing Practices: Introduction, US cGMP Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical device and IVDs Global Harmonization Task Force(GHTF) Guidance docs.	12 Hrs
2	Good Laboratory Practices: Introduction, USFDA GLP Regulations (Subpart A to Subpart K), Controlling the GLP inspection process, Documentation, Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, relevant ISO and Quality Council of India(QCI) Standards	12 Hrs
3	Good Automated Laboratory Practices: Introduction to GALP, Principles of GALP, GALP Requirements, SOPs of GALP, Training Documentation, 21 CFR Part 11, General check list of 21CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards.	12 Hrs

4	Good Distribution Practices: Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self-Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards	12 Hrs
5	Quality management systems: Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)]and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents.	12 Hrs

REFERENCES

1. Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth Edition Drugs and the Pharmaceutical Sciences, Vol.168
2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press
3. Establishing a cGMP Laboratory Audit System, A practical Guide by David M.Bleisner, Wiley Publication.
4. How to practice GLP by PP Sharma, Vandana Publications.
5. Laboratory Auditing for Quality and Regulatory compliance bu Donald C.Singer, Drugs and the Pharmaceutical Sciences, Vol.150.
6. Drugs & Cosmetics Act, Rules & Amendments

DOCUMENTATION AND REGULATORY WRITING (MRA 102T)

Scope

This course is designed to impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.

Objectives

Upon completion of the course the student shall be able to,

- Know the various documents pertaining to drugs in pharmaceutical industry
- Understand the basics of regulatory compilation
- Create and assemble the regulation submission as per the requirements of agencies
- Follow up the submissions and post approval document requirements

THEORY

60 Hrs

1. **Documentation in pharmaceutical industry:** Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF). 12 Hrs

2. **Dossier preparation and submission:** Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions; Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non eCTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission. Submission in Sugam system of CDSCO. 12 Hrs

3	Audits: Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document. ISO 13485.	12 Hrs
4	Inspections: Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA).	12 Hrs
5	Product life cycle management: Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Effected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard	12 Hrs

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-Ioana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
5. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
6. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002

7. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
8. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001
9. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
10. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
11. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
12. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications
13. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP)

CLINICAL RESEARCH REGULATIONS (MRA 103T)

Scope

This course is designed to impart the fundamental knowledge on the clinical development process of drugs, pharmaceuticals and Medical Devices, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in India, USA and EU. It prepares the students to learn in detail on various laws, legislations and guidance related to safety, efficacy, ethical conduct and regulatory approval of clinical research.

Objectives

Upon completion of the course, the student shall be able to (know, do and appreciate)

- History, origin and ethics of clinical and biomedical research and evaluation
- Clinical drug, medical device development process and different types and phases of clinical trials
- Regulatory requirements and guidance for conduct of clinical trials and research

Theory

60 Hrs

1. Clinical Drug Development Process

12

Hrs

- Different types of Clinical Studies
- Phases of clinical trials, Clinical Trial protocol
- Phase 0 studies
- Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points)
- Phase II studies (proof of concept or principle studies to establish efficacy)
- Phase III studies (Multi ethnicity, global clinical trial, registration studies)
- Phase IV studies (Post Marketing Studies; PSUR)

Clinical Investigation and Evaluation of Medical Devices & IVDs

Different Types of Studies

Key Concepts of Medical Device Clinical Evaluation

Key concepts of Clinical Investigation

2	Ethics in Clinical Research: • Historical Perspectives: Nuremberg Code, Thalidomide study , Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki • Origin of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines. • The ethics of randomized clinical trials • The role of placebo in clinical trials • Ethics of clinical research in special population • Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data • Data safety monitoring boards. • Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research • Ethical principles governing informed consent process • Patient Information Sheet and Informed Consent Form • The informed consent process and documentation	12 Hrs
3	Regulations governing Clinical Trials India: Clinical Research regulations in India – Schedule Y & Medical Device Guidance USA: Regulations to conduct drug studies in USA (FDA) • NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug) • NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant) • ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product) • FDA Guidance for Industry - Acceptance of Foreign Clinical Studies • FDA Clinical Trials Guidance Document: Good Clinical Practice EU: Clinical Research regulations in European Union (EMA)	12 Hrs

4	Clinical Research Related Guidelines • Good Clinical Practice Guidelines (ICH GCP E6) • Indian GCP Guidelines • ICMR Ethical Guidelines for Biomedical Research • CDSCO guidelines GHTF study group 5 guidance documents	12 Hrs
	Regulatory Guidance on Efficacy and Safety ICH Guidance's • E4 – Dose Response Information to support Drug Registration • E7 – Studies in support of General Population: Geriatrics • E8 – General Considerations of Clinical Trials • E10 – Choice of Control Groups and Related Issues in Clinical Trials, • E 11 – Clinical Investigation of Medicinal Products in the Pediatric Population • General biostatistics principle applied in clinical research	
5	USA & EU Guidance USA: FDA Guidance • CFR 21Part 50: Protection of Human Subjects • CFR 21Part 54: Financial Disclosure by Clinical Investigators • CFR 21Part 312: IND Application • CFR 21Part 314: Application for FDA Approval to Market a New Drug • CFR 21Part 320: Bioavailability and bioequivalence requirements • CFR 21Part 812: Investigational Device Exemptions • CFR 21Part 822: Post-market surveillance • FDA Safety Reporting Requirements for INDs and BA/BE Studies • FDA Med Watch • Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment European Union: EMA Guidance • EU Directives 2001 • EudraLex (EMA) Volume 3 – Scientific guidelines for medicinal products for human use • EU Annual Safety Report (ASR) • Volume 9A – Pharmacovigilance for Medicinal Products for Human Use • EU MDD with respect to clinical research • ISO 14155	12 Hrs

REFERENCES

1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
2. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LL.M and Jennifer Kulynych, JD, PhD
3. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
4. Reviewing Clinical Trials: A Guide for the Ethics Committee; Johan PE Karlberg and Marjorie A Speers; Karlberg, Johan Petter Einar, Hong Kong.
5. International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy; Anthony C. Cartwright; Taylor & Francis Inc., USA.
6. New Drug Approval Process: The Global Challenge; Guarino, Richard A; Marcel Dekker Inc., NY.
7. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics; Douglas J. Pisano, David Mantus; CRC Press, USA
8. Country Specific Guidelines from official websites.
9. Drugs & Cosmetics Act & Rules and Amendments

RECOMMENDED WEBSITES:

1. EU Clinical Research Directive 2001: <http://www.eortc.be/services/doc/clinical-eudirective-04-april-01.pdf>
2. Code of Federal Regulations, FDA: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>
3. Guidelines of International Conference on Harmonization: <http://www.ich.org/products/guidelines.html>
4. Eudralex Guidelines: <http://www.gmpcompliance.info/euguide.htm>
5. FDA New Drug Application:
6. <http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDrugsandCosmeticActFDCAAct/FDCAActChapterVDrugsandDevices/ucm108125.htm>
7. Medicines and Healthcare products Regulatory Agency: <http://www.mhra.gov.uk>
8. Central Drugs Standard Control Organization Guidance for Industry: <http://cdsco.nic.in/CDSCO-GuidanceForIndustry.pdf>
9. ICMR Ethical Guidelines for Biomedical Research: http://icmr.nic.in/ethical_guidelines.pdf

**REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS,
MEDICAL DEVICES, BIOLOGICALS & HERBALS, AND FOOD &
NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY
RIGHTS
(MRA 104T)**

Scope

This course is designed to impart fundamental knowledge on regulations and legislation in India w.r.t. Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. It prepares the students for basic regulatory requirements in India of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. for manufacture, import & registration, export, sale, marketing authorization, clinical trials and intellectual property rights.

Objectives

Upon the completion of the course the student shall be able to:

- Know different Acts and guidelines that regulate Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals industry in India.
- Understand the approval process and regulatory requirements for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals

THEORY

60 Hrs

1. Biologicals & Herbals, and Food & Nutraceuticals

12

Acts and Rules (with latest amendments):

Hrs

1. Drugs and Cosmetics Act 1940 and Rules 1945: DPCO and NPPA
2. Other relevant provisions (rules schedules and guidelines for approval of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India

Other relevant Acts: Narcotics Drugs and Psychotropic Substances Act; Medicinal and Toilet Preparations (Excise Duties) Act, 1955; Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955; Prevention of Cruelty to Animals Act.

2	Regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals	12 Hrs

CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities

- Rules, regulations, guidelines and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals
- Format and contents of Regulatory dossier filing

Clinical trial/ investigations

3	Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards	12 Hrs

4	Bioavailability and Bioequivalence data (BA &BE), BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study	12 Hrs

Stability requirements: ICH and WHO

Guidelines for Drug testing in animals/Preclinical Studies

Animal testing: Rationale for conducting studies, CPCSEA Guidelines

Ethical guidelines for human participants

ICMR-DBT Guidelines for Stem Cell Research

5	Intellectual Property Rights: Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. IPR vs Regulatory Affairs	12 Hrs

REFERENCES

1. Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Office of India
2. Patent Failure How Judges, Bureaucrats, and Lawyers put innovators at risk by James Bessen and Michael J. Meurer
3. Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee
4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New delhi 2006.
5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA)

6. ICH E6 Guideline — Good Clinical Practice by ICH Harmonised Tripartite
7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation)
8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO
9. Guidelines for Import and Manufacture of Medical Devices by CDSCO
10. Guidelines from official website of CDSCO

REGULATORY AFFAIRS PRACTICAL - I

(MRA 105P)

1. Case studies (4 Nos.) of each of Good Pharmaceutical Practices.
2. Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.
3. Preparation of SOPs, Analytical reports (Stability and validation)
4. Protocol preparation for documentation of various types of records (BMR, MFR, DR)
5. Labeling comparison between brand & generics.
6. Preparation of clinical trial protocol for registering trial in India
7. Registration for conducting BA/ BE studies in India
8. Import of drugs for research and developmental activities
9. Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM
10. Registering for different Intellectual Property Rights in India
11. GMP Audit Requirements as per CDSCO
12. Preparation and documentation for Indian Patent application.
13. Preparation of checklist for registration of IND as per ICH CTD format.
14. Preparation of checklist for registration of NDA as per ICH CTD format.
15. Preparation of checklist for registration of ANDA as per ICH CTD format.
16. Case studies on response with scientific rationale to USFDA Warning Letter
17. Preparation of submission checklist of IMPD for EU submission.
18. Comparison study of marketing authorization procedures in EU.
19. Comparative study of DMF system in US, EU and Japan
20. Preparation of regulatory submission using eCTD software
21. Preparation of Clinical Trial Application (CTA) for US submission
22. Preparation of Clinical Trial Application (CTA) for EU submission
23. Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form.
24. Regulatory requirements checklist for conducting clinical trials in India.
25. Regulatory requirements checklist for conducting clinical trials in Europe.
26. Regulatory requirements checklist for conducting clinical trials in USA

SEMESTER II

REGULATORY ASPECTS OF DRUGS & COSMETICS

(MRA 201T)

Scope

This course is designed to impart the fundamental knowledge on the drug development process, regulatory requirements for approval of new drugs, drug products and cosmetics in regulated and semi-regulated countries. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products and cosmetics in regulated and semi-regulated countries.

Objectives

Upon completion of the course, the student shall be able to know

- process of drug discovery and development and generic product development
- regulatory approval process and registration procedures for API and drug products in US, EU
- Cosmetics regulations in regulated and semi-regulated countries
- A comparative study of India with other global regulated markets

Theory

60 Hrs

1. **USA & CANADA:** Organization structure and functions of FDA. 12
Federal register and Code of Federal Regulations (CFR), History 12
and evolution of United States Federal, Food, Drug and Cosmetic
Act (FFDCA), Hatch Waxman act and Orange book, Purple book,
Drug Master Files (DMF) system in US, Regulatory Approval
Process for Investigational New Drug (IND), New Drug
Application (NDA), Abbreviated New Drug Application (ANDA),
Supplemental New Drug Application (SNDA); Regulatory
requirements for Orphan drugs and Combination Products,
Changes to an approved NDA / ANDA. Regulatory considerations
for manufacturing, packaging and labeling of pharmaceuticals in
USA. Legislation and regulations for import, manufacture,
distribution and sale of cosmetics in USA and Canada.
2. **European Union & Australia:** Organization and structure of EMA 12
& EDQM, General guidelines, Active Substance Master Files 12
(ASMF) system in EU, Content and approval process of IMPD,
Marketing Authorization procedures in EU (Centralized procedure,

- Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union & Australia.
- 3 **Japan:** Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in Japan. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan 12 Hrs
- 4 **Emerging Market:** Introduction, Countries covered, Study of the world map, study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC) 12 Hrs
WHO: WHO, GMP, Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product (CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana)
- 5 **Brazil, ASEAN, CIS and GCC Countries:** 12
ASIAN Countries: Introduction to ACTD, Regulatory Requirements for registration of drugs and post approval requirements in China and South Korea & Association of Southeast Asian Nations (ASEAN) Region i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand.
CIS (Commonwealth Independent States): Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine GCC (Gulf Cooperation Council) for Arab states: Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE
 Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries.

REFERENCES :

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series, Vol.144
3. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185 Informa Health care Publishers.
4. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
5. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
6. Drugs: From Discovery to Approval, Second Edition By Rick Ng
7. New Drug Development: A Regulatory Overview, Eighth Edition By Mark Mathieu
8. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
9. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema
10. Country Specific Guidelines from official websites.
11. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ListMRAWebsites.pdf
12. Roadmap to an ASEAN economic community Edited by Denis Hew. ISEAS Publications, Singapore 2005, ISBN981-230-347-2
13. ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978-981-230-750-7
14. Building a Future with Brics: The Next Decade for Offshoring, Mark Kobayashi-Hillary, Springer
15. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer Trade performance and Regional Integration of the CIS Countries, Lev Freinkman,
16. The world Bank, Washington, DC, ISBN: 0-8212-5896-0
17. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World ByFrederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes 139
18. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low and Lorraine Carlos Salazar (Nov 22, 2010)
19. Doing Business in the Asean Countries, Balbir Bhasin, Business Expert Press ISBN:13:978-1-60649-108-9
20. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Institute of South east asian studies, Singapore

REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS (MRA 202T)

Scope

This course is designed to impart fundamental knowledge on Regulatory Requirements, Licensing and Registration, Regulation on Labelling of Biologics in India, USA and Europe

It prepares the students to learn in detail on Regulatory Requirements for biologics, Vaccines and Blood Products

Objectives

Upon the completion of the course the student shall be able to :

- Know the regulatory Requirements for Biologics and Vaccines
- Understand the regulation for newly developed biologics and biosimilars
- Know the pre-clinical and clinical development considerations of biologics
- Understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements

Theory

60 Hrs

1. **India** : Introduction, Applicable Regulations and Guidelines , 12 Hrs
Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance. GMP and GDP.
2. **USA:** Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics 12 Hrs
3. **European Union:** Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ biosimilarity assessment, Plasma master file, TSE/ BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars), pre-clinical 12 Hrs

and clinical development considerations; stability, safety, advertising, labelling and packing of biologics in EU

- 4 **Vaccine regulations in India, US and European Union:** Clinical evaluation, Marketing authorisation, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements Blood and Blood Products Regulations in India, US and European Union: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilance Network) 12 Hrs
- 5 **Herbal Products:** Quality, safety and legislation for herbal products in India, USA and European Union. 12 Hrs

REFERENCES

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano , David S. Mantus ; Informa ,2008
2. Biological Drug Products: Development and Strategies; Wei Wang , Manmohan Singh ; wiley ,2013
3. Development of Vaccines: From Discovery to Clinical Testing; Manmohan Singh , Indresh K. Srivastava ;Wiley, 2011
4. www.who.int/biologicals/en
5. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/
6. www.ihn-org.com
7. www.isbtweb.org
8. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India
9. www.cdsco.nic.in
10. www.ema.europa.eu › scientific guidelines › Biologics
11. www.fda.gov/biologicsbloodVaccines/GuidanceComplianceRegulatoryInformation (Biologics)

REGULATORY ASPECTS OF MEDICAL DEVICES (MRA 203T)

Scope

This course is designed to impart the fundamental knowledge on the medical devices and *in vitro* diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU and Asian countries along with WHO regulations. It prepares the students to learn in detail on the harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketing medical devices and IVDs in regulated countries.

Objectives

Upon completion of the course, the student shall be able to know

- basics of medical devices and IVDs, process of development, ethical and quality considerations
- harmonization initiatives for approval and marketing of medical devices and IVDs
- regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN
- clinical evaluation and investigation of medical devices and IVDs

Theory

60 Hrs

1. **Medical Devices:** Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs. Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals, History of Medical Device Regulation, Product Lifecycle of Medical Devices and Classification of Medical Devices. 12 Hrs
IMDRF/GHTF: Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN).
2. **Ethics:** Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011) 12 Hrs
Quality: Quality System Regulations of Medical Devices: ISO 13485, Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device

3	USA: Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and <i>In vitro</i> Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of <i>In vitro</i> diagnostics, classification and approval process.	12 Hrs
4	European Union: Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and <i>In vitro</i> Diagnostics (<i>In Vitro</i> Diagnostics Directive), CE certification process. Basics of <i>In vitro</i> diagnostics, classification and approval process.	12 Hrs
5	ASEAN, China & Japan: Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation. IMDRF study groups and guidance documents.	12 Hrs

REFERENCES

1. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics by Douglas J. Pisano, David Mantus.
2. Medical Device Development: A Regulatory Overview by Jonathan S. Kahan
3. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh
4. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics by Carmen Medina
5. Country Specific Guidelines from official websites.

REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS (MRA 204T)

Scope

This course is designed to impart the fundamental knowledge on Regulatory Requirements, Registration and Labeling Regulations of Nutraceuticals in India, USA and Europe.

It prepares the students to learn in detail on Regulatory Aspects for nutraceuticals and food supplements.

Objectives

Upon completion of the course, the student shall be able to

- Know the regulatory Requirements for nutraceuticals
- Understand the regulation for registration and labeling of nutraceuticals and food supplements in India, USA and Europe.

Theory

60 Hrs

1.	Nutraceuticals: Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market.	12 Hrs
2	Global Aspects: WHO guidelines on nutrition. NSF International: Its Role in the Dietary Supplements and Nutraceuticals Industries, NSF Certification, NSF Standards for Food And Dietary Supplements. Good Manufacturing Practices for Nutraceuticals.	12 Hrs
3	India : Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and Functions, Regulations for import, manufacture and sale of nutraceutical products in India, Recommended Dietary Allowances (RDA) in India.	12 Hrs
4	USA: US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements, Labelling Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the U.S	12 Hrs

- 5 **European Union:** European Food Safety Authority (EFSA): 12
Organization and Functions. EU Directives and regulations for Hrs
manufacture and sale of nutraceuticals and dietary supplements.
Nutrition labelling. European Regulation on Novel Foods and
Novel Food Ingredients. Recommended Dietary Allowances
(RDA) in Europe.

REFERENCES

1. Regulation of Functional Foods and Nutraceuticals: A Global Perspective by Clare M. Hasler (Wiley Online Library)
2. Nutraceutical and Functional Food Regulations in the United States and Around the World by Debasis Bagchi (Academic Press, Elsevier)
3. <http://www.who.int/publications/guidelines/nutrition/en/>
4. [http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU\(2015\)536324_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU(2015)536324_EN.pdf)
5. Handbook of Nutraceuticals by Yashwant Pathak (CRC Press)
6. Food Regulation: Law, Science, Policy and Practice by Neal D. Fortin (Wiley)
7. Country Specific Guidelines from official websites.

REGULATORY AFFAIRS PRACTICAL - II

(MRA 205P)

1. Case studies on
2. Change Management/ Change control. Deviations
3. Corrective & Preventive Actions (CAPA)
4. Documentation of raw materials analysis as per official monographs
5. Preparation of audit checklist for various agencies
6. Preparation of submission to FDA using eCTD software
7. Preparation of submission to EMA using eCTD software
8. Preparation of submission to MHRA using eCTD software
9. Preparation of Biologics License Applications (BLA)
10. Preparation of documents required for Vaccine Product Approval
11. Comparison of clinical trial application requirements of US, EU and India of Biologics
12. Preparation of Checklist for Registration of Blood and Blood Products
13. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization
14. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization
15. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization
16. Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization
17. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization
18. Checklists for 510k and PMA for US market
19. Checklist for CE marking for various classes of devices for EU
20. STED Application for Class III Devices
21. Audit Checklist for Medical Device Facility
22. Clinical Investigation Plan for Medical Devices

PHARMACEUTICAL BIOTECHNOLOGY (MPB)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPB 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know,

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY

60 Hrs

- 1. a. UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. **12 Hrs**
IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy
b. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
c. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.
- 2. NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy. **12 Hrs**

3	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy	12 Hrs
4	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography	12 Hrs
5	a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder diffraction technique, Types of crystals and applications of X-ray diffraction.	12 Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

MICROBIAL AND CELLULAR BIOLOGY (MPB 102T)

Scope

This subject is designed to provide the advanced knowledge to the biotechnology students in invaluable areas of advanced microbiology which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry.

Objective

At the completion of this course it is expected that the students will get an understanding about the following aspects;

- Importance of Microorganisms in Industry
- Central dogma of molecular biology
- Structure and function of cell and cell communication
- Cell culture technology and its applications in pharmaceutical industries.
- Microbial pathogenesis and correlating it to rational use of antimicrobial agents.

THEORY

60Hrs

1.	Microbiology Introduction – Prokaryotes and Eukaryotes. Bacteria, fungi, actinomycetes and virus - structure, chemistry and morphology, cultural, physiological and reproductive features. Methods of isolation, cultivation and maintenance of pure cultures. Industrially important microorganisms - examples and applications	12 Hrs
2	Molecular Biology: Structure of nucleus and chromosome, Nucleic acids and composition, structure and types of DNA and RNA. Central dogma of molecular biology: Replication, Transcription and translation. Gene regulation Gene copy number, transcriptional control and translational control. RNA processing Modification and Maturation, RNA splicing, RNA editing, RNA amplification. Mutagenesis and repair mechanisms, types of mutants, application of mutagenesis in strain improvement, gene mapping of plasmids- types purification and application. Phage genetics, genetic organization, phage mutation and lysogeny.	12 Hrs

3	Cell structure and function Cell organelles, cytoskeleton & cell movements, basic aspects of cell regulation, bioenergetics and fuelling reactions of aerobics and anaerobics, secondary metabolism & its applications. Cell communication, cell cycle and apoptosis, mechanism of cell division. Cell junctions/adhesion and extra cellular matrix, germ cells and fertilization, histology – the life and death of cells in tissues. Cell Cycle and Cytoskeleton Cell Division and its Regulation, G-Protein Coupled Receptors, Kinases, Nuclear receptors, Cytoskeleton & cell movements, Intermediate Filaments. Apoptosis and Oncogenes Programmed Cell Death, Tumor cells, carcinogens & repair. Differentiation and Developmental Biology Fertilization, Events of Fertilization, <i>In vitro</i> Fertilization, Embryonic Germ Cells, Stem Cells and its Application.	12 Hrs
4	Principles of microbial nutrition Physical and chemical environment for microbial growth, Stability and degeneration of microbial cultures. Growth of animal cells in culture General procedure for cell culture, Nutrient composition, Primary, established and transformed cell cultures, applications of cell cultures in pharmaceutical industry and research. Growth of viruses in cell culture propagation and enumeration. <i>In-vitro</i> screening techniques- cytotoxicity, anti-tumor, anti-viral assays.	12 Hrs
5	Microbial pathology Identifying the features of pathogenic bacteria, fungi and viruses. Mechanism of microbial pathogenicity, etiology and pathology of common microbial diseases and currently recommended therapies for common bacterial, fungal & viral infections. Mechanism of action of antimicrobial agents and possible sites of chemotherapy.	12 Hrs

REFERENCES

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn, Industrial Microbiology, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. David Freifelder, Molecular Biology, 2nd edition, Narosa Publishing House.
5. R. Ian Freshney, Culture of animal cells – A manual of Basic techniques, 6th edition, Wileys publication house.
6. David Baltimore, Molecular cell biology, W H Freeman & Co publishers.
7. Cell biology vol-I,II,III by Julio E. Cells
8. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company.

BIOPROCESS ENGINEERING AND TECHNOLOGY (MPB 103T)

Scope

This paper has been designed to provide the knowledge to the biotechnology students in invaluable areas of bioprocess technology to develop skills to modify, design and operate different types of fermenters, to understand and implement various fermentation procedures, to train students in scale up fermentation operations.

Objective

At the completion of this subject it is expected that students will be able to,

- Understand basics and design of fermentation technology
- Scale up and scale down processing of fermentation technology
- Bioprocessing of the industrially important microbial metabolites in industries and R & D organizations.
- Regulation governing the manufacturing of biological products
- Understand and conduct fermentation process kinetics.

THEORY

60 Hrs

1. Introduction to fermentation technology

12

Basic principles of fermentation

Hrs

Study of the design and operation of bioreactor

Ancillary parts and function, impeller design and agitation, power requirements on measurements and control of dissolved oxygen, carbon dioxide, temperature, pH and foam.

Types of bioreactor

CSTR, tower, airlift, bubble column, packed glass bead, hollow fiber, configuration and application

Computer control of fermentation process

System configuration and application

2. Mass transfer

12

Theory, diffusional resistance to oxygen requirements of microorganisms, measurements of mass transfer co-efficient and factor affecting them, effects of aeration and agitation on mass transfer, supply of air, air compressing, cleaning and sterilization of air and plenum ventilation, air sampling and testing standards for air purity.

Hrs

Rheology

Rheological properties of fermentation system and their importance in bioprocessing.

3	Scale up of fermentation process Principles, theoretical considerations, techniques used, media for fermentation, HTST sterilization, advantage and disadvantage, liquid sterilization. Cultivation and immobilized culture system Cultivation system - batch culture, continuous culture, synchronous cultures, fed batch culture. Graphical plot representing the above systems. Introduction to immobilization Techniques, immobilization of whole cell, immobilized culture system to prepare fine chemicals. Immobilization of enzymes and their applications in the industry. Reactors for immobilized systems and perspective of enzyme engineering.	12 Hrs
4	Scale down of fermentation process Theory, equipment design and operation, methods of filtration, solvent extraction, chromatographic separation, crystallization turbidity analysis and cell yield determination, metabolic response assay, enzymatic assay, bioautographic techniques and disruption of cells for product recovery. Isolation and screening Primary and secondary, maintenance of stockculture, strain improvement for increased yield.	12 Hrs
5	Bioprocessing of the industrially important microbial metabolites a) Organic solvents – Alcohol and Glycerol b) Organic acids - Citric acids, Lactic acids, c) Amino acids - Glutamic acids, Lysine, Cyclic AMP and GMP d) Antibiotics - Penicillin, Streptomycin, Griseofulvin, e) Vitamins - B12, Riboflavin and Vitamin C Biosynthetic pathways for some secondary metabolites, microbial transformation of steroids and alkaloids Regulation governing the manufacturing of biological products .	12 Hrs

REFERENCES

1. Peter Stanbury, Allan Whitaker, Stephen Hall, Principles of Fermentation technology, Elsevier stores.
2. L.E. Casida, Industrial Microbiology, John Wiley & sons Inc.
3. F.M. Asubel, Current protocols in molecular biology, volume I and II, John Wiley Publishers.
4. Biotol Board, Bioreactor design and product yield, Butterworth and Helhemann Publishers.
5. H. Patel, Industrial microbiology, Macmillan India Limited.

ADVANCED PHARMACEUTICAL BIOTECHNOLOGY (MPB 104T)

Scope

This paper has been designed to provide the knowledge to the students to develop skills of advanced techniques of isolation and purification of enzymes, to enrich students with current status of development of vaccines and economic importance of biotechnology products.

Objective

At the completion of this subject it is expected that students will be able to

- Understand about the latest technology development in biotechnology technique, tools and their uses in drug and vaccine development.
- Identify appropriate sources of enzymes.
- Understand and perform genetic engineering techniques in gene manipulation, r-DNA technology and gene amplification.
- Understand the overview of pharmacogenomics.
- Learn the regulatory approval process and key regulatory agencies for new drugs, biologics, devices, and drug-device combinations.

THEORY

60 Hrs

1. Enzyme Technology

12

Classification, general properties of enzymes, dynamics of enzymatic activity, sources of enzymes, extraction and purification, pharmaceutical, therapeutic and clinical application. Production of amyloglucosidase, glucose isomerase, amylase and trypsin.

2 Genetic Engineering

12

Techniques of gene manipulation, cloning strategies, procedures, cloning vectors expression vectors, recombinant selection and screening, expression in E.coli and yeast.

Site directed mutagenesis, polymerase chain reaction, and analysis of DNA sequences.

Gene library and cDNA

Applications of the above technique in the production of,

• Regulatory proteins	- Interferon, Interleukins
• Blood products	- Erythropoietin
• Vaccines	- Hepatitis-B
• Hormones	- Insulin

3	Therapeutic peptides Study on controlled and site specified delivery of therapeutic peptides and proteins through various routes of administration. Transgenic animals Production of useful proteins in transgenic animals and gene therapy. Human Genome The human genome project-a brief study, Human chromosome – Structure and classification, chromosomal abnormalities – Syndromes	12 Hrs
4	Signal transduction Introduction, cell signaling pathways, Ion channels, Sensors and effectors, ON and OFF mechanisms, Spatial and temporal aspects of signaling, cellular process, development, cell cycle and proliferation, neuronal signaling, cell stress, inflammatory responses and cell death, signaling defects and diseases. Oncogenes Introduction, definition, various oncogenes and their proteins.	12 Hrs
5	Microbial Biotransformation Biotransformation for the synthesis of chiral drugs and steroids. Microbial Biodegradation Biodegradation of xenobiotics, chemical and industrial wastes, Production of single-cell protein, Applications of microbes in environmental monitoring. Biosensors Definition, characteristics of ideal biosensors, types of biosensors, biological recognition elements, transducers, application of biosensors.	12 Hrs

REFERENCES

1. Biotechnology-The biological principles: MD Trevan, S Boffey, KH Goulding and P.F. Stanbury.
2. Immobilization of cells and enzymes: HosevearKennadycabral& Bicker staff
3. Principles of Gene Manipulating: RW Old and S.B.Primrose.
4. Molecular Cell Biology: Harvey Lodish, David Baltimore, Arnold Berk, S LawenceZipursky, Paul Matsudaira, James Darnell.
5. Modern Biotechnology: S.B Primrose

6. Gene transfer and expression protocols-methods in Molecular Biology, vol. VII, Edit E.T. Murray
7. Current protocols in Molecular Biology, Vo1.I & II:F.M. Asubel, John wiley Publishers
8. Current protocols in cellular biology, Vo1.1 & II John wiley publishers.
9. Principles of human genetics; by Curt Stern, published by W.H. Freeman.

PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL - I

(MPB 105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Isolation and Purification of microorganism from the soil
8. Microbial contamination of Water and biochemical parameters.
9. Determination of Minimum Inhibitory concentration by gradient plate technique and serial dilution method.
10. UV- survival curve and Dark repair
11. Sterility test for pharmaceutical preparations
12. Sub culturing of cells and cytotoxicity assays.
13. Construction of growth curve and determination of specific growth rate and doubling time
14. Fermentation process of alcohol and wine production
15. Fermentation of vitamins and antibiotics
16. Whole cell immobilization engineering
17. Thermal death kinetics of bacteria
18. Replica plating
19. Bio-autography.
20. Isolation and estimation of DNA
21. Isolation and estimation of RNA
22. Isolation of plasmids
23. Agarose gel electrophoresis.
24. Transformation techniques
25. SDS – polyacrylamide gel electrophoresis for proteins
26. Polymerase chain reaction technique.

PROTEINS AND PROTEIN FORMULATIONS (MPB 201T)

Scope

This course is designed to impart knowledge and skills necessary for knowing fundamental aspects of proteins and their formulations is a part of drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of information for protein formulation and design are provided to help the students to clarify the various biological concepts of protein.

Objective

At the completion of this course it is expected that students will be able to understand,

- Various methods of purification of proteins
- Peptides in drug development
- Protein identification and characterization
- Protein based formulations
- Sequencing proteins

THEORY

60 Hrs

1.	Protein engineering	12 Hrs
	Concepts for protein engineering. Isolation and purification of proteins, Stability and activity based approaches of protein engineering, Chemical and Physical Considerations in Protein and Peptide Stability, Different methods for protein engineering, gene shuffling, and direct evolution.	
2	Peptidomimetics	12 Hrs
	Introduction, classification; Conformationally restricted peptides, design, pseudopeptides, peptidomimetics and transition state analogs; Biologically active template; Amino acid replacements; Peptidomimetics and rational drug design; CADD techniques in peptidomimetics; Development of non peptide peptidomimetics.	
3	Proteomics	12 Hrs
	Protein identification and characterization: Methods/strategies, protein identification, de novo protein characterization, Isotope labelling, N- and C-terminal tags.	

2-Dimensional gel electrophoresis

Methods including immobilized pH gradients (IPGs), resolution, reproducibility and image analysis, future developments

4	Protein formulation	12
	Different strategies used in the formulation of DNA and proteins, Analytical and biophysical parameters of proteins and DNA in pre-formulation, Liposomes, Neon-spears, Neon-particulate system, PEGylation, Biological Activity, Biophysical Characterization Techniques, Forced degradation studies of protein.	
5	Methods of protein sequencing	12
	Various methods of protein sequencing, characterisation, Edman degradation, Tryptic and/or Chymotryptic Peptide Mapping.	

REFERENCES

1. H. Lodhishet. Al. Molecular Cell Biology, W. H. Freeman and Company
2. Protein Purification – Hand Book, Amersham pharmacia biotech
3. EngelbertBuxbaum, Fundamentals of Protein Structure and Function, Springer Science
4. Sheldon J. Park, Jennifer R. Cochran, Protein Engineering and Design, CRC press.
5. Robert K. Skopes. Protein purification, principle and practice, springer link.
6. David Whitford, Proteins-Structure and Function, John Wiley & Sons Ltd.
7. James Swarbrick, Protein Formulation and Delivery Informa Healthcare USA, Inc.
8. Rodney Pearlman, Y. John Wang Formulation, Characterization, and Stability of Protein Drugs, Kluwer Academic Publishers.

IMMUNOTECHNOLOGY (MPB 202T)

Scope

This course is designed to impart knowledge on production and engineering of antibodies, the application of antigens, the design of (recombinant) vaccines, strategies for immune intervention, etc. The Immunotechnology - based techniques will be used for therapeutics and diagnostics, industries in the production, quality control and quality assurance, and in R&D.

Objective

After this course, the students will be able to:-

- Understand the techniques like immunodiagnostic tests,
- Characterization of lymphocytes, purification of antigens and antibody, etc.
- Access health problems with immunological background;
- Develop approaches for the immune intervention of diseases

THEORY

60 Hrs

1. Fundamental aspects of immunology

12

Introduction, cells and organs of the immune system, cellular basis of Immune response, primary and secondary lymphoid organs, antigen antibody and their structure.

Types of immune responses, anatomy of immune response.

Overview of innate and adaptive Immunity.

Humoral Immunity

B – Lymphocytes and their activation. Structure and function of immunoglobulins, idiotypes and anti idiotypic antibodies.

Cell mediated Immunity

Thymus derived lymphocytes (T cells) – their ontogeny and types, MHC complex, antigen presenting cells (APC), mechanisms of T cell activation, macrophages, dendritic cells, langerhans cells, mechanism of phagocytosis

2 Immune Regulation and Tolerance

12

Complement activation and types and their biological functions, cytokines and their role in immune response.

Hypersensitivity

Hypersensitivity Types I-IV, Hypersensitivity reactions and treatment

Autoimmune diseases

3	Vaccine technology Vaccine and their types, conventional vaccines, novel methods for vaccine production, antiidiotype vaccine, DNA vaccine, genetically engineered vaccine, iscoms, synthetic peptides, and immunodiagnosics. Stem cell technology Stem cell technology and applications to immunology	12 Hrs
4	Hybridoma Technology Hybridoma techniques – fusion methods for myeloma cells and B-Lymphocytes, selection and screening techniques. Production and purification of monoclonal antibodies and their applications in Pharmaceutical industry.	12 Hrs
5	Immunological Disorder Autoimmune disorders and types, pathogenic mechanisms, treatment, experimental models of auto immune diseases, primary and secondary immunodeficiency disorders. Immunodiagnosis Antigen antibody interaction – Precipitation reaction, Agglutination reactions, Principles and applications of ELISA, Radio Immuno Assay, Western blot analysis, immune-electrophoresis, immuno fluorescence, chemiluminescence assay, complement fixation reaction.	12 Hrs

REFERENCES

1. J. Kubey, Immunology – an Introduction.
2. S.C. Rastogi, Immunodiagnosics, New Age International.
3. Ashim Chakravathy, Immunology and Immunotechnology, Oxford University Press.
4. E. Benjamini, Molecular Immunology.

BIOINFORMATICS AND COMPUTATIONAL BIOTECHNOLOGY (MPB 203T)

Scope

This paper has been designed to provide the advanced knowledge to the biotechnology students in invaluable areas of advanced bioinformatics which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry.

Objectives

Upon completion of this course it is expected that the students will be able to understand,

- Use of computers in developing a new drugs
- Biological concepts for bioinformatics
- Proteins and their diversity
- Various gene finding methods
- Searching the biological databases
- Target searching
- Various methods of drug designing

THEORY

60 Hrs

1.	Introduction to Bioinformatics	12
	Definition and History of Bioinformatics, Internet and Bioinformatics, Introduction to Data Mining, Applications of Data Mining to Bioinformatics,	Hrs
	Biological Database	
	Protein and nucleic acid databases. Structural data bases. Collecting and storing the sequence and Applications of Bioinformatics.	
2	Sequence analysis	12
	Sequence alignment, pair wise alignment techniques, multiple sequence analysis, multiple sequence alignment; Flexible sequence similarity searching with the FAST3 program package, the use of CLUSTAL W and CLUSTAL X for the multiple sequence alignment. Tools used for sequence analysis.	Hrs
3	Protein informatics	12
	Introduction; Force field methods; Energy, buried and exposed residues, side chains and neighbours; Fixed regions, hydrogen bonds, mapping properties onto surfaces; Fitting monomers, R &	Hrs

S fit of conformers, assigning secondary structures; Sequence alignment-methods, evaluation, scoring; Protein completion, backbone construction and side chain addition; Small peptide methodology, software accessibility, building peptides; Protein displays; Substructure manipulations, annealing.

Protein structure prediction

Protein folding and model generation; Secondary structure prediction, analyzing secondary structures; Protein loop searching, loop generating methods, loop analysis; Homology modeling, concepts of homology modeling, potential applications, description, methodology, homologous sequence identification; Align structures, align model sequence; Construction of variable and conserved regions, threading techniques, Topology fingerprint approach for prediction, evaluation of alternate models; Structure prediction on a mystery sequence, structure aided sequence techniques of structure prediction, structural profiles, alignment algorithms, mutation tables, prediction, validation, sequence based methods of structure prediction, prediction using inverse folding, fold prediction; Significance analysis, scoring techniques, sequence- sequence scoring.

Docking

Docking problems, methods for protein- ligand docking, validation studies and applications; Screening small molecule databases, docking of combinatorial libraries, input data, analyzing docking results.

4 Diversity of Genomes

12

Prokaryotic and Eukaryotic Gene Families. Genome Analysis: Introduction, Gene prediction methods, Gene mapping and applications- Genetic and Physical Mapping, Integrated map, Sequence assembly and gene expression.

Hrs

Completed Genomes

Bacterium, Nematode, Plant and Human

Evolution of Genomes

Lateral or Horizontal Transfer among Genomes, Transcriptome and Proteome-General Account

Phylogenetic analysis

Evolutionary Change in Nucleotide Sequences, Rates and Patterns of Nucleotide Substitution, Models for Nucleotide Substitution, Construction of Phylogenetic Tree, Genome Annotation technique.

5	Target searching and Drug Designing	12
	Target and lead, timeline for drug development, target discovery, target modulators, <i>In-silico</i> gene expression, microarray, and lead discovery, libraries of ligands, active site analysis, and prediction of drug quality.	Hrs

REFERENCES

1. David W. Mount, Bioinformatics Sequence and Genome Analysis, CBS Publishers and Distributors
2. S. C. Rastogi et al. Bioinformatics- Concepts Skill and Applications, CBS Publishers and Distributors
3. T. E. Creighton, Protein Structure and Molecular Properties, W. H. Freeman and Company
4. Andreas D. Baxevanis, B. F. Francis Ouellette, Bioinformatics; A Practical Guide to the Analysis of Genes and Proteins, John Wiley & Sons, Inc.
5. Arthur M. Lesk, Introduction to Bioinformatics, Oxford University Press.
6. Shui Qing Ye. Bioinformatics: A Practical Approach, Chapman & Hall/CRC.
7. David Posada, Bioinformatics for DNA Sequence Analysis, Humana press.
8. Lesk, A.M. Introduction to Bioinformatics. Oxford University Press.
9. Letovsky, S.I. Bioinformatics. Kluwer Academic Publishers.
10. Baldi, P. and Brunak, S. Bioinformatics. The MIT Press.

BIOLOGICAL EVALUATION OF DRUG THERAPY (MPB 204T)

Scope

This paper has been designed to provide the knowledge to the biotechnology students to understand the importance of biological and evaluation of drug therapy of biological medicines.

Objective

At the completion of this subject it is expected that students will be able to,

- Understand about the general concept of standardization of biological.
- Understand the importance of transgenic animals and knockout animals.
- Understand the biological medicines in development of various diseases.
- Learn the biological evaluation of drugs *in vitro* and *in vivo*

THEORY

60 Hrs

1. Biological Standardization

12

General principles, Scope and limitation of bio-assay, bioassay of some official drugs.

Preclinical drug evaluation

Preclinical drug evaluation of its biological activity, potency and toxicity-Toxicity test in animals including acute, sub-acute and chronic toxicity, ED50 and LD50 determination, special toxicity test like teratogenicity and mutagenicity.

Guidelines for toxicity studies

Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials.

2 Pyrogens

12

Pyrogens: Sources, Chemistry and properties of bacterial pyrogens and endotoxins, Official pyrogen tests.

Microbiological assay

Assay of antibiotics and vitamins.

Biological evaluation of drugs

Screening and evaluation (including principles of screening, development of models for diseases: *In vivo* models / *In vitro* models / cell line study).

3	Biologic Medicines in Development for various diseases - By Therapeutic Category • Genetic Disorders • Eye related Disorders • Digestive Disorders • Diabetes/Related Conditions • Cardiovascular Disease • Cancer/Related Conditions • Blood Disorders • Autoimmune Disorders • Infectious Diseases • Neurologic Disorders • Skin Diseases • Organe Transplantation	12 Hrs
	Biologic Medicines in Development for various diseases – by Product Category • Antisense • Vaccines • Recombinant Hormones/Proteins • Monoclonal Antibodies (mAb) • Interferons • Growth Factors • Gene Therapy • RNA Interference	
4	Regulatory aspects : drugs, biologics and medical devices An introduction to the regulations and documents necessary for approval of a medical product. Regulatory consideration Regulatory consideration for pre-clinical testing and clinical testing of drugs, biologics and medical devices. New Drug Applications for Global Pharmaceutical Product Approvals	12 Hrs
5	Bioavailability Objectives and consideration in bio-availability studies of Biopharmaceuticals, Concept of equivalents, Measurements of bio-availability.	12 Hrs

Determination of the rate of absorption, Bioequivalence and its importance, Regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems of Biopharmaceuticals.

Pharmacokinetics

Pharmacokinetics:- Basic consideration, Pharmacokinetic models, Application of Pharmacokinetics in new drug development of Biopharmaceuticals and designing of dosage forms and Novel drug delivery systems of Biopharmaceuticals.

REFERENCES

1. Perkins F.T., Hennessen W. Standardization and Control of Biologicals Produced by Recombinant DNA Technology, International Association of Biological Standardization
2. J.H. Burn., Biological Standardization, Oxford University Press
3. Drug Discovery and Evaluation in Pharmacology assay: Vogel
4. Chow, Shein, Ching, Design and analysis of animal studies in pharmaceutical development,
5. Nodine and Siegler, Animal and Clinical pharmacologic Techniques in Drug Evaluation.
6. Screening methods in pharmacology (vol I & II), R.A. Turner.

PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL - II
(MPB 205P)

1. Protein identification
2. Protein characterization
3. Protein biochemistry
4. Recombinant DNA Technology
5. Protein expression
6. Protein formulations
7. Database searching
8. Sequence analysis methods
9. Protein structure prediction
10. Gene annotation methods
11. Phylogenetic analysis
12. Protein, DNA binding studies
13. Preparation of DNA for PCR applications – Isolation, Purity and Quantification
14. Introduction to PCR – working of PCR, Programming.
15. Introduction to RT-PCR – working, programming.
16. Primer design using softwares.
17. Gene DNA amplification by random / specific primers.
18. Southern Hybridization
19. Western Blotting
20. Gene transformation

PHARMACY PRACTICE (MPP)

CLINICAL PHARMACY PRACTICE (MPP 101T)

Scope

This course is designed to impart the basic knowledge and skills that are required to practice pharmacy including the provision of pharmaceutical care services to both healthcare professionals and patients in clinical settings.

Objectives

Upon completion of this course it is expected that students shall be able to :

- Understand the elements of pharmaceutical care and provide comprehensive patient care services
- Interpret the laboratory results to aid the clinical diagnosis of various disorders
- Provide integrated, critically analyzed medicine and poison information to enable healthcare professionals in the efficient patient management

THEORY

60 Hrs

1. **Introduction to Clinical Pharmacy:** Definition, evolution and scope of clinical pharmacy, International and national scenario of clinical pharmacy practice, Pharmaceutical care
Clinical Pharmacy Services: Ward round participation, Drug therapy review (Drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions) 12 Hrs
2. **Clinical Pharmacy Services:** Patient medication history interview, Basic concept of medicine and poison information services, Basic concept of pharmacovigilance, Hemovigilance, Materiovigilance and AEFI, Patient medication counselling, Drug utilisation evaluation, Documentation of clinical pharmacy services, Quality assurance of clinical pharmacy services. 12 Hrs
3. **Patient Data Analysis:**
Patient Data & Practice Skills: Patient's case history - its structure and significances in drug therapy management, Common medical abbreviations and terminologies used in clinical practice, Communication skills: verbal and non-verbal communications, its applications in patient care services. 12 Hrs

Lab Data Interpretation: Hematological tests, Renal function tests, Liver function tests

4	Lab Data Interpretation: Tests associated with cardiac disorders, Pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, Microbiological culture sensitivity tests	12 Hrs
5	Medicines & Poison Information Services Medicine Information Service: Definition and need for medicine information service, Medicine information resources, Systematic approach in answering medicine information queries, Preparation of verbal and written response, Establishing a drug information centre. Poison Information Service: Definition, need, organization and functions of poison information centre.	12 Hrs

REFERENCES

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
2. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia
3. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc
4. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS-I (MPP 102T)

Scope

This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence based medicine
- Prepare individualized therapeutic plans based on diagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time- course of clinical and laboratory indices of therapeutic response and adverse effect/s)

THEORY

60 Hrs

Etiopathogenesis and pharmacotherapy of diseases associated with following systems

1.	Cardiovascular system: Hypertension, Congestive cardiac failure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias.	12 Hrs
2	Respiratory system: Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases Endocrine system: Diabetes, Thyroid diseases	12 Hrs
3	Gastrointestinal system: Peptic ulcer diseases, Reflux esophagitis, Inflammatory bowel diseases, Jaundice & hepatitis	12 Hrs
4	Gastrointestinal system: Cirrhosis, Diarrhea and Constipation, Drug-induced liver disease	12 Hrs

Hematological diseases: Anemia, Deep vein thrombosis, Drug induced hematological disorders

- 5 **Bone and joint disorders:** Rheumatoid arthritis, Osteoarthritis, 12
Gout, Osteoporosis Hrs

Dermatological Diseases: Psoriasis, Eczema and scabies,
impetigo, drug induced skin disorders

Ophthalmology: Conjunctivitis, Glaucoma

REFERENCES

1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice— McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

HOSPITAL & COMMUNITY PHARMACY (MPP 103T)

Scope

This course is designed to impart basic knowledge and skills that are required to practice pharmacy in both hospital and community settings.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Understand the organizational structure of hospital pharmacy
- Understand drug policy and drug committees
- Know about procurement & drug distribution practices
- Know the admixtures of radiopharmaceuticals
- Understand the community pharmacy management
- Know about value added services in community pharmacies

THEORY

60 Hrs

1.	1. Introduction to Hospitals – Definition, classification, organizational structure Hospital Pharmacy: Definition, Relationship of hospital pharmacy department with other departments, Organizational structure, legal requirements, work load statistics, Infrastructural requirements, Hospital Pharmacy Budget and Hospital Pharmacy management Hospital Drug Policy: Pharmacy & Therapeutics Committee, Infection Control committee, Research & Ethics Committee, Management of Medicines as per NABH	12 Hrs
2	2. Hospital Formulary Guidelines and its development, Developing Therapeutic guidelines, Drug procurement process, and methods of Inventory control, Methods of Drug distribution, Intravenous admixtures, Hospital Waste Management	12 Hrs
3	3. Education and training: Training of technical staff, training and continuing education for pharmacists, Pharmacy students, Medical staff and students, Nursing staff and students, Formal and informal meetings and lectures, Drug and therapeutics newsletter. Community Pharmacy Practice: Definition, roles & responsibilities of community pharmacists, and their relationship with other health care providers.	12 Hrs

Community Pharmacy management: Legal requirements to start community pharmacy, site selection, lay out & design, drug display, super drug store model, accounts and audits, Good dispensing practices, Different softwares & databases used in community pharmacies. Entrepreneurship in community pharmacy.

- 4 **Prescription** – Legal requirements & interpretation, prescription related problems 12 Hrs
Responding to symptoms of minor ailments: Head ache, pyrexia, menstrual pains, food and drug allergy,
OTC medication: Rational use of over the counter medications
Medication counseling and use of patient information leaflets
Medication adherence – Definition, factors influencing adherence behavior, strategies to improve medication adherence
Patient referrals to the doctors
ADR monitoring in community pharmacies

- 5 **Health Promotion** – Definition and health promotion activities, family planning, Health screening services, first aid, prevention of communicable and non-communicable diseases, smoking cessation, Child & mother care 12 Hrs
National Health Programs- Role of Community Pharmacist in Malaria and TB control programs
Home Medicines review program – Definition, objectives, Guidelines, method and outcomes
Research in community pharmacy Practice

REFERENCES

1. Hospital Pharmacy - Hassan WE. Lea and Febiger publication.
2. Textbook of hospital pharmacy - Allwood MC and Blackwell.
3. Avery's Drug Treatment, Adis International Limited.
4. Community Pharmacy Practice – Ramesh Adepu, BSP Publishers, Hyderabad
5. Remington Pharmaceutical Sciences.
6. Relevant review articles from recent medical and pharmaceutical literature

CLINICAL RESEARCH (MPP 104T)

Scope

This course aims to provide the students an opportunity to learn drug development process especially the phases of clinical trials and also the ethical issues involved in the conduct of clinical research. Also, it aims to impart knowledge and develop skills on conceptualizing, designing, conducting and managing clinical trials.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Know the new drug development process.
- Understand the regulatory and ethical requirements.
- Appreciate and conduct the clinical trials activities
- Know safety monitoring and reporting in clinical trials
- Manage the trial coordination process

THEORY

60 Hrs

1. **Drug development process:** Introduction, various approaches to drug discovery, Investigational new drug application submission
Ethics in Biomedical Research: Ethical Issues in Biomedical Research – Principles of ethics in biomedical research, Ethical committee [institutional review board] - its constitution and functions, Challenges in implementation of ethical guidelines, ICH GCP guidelines and ICMR guidelines in conduct of Clinical trials, Drug Safety Reporting. 12 Hrs
2. **Types and Designs used in Clinical Research:** Planning and execution of clinical trials, Various Phases of clinical trials, Bioavailability and Bioequivalence studies, Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification), Types of research designs based on Controlling Method (Experimental, Quasi experimental, and Observational methods) Time Sequences (Prospective and Retrospective), Sampling methods (Cohort study, case Control study and cross sectional study), Health outcome measures (Clinical & Physiological, Humanistic and economic) 12 Hrs
Clinical Trial Study team: Roles and responsibilities of: Investigator, Study Coordinator, Sponsor, Monitor, Contract Research Organization.

- 3 **Clinical trial Documents:** Guidelines to the preparation of following documents: Protocols, Investigator's Brochure, Informed Consent Form, Case report forms, Contracts and agreements, Dairy Cards 12 Hrs
- Clinical Trial Start up activities:** Site Feasibility Studies, Site/Investigator selection, Pre-study visit, Investigator meeting, Clinical trial agreement execution, Ethics committee document preparation and submission
- 4 **Investigational Product:** Procurement and Storage of investigation product 12 Hrs
- Filing procedures:** Essential documents for clinical trial, Trial Master File preparation and maintenance, Investigator Site File, Pharmacy File, Site initiation visit, Conduct, Report and Follow up
- Clinical Trial Monitoring and Close out:**
- Preparation and conduct of monitoring visit:*** Review of source documents, CRF, ICF, IP storage, accountability and reconciliation, Study Procedure, EC communications, Safety reporting, Monitoring visit reporting and follow-up
- Close-Out visit:** Study related documents collection, Archival requirement, Investigational Product reconciliation and destruction, Close-Out visit report.
- 5 **Quality Assurance and Quality Control in Clinical Trials:** 12 Hrs
- Types of audits, Audit criteria, Audit process, Responsibilities of stakeholders in audit process, Audit follow-up and documentation, Audit resolution and Preparing for FDA inspections, Fraud and misconduct management
- Data Management**
- Infrastructure and System Requirement for Data Management:*** Electronic data capture systems, Selection and implementation of new systems, System validation and test procedures, Coding dictionaries, Data migration and archival
- Clinical Trial Data Management:** Standard Operating Procedures, Data management plan, CRF & Data base design considerations, Study set-up, Data entry, CRF tracking and corrections, Data cleaning, Managing laboratory and ADR data, Data transfer and database lock, Quality Control and Quality Assurance in CDM, Data mining and warehousing.

REFERENCES

1. Principles and practice of pharmaceutical medicine, Second edition. Authors: Lionel D. Edward, Andrew J. Flether, Anthony W. Fos, Peter D. Sloaier. Publisher: Wiley;
2. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone
3. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
4. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health.
5. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice. E6; May 1996.
6. Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research, New Delhi.
7. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, John Wiley and Sons.
8. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
9. Goodman & Gilman: JG Hardman, LE Limbard, McGraw Hill Publications.
10. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACY PRACTICE PRACTICAL – I (MPP 105P)

Pharmacy Practice practical component includes experiments covering important topics of the courses Clinical Pharmacy Practice, Pharmacotherapeutics-I, Hospital & Community Pharmacy and Clinical Research.

List of Experiments (24)

1. Treatment Chart Review (one)
2. Medication History Interview (one)
3. Patient Medication Counseling (two)
4. Drug Information Query (two)
5. Poison Information Query (one)
6. Lab Data Interpretation (two)
7. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
8. ABC Analysis of a given list of medications (one)
9. Preparation of content of a medicine, with proper justification, for the inclusion in the hospital formulary (one)
10. Formulation and dispensing of a given IV admixtures (one)
11. Preparation of a patient information leaflet (two)
12. Preparation of Study Protocol (one)
13. Preparation of Informed Consent Form (one)

PRINCIPLES OF QUALITY USE OF MEDICINES (MPP 201T)

Scope:

This course is designed to impart basic knowledge and skills that are required to practice quality use of medicines (QUM) in different healthcare settings and also to promote quality use of medicines, in clinical practice, through evidence-based medicine approach.

Objectives:

Upon completion of this course it is expected that students shall be able to:

- Understand the principles of quality use of medicines
- Know the benefits and risks associated with use of medicines
- Understand regulatory aspects of quality use of medicines
- Identify and resolve medication related problems
- Promote quality use of medicines
- Practice evidence-based medicines

THEORY

60 Hrs

1.	Introduction to Quality use of medicines (QUM): Definition and Principles of QUM, Key partners and responsibilities of the partners, Building blocks in QMC, Evaluation process in QMC, Communication in QUM, Cost effective prescribing.	12 Hrs
2	Concepts in QUM Evidence based medicine: Definition, concept of evidence based medicine, Approach and practice of evidence based medicine in clinical settings Essential drugs: Definition, need, concept of essential drug, National essential drug policy and list Rational drug use: Definition, concept and need for rational drug use, Rational drug prescribing, Role of pharmacist in rational drug use.	12 Hrs
3	QUM in various settings: Hospital settings, Ambulatory care/Residential care, Role of health care professionals in promoting the QUM, Strategies to promote the QUM, Impact of QUM on E-health, integrative medicine and multidisciplinary care. QUM in special population: Pediatric prescribing, Geriatric prescribing, Prescribing in pregnancy and lactation, Prescribing in immune compromised and organ failure patients.	12 Hrs

4	Regulatory aspects of QUM in India: Regulation including scheduling, Regulation of complementary medicines, Regulation of OTC medicines, Professional responsibility of pharmacist, Role of industry in QUM in medicine development.	12 Hrs
5	Medication errors: Definition, categorization and causes of medication errors, Detection and prevention of medication errors, Role of pharmacist in monitoring and management of medication errors Pharmacovigilance: Definition, aims and need for pharmacovigilance, Types, predisposing factors and mechanism of adverse drug reactions (ADRs), Detection, reporting and monitoring of ADRs, Causality assessment of ADRs, Management of ADRs, Role of pharmacist in pharmacovigilance.	12 Hrs

REFERENCES:

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
2. Andrews EB, Moore N. Mann's Pharmacovigilance
3. Dipiro JT, Talbert RL, Yee GC. Pharmacotherapy: A Pathophysiologic Approach
4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teach it
5. Cohen MR. Medication Errors
6. Online:
 - http://medicinesaustralia.com.au/files/2012/05/MA_QUM_External_Reduced.pdf
 - <http://curriculum.racgp.org.au/statements/quality-use-of-medicines/>
 - http://www.rug.nl/research/portal/files/14051541/Chapter_2.pdf
7. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS II (MPP 202T)

Scope

This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence based medicine
- Prepare individualized therapeutic plans based on diagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time- course of clinical and laboratory indices of therapeutic response and adverse effect/s)

THEORY

60 Hrs

1. **Nervous system:** Epilepsy, Parkinson's disease, Stroke, Headache, Alzheimer's disease, Neuralgias and Pain pathways and Pain management. 12 Hrs
2. **Psychiatric disorders:** Schizophrenia, Depression, Anxiety disorders, Sleep disorders, Drug induced psychiatric disorders 12 Hrs
Renal system: Acute renal failure, Chronic renal failure, Renal dialysis, Drug induced renal disease
3. **Infectious diseases:** General guidelines for the rational use of antibiotics and surgical prophylaxis, Urinary tract infections, Respiratory tract infections, Gastroenteritis, Tuberculosis, Malaria, Bacterial endocarditis, Septicemia. 12 Hrs
4. **Infectious diseases:** Meningitis, HIV and opportunistic infections, Rheumatic fever, Dengue fever, H1N1, Helmenthiasis, Fungal infections 12 Hrs
Gynecological disorders: Dysmenorrhea, Hormone replacement therapy.

- 5 **Oncology:** General principles of cancer chemotherapy, 12 pharmacotherapy of breast cancer, lung cancer, head & neck Hrs cancer, hematological malignancies, Management of nausea and vomiting, Palliative care

REFERENCES

1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication.
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice— McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING (MPP 203T)

Scope

This course is designed to enable students to understand the basic principles and applications of pharmacokinetics in designing the individualized dosage regimen, to interpret the plasma drug concentration profile in altered pharmacokinetics, drug interactions and in therapeutic drug monitoring processes to optimize the drug dosage regimen. Also, it enables students to understand the basic concepts of pharmacogenetics, pharmacometrics for modeling and simulation of pharmacokinetic data.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Design the drug dosage regimen for individual patients
- Interpret and correlate the plasma drug concentrations with patients' therapeutic outcomes
- Recommend dosage adjustment for patients with renal/ hepatic impairment
- Recommend dosage adjustment for paediatrics and geriatrics
- Manage pharmacokinetic drug interactions
- Apply pharmacokinetic parameters in clinical settings
- Interpret the impact of genetic polymorphisms of individuals on pharmacokinetics and or pharmacodynamics of drugs
- Do pharmacokinetic modeling for the given data using the principles of pharmacometrics

THEORY

60 Hrs

1. **Introduction to Clinical pharmacokinetics:** Compartmental and Non compartmental models, Renal and non-renal clearance, Organ extraction and models of hepatic clearance, Estimation and determinants of bioavailability, Multiple dosing, Calculation of loading and maintenance doses 12 Hrs
Designing of dosage regimens: Determination of dose and dosing intervals, Conversion from intravenous to oral dosing, Nomograms and Tabulations in designing dosage regimen.

- 2 **Pharmacokinetics of Drug Interaction:** Pharmacokinetic drug interactions, Inhibition and Induction of Drug metabolism, Inhibition of Biliary Excretion
Pharmacogenetics: Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes, Genetic Polymorphism in Drug Transport and Drug Targets, Pharmacogenetics and Pharmacokinetic / Pharmacodynamic considerations
Introduction to Pharmacometrics: Introduction to Bayesian Theory, Adaptive method or Dosing with feedback, Analysis of Population pharmacokinetic Data. 12 Hrs
- 3 **Non Linier Mixed Effects Modelling:** The Structural or Base Model, Modeling Random Effects, Modeling Covariate Relationships, Mixture Model, Estimation Methods, Model Building Techniques, Covariate Screening Methods, Testing the model assumptions, Precision of the parameter estimates and confidence intervals, Model misspecification and violation of the model assumptions, Model Validation, Simulation of dosing regimens and dosing recommendations, Pharmacometrics software. 12 Hrs
- 4 **Altered Pharmacokinetics:** Drug dosing in the elderly, Drug dosing in the paediatrics, Drug dosing in the obese patients, Drug dosing in the pregnancy and lactation, Drug dosing in the renal failure and extracorporeal removal of drugs, Drug dosing in the hepatic failure. 12 Hrs
- 5 **Therapeutic Drug monitoring:** Introduction, Individualization of drug dosage regimen (Variability – Genetic, age, weight, disease and Interacting drugs), Indications for TDM, Protocol for TDM, Pharmacokinetic/Pharmacodynamic Correlation in drug therapy, TDM of drugs used in the following conditions: Cardiovascular disease: Digoxin, Lidocaine, Amiodarone; Seizure disorders: Phenytoin, Carbamazepine, Sodium Valproate; Psychiatric conditions: Lithium, Fluoxetine, Amitriptyline; Organ transplantations: Cyclosporine; Cytotoxic Agents: Methotrexate, 5-FU, Cisplatin; Antibiotics: Vancomycin, Gentamicin, Meropenem. 12 Hrs

REFERENCES

1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics. New York: Mc Graw Hill.
2. Peter L. Bonate. Pharmacokinetic - Pharmacodynamic Modeling and Simulation. Springer Publications.
3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E. Evans. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring. lippincott Williams & Wilkins.
4. Steven How-Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. CRC Press, USA.
5. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press.
6. Joseph T. Dipiro, William J. Spruill, William E. Wade, Robert A. Blouin and Jane M. Pruemer. Concepts in Clinical Pharmacokinetics. American Society of Health-System Pharmacists, USA.
7. Malcolm Rowland, Thomas N. Tozer. Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. lippincott Williams & Wilkins, USA.
8. Evans, Schentag, Jusko. Applied pharmacokinetics. American Society of Health system Pharmacists, USA.
9. Michael E. Winter. Basic Clinical Pharmacokinetics. lippincott Williams & Wilkins, USA.
10. Milo Gibaldi. Biopharmaceutics and Clinical Pharmacokinetics. Pharma Book Syndicate, USA.
11. Dhillon and Kostrzewski. Clinical pharmacokinetics. Pharmaceutical Press, London.
12. John E. Murphy. Clinical Pharmacokinetics. 5th edition. US: American Society of Health- System Pharmacist, USA.
13. Relevant review articles from recent medical and pharmaceutical literature

PHARMACOEPIDEMOLOGY & PHARMACOECONOMICS (MPP 204T)

Scope

This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health care regimen.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Understand the various epidemiological methods and their applications
- Understand the fundamental principles of Pharmacoeconomics.
- Identify and determine relevant cost and consequences associated with pharmacy products and services.
- Perform the key Pharmacoeconomics analysis methods
- Understand the Pharmacoeconomic decision analysis methods and its applications.
- Describe current Pharmacoeconomic methods and issues.
- Understand the applications of Pharmacoeconomics to various pharmacy settings.

THEORY

60 Hrs

1. **Introduction to Pharmacoepidemiology:** Definition, Scope, 12
Need, Aims & Applications; Outcome measurement: Outcome Hrs
measures, Drug use measures: Monetary units, Number of
prescriptions, units of drug dispensed, defined daily doses,
prescribed daily doses, Diagnosis and Therapy surveys,
Prevalence, Incidence rate, Monetary units, number of
prescriptions, unit of drugs dispensed, defined daily doses and
prescribed daily doses, medications adherence measurements.
Concept of risk: Measurement of risk, Attributable risk and
relative risk, Time- risk relationship and odds ratio
2. **Pharmacoepidemiological Methods:** Qualitative models: Drug 12
Utilization Review; Quantitative models: case reports, case series, Hrs
Cross sectional studies, Cohort and case control studies,
Calculation of Odds' ratio, Meta analysis models, Drug effects
study in populations: Spontaneous reporting, Prescription event

monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology

- 3 **Introduction to Pharmacoeconomics:** Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. 12 Hrs
Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs.
Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost Effective Ratio, Average Cost Effective Ratio. Person Time, Willingness To Pay, Time Trade Off and Discounting.

- 4 **Pharmacoeconomic evaluations:** Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA). 12 Hrs

- 5 **Definition, Steps involved, Applications, Advantages and disadvantages of the following:** 12 Hrs
Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, Common HRQOL measures.
Definition, Steps involved, Applications of the following: Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in pharmacoeconomic analysis, Applications of Pharmacoeconomics.

REFERENCES

1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwer Lippincott Williams & Wilkins, Philadelphia.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons, USA.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health Economic Evaluation, Oxford University Press, London.
4. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press, London.

5. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics.
6. Graker, Dennis. Pharmacoeconomics and outcomes.
7. Walley, Pharmacoeconomics.
8. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
9. Relevant review articles from recent medical and pharmaceutical literature

PHARMACY PRACTICE PRACTICAL - II (MPP 205P)

Pharmacy Practice practical component includes experiments covering important topics of the courses Principles of Quality Use of Medicines, Pharmacotherapeutics-II, Clinical Pharmacokinetics & Therapeutic Drug Monitoring and Pharmacoepidemiology and Pharmacoeconomics.

List of Experiments (24)

1. Causality assessment of adverse drug reactions (three)
2. Detection and management of medication errors (three)
3. Rational use of medicines in special population (three)
4. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
5. Calculation of Bioavailability and Bioequivalence from the given data (two)
6. Interpretation of Therapeutic Drug Monitoring reports of a given patient (three)
7. Calculation of various Pharmacoeconomic outcome analysis for the given data (two)

PHARMACOLOGY (MPL)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPL 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know about,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY

60 Hrs

- 1. UV-Visible spectroscopy:** Introduction, Theory, Laws, **10 Hrs**
Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.
IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.
Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.
- 2. NMR spectroscopy:** Quantum numbers and their role in NMR, **10 Hrs**
Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy.

- 3 Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. **10 Hrs**
- 4 Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: **10 Hrs**
- j) Thin Layer chromatography
 - k) High Performance Thin Layer Chromatography
 - l) Ion exchange chromatography
 - m) Column chromatography
 - n) Gas chromatography
 - o) High Performance Liquid chromatography
 - p) Ultra High Performance Liquid chromatography
 - q) Affinity chromatography
 - r) Gel Chromatography
- 5 Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: **10 Hrs**
- a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
- X ray Crystallography:** Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.
- 6 Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry. **10 Hrs**
- Thermal Techniques:** Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

ADVANCED PHARMACOLOGY - I

(MPL 102T)

Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved

Objectives

Upon completion of the course the student shall be able to :

- Discuss the pathophysiology and pharmacotherapy of certain diseases
- Explain the mechanism of drug actions at cellular and molecular level
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

THEORY

60 Hrs

1.	General Pharmacology	12 Hrs
	a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding.	
	b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.	
2	Neurotransmission	12 Hrs
	a. General aspects and steps involved in neurotransmission.	
	b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline).	
	c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine).	
	d. Non adrenergic non cholinergic transmission (NANC). Co-transmission	

Systemic Pharmacology

A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems

Autonomic Pharmacology

Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

3	Central nervous system Pharmacology General and local anesthetics Sedatives and hypnotics, drugs used to treat anxiety. Depression, psychosis, mania, epilepsy, neurodegenerative diseases. Narcotic and non-narcotic analgesics.	12 Hrs
4	Cardiovascular Pharmacology Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants , anticoagulants, fibrinolytics and anti-platelet drugs	12 Hrs
5	Autocoid Pharmacology The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists.	12 Hrs

REFERENCES

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman's
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists.

10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company
12. KD.Tripathi. Essentials of Medical Pharmacology.
13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14. Clinical Pharmacokinetics & Pharmacodynamics : Concepts and Applications – Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
15. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I (MPL 103T)

Scope

This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various *in-vitro* and *in-vivo* preclinical evaluation processes

Objectives

Upon completion of the course the student shall be able to,

- Appraise the regulations and ethical requirement for the usage of experimental animals.
- Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
- Describe the various newer screening methods involved in the drug discovery process
- Appreciate and correlate the preclinical data to humans

THEORY

60 Hrs

1. Laboratory Animals

12

Common laboratory animals: Description, handling and applications of different species and strains of animals.

Transgenic animals: Production, maintenance and applications

Anaesthesia and euthanasia of experimental animals.

Maintenance and breeding of laboratory animals.

CPCSEA guidelines to conduct experiments on animals

Good laboratory practice.

Bioassay-Principle, scope and limitations and methods

2. Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models.

12

Hrs

General principles of preclinical screening. CNS Pharmacology: behavioral and muscle coordination, CNS stimulants and

depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.

- 3 **Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models.** 12 Hrs

Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti -emetic, anti-diarrheal and laxatives.

- 4 **Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models.** 12 Hrs

Cardiovascular Pharmacology: antihypertensives, antiarrhythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods.

- 5 **Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models.** 12 Hrs

Immunomodulators, Immunosuppressants and immunostimulants

General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin

Limitations of animal experimentation and alternate animal experiments.

Extrapolation of *in vitro* data to preclinical and preclinical to humans

REFERENCES

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M.N.Ghosh
6. Pharmacological experiment on intact preparations by Churchill Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K.Goyal.
9. Preclinical evaluation of new drugs by S.K. Guta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3rd Edition.
12. David R.Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.
13. Screening Methods in Pharmacology, Robert A.Turner.
14. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)

CELLULAR AND MOLECULAR PHARMACOLOGY (MPL 104T)

Scope:

The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process.

Objectives:

Upon completion of the course, the student shall be able to,

- Explain the receptor signal transduction processes.
- Explain the molecular pathways affected by drugs.
- Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
- Demonstrate molecular biology techniques as applicable for pharmacology

THEORY

60 Hrs

1. Cell biology

12

Structure and functions of cell and its organelles

Hrs

Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing

Cell cycles and its regulation.

Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis.

Necrosis and autophagy.

2. Cell signaling

12

Intercellular and intracellular signaling pathways.

Hrs

Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors.

Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol.

Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

3	Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting. Recombinant DNA technology and gene therapy Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology. Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.	12 Hrs
4	Pharmacogenomics Gene mapping and cloning of disease gene. Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism Genetic variation in drug transporters Genetic variation in G protein coupled receptors Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics Immunotherapeutics Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice	12 Hrs
5	a. Cell culture techniques Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays Principles and applications of flow cytometry b. Biosimilars	12 Hrs

REFERENCES:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current protocols in molecular biology vol I to VI edited by Frederick M.Ausubel et la.

PHARMACOLOGICAL PRACTICAL - I

(MPL 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

Handling of laboratory animals.

1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Bradford/Lowry's in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based *in-vitro* assays (MPO, AChEs, α amylase, α glucosidase).
16. Cell viability assays (MTT/Trypan blue/SRB).
17. DNA fragmentation assay by agarose gel electrophoresis.
18. DNA damage study by Comet assay.
19. Apoptosis determination by fluorescent imaging studies.
20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
21. Enzyme inhibition and induction activity
22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

REFERENCES

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds - Robert M Silverstein,
6. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman,
7. Vogel's Text book of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney,
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille
9. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi(Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd

ADVANCED PHARMACOLOGY - II (MPL 201T)

Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, the subject helps the student to understand the concepts of drug action and mechanism involved

Objectives

Upon completion of the course the student shall be able to:

- Explain the mechanism of drug actions at cellular and molecular level
- Discuss the Pathophysiology and pharmacotherapy of certain diseases
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

THEORY

60 Hrs

1.	Endocrine Pharmacology Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation	12 Hrs
2	Chemotherapy Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as β -lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.	12 Hrs
3	Chemotherapy Drugs used in Protozoal Infections Drugs used in the treatment of Helminthiasis Chemotherapy of cancer Immunopharmacology Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD. Immunosuppressants and Immunostimulants	12 Hrs

4	GIT Pharmacology Antilucer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome. Chronopharmacology Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer	12 Hrs
5	Free radicals Pharmacology Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidant Recent Advances in Treatment: Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus	12 Hrs

REFERENCES

1. The Pharmacological basis of therapeutics- Goodman and Gill man's
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G -Katzung
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists
9. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
10. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company.
11. KD.Tripathi. Essentials of Medical Pharmacology
12. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II (MPL 202T)

Scope:

This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

Objectives:

Upon completion of the course, the student shall be able to,

- Explain the various types of toxicity studies.
- Appreciate the importance of ethical and regulatory requirements for toxicity studies.
- Demonstrate the practical skills required to conduct the preclinical toxicity studies.

THEORY

60 Hrs

1.	Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice (GLP) History, concept and its importance in drug development	12 Hrs
2	Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization- importance and methods in regulatory toxicology studies	12 Hrs
3	Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenicity studies (segment II) Genotoxicity studies (Ames Test, <i>in vitro</i> and <i>in vivo</i> Micronucleus and Chromosomal aberrations studies) <i>In vivo</i> carcinogenicity studies	12 Hrs
4	IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission.	12 Hrs

Safety pharmacology studies- origin, concepts and importance of safety pharmacology.

Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies

- 5 Toxicokinetics- Toxicokinetic evaluation in preclinical studies, 12 saturation kinetics Importance and applications of toxicokinetic Hrs studies.
Alternative methods to animal toxicity testing.

REFERENCES

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (<http://www.who.int/tdr/publications/documents/glp-handbook.pdf>).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan
5. OECD test guidelines.
6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf>)

PRINCIPLES OF DRUG DISCOVERY (MPL 203T)

Scope:

The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

Objectives:

Upon completion of the course, the student shall be able to,

- Explain the various stages of drug discovery.
- Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery
- Explain various targets for drug discovery.
- Explain various lead seeking method and lead optimization
- Appreciate the importance of the role of computer aided drug design in drug discovery

THEORY

60 Hrs

1.	An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.	12 Hrs
2	Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification. Protein structure Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction	12 Hrs
3	Rational Drug Design Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches	12 Hrs

- Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,
- | | | |
|---|---|-----------|
| 4 | Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them. | 12
Hrs |
| 5 | QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design | 12
Hrs |

REFERENCES

1. MouldySioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott Markelln. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL 204T)

Scope:

This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

Objectives:

Upon completion of the course, the student shall be able to,

- Explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance

THEORY

60 Hrs

- 1. Regulatory Perspectives of Clinical Trials:** 12 Hrs
Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines
Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR
Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process
- 2. Clinical Trials: Types and Design** 12 Hrs
Experimental Study- RCT and Non RCT,
Observation Study: Cohort, Case Control, Cross sectional
Clinical Trial Study Team
Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management

3	Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.	12 Hrs
4	Basic aspects, terminologies and establishment of pharmacovigilance History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance	12 Hrs
5	Methods, ADR reporting and tools used in Pharmacovigilance International classification of diseases, International Non-proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.	12 Hrs
6	Pharmacoepidemiology, pharmacoconomics, safety pharmacology	12 Hrs

REFERENCES

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.

3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

PHARMACOLOGICAL PRACTICAL - II

(MPL 205P)

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of PA_2 values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial.(3 Nos.)
17. Design of ADR monitoring protocol.
18. *In-silico* docking studies. (2 Nos.)
19. *In-silico* pharmacophore based screening.
20. *In-silico* QSAR studies.
21. ADR reporting

REFERENCES

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. Text book of *in-vitro* practical Pharmacology by Ian Kitchen
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and William Thomsen
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

PHARMACOGNOSY (MPG)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPG 101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know,

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY

60 Hrs

- 1. UV-Visible spectroscopy:** Introduction, Theory, Laws, **12 Hrs**
Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.
IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy
Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.
- 2. NMR spectroscopy:** Quantum numbers and their role in NMR, **12 Hrs**
Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy.1

- 3 **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. 10 Hrs
- 4 **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: 10 Hrs
- Thin Layer chromatography
 - High Performance Thin Layer Chromatography
 - Ion exchange chromatography
 - Column chromatography
 - Gas chromatography
 - High Performance Liquid chromatography
 - Ultra High Performance Liquid chromatography
 - Affinity chromatography
 - Gel Chromatography
- 5 **Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: 10 Hrs
- Paper electrophoresis
 - Gel electrophoresis
 - Capillary electrophoresis
 - Zone electrophoresis
 - Moving boundary electrophoresis
 - Iso electric focusing
- X ray Crystallography:** Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.
- 6 **Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry. 10 Hrs
- Thermal Techniques:** Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and

cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley eastern Ltd., Delhi.

ADVANCED PHARMACOGNOSY - I (MPG 102T)

SCOPE

To learn and understand the advances in the field of cultivation and isolation of drugs of natural origin, various phytopharmaceuticals, nutraceuticals and their medicinal use and health benefits.

OBJECTIVES

Upon completion of the course, the student shall be able to know the,

- advances in the cultivation and production of drugs
- various phyto-pharmaceuticals and their source, its utilization and medicinal value.
- various nutraceuticals/herbs and their health benefits
- Drugs of marine origin
- Pharmacovigilance of drugs of natural origin

THEORY

60 Hrs

1. **Plant drug cultivation:** General introduction to the importance of Pharmacognosy in herbal drug industry, Indian Council of Agricultural Research, Current Good Agricultural Practices, Current Good Cultivation Practices, Current Good Collection Practices, Conservation of medicinal plants- *Ex-situ* and *In-situ* conservation of medicinal plants. 12 Hrs
2. **Marine natural products:** General methods of isolation and purification, Study of Marine toxins, Recent advances in research in marine drugs, Problems faced in research on marine drugs such as taxonomical identification, chemical screening and their solution. 12 Hrs
3. **Nutraceuticals:** Current trends and future scope, Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibres, Cereals and grains, Health drinks of natural origin, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods, Formulation and standardization of nutraceuticals, Regulatory aspects, FSSAI guidelines, Sources, name of marker compounds and their chemical nature, medicinal uses and health benefits of following 12 Hrs
 - i) Spirulina
 - ii) Soya bean
 - iii) Ginseng
 - iv) Garlic
 - v) Broccoli
 - vi) Green and Herbal Tea
 - vii) Flax seeds
 - viii) Black cohosh
 - ix) Turmeric.

- 4 **Phytopharmaceuticals:** Occurrence, isolation and characteristic features (Chemical nature, uses in pharmacy, medicinal and health benefits) of following. 12 Hrs
- Carotenoids – i) α and β - Carotene ii) Xanthophyll (Lutein)
 - Limonoids – i) d-Limonene ii) α – Terpineol
 - Saponins – i) Shatavarins
 - Flavonoids – i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin
 - Phenolic acids- Ellagic acid
 - Vitamins
 - Tocotrienols and Tocopherols
 - Andrographolide, Glycolipids, Gugulipids, Withanolides, Vascine, Taxol
 - Miscellaneous
- 5 **Pharmacovigilance of drugs of natural origin:** WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for biodrug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. 12 Hrs

REFERENCES (*Latest Editions of*)

- Pharmacognosy - G. E. Trease and W.C. Evans. Saunders Edinburgh, New York.
- Pharmacognosy-Tyler, Brady, Robbers
- Modern Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
- Text Book of Pharmacognosy by T.E. Wallis
- Marine Natural Products-Vol.I to IV.
- Natural products: A lab guide by Raphael Ikan , Academic Press 1991.
- Glimpses of Indian Ethano Pharmacology, P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute, 1995.
- Medicinal natural products (a biosynthetic approach), Paul M. Dewick, John Wiley & Sons Ltd., England, 1998.
- Chemistry of Marine Natural Products- Paul J. Schewer 1973.
- Herbal Drug Industry by RD. Choudhary, Eastern Publisher, New Delhi, 1996.
- Cultivation of Medicinal Plants by C.K. Atal & B.M. Kapoor.
- Cultivation and Utilization of Aromatic Plants, C.K. Atal & B.M. Kapoor
- Cultivation of medicinal and aromatic crops, AA Farooqui and B.S. Sreeramu. University Press, 2001.

14. Natural Products from Plants, 1st edition, by Peter B. Kaufman, CRC Press, New York, 1998
15. Recent Advances in Phytochemistry- Vol. 1&4: Scikel Runeckles- Appleton Century crofts.
16. Text book of Pharmacognosy, C.K.Kokate, Purohit, Ghokhale, Nirali Prakasshan, 1996.
17. Pharmacognosy and Pharmacobiotechnology, Ashutoshkar, New Age Publications, New Delhi.

PHYTOCHEMISTRY (MPG 103T)

SCOPE

Students shall be equipped with the knowledge of natural product drug discovery and will be able to isolate, identify and extract and the phyto-constituents

OBJECTIVES

Upon completion of the course, the student shall be able to know the,

- different classes of phytoconstituents, their biosynthetic pathways, their properties, extraction and general process of natural product drug discovery
- phytochemical fingerprinting and structure elucidation of phytoconstituents.

THEORY

60 Hrs

1. **Biosynthetic pathways and Radio tracing techniques:** 12 Hrs
Constituents & their Biosynthesis, Isolation, Characterization and purification with a special reference to their importance in herbal industries of following phyto-pharmaceuticals containing drugs:
 - a) Alkaloids: Ephedrine, Quinine, Strychnine, Piperine, Berberine, Taxol, Vinca alkaloids.
 - b) Glycosides: Digoxin, Glycyrrhizin, Sennosides, Bacosides, Quercetin.
 - c) Steroids: Hecogenin, guggulosterone and withanolides
 - d) Coumarin: Umbelliferone.
 - e) Terpenoids: Cucurbitacins
2. **Drug discovery and development:** History of herbs as source of drugs and drug discovery, the lead structure selection process, structure development, product discovery process and drug registration, Selection and optimization of lead compounds with suitable examples from the following source : artemisinin, andrographolides. Clinical studies emphasising on phases of clinical trials, protocol design for lead molecules. 12 Hrs
3. **Extraction and Phytochemical studies:** Recent advances in extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used like microwave 12 Hrs

assisted extraction, Methods of fractionation. Separation of phytoconstituents by latest CCCET, SCFE techniques including preparative HPLC and Flash column chromatography.

4	Phytochemical finger printing: HPTLC and LCMS/GCMS applications in the characterization of herbal extracts. Structure elucidation of phytoconstituents.	12 Hrs
5	Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (1H, 13C) a. Carvone, Citral, Menthol b. Luteolin, Kaempferol c. Nicotine, Caffeine iv) Glycyrrhizin.	12 Hrs

REFERENCES (*Latest Editions of*)

1. Organic chemistry by I.L. Finar Vol.II
2. Pharmacognosy by Trease and Evans, ELBS.
3. Pharmacognosy by Tylor and Brady.
4. Text book of Pharmacognosy by Wallis.
5. Clark's isolation and Identification of drugs by A.C. Mottal.
6. Plant Drug Analysis by Wagner & Bladt.
7. Wilson and Gisvolds text book of Organic Medicinnal and Pharmaceutical Chemistry by George. R.F.
8. The Chemistry of Natural Products, Edited by R.H. Thomson, Springer International Edn. 1994.
9. Natural Products Chemistry Practical Manual by Anees A Siddiqui and SeemiSiddiqui
10. Organic Chemistry of Natural Products, Vol. 1&2. Gurdeep R Chatwal.
11. Chemistry of Natural Products- Vol. 1 onwards IWPAC.
12. Modern Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
13. Medicinal Natural products – a biosynthetic approach, Dewick PM, John Wiley & Sons, Toronto, 1998.
14. Chemistry of Natural Products, Bhat SV, Nagasampagi BA, Meenakshi S, Narosa Publishing House, New Delhi.
15. Pharmacognosy & Phytochemistry of Medicinal Plants, 2nd edition, Bruneton J, Interceptt Ltd., New York, 1999.

INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY (MPG 104T)

SCOPE

To understand the Industrial and commercial potential of drugs of natural origin, integrate traditional Indian systems of medicine with modern medicine and also to know regulatory and quality policy for the trade of herbals and drugs of natural origin.

OBJECTIVES

By the end of the course the student shall be able to know,

- the requirements for setting up the herbal/natural drug industry.
- the guidelines for quality of herbal/natural medicines and regulatory issues.
- the patenting/IPR of herbals/natural drugs and trade of raw and finished materials.

THEORY

60 Hrs

1. **Herbal drug industry:** Infrastructure of herbal drug industry 12 Hrs
involved in production of standardized extracts and various dosage forms. Current challenges in upgrading and modernization of herbal formulations. Entrepreneurship Development, Project selection, project report, technical knowledge, Capital venture, plant design, layout and construction. Pilot plant scale –up techniques, case studies of herbal extracts. Formulation and production management of herbals.
2. **Regulatory requirements for setting herbal drug industry:** 12 Hrs
Global marketing management. Indian and international patent law as applicable herbal drugs and natural products. Export - Import (EXIM) policy, TRIPS. Quality assurance in herbal/natural drug products. Concepts of TQM, GMP, GLP, ISO-9000.
3. **Monographs of herbal drugs:** General parameters of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, Siddha and Unani Pharmacopoeia, American herbal pharmacopoeia, British herbal pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

- 4 **Testing of natural products and drugs:** Herbal medicines - 12
clinical laboratory testing. Stability testing of natural products, Hrs
protocols.

- 5 **Patents:** Indian and international patent laws, proposed 12
amendments as applicable to herbal/natural products and Hrs
process. Geographical indication, Copyright, Patentable subject
matters, novelty, non obviousness, utility, enablement and best
mode, procedure for Indian patent filing, patent processing, grant
of patents, rights of patents, cases of patents, opposition and
revocation of patents, patent search and literature, Controllers of
patents.

REFERENCES (Latest Editions of)

1. Herbal drug industry by R.D. Choudhary (1996), Eastern Publisher, New Delhi.
2. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee (2003), 1st Edition, Business horizons Robert Verpoorte, New Delhi.
3. Quality control of herbal drugs by Pulok K Mukarjee (2002), Business Horizons Pharmaceutical Publisher, New Delhi.
4. PDR for Herbal Medicines (2000), Medicinal Economic Company, New Jersey.
5. Indian Herbal Pharmacopoeia (2002), IDMA, Mumbai.
6. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (1996), Nirali Prakashan, New Delhi.
7. Text book of Pharmacognosy and Phytochemistry by Vinod D. Rangarl (2002), Part I & II, Career Publication, Nasik, India.
8. Plant drug analysis by H.Wagner and S.Bladt, Springer, Berlin.
9. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern Publisher, New Delhi.
10. Phytochemical Dictionary. Handbook of Bioactive Compounds from Plants by J.B.Harborne, (1999), 11nd Edition, Taylor and Francis Ltd, UK.
11. Herbal Medicine. Expanded Commission E Monographs by M.Blumenthal, (2004), IST Edition,
12. Drug Formulation Manual by D.P.S.Kohli and D.H.Shah (1998), Eastern Publisher, New Delhi.

PHARMACOGNOSY PRACTICAL - I

(MPG I05P)

1. Analysis of Pharmacopoeial compounds of natural origin and their formulations by UV Vis spectrophotometer
2. Analysis of recorded spectra of simple phytoconstituents
3. Experiments based on Gas Chromatography
4. Estimation of sodium/potassium by flame photometry
5. Development of fingerprint of selected medicinal plant extracts commonly used in herbal drug industry viz. Ashwagandha, Tulsi, Bael, Amla, Ginger, Aloe, Vidang, Senna, Lawsonia by TLC/HPTLC method.
6. Methods of extraction
7. Phytochemical screening
8. Demonstration of HPLC- estimation of glycerrhizin
9. Monograph analysis of clove oil
10. Monograph analysis of castor oil.
11. Identification of bioactive constituents from plant extracts
12. Formulation of different dosage forms and their standardisation.

MEDICINAL PLANT BIOTECHNOLOGY (MPG 201T)

SCOPE

To explore the knowledge of Biotechnology and its application in the improvement of quality of medicinal plants

OBJECTIVES

Upon completion of the course, the student shall be able to,

- Know the process like genetic engineering in medicinal plants for higher yield of Phytopharmaceuticals.
- Use the biotechnological techniques for obtaining and improving the quality of natural products/medicinal plants

THEORY

60 Hrs

1. **Introduction to Plant biotechnology:** Historical perspectives, prospects for development of plant biotechnology as a source of medicinal agents. Applications in pharmacy and allied fields. Genetic and molecular biology as applied to pharmacognosy, study of DNA, RNA and protein replication, genetic code, regulation of gene expression, structure and complicity of genome, cell signaling, DNA recombinant technology. 12 Hrs
2. **Different tissue culture techniques:** Organogenesis and embryogenesis, synthetic seed and monoclonal variation, Protoplast fusion, Hairy root multiple shoot cultures and their applications. Micro propagation of medicinal and aromatic plants. Sterilization methods involved in tissue culture, gene transfer in plants and their applications. 15 Hrs
3. **Immobilisation techniques & Secondary Metabolite Production:** Immobilization techniques of plant cell and its application on secondary metabolite Production. Cloning of plant cell: Different methods of cloning and its applications. Advantages and disadvantages of plant cell cloning. Secondary metabolism in tissue cultures with emphasis on production of medicinal agents. Precursors and elicitors on production of secondary metabolites. 15 Hrs
4. **Biotransformation and Transgenesis:** Biotransformation, bioreactors for pilot and large scale cultures of plant cells and retention of biosynthetic potential in cell culture. Transgenic 13 Hrs

plants, methods used in gene identification, localization and sequencing of genes. Application of PCR in plant genome analysis.

- 5 **Fermentation technology:** Application of Fermentation 05 technology, Production of ergot alkaloids, single cell proteins, Hrs enzymes of pharmaceutical interest.

REFERENCES (Latest Editions of)

1. Plant tissue culture, Bhagwani, vol 5, Elsevier Publishers.
2. Plant cell and Tissue Culture (Lab. Manual), JRMM. Yeoman.
3. Elements in biotechnology by PK. Gupta, Rastogi Publications, New Delhi.
4. An introduction to plant tissue culture by MK. Razdan, Science Publishers.
5. Experiments in plant tissue culture by John HD and Lorin WR., Cambridge University Press.
6. Pharmaceutical biotechnology by SP. Vyas and VK. Dixit, CBS Publishers.
7. Plant cell and tissue culture by Jeffrey W. Pollard and John M Walker, Humana press.
8. Plant tissue culture by Dixon, Oxford Press, Washington DC, 1985
9. Plant tissue culture by Street.
10. Pharmacognosy by G. E. Trease and WC. Evans, Elsevier.
11. Biotechnology by Purohit and Mathur, Agro-Bio, 3rd revised edition.
12. Biotechnological applications to tissue culture by Shargool, Peter D, Shargoal, CKC Press.
13. Pharmacognosy by Varo E. Tyler, Lynn R. Brady and James E. Robberrt, That Tjen, NGO.
14. Plant Biotechnology, Ciddi Veerasham.

ADVANCED PHARMACOGNOSY - II (MPG 202T)

SCOPE

To know and understand the Adulteration and Deterioration that occurs in herbal/natural drugs and methods of detection of the same. Study of herbal remedies and their validations, including methods of screening

OBJECTIVES

Upon completion of the course, the student shall be able to know the,

- validation of herbal remedies
- methods of detection of adulteration and evaluation techniques for the herbal drugs
- methods of screening of herbals for various biological properties

THEORY

60 Hrs

1. **Herbal remedies – Toxicity and Regulations:** Herbals vs 12
Conventional drugs, Efficacy of Herbal medicine products, Hrs
Validation of herbal therapies, Pharmacodynamic and
Pharmacokinetic issues.
2. **Adulteration and Deterioration:** Introduction, Types of 12
Adulteration/ Substitution of Herbal drugs, Causes and Measures Hrs
of Adulteration, Sampling Procedures, Determination of Foreign
Matter, DNA Finger printing techniques in identification of drugs of
natural origin, detection of heavy metals, pesticide residues,
phytotoxin, microbial contamination in herbs and their
formulations.
3. **Ethnobotany and Ethnopharmacology:** Ethnobotany in herbal 12
drug evaluation, Impact of Ethnobotany in traditional medicine, Hrs
New development in herbals, Bio-prospecting tools for drug
discovery, Role of Ethnopharmacology in drug evaluation,
Reverse Pharmacology.
4. **Analytical Profiles of herbal drugs:** Andrographis paniculata, 12
Boswellia serata, Coleus forskholii, Curcuma longa, Embelica Hrs
officinalis, Psoralea corylifolia.
5. **Biological screening of herbal drugs:** Introduction and Need for 12
Phyto-Pharmacological Screening, New Strategies for evaluating Hrs

Natural Products, *In vitro* evaluation techniques for Antioxidants, Antimicrobial and Anticancer drugs. In vivo evaluation techniques for Anti-inflammatory, Antiulcer, Anticancer, Wound healing, Antidiabetic, Hepatoprotective, Cardio protective, Diuretics and Antifertility, Toxicity studies as per OECD guidelines.

REFERENCES (*Latest Editions of*)

1. Glimpses of Indian Ethano Pharmacology by P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute.
2. Natural products: A lab guide by Raphael Ikan, Academic Press.
3. Pharmacognosy - G. E. Trease and W.C. Evans. WB. Saunders Edinburgh, New York.
4. Pharmacognosy-Tyler, Brady, Robbers, Lee & Fetiger.
5. Modern Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I & II, Springer Publishers.
6. Herbal Drug Industry by RD. Choudhary, Eastern Publishers, New Delhi.
7. Text book of Pharmacognosy by C.K.Kokate, Purohit, Ghokhale, Nirali Prakashan.
8. Text Book of Pharmacognosy by T.E. Wallis, J & A Churchill Ltd., London.
9. Quality control of herbal drugs by Pulk K Mukherjee, Business Horizons Pharmaceutical Publishers, New Delhi.
10. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
11. Text book of Pharmacognosy and Phytochemistry by Vinod D. Rangarl, Part I & II, Career Publication, Nasik, India.
12. Plant drug analysis by H.Wagner and S.Bladt, 2nd edition, Springer, Berlin.
13. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern PublisherS, New Delhi.
14. Herbal Medicine. Expanded Commission E Monographs, M.Blumenthal.

INDIAN SYSTEMS OF MEDICINE (MPG 203T)

SCOPE

To make the students understand thoroughly the principles, preparations of medicines of various Indian systems of medicine like Ayurveda, Siddha, Homeopathy and Unani. Also focusing on clinical research of traditional medicines, quality assurance and challenges in monitoring the safety of herbal medicines.

OBJECTIVES

After completion of the course, student is able to

- To understand the basic principles of various Indian systems of medicine
- To know the clinical research of traditional medicines, Current Good Manufacturing Practice of Indian systems of medicine and their formulations.

THEORY

60 Hrs

1. Fundamental concepts of Ayurveda, Siddha, Unani and Homoeopathy systems of medicine 12 Hrs
Different dosage forms of the ISM.
Ayurveda: Ayurvedic Pharmacopoeia, Analysis of formulations and bio crude drugs with references to: Identity, purity and quality.
Siddha: Gunapadam (Siddha Pharmacology), raw drugs/Dhatu/Jeevam in Siddha system of medicine, Purification process (Suddhi).
2. **Naturopathy, Yoga and Aromatherapy practices** 12 Hrs
 - a) Naturopathy - Introduction, basic principles and treatment modalities.
 - b) Yoga - Introduction and Streams of Yoga. Asanas, Pranayama, Meditations and Relaxation techniques.
 - c) Aromatherapy – Introduction, aroma oils for common problems, carrier oils.
3. **Formulation development of various systems of medicine** 12 Hrs
Salient features of the techniques of preparation of some of the important class of Formulations as per Ayurveda, Siddha, Homeopathy and Unani Pharmacopoeia and texts.
Standardization,
Shelf life and Stability studies of ISM formulations.

4	Schedule T – Good Manufacturing Practice of Indian systems of medicine Components of GMP (Schedule – T) and its objectives, Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records. Quality assurance in ISM formulation industry - GAP, GMP and GLP. Preparation of documents for new drug application and export registration. Challenges in monitoring the safety of herbal medicines: Regulation, quality assurance and control, National/Regional Pharmacopoeias.	12 Hrs
5	TKDL, Geographical indication Bill, Government bills in AYUSH, ISM, CCRAS, CCRS, CCRH, CCRU	12 Hrs

REFERENCES (*Latest Editions of*)

1. Ayurvedic Pharmacopoeia, The Controller of Publications, Civil Lines, Govt. of India, New Delhi.
2. Hand Book on Ayurvedic Medicines, H. Panda, National Institute of Industrial Research, New Delhi.
3. Ayurvedic System of Medicine, Kaviraj Nagendranath Sengupata, Sri Satguru Publications, New Delhi.
4. Ayurvedic Pharmacopoeia. Formulary of Ayurvedic Medicines, IMCOPS, Chennai.
5. Homeopathic Pharmacopoeia. Formulary of Homeopathic Medicines, IMCOPS, Chennai.
6. Homeopathic Pharmacy : An introduction & Hand book, Steven B. Kayne, Churchill Livingstone, New York.
7. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
8. British Herbal Pharmacopoeia, bBRITISH Herbal Medicine Association, UK.
9. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine, Pulok K Mukharjee, Business Horizons, New Delhi.
10. Indian System of Medicine and Homeopathy in India, Planning and Evaluation Cell, Govt. of India, New Delhi.
11. Essential of Food and Nutrition, Swaminathan, Bappco, Bangalore.
12. Clinical Dietetics and Nutrition, F.P. Antia, Oxford University Press, Delhi.
13. Yoga - The Science of Holistic Living by V.K.Yoga, Vivekananda Yoga Prakashna Publishing, Bangalore.

HERBAL COSMETICS (MPG 204T)

SCOPE

This subject deals with the study of preparation and standardization of herbal/natural cosmetics. This subject gives emphasis to various national and international standards prescribed regarding herbal cosmeceuticals.

OBJECTIVES

After completion of the course, student shall be able to,

- understand the basic principles of various herbal/natural cosmetic preparations
- current Good Manufacturing Practices of herbal/natural cosmetics as per the regulatory authorities

THEORY

60 Hrs

1. **Introduction:** Herbal/natural cosmetics, Classification & Economic aspects. 12 Hrs
Regulatory Provisions relation to manufacture of cosmetics: - License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics.
2. Commonly used herbal cosmetics, raw materials, preservatives, surfactants, humectants, oils, colors, and some functional herbs, preformulation studies, compatibility studies, possible interactions between chemicals and herbs, design of herbal cosmetic formulation. 12 Hrs
3. **Herbal Cosmetics :** Physiology and chemistry of skin and pigmentation, hairs, scalp, lips and nail, Cleansing cream, Lotions, Face powders, Face packs, Lipsticks, Bath products, soaps and baby product, Preparation and standardisation of the following : 12 Hrs
Tonic, Bleaches, Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails.
4. **Cosmeceuticals of herbal and natural origin:** Hair growth formulations, Shampoos, Conditioners, Colorants & hair oils, Fairness formulations, vanishing & foundation creams, anti-sun burn preparations, moisturizing creams, deodorants. 12 Hrs

- 5 Analysis of Cosmetics, Toxicity screening and test methods: 12
 Quality control and toxicity studies as per Drug and Cosmetics Hrs
 Act.

REFERENCES (*Latest Editions of*)

1. Panda H. Herbal Cosmetics (Hand book), Asia Pacific Business Press Inc, New Delhi.
2. Thomson EG. Modern Cosmetics, Universal Publishing Corporation, Mumbai.
3. P.P.Sharma. Cosmetics - Formulation, Manufacturing & Quality Control, Vandana Publications, New Delhi.
4. Supriya K B. Handbook of Aromatic Plants, Pointer Publishers, Jaipur.
5. Skaria P. Aromatic Plants (Horticulture Science Series), New India Publishing Agency, New Delhi.
6. Kathi Keville and Mindy Green. Aromatherapy (A Complete Guide to the Healing Art), Sri Satguru Publications, New Delhi.
7. Chattopadhyay PK. Herbal Cosmetics & Ayurvedic Medicines (EOU), National Institute of Industrial Research, Delhi.
8. Balsam MS & Edward Sagarin. Cosmetics Science and Technology, Wiley Interscience, New York.

HERBAL COSMETICS PRACTICALS
(MPG 205P)

1. Isolation of nucleic acid from cauliflower heads
2. Isolation of RNA from yeast
3. Quantitative estimation of DNA
4. Immobilization technique
5. Establishment of callus culture
6. Establishment of suspension culture
7. Estimation of aldehyde contents of volatile oils
8. Estimation of total phenolic content in herbal raw materials
9. Estimation of total alkaloid content in herbal raw materials
10. Estimation of total flavonoid content in herbal raw materials
11. Preparation and standardization of various simple dosage forms from Ayurvedic, Siddha, Homoeopathy and Unani formulary
12. Preparation of certain Aromatherapy formulations
13. Preparation of herbal cosmetic formulation such as lip balm, lipstick, facial cream, herbal hair and nail care products
14. Evaluation of herbal tablets and capsules
15. Preparation of sunscreen, UV protection cream, skin care formulations.
16. Formulation & standardization of herbal cough syrup.

Semester III

MRM 301T - Research Methodology & Biostatistics

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students “t” test, ANOVA, Correlation coefficient, regression), non-parametric tests (Wilcoxon rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.



PHARMACY COUNCIL OF INDIA

Combined Council's Building, Kotla Road,
Aiwan-E-Ghalib Marg, New Delhi-110 002.
Website : www.pci.nic.



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4ನೇ ಟಿ ಬ್ಲಾಕ್, ಜಯನಗರ, ಬೆಂಗಳೂರು - 560 041.

RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES, KARNATAKA

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website : www.rguhs.ac.in, E-mail : rguhsregistrar@gmail.com

AUTH/MPHARM/REV/022/2013-14

04.07.2013

Ref. :

NOTIFICATION

Date :

Sub: Revised Ordinance Governing Master of Pharmacy (M.Pharm)

Ref: 1) University Notification No. UA/SYN/Ord-M.Pharm/53/2003-04 dated
28.11.2003 and 14.12.2004

2) Decision of the Syndicate in its special meeting dated 20.04.2013

In exercise of powers conferred under Section 35(2) of RGUHS Act, 1994, the Syndicate at its meeting held on 20.04.2013 pleased to notify the revised ordinance governing Master of Pharmacy (M.Pharm) in following specialties as shown in the Annexure appended herewith.

M.Pharm Courses
Pharmaceutics
Industrial Pharmacy
Pharmaceutical Technology
Pharmaceutical Chemistry
Pharmacology
Bulk-Drugs
Pharmaceutical Biotechnology
Pharmaceutical Analysis
Quality Assurance
Pharmaceutical Marketing & Management
Pharmacognosy
Pharmacy Practice
Drug Regulatory Affairs (New Course/specialty)

The above Ordinance shall come into effect from the academic year 2013-14.

By Order,

REGISTRAR

To

The Directors/Deans/Principals of all Pharmacy Colleges affiliated to RGUHS

Copy to:

1. The Secretary to Governor, Governor's Secretariat, Raj Bhavan, Bangalore - 560 001.
2. The Principal Secretary to Government, Health & Family Welfare Department, (Medical Education), Vidhana Soudha, Bangalore -560 001.
3. The Director, Department of Medical Education, Anand Rao Circle, Bangalore - 560 009.
4. Director, Curriculum Development, RGUHS.
5. PA to Vice-Chancellor / Registrar / Registrar (Eva.) / Finance Officer.
6. Public Information Officer.
7. The Home Page of RGUHS & Guard File / Office Copy.

MODERN PHARMACEUTICAL ANALYSIS

THEORY

GOALS:

The important goals of this course are to give through understanding of the spectroscopy, Mass and chromatographic techniques so that the post graduate students can work in the pharmaceutical companies and research laboratories. Goal of this course is also to train the students structural elucidation of organic compounds.

OBJECTIVES:

On completion of the course, the student shall be able to-

- Know the fundamentals principles, instrumentation and applications of UV-Visible, IR, NMR, Mass spectroscopy, ORD and chromatographic techniques.
- Know ORD, Electrophoresis and statistical analysis.
- Shall be able to analyze drugs and pharmaceuticals using the above instruments.
- Shall be able to interpret the structure of the organic compounds with the given spectral data.
- Shall be able to appreciate the importance of modern instruments in the quality control and research

COURSE CONTENTS

THEORY: 75 hr (3hr/week)

1. UV-VISUAL SPECTROSCOPY: Brief review of electromagnetic spectrum, UV-Visible range, energy, wavelength and color relationships. Interaction of electromagnetic radiation (UV-Visible) with matter and its effects. Chromophores and their interaction with E.M.R. Absorption spectra of organic compounds and complexes illustrating the phenomenon and its utilization in qualitative and quantitative studies of drugs. Shifts and their interpretation (including solvent effects). Empirical correlation of structure with absorption phenomena (Woodward's rules etc), Quantitative estimations, Modern instrumentation. Beer-Lambert Law, Absorption spectra of biomolecules. Theoretical aspects of simultaneous estimation of drugs

6 Hours (10-12 marks)

2. INFRARED SPECTROSCOPY: Nature of infra-red radiation. Interaction of I.R radiation with organic molecules and effects on bonds, Hookes' law. Symmetry rules for observing IR spectrum of molecules. Molecular Infrared spectra. Brief outline of classical I.R instrumentation and particle details of obtaining spectra, including sample preparation for spectroscopy, qualitative interpretation and quantitative applications of FTIR spectra. Theory and applications of FT-IR, ATR and micro ATR. Significance of NIR.

5 Hours (08-10 marks)

3. OPTICAL ROTATORY DISPERSION: Fundamentals principles of ORD. Cotton effect curves, their characteristics and interpretation. Octant rule and its application with examples. Circular dichroism and its relation to ORD.

3 Hours (05-07 marks)

4. NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY: Fundamentals principles of NMR (Magnetic properties of nuclei; applied field and precession; absorption and transition; frequency). Chemical shifts concept; isotopic nuclei, Reference standards: Proton Magnetic spectra, their characteristics, presentation terms used in describing spectra and their interpretation (Signal No., Position, Intensity). Brief outline of instrumental arrangements and some practical details. Signal multiplicity phenomenon in high resolution PMR. Spin-spin coupling. Application of Signal Split and coupling constant data to interpretation of spectra. De-coupling and shift reagent methods. Brief outline of principles of FT-NMR with reference to ^{13}C NMR: Spin-spin and spin-lattice relaxation phenomenon. Free induction decay (FID) proton noise de-coupling signal, average time domain and frequency domain signals nuclear overhauser enhancement ^{13}C NMR spectra, their presentation, characteristics, interpretation, examples and applications. Brief indication of application of magnetic resonance spectral data of other nuclei by modern NMR instruments. Introduction to 2-D NMR techniques, TOCSY, NOESY, COSY and INADEQUATE. Methods for Structure determination of small molecules by NMR.
14 Hours (24-27 marks)

5. MASS SPECTROMETRY: Basic principles and brief outline of instrumentation. Ionization techniques Molecular ion, Meta stable ions, fragmentation processes. Fragmentation patterns and fragmentation characteristics in relation to parent structure and functional groups. Relative abundances of isotopes and their contribution to characteristic peaks. Mass spectrum, its characteristics, presentation and its interpretation. Interfacing a LC and GC in MS
9 Hours (15-17 marks)

6. CHROMATOGRAPHIC TECHNIQUES: Classification of chromatographic methods based on mechanism of separation. Chromatographic theory, efficiency parameters, Selection of adsorbents and mobile phase for TLC. HPTLC- instrumentation and applications, Programmed multiple development techniques.
4 Hours (07-09 marks)

7. GAS CHROMATOGRAPHY: Instrumentation, packed and open tubular columns, Liquid stationary phases, derivatization techniques, detectors and critical comparison. Head space GC and temperature programmed GC. Interfacing a GC in FTIR and optical emission spectroscopy. **5 Hours (10-12 marks)**

8. LIQUID CHROMATOGRAPHY: Instrumentation in HPLC, Analytical, preparative and micro-bore columns, ion-exchange columns, size-exclusion columns and chiral columns, Reverse phase HPLC, column selection, mobile phase selection, detectors and its comparison Super fluid critical chromatography and affinity chromatography. Salient features of UPLC. Interfacing a LC in MS & NMR
8 Hours (15-17 marks)

9. ELECTROPHORESIS: Theory and factors affecting electrophoresis, Moving boundary electrophoresis, zone electrophoresis, Isotachopheresis, Isoelectric focusing and immunoelectrophores, continuous electrophoresis (preparative) application. 2D Gel electrophoresis. **2 Hours (04-06 marks)**

10. X-RAY DIFFRACTION METHODS: Introduction, Generation of X-rays, Elementary crystallography, Miller Indices, X-ray diffraction, Bragg's law, X-ray powder diffraction, X-ray powder diffractometer, obtaining and interpretation of X-ray powder diffraction data and application in polymorphism.
4 Hours (07-09 marks)

11. THERMO ANALYTICAL METHODS OF ANALYSIS: Thermo gravimetric analysis, Differential Scanning Calorimetry, application in drug interaction and interpretation.

3 Hours (05-07 marks)

12. STATISTICAL ANALYSIS: Introduction, significance of statistical methods, Normal distribution, probability, Degrees of freedom, measures of variation-standard deviation, variance, standard error, tests for statistical significance- students 'T' test, chi-square test.

5 Hours (08-10 marks)

13. TEACHING SKILLS, RESEARCH METHODOLOGY AND LITERATURE SOURCES: Fundamentals of teaching and learning; art and science of teaching. Thesis writing and presentation of the work. Citation of references.

3 Hours (05-07 marks)

14. ETHICS IN PHARMACY:

Research Ethics

-  Animal and experimental research/humanness
-  Human experimentation
-  Human volunteer research-informed consent
-  Clinical trials
-  Gathering all scientific factors
-  Gathering all value factors
-  Identifying areas of value-conflict, setting priorities
-  Working out criteria towards decision
-  ICMR/CPCSEA/INSA Guidelines for human / animal experimentation **2 Hours (04-06 marks)**

PRACTICALS:

150 hr (6hr/week)

Major experiments:

1. Atleast 4 simultaneous estimation of fixed dose combinations by UV-Visible spectroscopic methods.
5. UV-Visible spectrum scanning of certain organic compounds- absorption and correlation of structures. Comparison of UV spectrum of drugs.
6. Comparison of three different analytical methods for three official drugs.
- 7-8. Experiments based on HPLC and GC. (2 expts)
9. Experiments based on IR
- 10-15. Structural interpretation of at least 6 different compounds/drugs by UV, IR and Mass data

Minor experiments:

16. Effect of pH and solvent on U.V Spectrum of certain drugs.
- 17-20. Monograph analysis of paracetamol IP. (minor expts)
21. Separation of amino acids by electrophoresis
22. Any other relevant exercises based on theory.

Text Books

1. Spectrometric Identification of Organic Compounds, 7th Edition Robert M. Silverstein et.al
2. *Fundamentals of Applied Statistics by Gupta Sc Kapoor* Vk.
3. Instrumental methods of analysis SKOOG and West and Holler
4. *Willard, H.H.; Merrit, L.L.; Dean, J.A.; Settle, F.A. Instrumental Methods of Analysis*, 7TH Ed CBS publishers and Distributors, New Delhi,.
5. A.H. Beckett and J.B. Stenlake Practical Pharmaceutical Chemistry, Fourth edition, Part-II
6. Kalsi, P. S. Spectroscopy of Organic compounds, New Age Publishers, New Delhi.
7. http://icmr.nic.in/bioethics/final_cpcsea
8. http://icmr.nic.in/ethical_guidelines

Reference Books

1. *X-Ray methods* — Clive Whiston — John Wiley & Sons. 1987
2. Statistics by Gofeti Radhakrishna
3. Biostatistics by Sadkar
4. Instrumental methods of analysis Scoog and West
5. Instrumental Method of Analysis - modern methods Part-B, Vol-2, pages 11 to 54 Editor by J.W. Munson (Marcel Dekker) 4.
6. Kemp William, Organic spectroscopy, Pal Grave, New York.
7. Kalsi, P. S. Spectroscopy of Organic compounds, New Age Publishers, New Delhi.
8. Willard HH, Merritt LL Dean, JA, Settle FA: Instrumental methods of. Analysis, 7th edition, CBS publishers and Distributors, New Delhi,.
9. Robert M. Silverstein, Spectrometric Identification of Organic Compounds, Wiley
10. Stahl, E.: Thin-Layer Chromatography, A Laboratory Handbook, 2nd. Edit.,
11. Modern NMR Techniques for Chemistry Research. A. E. Derome. Pergamon Press

Journals:

At least one International journal is to be subscribed

Teaching/ Learning activities:

1. Journal Club: Minimum of one presentation per term per student and evaluation is compulsory.
2. Seminar: Minimum of one seminar per term per student.
3. Field visits/ Industrial visits: Minimum of one visit during first year.
4. Conferenc/ meeting in their respective discipline.

Scheme of the examination:

Subjects	Sessionals	Seminar/record marks	Annual Examination Marks	Total marks
Theory	30	20 (Journal Club/ Seminar)	100 (3 Hours)	150
Practical Record	30	20 (Seminar/record marks)	100 (6 Hours)	150

University practical Examination

Synopsis	10 marks
Major Experiment	40 marks
Minor Experiment	30 marks
Viva-Voce	20 marks
Total	100 marks

I - M.PHARM

PHARMACEUTICS

GOAL: To produce a competent Industrial Pharmacist.

OBJECTIVE: Upon completion of the course, the candidate shall have:

- ❖ An understanding of the concept and design of various pharmaceutical dosage forms
- ❖ The ability to formulate and evaluate various dosage forms
- ❖ The ability to work independently and as a member of the team
- ❖ The ability to plan his / her work for efficient use of time and resources
- ❖ The ability to identify the cause and to solve the problem
- ❖ The ability to think and evaluate scientifically and critically

Teaching/ Learning Activities:

1. **Journal Club:** weekly, Journal club meetings to be held to discuss the recent development in the subject published in the national and international journals.
2. **Seminars:** Seminars (5-6 in a year) shall be arranged from experts in the field.
3. **Industrial visits:** Visits to pharmaceutical industries to understand shop floor activities.
4. **Conferences and meetings:** Staff and students are to be encouraged to participate in seminars, workshops and conferences in the area of this subject.

TITLE OF PAPERS

Paper I: Modern Pharmaceutical Analysis

Paper II: Preformulation and Production Management

Paper III: Biopharmaceutics and Pharmacokinetics

Paper IV: Advances in Drug Delivery Systems

Appendix I: List of Required Equipments/Instruments:

The following common and specialized equipments/instruments, and charts are to be provided by the course conducting department/institution.

Common Equipments:

Single pan balances (analytical): 02

Single pan balances (electronic/digital): 02

Hot air oven: 02

Magnetic stirrers: 08

Mechanical stirrers (1,2,5 ltrs): 04

Double pan balances (analytical): 01

Thermostatic digital water baths: 02

Distillation assembly: 5 ltrs. capacity

Hot plates: 04

Refrigerator: 01

TLC Kit and plates

Sieves of different mesh sizes (10, 12, 16, 22, 44, 60, 80, 120): 2 each

Special Equipments:

Monsanto & Pfizer hardness testers: 02 each

Disintegration test apparatus: 02

Dissolution test apparatus (single jar): 04

Dissolution test apparatus (6/8 Jars):01

UV-Visible spectrophotometer (Double beam): 01

Tablet compression machine single station: 01

Rotary tablet compression machine (5-10 station): 01

Bath sonicator: 01

Table top centrifuge: 01

Capsule filling machine: 01

Stability chamber: 01

Coating & Polishing pan: 01

Vacuum pump with accessories: 01

Pocket / pen pH meters: 02

Vacuum filtration units: 01

Rotary evaporator: 01

Rotary shaker: 01

Filtration sets: 02

Brookefield Viscometer : 01

Desirable

High performance Liquid Chromatography (HPLC): 01

Computers with UPS and a printer: 04

Freeze dryer: 01

Glassware

Common laboratory glassware for regular experiments: Beakers, measuring cylinders, conical flasks, RB & FB Flasks (1& 2 lt. capacity), filtration unit, distillation unit, thermometers 110 & 360 degree Celsius etc..

Chemicals and Reagents

Common pharma grade pure drug samples, polymers and other adjuvants, solvents etc. for the purpose of formulation required for the regular practicals.

PAPER II: PREFORMULATION AND PRODUCTION MANAGEMENT

GOAL: To train the students to be on par with the routine of Industrial activities in R&D, F&D, IPR, RA and Production

OBJECTIVES: The candidates shall be able to:

- Confidently handle the scheduled activities in a Pharmaceutical firm.
- Manage the production of large batches of pharmaceutical formulations.
- Assist in Regulatory Audit process.
- To establish safety guidelines, which prevent industrial hazards.

COURSE DESCRIPTION

THEORY

50 Hours (T:2Hours/Week)

1. PREFORMULATION STUDIES

06 Hrs.

(Marks allotment : 15)

Introduction, Consideration of physico-chemical properties of new drug molecules for different dosage forms. Aqueous solubility, organic solubility, intrinsic solubility, methods of enhancement of solubility-surfactants, pH, co-solvency, solid dispersion, complexation. Techniques for the study of crystal properties and polymorphism - DSC, TGA, PXRD, Optical microscopy, hot stage microscopy. Excipient compatibility studies, Preformulation stability studies.

2. COMPACTION, COMPRESSION, AND CONSOLIDATION

05 Hrs.

(Marks allotment : 15)

Compression, consolidation, decompression, compaction of powders with a particular reference to distribution and measurement of forces within the powder mass undergoing compression. Influence of compression force on the properties of tablets. Effect of particle size, moisture content, lubrication etc. on strength of tablets. A brief study on formulation aspects of tablets such as mouth dissolving tablets, dispersible tablets, chewable tablets and medicated lozenges.

3. QUALITY BY DESIGN, DESIGN OF EXPERIMENTS, FORMULATION BY DESIGN **04 Hrs.**

(Marks allotment : 10)

USFDA's view of QbD, Elements of QbD, QbD tools, Design of experiments – Methods and applications Optimization techniques: Concept of optimization, optimization parameters, classical optimization. Statistical design (Simplex and factorial design)

4. STABILITY TESTING - DRUGS AND DOSAGE FORMS **04Hrs.**

(Marks allotment : 10)

Solid state drug stability, dosage form stability, accelerated stability testing, shelf life calculations, strategies for prolonging shelf life. Effect of packaging materials on dosage form stability. Basic principles of ICH, stability testing of new drug substance and formulations, photostability testing and oxidative stability, role of containers in stability testing. WHO stability guidelines.

5. cGMP, ISO 9000 & 14000 SERIES, VALIDATION **06 Hrs.**

(Marks allotment : 20)

ISO 9000 & 14000 series, guide to Pharmaceutical manufacturing facilities, cGMP considerations with emphasis on documentation practices.

Validation- General concepts, types, approaches to validation and scope of validation. Relationship between calibration, validation & qualification. Validation master plan, qualifications of utilities - HVAC systems, validation of water systems. Validation of manufacturing process for sterile and non-sterile products (briefly protocols and reports), Equipment qualification and cleaning validation.

6. INVENTORY MANAGEMENT **03 Hrs.**

(Marks allotment : 10)

Costs in inventory, inventory categories- special considerations, selective inventory control, reorder quantity methods and EOQ, inventory models, safety stock – stock out, lead time – reorder time methods, modern inventory management systems, inventory evaluation.

7. MATERIAL MANAGEMENT**06 Hrs.****(Marks allotment : 15)**

Materials–quality and quantity, value analysis, purchasing–centralized and decentralized, vendor development, buying techniques, purchasing cycle and procedures, stores management, salvaging and disposal of scrap and surplus. Selection of material handling systems, maintenance of material handling equipment, unit-load, pelletization and containerization, types of material handling systems.

8. PILOT PLANT SCALE UP TECHNIQUES**06 Hrs.****(Marks allotment : 15)**

Scale up of batches for product development, layout of pharmaceutical pilot plant, organization structure, personnel, activities. Pilot plant of tablets, capsules, solutions, dispersions, semisolids, and parenterals. Protocols for technology transfer. Process automation technology (PAT) in Pharmaceutical manufacturing. Introduction to SUPAC guidelines.

9. IPR AND REGULATORY GUIDELINES**07 Hrs.****(Marks allotment : 15)**

Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filling of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in Patent. Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating Indian Pharmaceutical sector, CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA regulatory requirements for contract research organization. Regulations for Biosimilars. Role of GATT, TRIPS, and WIPO.

10. INDUSTRIAL HAZARDS AND PLANT SAFETY**03 Hrs.****(Marks allotment : 5)**

Industrial accidents, mechanical hazards, electrical hazards, chemical hazards, gas hazards, dust explosion, fire and explosion hazards, prevention and control of all these hazards, safety management. Industrial pollution and Control measurements.

PRACTICALS

(T:6Hours/Week)

1. Preformulation study of tablet formulation using various diluents
2. Preformulation study of tablet formulation using various binders.
3. To study the effect of surfactants/Co-solvents on the solubility of drugs.
4. To study the effect of various excipients on the compressibility of tablets.
5. Preparation and evaluation of Diclofenac sodium gel containing different gel bases.
6. Study of the effects of pH on rheological characteristics of carbopol gels using Brookefield viscometer.
7. cGMP considerations for tablets.
8. cGMP considerations for injectables.
9. Preparation and comparative evaluation with marketed product for efficiency of neutralizing property of antacid suspensions.
10. Process validation of tablets.
11. Equipment qualification of an analytical instrument.
12. Equipment qualification of processing equipment.
13. Cleaning validation of an equipment.
14. Designing of plant layouts for tablets and parenterals.
15. Stability studies of dosage form at $30^{\circ}\text{C}\pm 2$, $65\pm 5\%$ RH and $40^{\circ}\text{C}\pm 2$, $75\pm 5\%$ RH.

SCHEME OF EXAMINATION

1. Synopsis - 20 marks

2. Experiment

Major - 35 marks

Minor - 25 marks

3. Viva-voce - 20 marks

Total - 100 marks

REFERENCE BOOKS

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann , Latest edition.
2. Modern Pharmaceutics by Gillbert and S. Banker 4th Edition .
3. Pharmaceutical Process Validation: By Fra R. Berry and Robert A. Nash, Vol 57, 2nd edition
4. Applied Production and Operation Management By Evans, Anderson and Williams
GMP for pharmaceuticals Material Management by K.K. Ahuja Published by CBS publishers
5. Pharmaceutical Preformulations by J.J Wells
6. Pharmaceutical Dosage Forms: Tablets vol 1-3 by Leon Lachmann
7. Text book of Remington's Pharmaceutical sciences Vol I and II, 21st edition
8. Physical Pharmaceutics by Alfred Martin, 4th edition
9. Bentley's textbook of Pharmaceutics-Rawbins
10. ISO 9000-Norms and explanations
11. GMP for pharmaceuticals- Willing S.H. Marcel and Dekker
12. Pharmaceutical powder compaction technology by Goran Alderborn, 1996. Marcel and Dekker
13. D and C act by Vijay Malik, Latest edition, Eastern book company, Lucknow

JOURNALS

1. Drug Development and Industrial pharmacy
2. Indian Journal of Pharmaceutical sciences
3. Journal of Pharmaceutical Sciences
4. Indian drugs

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2. www.journals.elsevier.com
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5. www.anvisa.gov.br/eng/legis/index.htm
6. www.pharmaguideline.com/2010/10/mcc.html
7. www.biosimilarnews.com/european-biosimilars-guidelines.

PAPER III - BIOPHARMACEUTICS AND PHARMACOKINETICS

Goal: To train the students in the area of biopharmaceutics and pharmacokinetics to work efficiently in the R&D Dept of industry, to take part in clinical research (clinical trials)

Objectives: Upon completion of the course, the candidate shall have the ability to:

- Calculate Pharmacokinetics parameters from the given data.
- Apply the principle of Pharmacokinetics in new drug development as well as in the design of new formulations.

COURSE DESCRIPTION

THEORY

50 Hours (T:2Hours/Week)

1. ABSORPTION OF DRUGS

(8 Hrs.)

(Marks allotment : 20)

Structure of cell membrane, Gastro-intestinal absorption of drugs, mechanisms of drug absorption, Factors affecting drug absorption: Biological, Physiological, Physico-chemical and Pharmaceutical. Absorption of drugs from non-per oral routes, Methods of determining absorption: *In-vitro*, *in-situ* and *in-vivo* methods.

2. BIOAVAILABILITY

(7 Hrs.)

(Marks allotment : 15)

Objectives and consideration in bioavailability studies, Concept of equivalence, Measurement of bioavailability, Determination of the rate of absorption, Bioequivalence protocol and its importance, Bioequivalence studies.

3. DISSOLUTION

(3 Hrs.)

(Marks allotment : 10)

BCS Classification, Noyes-Whitney's dissolutions rate law, Study of various approaches to improve dissolution of poorly soluble drug, *In-vitro* dissolution testing models, *In-vitro* release kinetic models, similarity and dissimilarity factors, biowaivers, *In-vitro*- *In-vivo* correlation.

4. PHARMACOKINETICS

(10 Hrs.)

(Marks allotment : 25)

Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model - IV bolus, IV infusion, Extravascular; Multi Compartment models; Two compartment model - IV bolus, IV infusion, Extravascular, Three Compartment model in brief, Application of Pharmacokinetics in new drug development and designing of dosage forms and Novel drug delivery systems.

5. NON-LINEAR PHARMACOKINETICS

(3 Hrs.)

(Marks allotment : 10)

Causes of non-linearity, Detection of non – linearity, Michaelis-Menten equation, Estimation of K_m and V_{max} with respect to individualization of a drug therapy.

6. NON-COMPARTMENT PHARMACOKINETICS

(3 Hrs.)

(Marks allotment : 10)

Statistical moment theory, MRT for various compartment models, Physiological pharmacokinetic models.

7. DRUG DISTRIBUTION

(3 Hrs.)

(Marks allotment : 10)

Factors affecting drug distribution, Volume of distribution, Protein binding- factors affecting, significance and kinetics of protein binding and drug displacement interactions.

8. BIOTRANSFORMATION

(3 Hrs.)

(Marks allotment : 5)

Phase I (oxidative, reductive and hydrolytic reactions) and Phase II reactions (conjugation), factors affecting biotransformation.

9. EXCRETION OF DRUGS

(3Hrs.)

(Marks allotment: 5)

Renal and non-renal excretion. Concept of clearance- renal clearance, organ clearance and hepatic clearance.

10. DOSAGE REGIMEN

(7 Hrs.)

(Marks allotment : 20)

Multiple dosing with respect to I.V and oral route, concept of loading dose, maintenance dose, accumulation index, adjustment of dosage in renal and hepatic impairment, individualization of therapy, Therapeutic Drug Monitoring.

PRACTICALS

(T:6 Hours/Week)

1. Improvement of dissolution characteristics of slightly soluble drugs by Solid Dispersion.
2. Improvement of dissolution characteristics of slightly soluble drugs by Solvent deposition.
3. Improvement of dissolution characteristics of slightly soluble drugs by complexation.
4. Improvement of dissolution characteristics of slightly soluble drugs by solvent evaporation.

5. Comparison of dissolution studies of two different conventional marketed products of same drug. - 2 experiments
6. Influence of polymorphism on solubility.
7. Influence of polymorphism on dissolution.
8. Protein binding studies of a highly protein bound drug.
9. Protein binding studies of a poorly protein bound drug.
10. Permeation study of drug through biological membrane.
11. Calculation of K_a , K_e , $t_{1/2}$, C_{max} , and T_{max} for two sets of data. -2 experiments
12. Calculation of bioavailability from urinary excretion data for two drugs. -2 experiments
13. Calculation of AUC and bioequivalence from the given data for two drugs. -2 experiments

SCHEME OF EXAMINATION

1. Synopsis	-	20 Marks
2. Experiment	-	40 Marks
3. Calculation	-	20 Marks
4. Viva-voce	-	20 Marks
Total	-	100 Marks

REFERENCE BOOKS

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991.
2. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmanekar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. L and Yu ABC, 2nd edition, Connecticut, Appleton Century Crofts, 1985.
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Books Pvt Ltd, Bangalore, 2000
5. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 2nd edition, Marcel Dekker Inc., New York, 1982.
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970.
7. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febiger, Philadelphia, 1995.

8. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
9. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebert F Notari Marcel Dekker Inc, New York and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G. Wagner and M. Pernarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

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1. European Journal of Bio pharmaceutics and Pharmacokinetics, Publisher- Elsevier Science, www.elsevier.com.
2. Indian Drugs.
3. Indian Journal of Pharmaceutical Sciences.
4. <http://www.columbia.edu/itc/gsas/g9600/2004/GrazianoReadings/Drugabs.pdf>
5. http://www.google.co.in/url?sa=t&rct=j&q=absorption%20of%20drugs&source=web&cd=9&sqi=2&ved=0CG4QFjAI&url=http%3A%2F%2Fdaactarbhatti.weebly.com%2Fuploads%2F3%2F5%2F1%2F6%2F3516207%2Fabsorption_of_drugs_by_dr._soban.ppt&ei=30AiUI-1N8-srAf1_ICwBg&usg=AFQjCNF0Vj-xdwOpKtzhkKhPHlmjs1HKg
6. http://www.iuphar.org/pdf/hum_55.pdf
7. http://www.synchronresearch.com/pdf_files/ba-be-trials.pdf
8. http://fip.org/files/fip/BPS/Dissolution/FIP_AAPS_Guidelines%20for%20Dissolution.pdf
9. http://www.dissolutiontech.com/DTresour/200702Articles/DT200702_A02.pdf
10. http://www.pharmpress.com/files/docs/clinical_pharmacokinetics_samplechapter.pdf
11. http://rmipharmacokinetics.com/uploads/Public_Documents/Introduction%20To%20Pharmacokinetics.pdf
12. http://www.pharmpress.com/files/docs/clinical_pharmacokinetics_samplechapter.pdf
13. <http://archive.ajpe.org/legacy/pdfs/aj650212.pdf>
14. <http://www2.courses.vcu.edu/ptxed/m2/powerpoint/download/Lamb%20Drug%20Distribution.pdf>
15. http://physiologie.envt.fr/spip/IMG/pdf/Volumes_of_distribution.pdf
16. <http://books.mcgraw-hill.com/medical/goodmanandgilman/pdfs/CHAPTER3.pdf>
17. <http://el.trc.gov.om:4000/htmlroot/MEDICAL/tcolon/pharmacology/General/E-Books/Metabolism%20Excretion.pdf>
18. https://apps.who.int/chd/publications/referral_care/referencepdf/15app2.pdf

PAPER IV- ADVANCES IN DRUG DELIVERY SYSTEMS

GOAL

To train the students in the area of novel drug delivery systems.

OBJECTIVE

Upon the completion of the course, the student shall have an understanding of the need, concept, design and evaluation of various sustained and controlled release dosage forms.

COURSE DESCRIPTION

THEORY

50 Hours (T:2Hours/Week)

1. CONCEPTS OF CONTROLLED RELEASE DRUG DELIVERY SYSTEMS

(Marks allotment :20) (7 Hrs.)

Introduction, concept, advantages & disadvantages. Factors to be considered for designing controlled release dosage forms. Dissolution, Diffusion, Combination of dissolution and diffusion controlled drug delivery systems. Evaluation of CRDF.

2. POLYMER SCIENCE (3 Hrs.)

(Marks allotment : 5)

Polymer: Introduction, classification, general synthesis and evaluation techniques. Application of polymers in drug delivery.

3. APPROACHES TO CONTROLLED DRUG DELIVERY SYSTEM (8 Hrs.)

(Marks allotment : 20)

Classification of rate-controlled drug delivery systems. Rate-programmed release, activation-modulated and feedback regulated drug delivery systems. Effect of system parameters on controlled drug delivery. Hydrodynamically balanced systems, Osmotic pressure controlled, pH controlled, ion exchange controlled systems.

4. MUCO ADHESIVE DRUG DELIVERY SYSTEMS (8 Hrs.)

(Marks allotment : 15)

Concepts, advantages and disadvantages, structure of oral mucosa, transmucosal permeability, theories of muco adhesion and muco adhesive polymers, mucosal membrane models, permeability enhancers. Development and evaluation of buccal, nasal, pulmonary, rectal, vaginal and ocular drug delivery systems and their applications.

5. TRANSDERMAL DRUG DELIVERY SYSTEMS

(7 Hrs.)

(Marks allotment : 15)

Rationale behind transdermal drug delivery, Permeation through skin, factors affecting permeation, basic components of TDDS, formulation approaches used in development of TDDS and their evaluation, permeation enhancers. Iontophoresis, sonophoresis and magnetophoresis.

6. PARENTERAL CONTROLLED RELEASE DRUG DELIVERY SYSTEMS

(Marks allotment: 15) (5 Hrs.)

Approaches for injectable controlled release formulations. Development and evaluation of Implantable drug delivery systems, subcutaneous, intramuscular and intrauterine implants.

7. NANO DRUG DELIVERY SYSTEMS

(7 Hrs.)

(Marks allotment : 25)

Formulation, development and evaluation of Nanoparticles- Polymeric nano particles, Nano crystals, Solid Lipid Nanoparticles (SLN), Metal Nanoparticles. Vesicular Systems- Liposomes, Transferosomes, Ethosomes, Niosomes, Virosomes. Carbon Nano Tubes (CNT) and Dendrimers. Safety issues related to nano drug delivery systems.

8. TARGETED DRUG DELIVERY

(5 Hrs.)

(Marks allotment : 15)

Concept, advantages and disadvantages, types of targeting and applications. Monoclonal antibodies- hybridoma cell production, diagnostic and therapeutic applications – cancer and autoimmune diseases. Problems related to monoclonal antibodies.

PRACTICALS

(T:6Hours/Week)

1. Comparative evaluation of marketed sustained release tablets and data treatment.
2. Preparation and evaluation of matrix tablets using natural polymers.
3. Preparation and evaluation of matrix tablets using synthetic polymers.
4. Preparation and evaluation of microspheres by solvent evaporation.
5. Preparation and evaluation of muco- adhesive microspheres by ionic gelation method.
6. Preparation and evaluation of microspheres by temperature change method.
7. Preparation and evaluation of microcapsules by wax embedded method.
8. Preparation and evaluation of buccal patches.
9. Preparation and evaluation of buccal tablets.
10. Preparation and evaluation of transdermal films.
11. Evaluation of the effect of various permeation enhancers on transdermal drug delivery.
12. Preparation and evaluation of hydrodynamically balanced tablets.
13. Preparation and evaluation of ocular *insitu* gel.

SCHEME OF EXAMINATION

1. Synopsis	- 20 marks
2. Experiment	
a) Formulation	- 35 marks
b) Evaluation	- 25 marks
3. Viva-voce	- 20 marks
Total:	100 marks

REFERENCES

1. Chien YW., Novel drug delivery systems, 2nd edition, revised and expanded, Marcel Decker, Inc., New York, 1992.
2. Robinson JR., Lee VHL. Controlled drug delivery systems, Marcel Decker, Inc., New York, 1992.
3. John Wiley and sons, Inc, Encyclopedia of controlled delivery, Editor-Edith Mathiowitz, Published by Wiley Interscience Publication, New York/Chichester/Weinheim
4. Jain NK., Controlled and novel drug delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001)
5. Vyas SP., Khar RK., Controlled drug delivery-concepts and advances, Vallabh Prakashan, New Delhi, first edition 2002.
6. Indian Pharmacopoeia 2010. Volume-I, II & III, Indian Pharmacopoeia Commission. New Delhi.
7. United States Pharmacopoeia, US Publications, US
8. British pharmacopoeia
9. Howard C. Ansel, Nicholas G., Popovid loyd, Allen junior BI. Pharmaceutical dosage forms & drug delivery systems. Waverly pvt, Ltd, New Delhi, Sixth edition
10. Leon Lachman, Lieberman, Kanig JL., Theory and Practice of Industrial Pharmacy, Varghese Publishing House, Bombay, 3rd Edition, 1987.
11. Banker and Rhodes, Modern Pharmaceutics, Marcel Decker Inc., New York, 2nd Edition, 1990.
12. Ansel HC., Introduction to Pharmaceutical Dosage Forms and Drug Delivery Systems, Lippincott Williams and Wilkins, New York, 7th Edition, 2000.
13. Remington, the Science and Practice of Pharmacy, Lippincott Williams, 21st Edition, 2000.
14. Patrick J. Sinko. Lippincott Williams and Wilkins. Martin's physical pharmacy and pharmaceutical sciences. Fifth edition.
15. Wilium Alfred Martin P, Bustamante AH., Chun. Physical Pharmacy, B. I. Waverly Pvt Ltd, new Delhi, 4th edition 1995
16. S.Bharath. Pharmaceutical Technology-Concepts and Applications, Pearson Education in South Asia, First edition, 2013.

JOURNALS

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of Pharmaceutical Education and Research
4. Dissolution Technologies
5. Journal of Controlled Release (Elsevier Sciences), desirable
6. Drug Development and Industrial Pharmacy (Francis and Taylor) desirable
7. European journal of Pharmaceutical sciences

8. European Journal of Biopharmaceutics
9. International Journal of Pharmaceutics
10. Journal of Pharmaceutical Sciences
11. DARU: Journal of Pharmaceutical Sciences
12. Asian Journal of Pharmaceutical Sciences
13. AAPS Pharma Sci Tech
14. Advances in Drug Delivery Reviews
15. Rajiv Gandhi Journal of Pharmaceutical sciences

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<http://pharmacie-globale.info/>

<http://www.pharmacy.org/>

<http://www.dissolutiontech.com/>

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<http://www.uspharmacist.com>

<http://www.pharmpress.com/>

<http://www.elsevier.com/>

M. PHARM
INDUSTRIAL PHARMACY

GOAL : To produce a competent Industrial Pharmacist

OBJECTIVE : Upon completion of the course, the candidate shall have

Knowledge – an understanding of the concept and design of various pharmaceutical dosage forms

Skill – the ability to formulate and evaluate various dosage forms

Attitude

- the ability to work independently and as a member of the team
- the ability to plan his / her work for efficient use of time and resources
- the ability to identify the cause and to solve the problem
- the ability to think and evaluate scientifically and critically

TITLE OF PAPERS

Paper I	Modern Pharmaceutical Analysis	(T:3 Hrs/wk, P:6Hrs/wk)
Paper II	Advanced Industrial Pharmacy	(T:2 Hrs/wk, P:6Hrs/wk)
Paper III	Biopharmaceutics and Pharmacokinetics	(T:2 Hrs/wk, P:6Hrs/wk)
Paper IV	Advances in Drug Delivery Systems	(T:2 Hrs/wk, P:6Hrs/wk)

Appendix – I : List of required equipments:

The following common and specialized equipments and charts are to be provided by the course conducting departments/institution.

Common Equipments:

Single pan balances (analytical)	-	1
Single pan balances (electronic/digital)	-	2
Hot air oven	-	2
Magnetic stirrers	-	4
Mechanical stirrers-1, 2, 5 lt	-	1 each

Double pan balances (analytical)	-	1
Electrically operated with thermostat water baths		4
Distillation assembly, 5 lt	-	1
Hot plates	-	2
Refrigerator	-	1
Melting and boiling point apparatus	-	2 each
TLC Kit and plates	-	5
Sieves of different mesh sizes (22, 44, 60, 80, 120)		2 each

Special equipments

Monsanto & Pfizer hardness tester	-	2 each
Disintegration test apparatus	-	2
Dissolution test apparatus (single jar)	-	4
Dissolution test apparatus (6 jars)	-	1
UV-Visible spectrophotometer	-	1
Tablet compression machine single station	-	1
Rotary tablet compression machine	-	1
Capsule filling machine	-	1
Stability chambers	-	3
Coating & polishing pan	-	1
Vacuum pump with accessories	-	1
Pocket / pen pH meters	-	2
Vacuum filtration unit	-	1
Rotary evaporator	-	1
Rotary shaker bath	-	1
Filtration sets	-	2

Desirable:

High Performance Liquid Chromatography (HPLC) - 1

Computers with UPS and a printer - 2

Glassware:

Common laboratory glassware for regular experiments: Beakers, measuring cylinders, conical flasks, RB & FB flasks (1 & 2 lt capacity), filtration unit, distillation unit, thermometers 110, 360 degree Celsius.

Chemicals and Reagents:

Common pharma grade pure drug samples, polymers and other adjuvants, solvents etc for the purpose of formulation required for the regular practicals.

PAPER - II ADVANCED INDUSTRIAL PHARMACY

1. **Scope and objectives of the subject:** The subject provides a good manufacturing of the concepts, techniques and applications of production and operation management.

2. Objectives

2.1 **Knowledge upon the completion of the course, the student shall be able to**

- Know about industrial safety, effluent treatment and environmental control.
- Know about intellectual property rights.
- Know about documentation of records.
- Know about stability and its testing.

2.2 **Skills: Upon the completion of the course, the student shall be able to**

- Use laboratory scale production equipments.
- Communicate of laboratory results.
- Interpret the laboratory data.
- Present different production schedule plans for a specified period.

2.3 **Attitude: Upon the completion of the course, the student shall be able to**

- Create intuitiveness and ability to interact.
- Plan his work for efficient use of time and resources.
- Identify the cause and solve the problem.
- Think and evaluate scientifically and critically.

3. Teaching/ Learning Activities:

3.1 **Journal Club:** weekly, Journal club meetings to be held to discuss the recent development in the subject published in the national and international journals.

3.2 **Seminars:** Seminars (5-6 in a year) shall be arranged from experts in the field.

3.3 **Industrial visits:** Visits to pharmaceutical industries to understand shop floor activities.

3.4 **Conferences and meetings:** Staff and students are to be encouraged to participate in seminars, workshops and conferences in the area of this subject.

THEORY

50 hours (2 Hrs./Week)

1. Preformulation studies

06 Hrs

(Marks allotment : 15)

Introduction, Consideration of physicochemical properties of new drug molecules for different dosage forms. Aqueous solubility, organic solubility, intrinsic solubility, methods of enhancement of solubility-surfactants, pH, co-solvency, solid dispersion, complexation. Techniques for the study of crystal properties and polymorphism - DSC, TGA, PXRD, Optical microscopy, hot stage microscopy. Excipient compatibility studies, Preformulation stability studies.

2. Pilot plant scale-up techniques

06 Hrs

(Marks allotment : 15)

Scale of batches for product development, layout of pharmaceutical pilot plant, organization structure, personnel, activities. Pilot plant of tablets, capsules, solutions, dispersions, semisolids, and parenterals. Protocols for technology transfer. Process automation technology (PAT) in Pharmaceutical manufacturing. Introduction to SUPAC guidelines.

3. Drug stability kinetics - principles and applications **05 Hrs**
(Marks allotment : 15)

Chemical kinetics, complex chemical reactions, degradation pathways of drugs, factors affecting chemical stability, influence of temperature on drug degradation, influence of pH of the vehicle on drug degradation. Solid state drug stability, dosage form stability, accelerated stability testing, shelf life calculations.

4. Stability testing - drugs and dosage forms **04 Hrs**
(Marks allotment : 10)

Solid state drug stability, dosage form stability, accelerated stability testing, shelf life calculations, strategies for prolonging shelf life. Effect of packaging materials on dosage form stability. Basic principles of ICH, stability testing of new drug substance and formulations, photostability testing and oxidative stability, role of containers in stability testing. WHO stability guidelines.

5. Plant location, layouts, industrial hazards and plant safety **05 Hrs**
(Marks allotment : 15)

Pharmaceutical industry – location, layout, utilities, services. Accidents, mechanical hazards, electrical hazards, chemical hazards, gas hazards, dust explosion, fire and explosion hazards, prevention and control of all these hazards, safety management.

6. Environmental pollution, control, effluent analysis and treatment **06 Hrs**
(Marks allotment : 15)

Water pollution and control, air pollution and control, noise pollution and control, solid waste management, effluent analysis, effluent treatment in formulation plants, effluent treatment in synthetic drug industry, effluent treatment in fermentation industries. Different types of water used in pharma industry, preparation, and standards prescribed for water as per EPA, USA, WHO, and BIS.

7. Documentation and records **03 Hrs**
(Marks allotment : 10)

Material identification system, master formula records, control record, master production and control records, batch production and control records, equipment cleaning and usage log books, records related to container, closure and labeling, production record review, distribution records and complaint files.

8. IPRs and Regulatory guideline

7 Hrs

(Marks allotment : 15)

Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filing of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in Patent. Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating Indian Pharmaceutical sector, CDSCO, WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA regulatory requirements for contract research organization. Regulations for Biosimilars. Role of GATT, TRIPS, and WIPO.

9. Quality by design, design of experiments, formulation by design

4 Hrs

(Marks allotment : 10)

USFDA's view of QbD, Elements of QbD, QbD tools, Design of experiments –Methods and applications. Optimization techniques: Concept of optimization, optimization parameters, classical optimization. Statistical design (Simplex and factorial design).

10. Generic drug products

4 Hrs

(Marks allotment : 10)

Various stages of drug - New chemical entity (NCE), new drug, investigational new drug (IND), new drug applications (NDA), active pharmaceutical ingredient (API), abbreviated new drug application (ANDA), generic drug product. Hatch-Waxman act. Drug regulations of IND, NDA, ANDA, orphan drugs. Differences between generic drug products and brand name products. Generic drug product development and its approval.

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1. Rawlins EA. Bentley's textbook of pharmaceuticals. 8th Ed. New Delhi: ELBS Publication; 2010.
2. Remington: The Science and practice of pharmacy, Laura Moore Fox. 21st Ed. New York: Lippincott Williams & Wilkins; 2006.
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8. Herbert. Pharmaceutical dosage form- Tablets, Vol 1,2,3, 2nd Ed. New York: Marcel Dekker Inc; 2005.
9. Kohli DPS. Drug formulation manual. 3rd Ed. New Delhi: Eastern publishers; 2006.
10. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. New York: Marcel Dekker Inc; 1981.
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15. Tomski HW. A textbook of pharmacy management. London: Kogan Page ltd; 1976
16. Harold K, Cyril OD, Heinz W. Essentials of management. New Delhi: McGraw-Hill Book Company; 1986.
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JOURNALS

1. Indian Journal of Pharmaceutical Sciences.
2. Indian Drugs.
3. Journal of Scientific and Industrial Research.
4. RGUHS Compendium of Pharmacy Research Publication
5. Indian Journal of Pharmaceutical Education & Research

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4. www.gatt.org
5. <http://www.wipo.int>
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7. <http://www.madridprotocol.info/>
8. http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf
9. <http://www.tripsagreement.net/>
10. <http://www.law.cornell.edu/treaties/berne/overview.html>
11. www.uspto.gov
12. www.ipo.gov.uk
13. www.ipindia.nic.in
14. www.copyright.gov
15. www.iso.org
16. www.iso.com

17. www.isoindia.org

18. www.bis.org.in

PRACTICALS

Suggested practical experiments

1. Study on the effect of pH on the solubility of drugs.
2. Study on the effect of surfactants to improve the solubility of drugs.
3. Study on the effect of cosolvents to improve the solubility of drugs.
4. Study on diffusion of drugs through various polymeric membranes.
5. Study on the effect of pH on the stability of drug in solution at elevated temperature.
6. Accelerated stability study of aspirin or any other drug in solution dosage form.
7. Stability studies of drug in dosage form as per ICH guidelines.
8. Determination of pK_a of a drug (8-hydroxyquinoline/pimozide/meloxicam or any other) using spectrophotometry.
9. Study on the methods of effluent testing.
10. Study on the effect of particle size on dissolution/ compatibility/flow properties.
11. Testing of drug degradation compounds using TLC.
12. Compatibility evaluation of drugs and excipients using spectrophotometry.
13. Designing of plant layouts for tablets, liquid orals, and parenterals (3 experiments)
14. Dissolution of drugs in different pH media for comparison of performance with innovator.
15. Study of the effects of pH on rheological characteristics of carbopol gels using Brookefield viscometer.

SCHEME OF EXAMINATION

1. Synopsis	- 20 marks
2. Major experiment	- 35 marks
3. Minor experiment	- 25 marks
4. Viva-voce	- 20 marks

Total: 100 marks

PAPER III - BIOPHARMACEUTICS AND PHARMACOKINETICS

Goal: To train the students in the area of biopharmaceutics and pharmacokinetics to work efficiently in the R&D Dept of industry, to take part in clinical research (clinical trials)

Objectives: Upon completion of the course, the candidate shall have the ability to:

- Calculate Pharmacokinetics parameters from the given data.
- Apply the principle of Pharmacokinetics in new drug development as well as in the design of new formulations.

COURSE DESCRIPTION

THEORY

50 Hours (T:2Hours/Week)

1. ABSORPTION OF DRUGS

(8 Hrs.)

(Marks allotment : 20)

Structure of cell membrane, Gastro-intestinal absorption of drugs, mechanisms of drug absorption, Factors affecting drug absorption: Biological, Physiological, Physico-chemical and Pharmaceutical. Absorption of drugs from non-per oral routes, Methods of determining absorption: *In-vitro*, *in-situ* and *in-vivo* methods.

2. BIOAVAILABILITY

(7 Hrs.)

(Marks allotment : 15)

Objectives and consideration in bioavailability studies, Concept of equivalence, Measurement of bioavailability, Determination of the rate of absorption, Bioequivalence protocol and its importance, Bioequivalence studies.

3. DISSOLUTION

(3 Hrs.)

(Marks allotment : 10)

BCS Classification, Noyes-Whitney's dissolutions rate law, Study of various approaches to improve dissolution of poorly soluble drug, *In-vitro* dissolution testing models, *In-vitro* release kinetic models, similarity and dissimilarity factors, biowaivers, *In-vitro- In-vivo* correlation.

4. PHARMACOKINETICS

(10 Hrs.)

(Marks allotment : 25)

Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model - IV bolus, IV infusion, Extravascular; Multi Compartment models; Two compartment model - IV bolus, IV infusion, Extravascular, Three Compartment model in brief, Application of Pharmacokinetics in new drug development and designing of dosage forms and Novel drug delivery systems.

5. NON-LINEAR PHARMACOKINETICS**(3 Hrs.)****(Marks allotment : 10)**

Causes of non-linearity, Detection of non – linearity, Michaelis-Menten equation, Estimation of K_m and V_{max} with respect to individualization of a drug therapy.

6. NON-COMPARTMENT PHARMACOKINETICS**(3 Hrs.)****(Marks allotment : 10)**

Statistical moment theory, MRT for various compartment models, Physiological pharmacokinetic models.

7. DRUG DISTRIBUTION**(3 Hrs.)****(Marks allotment : 10)**

Factors affecting drug distribution, Volume of distribution, Protein binding- factors affecting, significance and kinetics of protein binding and drug displacement interactions.

8. BIOTRANSFORMATION**(3 Hrs.)****(Marks allotment : 5)**

Phase I (oxidative, reductive and hydrolytic reactions) and Phase II reactions (conjugation), factors affecting biotransformation.

9. EXCRETION OF DRUGS**(3Hrs.)****(Marks allotment: 5)**

Renal and non-renal excretion. Concept of clearance- renal clearance, organ clearance and hepatic clearance.

10. DOSAGE REGIMEN**(7 Hrs.)****(Marks allotment : 20)**

Multiple dosing with respect to I.V and oral route, concept of loading dose, maintenance dose, accumulation index, adjustment of dosage in renal and hepatic impairment, individualization of therapy, Therapeutic Drug Monitoring.

PRACTICALS**(T:6 Hours/Week)**

1. Improvement of dissolution characteristics of slightly soluble drugs by Solid Dispersion.
2. Improvement of dissolution characteristics of slightly soluble drugs by Solvent deposition.
3. Improvement of dissolution characteristics of slightly soluble drugs by complexation.

4. Improvement of dissolution characteristics of slightly soluble drugs by solvent evaporation.
5. Comparison of dissolution studies of two different conventional marketed products of same drug. - 2 experiments
6. Influence of polymorphism on solubility.
7. Influence of polymorphism on dissolution.
8. Protein binding studies of a highly protein bound drug.
9. Protein binding studies of a poorly protein bound drug.
10. Permeation study of drug through biological membrane.
11. Calculation of K_a , K_e , $t_{1/2}$, C_{max} , and T_{max} for two sets of data. -2 experiments
12. Calculation of bioavailability from urinary excretion data for two drugs. -2 experiments
13. Calculation of AUC and bioequivalence from the given data for two drugs. -2 experiments

SCHEME OF EXAMINATION

1. Synopsis	-	20 Marks
2. Experiment	-	40 Marks
3. Calculation	-	20 Marks
4. Viva-voce	-	20 Marks
Total	-	100 Marks

REFERENCE BOOKS

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2. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmanekar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. L and Yu ABC, 2nd edition, Connecticut, Appleton Century Crofts, 1985.
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9. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Robert F Notari Marcel Dekker Inc, New York and Basel, 1987.
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11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Royle, Marcel Dekker Inc, New York 1996.

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4. <http://www.columbia.edu/itc/gsas/g9600/2004/GrazianoReadings/Drugabs.pdf>
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6. http://www.iuphar.org/pdf/hum_55.pdf
7. http://www.synchronresearch.com/pdf_files/ba-be-trials.pdf
8. http://fip.org/files/fip/BPS/Dissolution/FIP_AAPS_Guidelines%20for%20Dissolution.pdf
9. http://www.dissolutiontech.com/DTresour/200702Articles/DT200702_A02.pdf
10. http://www.pharmpress.com/files/docs/clinical_pharmacokinetics_samplechapter.pdf
11. http://rmipharmacokinetics.com/uploads/Public_Documents/Introduction%20To%20Pharmacokinetics.pdf
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13. <http://archive.ajpe.org/legacy/pdfs/aj650212.pdf>
14. <http://www2.courses.vcu.edu/ptxed/m2/powerpoint/download/Lamb%20Drug%20Distribution.pdf>
15. http://physiologie.envt.fr/spip/IMG/pdf/Volumes_of_distribution.pdf
16. <http://books.mcgraw-hill.com/medical/goodmanandgilman/pdfs/CHAPTER3.pdf>

17. <http://el.trc.gov.om:4000/htmlroot/MEDICAL/tcolon/pharmacology/General/E-Books/Metabolism%20Excretion.pdf>
18. https://apps.who.int/chd/publications/referral_care/referencepdf/15app2.pdf

PAPER IV- ADVANCES IN DRUG DELIVERY SYSTEMS

GOAL

To train the students in the area of novel drug delivery systems.

OBJECTIVE

Upon the completion of the course, the student shall have an understanding of the need, concept, design and evaluation of various sustained and controlled release dosage forms.

COURSE DESCRIPTION

THEORY

50 Hours (T:2Hours/Week)

1. CONCEPTS OF CONTROLLED RELEASE DRUG DELIVERY SYSTEMS

(Marks allotment :20) (7 Hrs.)

Introduction, concept, advantages & disadvantages. Factors to be considered for designing controlled release dosage forms. Dissolution, Diffusion, Combination of dissolution and diffusion controlled drug delivery systems. Evaluation of CRDF.

2. POLYMER SCIENCE

(3 Hrs.)

(Marks allotment : 5)

Polymer: Introduction, classification, general synthesis and evaluation techniques. Application of polymers in drug delivery.

3. APPROACHES TO CONTROLLED DRUG DELIVERY SYSTEM

(8 Hrs.)

(Marks allotment : 20)

Classification of rate-controlled drug delivery systems. Rate-programmed release, activation-modulated and feedback regulated drug delivery systems. Effect of system parameters on

controlled drug delivery. Hydrodynamically balanced systems, Osmotic pressure controlled, pH controlled, ion exchange controlled systems.

4. MUCO ADHESIVE DRUG DELIVERY SYSTEMS

(8 Hrs.)

(Marks allotment : 15)

Concepts, advantages and disadvantages, structure of oral mucosa, transmucosal permeability, theories of muco adhesion and muco adhesive polymers, mucosal membrane models, permeability enhancers. Development and evaluation of buccal, nasal, pulmonary, rectal, vaginal and ocular drug delivery systems and their applications.

5. TRANSDERMAL DRUG DELIVERY SYSTEMS

(7 Hrs.)

(Marks allotment : 15)

Rationale behind transdermal drug delivery, Permeation through skin, factors affecting permeation, basic components of TDDS, formulation approaches used in development of TDDS and their evaluation, permeation enhancers. Iontophoresis, sonophoresis and magnetophoresis.

6. PARENTERAL CONTROLLED RELEASE DRUG DELIVERY SYSTEMS

(Marks allotment: 15) (5 Hrs.)

Approaches for injectable controlled release formulations. Development and evaluation of Implantable drug delivery systems, subcutaneous, intramuscular and intrauterine implants.

7. NANO DRUG DELIVERY SYSTEMS

(7 Hrs.)

(Marks allotment : 25)

Formulation, development and evaluation of Nanoparticles- Polymeric nano particles, Nano crystals, Solid Lipid Nanoparticles (SLN), Metal Nanoparticles. Vesicular Systems-Liposomes, Transferosomes, Ethosomes, Niosomes, Virosomes. Carbon Nano Tubes (CNT) and Dendrimers. Safety issues related to nano drug delivery systems.

8. TARGETED DRUG DELIVERY

(5 Hrs.)

(Marks allotment : 15)

Concept, advantages and disadvantages, types of targeting and applications. Monoclonal antibodies- hybridoma cell production, diagnostic and therapeutic applications – cancer and

autoimmune diseases. Problems related to monoclonal antibodies.

PRACTICALS

(T:6Hours/Week)

1. Comparative evaluation of marketed sustained release tablets and data treatment.
2. Preparation and evaluation of matrix tablets using natural polymers.
3. Preparation and evaluation of matrix tablets using synthetic polymers.
4. Preparation and evaluation of microspheres by solvent evaporation.
5. Preparation and evaluation of muco- adhesive microspheres by ionic gelation method.
6. Preparation and evaluation of microspheres by temperature change method.
7. Preparation and evaluation of microcapsules by wax embedded method.
8. Preparation and evaluation of buccal patches.
9. Preparation and evaluation of buccal tablets.
10. Preparation and evaluation of transdermal films.
11. Evaluation of the effect of various permeation enhancers on transdermal drug delivery.
12. Preparation and evaluation of hydrodynamically balanced tablets.
13. Preparation and evaluation of ocular *insitu* gel.

SCHEME OF EXAMINATION

1. Synopsis	- 20 marks
2. Experiment	
a) Formulation	- 35 marks
b) Evaluation	- 25 marks
3. Viva-voce	- 20 marks
Total:	100 marks

REFERENCES

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2. Indian drugs (IDMA)
3. Journal of Pharmaceutical Education and Research
4. Dissolution Technologies
5. Journal of Controlled Release (Elsevier Sciences), desirable
6. Drug Development and Industrial Pharmacy (Francis and Taylor) desirable
7. European journal of Pharmaceutical sciences
8. European Journal of Biopharmaceutics
9. International Journal of Pharmaceutics
10. Journal of Pharmaceutical Sciences
11. DARU: Journal of Pharmaceutical Sciences
12. Asian Journal of Pharmaceutical Sciences
13. AAPS Pharma Sci Tech
14. Advances in Drug Delivery Reviews
15. Rajiv Gandhi Journal of Pharmaceutical sciences

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SYLLABUS REVISION

I - M.PHARM

PHARMACEUTICAL TECHNOLOGY

GOAL: To produce a competent Pharmaceutical technologist.

OBJECTIVE: Upon completion of the course, the candidate shall have:

- ❖ An understanding of the concept and design of various pharmaceutical dosage forms
- ❖ The ability to formulate and evaluate various dosage forms
- ❖ The ability to work independently and as a member of the team
- ❖ The ability to plan his / her work for efficient use of time and resources
- ❖ The ability to identify the cause and to solve the problem
- ❖ The ability to think and evaluate scientifically and critically

TEACHING/ LEARNING ACTIVITIES

1. **Journal Club:** weekly, Journal club meetings to be held to discuss the recent development in the subject published in the national and international journals.
2. **Seminars:** Seminars (5-6 in a year) shall be arranged from experts in the field.
3. **Industrial visits:** Visits to pharmaceutical industries to understand shop floor activities.
4. **Conferences and meetings:** Staff and students are to be encouraged to participate in seminars, workshops and conferences in the area of this subject.

TITLE OF PAPERS

Paper I: Modern Pharmaceutical Analysis

Paper II: Advanced Pharmaceutical Technology

Paper III: Biopharmaceutics and Pharmacokinetics

Paper IV: Advances in Drug Delivery Systems

Appendix I: List of Required Equipments/Instruments:

The following common and specialized equipments/instruments, and charts are to be provided by the course conducting department/institution.

Common Equipments:

Single pan balances (analytical): 02

Single pan balances (electronic/digital): 02

Hot air oven: 02

Magnetic stirrers: 08

Mechanical stirrers (1,2,5 ltrs): 04

Double pan balances (analytical): 01

Thermostatic digital water baths: 02

Distillation assembly: 5 ltrs. capacity

Hot plates: 04

Refrigerator: 01

TLC Kit and plates

Sieves of different mesh sizes (10, 12, 16, 22, 44, 60, 80, 120): 2 each

Special Equipments:

Monsanto & Pfizer hardness testers: 02 each

Disintegration test apparatus: 02

Dissolution test apparatus (single jar): 04

Dissolution test apparatus (6/8 Jars):01

UV-Visible spectrophotometer (Double beam): 01

Tablet compression machine single station: 01
Rotary tablet compression machine (5-10 station): 01
Bath sonicator: 01
Table top centrifuge: 01
Capsule filling machine: 01
Stability chamber: 01
Coating & Polishing pan: 01
Vacuum pump with accessories: 01
Pocket / pen pH meters: 02
Vacuum filtration units: 01
Rotary evaporator: 01
Rotary shaker: 01
Filtration sets: 02
Brookefield Viscometer : 01

Desirable

High performance Liquid Chromatography (HPLC): 01
Computers with UPS and a printer: 04
Freeze dryer: 01

Glassware

Common laboratory glassware for regular experiments: Beakers, measuring cylinders, conical flasks, RB & FB Flasks (1& 2 lt. capacity), filtration unit, distillation unit, thermometers 110 & 360 degree Celsius etc..

Chemicals and Reagents

Common pharma grade pure drug samples, polymers and other adjuvants, solvents etc. for the purpose of formulation required for the regular practicals.

PAPER II -ADVANCED PHARMACEUTICAL TECHNOLOGY

THEORY

50 Hours (2 Hrs/ Week)

1. PREFORMULATION STUDIES

(Marks allotment : 15) (6 Hrs.)

Introduction, Consideration of physicochemical properties of new drug molecules for different dosage forms. Aqueous solubility, organic solubility, intrinsic solubility, methods of enhancement of solubility-surfactants, pH, co-solvency, solid dispersion, complexation. Techniques for the study of crystal properties and polymorphism - DSC, TGA, PXRD, Optical microscopy, hot stage microscopy. Excipient compatibility studies, Preformulation stability studies.

2. PHARMACEUTICAL EXCIPIENTS & POLYMERS

(Marks allotment : 15) (6 Hrs.)

Factors affecting the selection of excipients, drug-excipient interactions, Study of cyclodextrins, ion exchange resins, film coating materials, super-disintegrants, directly compressible vehicles, surfactants and thickeners. Co-processed excipients.

Polymer classification, application of polymers in drug delivery, biodegradable, synthetic, semi-synthetic and natural polymers. Hydrogels and their applications.

3. TABLETING TECHNOLOGY

(Marks allotment : 15) (5 Hrs.)

Compression, consolidation, decompression, compaction at high loads, forces distribution during compression, compaction profiles, measurement of forces during compression, energy involved in compaction, properties of granules of compression, properties related to machinery for compression, influence of compression force on the properties of tablets.

4. CAPSULE TECHNOLOGY

(Marks allotment : 10) (4 Hrs.)

Manufacturing equipment and machinery used in capsule technology. Formulation and evaluation of hard gelatin capsules and soft gelatin capsules.

5. PARENTERALS TECHNOLOGY

(Marks allotment : 10) (5 Hrs.)

Manufacturing of LVP, SVP, Sterilization and sterility testing of parenterals, GMP & c GMP regulations of parenteral technology.

6. STABILITY TESTING - DRUGS AND DOSAGE FORMS

(Marks allotment : 10) (4 Hrs.)

Solid state drug stability, dosage form stability, accelerated stability testing, shelf life calculations, strategies for prolonging shelf life. Effect of packaging materials on dosage form stability. Basic principles of ICH, stability testing of new drug substance and

formulations, photostability testing and oxidative stability, role of containers in stability testing. WHO stability guidelines.

7. PHARMACEUTICAL PACKAGING TECHNOLOGY

(Marks allotment : 20) (6 Hrs.)

Selection and evaluation of pharmaceutical packaging materials, Containers and closures, Container-product interactions, Pharmacopoeial specifications, Tests and standards for packaging materials. Labels and labeling-Types of labels, adhesives, inject and bar-coding, Flexible packaging-Types of films, Co-extruded films, foils, coating and laminates, shrink and stretch films, Corrugated and solid fiber boards and boxes-Types of corrugation methods and types of box design and Quality control. Packaging Machinery-Including strip packaging, form, fill and seal machines, liquid and semisolid filling machines, capping machines. Modern packaging techniques.

8. QUALITY BY DESIGN, DESIGN OF EXPERIMENTS, FORMULATION BY DESIGN

(Marks allotment: 10) (4 Hrs)

USFDA's view of QbD, Elements of QbD, QbD tools, Design of experiments –Methods and applications Optimization techniques: Concept of optimization, optimization parameters, classical optimization. Statistical design (Simplex and factorial design)

9. IPRs and REGULATORY GUIDELINE

(Marks allotment : 15) (7 Hrs.)

Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filing of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in Patent. Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating Indian Pharmaceutical sector, CDSCO, WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA regulatory requirements for contract research organization. Regulations for Biosimilars. Role of GATT, TRIPS, and WIPO.

10. TOTAL QUALITY MANAGEMENT

(Marks allotment : 10) 3 Hrs.)

Principles of TQM, elements of TQM, Continuous improvement and learning, management tools of quality, tools and techniques of quality, new quality tools and techniques.

PRACTICALS

(6 hours/week)

- 1) Effect of surfactants on the solubility of drugs.
- 2) Effect of co-solvents on the solubility of drugs.
- 3) Preparation and evaluation of solid dispersion.
- 4) Preparation and evaluation of inclusion complex.
- 5) To study the effect of glidants and lubricants on flowability and compressibility of granules.
- 6) Effect of different granulating agents and disintegrants on the properties of tablets.
- 7) Preparation and evaluation of aspirin effervescent tablets.
- 8) Preparation and evaluation of chewable antacid tablets.
- 9) Preparation and evaluation of coated tablets by pan coating.
- 10) Formulation and evaluation of capsules.
- 11) Formulation and evaluation of small volume parenterals.
- 12) Formulation and evaluation of large volume parenterals.
- 13) Evaluation of glass as a pharmaceutical packaging material.
- 14) Evaluation of plastic as a pharmaceutical packaging material.
- 15) Accelerated stability testing, shelf-life determination and expiration dating of pharmaceuticals.

SCHEME OF EXAMINATION

1. Synopsis	-	20 marks
2. Experiment		
Major Experiment	-	35 marks
Minor Experiment	-	25 marks
3. Viva-voce	-	20 marks

Total: 100 marks

REFERENCE BOOKS

- 1) Lieberman HA and Lachman L. Pharmaceutical Dosage Forms: Tablets. Vol. I, II and III, Marcel Dekker, New York. Latest Edition.
- 2). Avis KE, Lachman L and Lieberman HA, Pharmaceutical Dosage Forms: Parenterals. Volume I and II, Marcel Dekker, New York. Latest Edition.
- 3) Robinson and Lee, Controlled drug delivery: Fundamentals and applications, Marcel Dekker.
- 4) Carstensen, Pharmaceutical principles of solid dosage forms, CRC.
- 5) Ray and Weller, Handbook of Pharmaceutical Excipients, Pharmaceutical Press.
- 6) Pharmaceutical dosage forms: Parenteral, Lachman, Libermann, and Avis, Vol. I & II
Marcel Dekker.
- 7) Nicholas P. Chezerision , Product design and testing polymeric materials.
- 8) Polymers in Controlled Drug Delivery 6 Ed. Lisbeth Ilerm, Stanley Davis.
- 9) Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
10. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
- 11) Pharmaceutical Pre-formulations; By J.J. Wells.
- 12) Packaging of Pharmaceuticals, By C.F. Ross.
- 13) Wiley's Encyclopedia of Packaging Technology.
- 14) Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
- 15) How to practice GMPs; By P. P. Sharma. Vandhana Publications, Agra.
- 16) Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash. Vol. 57,
Second Edition. Revised and Expanded.
- 17) Applied production and operations management; By Evans, Anderson, Sweeney and
Williams.

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1. Drug Development and Industrial pharmacy
2. Indian Journal of Pharmaceutical sciences
3. Journal of Pharmaceutical Sciences
4. Indian Drugs

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PAPER III - BIOPHARMACEUTICS AND PHARMACOKINETICS

Goal: To train the students in the area of biopharmaceutics and pharmacokinetics to work efficiently in the R&D Dept of industry, to take part in clinical research (clinical trials)

Objectives: Upon completion of the course, the candidate shall have the ability to:

- Calculate Pharmacokinetics parameters from the given data.
- Apply the principle of Pharmacokinetics in new drug development as well as in the design of new formulations.

COURSE DESCRIPTION

THEORY

50 Hours (T:2Hours/Week)

1. ABSORPTION OF DRUGS

(8 Hrs.)

(Marks allotment : 20)

Structure of cell membrane, Gastro-intestinal absorption of drugs, mechanisms of drug absorption, Factors affecting drug absorption: Biological, Physiological, Physico-chemical and Pharmaceutical. Absorption of drugs from non-per oral routes, Methods of determining absorption: *In-vitro*, *in-situ* and *in-vivo* methods.

2. BIOAVAILABILITY

(7 Hrs.)

(Marks allotment : 15)

Objectives and consideration in bioavailability studies, Concept of equivalence, Measurement of bioavailability, Determination of the rate of absorption, Bioequivalence protocol and its importance, Bioequivalence studies.

3. DISSOLUTION

(3 Hrs.)

(Marks allotment : 10)

BCS Classification, Noyes-Whitney's dissolutions rate law, Study of various approaches to improve dissolution of poorly soluble drug, *In-vitro* dissolution testing models, *In-vitro* release kinetic models, similarity and dissimilarity factors, biowaivers, *In-vitro*- *In-vivo* correlation.

4. PHARMACOKINETICS

(10 Hrs.)

(Marks allotment : 25)

Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model - IV bolus, IV infusion, Extravascular; Multi Compartment models; Two compartment model - IV bolus, IV infusion, Extravascular, Three Compartment model in brief, Application of Pharmacokinetics in new drug development and designing of dosage forms and Novel drug delivery systems.

5. NON-LINEAR PHARMACOKINETICS**(3 Hrs.)****(Marks allotment : 10)**

Causes of non-linearity, Detection of non – linearity, Michaelis-Menten equation, Estimation of K_m and V_{max} with respect to individualization of a drug therapy.

6. NON-COMPARTMENT PHARMACOKINETICS**(3 Hrs.)****(Marks allotment : 10)**

Statistical moment theory, MRT for various compartment models, Physiological pharmacokinetic models.

7. DRUG DISTRIBUTION**(3 Hrs.)****(Marks allotment : 10)**

Factors affecting drug distribution, Volume of distribution, Protein binding- factors affecting, significance and kinetics of protein binding and drug displacement interactions.

8. BIOTRANSFORMATION**(3 Hrs.)****(Marks allotment : 5)**

Phase I (oxidative, reductive and hydrolytic reactions) and Phase II reactions (conjugation), factors affecting biotransformation.

9. EXCRETION OF DRUGS**(3Hrs.)****(Marks allotment: 5)**

Renal and non-renal excretion. Concept of clearance- renal clearance, organ clearance and hepatic clearance.

10. DOSAGE REGIMEN**(7 Hrs.)****(Marks allotment : 20)**

Multiple dosing with respect to I.V and oral route, concept of loading dose, maintenance dose, accumulation index, adjustment of dosage in renal and hepatic impairment, individualization of therapy, Therapeutic Drug Monitoring.

PRACTICALS**(T:6 Hours/Week)**

1. Improvement of dissolution characteristics of slightly soluble drugs by Solid Dispersion.
2. Improvement of dissolution characteristics of slightly soluble drugs by Solvent deposition.
3. Improvement of dissolution characteristics of slightly soluble drugs by complexation.
4. Improvement of dissolution characteristics of slightly soluble drugs by solvent evaporation.

5. Comparison of dissolution studies of two different conventional marketed products of same drug. - 2 experiments
6. Influence of polymorphism on solubility.
7. Influence of polymorphism on dissolution.
8. Protein binding studies of a highly protein bound drug.
9. Protein binding studies of a poorly protein bound drug.
10. Permeation study of drug through biological membrane.
11. Calculation of K_a , K_e , $t_{1/2}$, C_{max} , and T_{max} for two sets of data. -2 experiments
12. Calculation of bioavailability from urinary excretion data for two drugs. -2 experiments
13. Calculation of AUC and bioequivalence from the given data for two drugs. -2 experiments

SCHEME OF EXAMINATION

1. Synopsis	-	20 Marks
2. Experiment	-	40 Marks
3. Calculation	-	20 Marks
4. Viva-voce	-	20 Marks
Total	-	100 Marks

REFERENCE BOOKS

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991.
2. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmarkar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. L and Yu ABC, 2nd edition, Connecticut, Appleton Century Crofts, 1985.
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Books Pvt Ltd, Bangalore, 2000
5. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 2nd edition, Marcel Dekker Inc., New York, 1982.
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970.
7. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febiger, Philadelphia, 1995.

8. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
9. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebert F Notari Marcel Dekker Inc, New York and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G. Wagner and M. Pernarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

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1. European Journal of Bio pharmaceutics and Pharmacokinetics, Publisher- Elsevier Science, www.elsevier.com.
2. Indian Drugs.
3. Indian Journal of Pharmaceutical Sciences.
4. <http://www.columbia.edu/itc/gsas/g9600/2004/GrazianoReadings/Drugabs.pdf>
5. http://www.google.co.in/url?sa=t&rct=j&q=absorption%20of%20drugs&source=web&cd=9&sqi=2&ved=0CG4QFjAI&url=http%3A%2F%2Fdaactarbhatti.weebly.com%2Fuploads%2F3%2F5%2F1%2F6%2F3516207%2Fabsorption_of_drugs_by_dr._soban.ppt&ei=30AiUI-1N8-srAf1_ICwBg&usg=AFQjCNF0Vj-xdwOpXKTzhkKhPHlmjs1HKg
6. http://www.iuphar.org/pdf/hum_55.pdf
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15. http://physiologie.envt.fr/spip/IMG/pdf/Volumes_of_distribution.pdf
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17. <http://el.trc.gov.om:4000/htmlroot/MEDICAL/tcolon/pharmacology/General/E-Books/Metabolism%20Excretion.pdf>
18. https://apps.who.int/chd/publications/referral_care/referencepdf/15app2.pdf

PAPER IV- ADVANCES IN DRUG DELIVERY SYSTEMS

GOAL

To train the students in the area of novel drug delivery systems.

OBJECTIVE

Upon the completion of the course, the student shall have an understanding of the need, concept, design and evaluation of various sustained and controlled release dosage forms.

COURSE DESCRIPTION

THEORY

50 Hours (T:2Hours/Week)

1. CONCEPTS OF CONTROLLED RELEASE DRUG DELIVERY SYSTEMS

(Marks allotment :20) (7 Hrs.)

Introduction, concept, advantages & disadvantages. Factors to be considered for designing controlled release dosage forms. Dissolution, Diffusion, Combination of dissolution and diffusion controlled drug delivery systems. Evaluation of CRDF.

2. POLYMER SCIENCE (3 Hrs.)

(Marks allotment : 5)

Polymer: Introduction, classification, general synthesis and evaluation techniques. Application of polymers in drug delivery.

3. APPROACHES TO CONTROLLED DRUG DELIVERY SYSTEM (8 Hrs.)

(Marks allotment : 20)

Classification of rate-controlled drug delivery systems. Rate-programmed release, activation-modulated and feedback regulated drug delivery systems. Effect of system parameters on controlled drug delivery. Hydrodynamically balanced systems, Osmotic pressure controlled, pH controlled, ion exchange controlled systems.

4. MUCO ADHESIVE DRUG DELIVERY SYSTEMS (8 Hrs.)

(Marks allotment : 15)

Concepts, advantages and disadvantages, structure of oral mucosa, transmucosal permeability, theories of muco adhesion and muco adhesive polymers, mucosal membrane models, permeability enhancers. Development and evaluation of buccal, nasal, pulmonary, rectal, vaginal and ocular drug delivery systems and their applications.

5. TRANSDERMAL DRUG DELIVERY SYSTEMS

(7 Hrs.)

(Marks allotment : 15)

Rationale behind transdermal drug delivery, Permeation through skin, factors affecting permeation, basic components of TDDS, formulation approaches used in development of TDDS and their evaluation, permeation enhancers. Iontophoresis, sonophoresis and magnetophoresis.

6. PARENTERAL CONTROLLED RELEASE DRUG DELIVERY SYSTEMS

(Marks allotment: 15) (5 Hrs.)

Approaches for injectable controlled release formulations. Development and evaluation of Implantable drug delivery systems, subcutaneous, intramuscular and intrauterine implants.

7. NANO DRUG DELIVERY SYSTEMS

(7 Hrs.)

(Marks allotment : 25)

Formulation, development and evaluation of Nanoparticles- Polymeric nano particles, Nano crystals, Solid Lipid Nanoparticles (SLN), Metal Nanoparticles. Vesicular Systems- Liposomes, Transferosomes, Ethosomes, Niosomes, Virosomes. Carbon Nano Tubes (CNT) and Dendrimers. Safety issues related to nano drug delivery systems.

8. TARGETED DRUG DELIVERY

(5 Hrs.)

(Marks allotment : 15)

Concept, advantages and disadvantages, types of targeting and applications. Monoclonal antibodies- hybridoma cell production, diagnostic and therapeutic applications – cancer and autoimmune diseases. Problems related to monoclonal antibodies.

PRACTICALS

(T:6Hours/Week)

1. Comparative evaluation of marketed sustained release tablets and data treatment.
2. Preparation and evaluation of matrix tablets using natural polymers.
3. Preparation and evaluation of matrix tablets using synthetic polymers.
4. Preparation and evaluation of microspheres by solvent evaporation.
5. Preparation and evaluation of muco- adhesive microspheres by ionic gelation method.
6. Preparation and evaluation of microspheres by temperature change method.
7. Preparation and evaluation of microcapsules by wax embedded method.
8. Preparation and evaluation of buccal patches.
9. Preparation and evaluation of buccal tablets.
10. Preparation and evaluation of transdermal films.
11. Evaluation of the effect of various permeation enhancers on transdermal drug delivery.
12. Preparation and evaluation of hydrodynamically balanced tablets.
13. Preparation and evaluation of ocular *insitu* gel.

SCHEME OF EXAMINATION

1. Synopsis	- 20 marks
2. Experiment	
a) Formulation	- 35 marks
b) Evaluation	- 25 marks
3. Viva-voce	- 20 marks
Total:	100 marks

REFERENCES

1. Chien YW., Novel drug delivery systems, 2nd edition, revised and expanded, Marcel Decker, Inc., New York, 1992.
2. Robinson JR., Lee VHL. Controlled drug delivery systems, Marcel Decker, Inc., New York, 1992.
3. John Wiley and sons, Inc, Encyclopedia of controlled delivery, Editor-Edith Mathiowitz, Published by Wiley Interscience Publication, New York/Chichester/Weinheim
4. Jain NK., Controlled and novel drug delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001)
5. Vyas SP., Khar RK., Controlled drug delivery-concepts and advances, Vallabh Prakashan, New Delhi, first edition 2002.
6. Indian Pharmacopoeia 2010. Volume-I, II & III, Indian Pharmacopoeia Commission. New Delhi.
7. United States Pharmacopoeia, US Publications, US
8. British pharmacopoeia
9. Howard C. Ansel, Nicholas G., Popovid loyd, Allen junior BI. Pharmaceutical dosage forms & drug delivery systems. Waverly pvt, Ltd, New Delhi, Sixth edition
10. Leon Lachman, Lieberman, Kanig JL., Theory and Practice of Industrial Pharmacy, Varghese Publishing House, Bombay, 3rd Edition, 1987.
11. Banker and Rhodes, Modern Pharmaceutics, Marcel Decker Inc., New York, 2nd Edition, 1990.
12. Ansel HC., Introduction to Pharmaceutical Dosage Forms and Drug Delivery Systems, Lippincott Williams and Wilkins, New York, 7th Edition, 2000.
13. Remington, the Science and Practice of Pharmacy, Lippincott Williams, 21st Edition, 2000.
14. Patrick J. Sinko. Lippincott Williams and Wilkins. Martin's physical pharmacy and pharmaceutical sciences. Fifth edition.
15. Wilium Alfred Martin P, Bustamante AH., Chun. Physical Pharmacy, B. I. Waverly Pvt Ltd, new Delhi, 4th edition 1995
16. S.Bharath. Pharmaceutical Technology-Concepts and Applications, Pearson Education in South Asia, First edition, 2013.

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1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. [Journal of Pharmaceutical Education](#) and Research
4. Dissolution Technologies
5. Journal of Controlled Release (Elsevier Sciences), desirable
6. Drug Development and Industrial Pharmacy (Francis and Taylor) desirable

7. European journal of Pharmaceutical sciences
8. European Journal of Biopharmaceutics
9. International Journal of Pharmaceutics
10. Journal of Pharmaceutical Sciences
11. DARU: Journal of Pharmaceutical Sciences
12. Asian Journal of Pharmaceutical Sciences
13. AAPS Pharma Sci Tech
14. Advances in Drug Delivery Reviews
15. Rajiv Gandhi Journal of Pharmaceutical sciences

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M.PHARM PHARMACEUTICAL CHEMISTRY

AIMS:

A post-graduate in Pharmaceutical Chemistry while undergoing the course in the institution should acquire adequate knowledge and necessary practical skills and attitude required for understanding reaction mechanisms, identification of lead molecules and their eventual refinement for development as drugs, knowledge of natural and synthetic molecules used as therapeutic agents.

OBJECTIVES:

The objectives are dealt under two headings namely

- (a) Knowledge and understanding
- (b) Attitudes

a) Knowledge and understanding:

A postgraduate student should acquire detailed theoretical knowledge and practical techniques of the following during the period of his/her course. He/she should acquire thorough theoretical knowledge and practical skills in Pharmaceutical Chemistry with special emphasis on all modern analytical instruments and techniques. He/she should acquire adequate theoretical knowledge and practical skills in QSAR, Computer Aided Drug Design and design of drugs targeted to act at specific sites. He/she should acquire adequate theoretical and practical knowledge about structure elucidation of natural products of medicinal interest and also mechanism of different reactions involved in the synthesis of various classes of drugs used in therapy.

b) Attitude:

A postgraduate student must inculcate attitude for applying his acquired knowledge of reaction mechanisms and drug design in the synthesis of new molecules to provide a cure for diseases of mankind. He/she has to maintain a high standard of professional ethics. He/she should continuously upgrade the acquired knowledge by keeping in touch with contemporary research through national and international journals and should be willing to participate in continuing education programs.

M. Pharm. I	TITLES OF PAPERS	Total Hours	Hours per week	
			Theory	Practical
PAPER-I	Modern Pharmaceutical Analysis	75	3	6
PAPER-II	Advanced Pharmaceutical Chemistry	50	2	6
PAPER-III	Medicinal Chemistry–I (Drug Design)	50	2	6
PAPER-IV	Medicinal Chemistry–II (Natural Products)	50	2	6
M. Pharm. II	Dissertation Work	One Year		

PAPER-II. ADVANCED PHARMACEUTICAL CHEMISTRY (Theory)

Total Hours: 50 (2 hr/week),	Examination	Max Marks
	Annual	100
	Internal Assessment Exam:	30
	Seminar Evaluation:	20
	Total:	150

GOAL:

The goal is to train the postgraduate students in various reaction mechanisms involved in the synthesis of various drug molecules.

OBJECTIVES:

1. To train a student in necessary skills involved in the synthesis of drug molecules in the laboratory and to ensure higher competence in the synthesis of newer molecules.
2. Each student has to achieve a high degree of proficiency and develop competence involved in the structural modification aimed at improved activity.

S.N	Syllabus	Hr/Week
1.	Reaction intermediates in organic synthesis.	23
a)	Carbocations: Formation, structure and stereochemistry, stability and reactivity of carbocations. Reactions (addition and substitution) involving carbocations, study of rearrangement reactions like, Wagner-Meerwein, Pinacol-pinacolone & trans-annular rearrangements.	5
b)	i) Carbanions: Formation, structure and stereochemistry, stability and reactivity of carbanions. Reactions (addition and substitution) involving carbanions, study of Perkin, Claisen, Benzoin, Aldol condensation, Cannizzaro reactions and Favorskii rearrangement.	5
	ii) Aromatic Nucleophilic reactions: Cyclohexadienyl anions and benzyne mechanism (cine substitution)	3
c)	Free radicals: Formation, structure and stereochemistry, stability and reactivity of free radicals. Reactions (addition and substitution) detection. Study of reactions involving free radicals including biological, addition to carbon – carbon multiple bonds.	4

d)	Carbenes: Formation, structure and stereochemistry, stability and reactivity. Reactions (addition and substitution) reactions involving carbenes. Study of Reimer – Tiemen reaction, Wolff rearrangement, ring expansion reaction-conversion of pyrrole to pyridine.	3
e)	Nitrenes: Formation, structure and stereochemistry, stability and reactivity. Reactions (addition and substitution). Study of reactions involving nitrenes, Hofman, Curtius- Schmidt- Lossen rearrangement.	3
2.	Catalysis	6
a)	Introduction, homogenous, heterogenous catalysis and their applications.	2
b)	Phase transfer catalysis in anhydride, epoxide, ester, nitrile and sulfide formation in ester hydrolysis and reduction reactions	2
c)	Stereospecific catalysis	2
3.	Green Chemistry	5
a)	Principles and various techniques of green chemistry, green reagents, green catalysts, ionic solvents, phase transfer catalysts (PTC) in green synthesis, applications of PTC in synthesis of heterocyclic compounds.	4
b)	Microwave enhanced organic synthesis and ultrasound enhanced organic synthesis (sonochemistry), introduction, instrumentation, advantages, synthetic applications and limitations.	1
4.	Combinatorial chemistry.	8
i).	Introduction to Combinatorial Libraries. Concepts and Terms	1
ii).	Parallel Organic Synthesis Technology	2
iii)	Polymer-Supported Synthesis of Organic Compounds and Libraries	2
iv).	Macro Beads in Solid-Phase Synthesis	2
v).	Combinatorial Libraries in Solution.	1
5.	Strategies in Organic Synthesis	8
a)	Introduction, Target Selection, disconnection approach, functional group interconversion (FGI), synthons, uses of synthon approaches in synthesis of Trimethoprim, Ibuprofen, Nifedipine and Ciprofloxacin. Retrosynthesis, Chemoselectivity, Regioselectivity, linear synthesis and convergent synthesis. Basic rules in disconnections, strategic bonds, disconnection of strategic bonds in carbocyclic and heterocyclic rings, biomimetic approach.	5

- b) Protecting and deprotecting groups; protection and deprotection of hydroxyl, carboxy, carbonyl, amino groups and carbon-carbon multiple bonds, chemo and regioselective protection and deprotection, illustration of protection and deprotection in synthesis. 2
- c) Study of polymorphism of few selected APIs like paracetamol, aspirin, barbiturates, chloramphenicol maleate. 1

PAPER-II. ADVANCED PHARMACEUTICAL CHEMISTRY (Practical)

Total Hours: 150 (6 hr/week),	Examination	Max Marks
	Annual	100
	Internal Assessment Exam:	30
	Practical record Evaluation:	20
	Total:	150

Part –1 Preparation: (Minor experiments)

- a) Study of experimental technique such as solvent purification, distillation (vacuum, fractional, steam and simple), preparative, column and TLC, Crystallization and filtration.
- b) Carryout the preparations of organic compounds by conventional as well as microwave assisted methods along with their purity, percentage yield, physical and spectral data(UV/ IR) for the following;
- 1) Preparation of benzanilide from benzophenone (Beckmann rearrangement)
Benzophenone ——— Benzophenone oxime — Benzilanilide
 - 2) Preparation of 2-Phenyl indole from acetophenone (Fischer indolisation)
Acetophenone ——— Acetophenone phenylhydrazine ——— 2-Phenylindole
 - 3) Preparation of 2,5-dihydroxy acetophenone from hydroquinone(Fries rearrangement) Hydroquinone———Hydroquinone diacetate———2,5-Dihydroxy acetophenone
 - 4) Preparation of Diethyl fumarate from maleic acid (conversion of cis isomer to trans isomer) Maleic acid———Fumaric acid———Diethyl fumarate
 - 5) Preparation of 2, 2'-Dihydroxy -1, 1'-binaphthyl from 2-naphthol (oxidation of 2-naphthol and free radical coupling)
 - 6) Preparation of Benzilic acid from Benzoin (Benzilic acid rearrangement)
 - 7) Preparation of 2-amino-3-cyano-4,5-tetrahydro(b)thiophene

- 8) Preparation of 2-amino-3-carbethoxy-4,5-diphenylfuran
- 9) Preparation of thiazolidine-2, 4-dione.
- c) Carryout at least two experiments on protection and de-protection of functional groups like hydroxyl, amino etc using Fmoc/BOC

Part-II Qualitative Analysis (Major experiment)

A minimum of six organic binary mixtures and four ternary mixtures should be analyzed systematically by ether/aqueous separation technique with the preparation of at least one derivative in each compound.

TEACHING AND LEARNING ACTIVITIES

Journal Club:

Each student is required to present any two recent articles relevant to the Advanced Pharmaceutical chemistry from any of the journals in a year.

Seminars:

Each student is required to give two seminars relevant to the subject in a year.

Field/ Industrial Visits:

It is desirable to make to one visit to the relevant Laboratory / Industry in a year.

Conference / Meetings:

Each student has to be encouraged to attend at least one relevant national conference.

Scheme of Practical Examination

Sl. No	Synopsis	Experiments		Viva-voce	Total
		Major	Minor		
1	20	35	25	20	100

Reference Books:

1. A Guide Book to Mechanisms in Organic Chemistry- Peter Sykes (Orient Longman, New Delhi)
2. Advanced Organic Chemistry- Reactions, Mechanism and Structure- Jerry March (Wiley Interscience Publication; 4th Edition, New York)
3. Advanced Practical Organic Chemistry-O.P. Agarwal
4. Combinatorial Chemistry- Synthesis and Applications S.R. Wilson & Anthony W. Czarnik (John Wiley and Sons, USA)
5. Designing Organic Syntheses: A Programmed Introduction to the Synthon Approach. Stuart Warren. John Wiley & Sons.
6. Elemental Practical Organic Chemistry Part I & II A. I. Vogel
7. Experimental Organic Chemistry Vol-I & II –P. R. Singh *et al.*
8. F. A. Cary and R. I. Sundberg, Advanced Organic Chemistry, Part A and B, 5th Edition, Springer, 2009.
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10. H G Brittain. Polymorphism in Pharmaceutical Solids. Marcel Dekker Inc. NY,1999
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12. M. B. Smith, Organic Synthesis, 2nd Edition, 2005
13. Microwaves in organic and medicinal Chemistry, C.O. Kappe, A. Stadler, (Wiley-Vch) June 2005
14. Organic Chemistry by Morison & Boyd (Prentice Hall), New Delhi
15. Organic Chemistry of Synthetic Drugs- Lednicer (Wiley, Interscience Publications, New York)
16. Organic Chemistry Vol-I and II by I. L. Finar, 5th Edition (ELBS, Longman, London).
17. Organic Synthesis: the disconnection approach, Stuart Warren, Paul Wyatt.
18. Physical Organic Chemistry – Jack Hine
19. Protective groups in organic synthesis, Green and Wuts, Iain Edn, John Wiley & sons.
20. Reaction Mechanisms in Organic Chemistry-S. Mukharjee and S P. Singh (Mc Millan India Ltd., New Delhi), 3rd Edition, Reprinted
21. Reactive Intermediates in Organic Chemistry – Tandon and Goel (Oxford and IBH Publisher)
22. Vogel's Text Book of Practical Organic Chemistry 4th Edition (ELBS, Longman, London).

Journals:

1. Indian Journal of Chemistry Section - B
2. Indian Journal of Heterocyclic Chemistry
3. Indian Journal of Pharmaceutical Sciences.
4. At least one International Journal is to be subscribed.



PAPER-III. MEDICINAL CHEMISTRY-I (DRUG DESIGN)(Theory)

Total Hours: 50 (2 hr/week),	Examination	Max Marks
	Annual	100
	Internal Assessment Exam:	30
	Seminar Evaluation:	20
	Total:	150

GOAL:

The goal of studying this paper is to train the candidates to ensure that he/she develops the skill in the designing of target specific molecules.

OBJECTIVES:

- 1) To train candidates with different theoretical aspects involved in drug design.
- 2) To know about the various basic molecules useful in designing newer compounds for the treatment of different disease conditions.
- 3) Ability to master the different techniques used in the synthesis of drug molecules.
- 4) Use information technology tools to carry out research.
- 5) update his/her knowledge by self-study and by attending advanced courses, conferences and seminars in drug design.

S.N	Syllabus	Hr/Week
1.	Theoretical aspects of Drug Design Introduction to drug design and discovery. Conventional methods of drug design. Lead, discovery of lead, lead optimization, objectives of lead optimization, pharmacophore identification and analog approach of drug discovery	4
2.	Targets in Drug Discovery and Development Introduction, Different biological targets for drug discovery: enzymes, nucleic acids, and polysaccharides. Cellular Communication, Receptor Nomenclature, Receptor Classes- G-Protein-Coupled Receptors, Ligand-Gated Ion Channels, Steroid Receptors, Orphan Receptors, Defining the Receptor-Ligand Interaction, Receptor Binding Assays, Functional Assays, Receptor Sources.	8
3.	History and development of QSAR.	8
a)	Theoretical compartment model for relationship between physical properties and biological activity(Hammet, Taft)	3
b)	Mathematical methods for the analysis of QSAR	
	i) Diagnosis mechanism	
	ii) Prediction of activity	

iii)	Optimization	
iv)	Refinement of synthetic Targets	3
c)	Application of Hansh Analysis	1
d)	Application of Free-Wilson Analysis	1
4.	In-silico and Computer Aided Drug design	10
	Molecular Mechanics, force fields (Potential energy function), Energy Minimization Methods, Conformational Analysis. Concepts of Virtual Screening, Drug likeness, Screening-Counting Schemes, Functional Group Filters, Topological Drug Classification-Pharmacophore Point Filter-Focused Screening Libraries for Lead Identification, Pharmacophore Screening, Structure-Based Virtual Screening, Protein Structures, Computational Protein-Ligand Docking Techniques, Rigid Docking, Flexible or induced fit Docking, <i>in silico</i> De Novo design.	
5.	Designing and applications of Prodrugs	5
	Basic concept, Prodrugs of functional group, Prodrug design to improve Patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery, and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.	
6.	Rational design of enzyme inhibitors	8
a)	Enzyme inhibitors- Reversible, irreversible, Kcat inhibitors, transition state analogs and their application with respect to drug design.	3
b)	Enzyme inhibitors of ACE, leukotrienes Lipoxygenase, Cyclooxygenase, Aromatase, Xanthine oxidase, Cytochrome P-450 Inhibitors, DHFR Inhibitors, and Gastric proton pump Inhibitors.	3
c)	HIV-Protease / Reverse Transcriptase, Integrase and DNA polymerase Inhibitors,	2
7.	Recent advances in the development of Immuno modulators	2
8.	Recombinant DNA technology	5
a)	Introduction; New drugs from Recombinant DNA technology	1
b)	Protein engineering and site directed mutagenesis.	2
c)	Development of t-PA as a therapeutic agents Epitope mapping and Human growth hormone.	1
d)	Screening of recombinant DNA libraries and development of HIV-tat inhibitor.	1

PAPER-III. MEDICINAL CHEMISTRY-I (DRUG DESIGN)(Practical)

Total Hours: 150 (6 hr/week),	Examination	Max Marks
	Annual	100
	Internal Assessment Exam:	30
	Practical record Evaluation:	20
	Total:	150

Part 1: Synthesis of the following important medicinal compounds involving more than one step and characterization using TLC. M.P. and IR spectroscopy.

1. INH
2. Methaqualone
3. Saccharin Sodium
4. Dapsone
5. Phenytoin from Benzoin
6. Sulfanilamide
7. 2-Methyl Benzimidazole from OPDA (Phillips synthesis)
8. 2-Mercapto Benzimidazole/Benzimidazolyl-2-thiol
9. Antipyrine

Part 2:

1. Determination of Partition coefficient by shake flask method (Diazepam, Pheytin and Caffeine)
2. Determination of pK_a value by potentiometric method (Phenobarbitone, Ibuprofen)
3. In vitro screening of medicinally important compounds for Anti-inflammatory, Antimicrobial and Antioxidant study.
4. In Silico QSAR based experiments (Three experiments)

TEACHING AND LEARNING ACTIVITIES

Journal Club:

Each student is required to present any two recent articles relevant to the Advanced Pharmaceutical chemistry from any of the journals in a year.

Seminars:

Each student is required to give two seminars relevant to the subject in a year.

Field/ Industrial Visits:

It is desirable to make to one visit to the relevant Laboratory / Industry in a year.

Conference / Meetings:

Each student has to be encouraged to attend at least one relevant national conference.

Scheme of Practical Examination

Sl. No	Synopsis	Experiments	Viva-voce	Total

1	20	Major	Minor	20	100
		35	25		

Reference Books:

1. A Biochemical basis – Medicinal chemistry by Thomas Nogrady
2. Introduction to quantitative drug design by Y.C.Martin
3. Selective Toxicity by Drein Albert
4. Comprehensive Medicinal Chemistry by Corwin and Hansch.
5. Medicinal Chemistry by Burger, 4th Edition.
6. Principles of Medicinal Chemistry by William O. Foye, 3rd Edition.
7. Drug design volumes by Ariens
8. Principles of Drug design by Smith
9. Strategy of Drug design by Brucell
10. The Organic Chemistry of the Drug design and Drug action by Richard B.Silverman

Journal: At least one international journal is to be subscribed

1. Indian Journal of Chemistry Section B
2. Indian Journal of Heterocyclic Chemistry
3. Indian Journal of Pharmaceutical Sciences



PAPER-IV: MEDICINAL CHEMISTRY–II (NATURAL PRODUCTS)(Theory)

Total Hours: 50 (2 hr/week),	Examination	Max Marks
	Annual	100
	Internal Assessment Exam:	30
	Seminar Evaluation:	20
	Total:	150

GOAL:

- To train the student to learn in detail about different biological constituents of plants and to study their biosynthetic path ways.
- To train the student to isolate and identify the different principles from plant source.

OBJECTIVES:

1. To impart a thorough knowledge to the student about different medicinally active principles, their formation, isolation and identification.
2. The candidate is trained to improve the yield of the active principles by suitable bio-chemical modifications.
3. The candidates are trained to modify the chemical structure of the active constituents to improve their pharmacological activity.

S.N	Syllabus	Hr/Week
1	A) General chemical methods of structural elucidation of natural products. B) Structure elucidation of the following compounds based on chemistry, chemical degradation and synthesis of the compounds;	15
a)	Morphine alkaloids: Morphine, Papavarine	3
b)	Cardiac glycosides: Lanatoside C, Ouabain	3
c)	Rauwolfia alkaloid: Reserpine	3
d)	Vinca alkaloids: Vinblastine and vincristine	3
e)	Ipecacuanha alkaloid: Emetine	3
2.	Microbial conversions as tools in the preparation of drugs	4
a)	Introduction	
b)	Practical aspects of microbial transformation	
c)	Some theoretical aspects of microbial transformation	
d)	Conversion by microorganism	
3.	A) General introduction and classification of steroids B) Hormones:	9
a)	Female and male sex hormones –development of antifertility agents.	3
b)	Adrenal cortex hormones and their derivatives	3
c)	Carotenoids and their therapeutic importance.	1
d)	Development of anabolic steroids and antifertility agents	2

4. Antibiotics :	10
a) Penicillins and Cephalosporins:	
i) Early Penicillins and cephalosporins	1
ii) AmidoPenicillins	1
iii) Beta lactamase stable cephalosporins	1
iv) Antipseudomonal penicillins and cephalosporins	2
v) New oral compounds and future prospects	1
b) Other betalactam agents	
i) Nocardins and monobactams	1
ii) Clavulanic acid analogs	1
iii) Carbapenams	1
Other fused Betalactam systems	1
5. Purine,Pyrimidines and their applications	8
a) The metabolism of purines and pyrimidines, allopurinol and xanthine oxidase	2
b) Purine and pyrimidine antimetabolites as antineoplastic agents	2
c) Purine and pyrimidine related Antiparasitic agents	2
d) Purine and pyrimidine related Antifungal agents	2
6. Chemistry of vitamins	4
a) Water soluble vitamins: Vitamin B ₁ , B ₂ , B ₆ and Vitamin C	2
b) Fat soluble vitamins: Vitamin A, D, E and K	2

PAPER-IV: MEDICINAL CHEMISTRY–II (NATURAL PRODUCTS)(Practical)

Total Hours: 150 (6 hr/week),	Examination	Max Marks
	Annual	100
	Internal Assessment Exam:	30
	Practical record Evaluation:	20
	Total:	150

Part –1: Isolation and Characterization of following active constituents

1. Eugenol from Clove
2. Curcumin from Turmeric
3. Sennosides from senna
4. Hesperidine from Orange Peel
5. Embelin from Embelia Ribes
6. Glycyrrhizin from Glycyrrhiza Glabra
7. Plumbagin from Plumbago Rosea
8. Solanine from potatoes
9. Naringin from Grape Fruit Peel
10. Trimyristin and Myristin from Nutmeg
11. Azylic acid from Castor Oil
12. Pectin from Orange Peel
13. Lycopene from Tomato Peel

14. Epicatechin from Cashew Kernel outer covering
15. Piperine from Black pepper

Part-II: Degradation reaction of following natural products and the identification of the degraded intermediates by micro TLC and qualitative tests.

1. Atropine,
2. Caffeine,
3. Ephedrine,
4. Saponification of Trimyristin

Scheme of Practical Examination

Sl. No	Synopsis	Experiments		Viva-voce	Total
		Major	Minor		
1	20	35	25	20	100

TEACHING AND LEARNING ACTIVITIES

Journal club

Each student is required to present any two recent articles relevant to the Advanced Pharmaceutical Chemistry from any of the journals in an year.

Seminars

Each student is required to give two seminars relevant to this subject in a year.

Field/Industrial visits

It is desirable to make to one visit to the relevant / Laboratory / Industry

Conference / Meetings

Each student has to be encouraged to attend at least one relevant national conference.

Reference Books:

1. Modern Methods of Plant Analysis- Peech and M.V. Tracey
2. Phytochemistry Vol-I and II by Miller, Jan Nostrant Rein Hold.
3. Recent Advances in Phytochemistry-Vol-I-IV Scikel Runeckles
4. Chemistry of Natural Products Vol-I onwards IWPAC
5. Natural Products Chemistry Nakanishi Golo
6. Natural Products Chemistry "A Laboratory Guide"-Raphael Ikan, IInd Edition, Academic Press New York.
7. The Alkaloid Chemistry and Physiology- Volumes RHF Manske
8. Introduction to Molecular Phytochemistry-CHJ Wells, Chapmanstall.
9. Comparative Phytochemistry edited by T.Swain
10. Organic Chemistry of Natural Products- Vol-I & II – Gurdeep Chatwal, Himalaya publishing house, Mumbai..
11. Organic Chemistry Vol-I & II by I.L. Finar, ELBS Longman, 5th Edition , London
12. Elements of biotechnology by P.K. Gupta

13. Pharmaceutical Biotechnology by S.P.Vyas and V.K.Dixit, CBS publisher, New Delhi.
14. Biotechnology by Purohit and Mathur , Agro Botanical publishers, Bikaner.
15. Phytochemistry method by Harborne
16. Burger's Medicinal Chemistry, 5th Edition, Vol.I, II. John Wiley and Sons, New York.
17. Burger's Medicinal Chemistry, 4th Edition, Vol. II, Part-II, John Wiley and Sons, New York.
18. Comprehensive Medicinal Chemistry, Vol.II by Corwin Hansch, Pergamon Press, New York

Journals:

(At least one international journal is to be subscribed)

1. Indian Journal of Pharmaceutical Sciences
2. JMAPS
3. Indian Journal of Natural Products
4. Phytopharma
5. Journal of Natural Products.
6. Indian Journal of Chemistry.
7. Phytochemistry



M . P H A R M

PHARMACOLOGY

GOAL: To produce competent Pharmacologists.

OBJECTIVES: Upon completion of the course, the candidate shall have knowledge of understanding the concepts of drug action and its mechanisms involved

Skill: the ability to screen new molecules for their potential pharmacological effects and toxicity

Attitude: the ability to

1. Work independently and as a member of a team
2. Plan his / her work for efficient use of time and resources
3. Identify the cause and to solve the problem
4. Think and evaluate scientifically, ethically and critically

TITLE OF PAPERS

PAPER I Modern Pharmaceutical Analysis (T:3Hrs/wk,P:6Hrs/wk)

PAPER II Advanced Pharmacology and Toxicology (T:2Hrs/wk, P:6Hrs/wk)

PAPER III Pharmacological Screening Methods and Clinical Evaluation **(T:2Hrs/wk, P:6Hrs/wk)**

PAPER IV Molecular Biology (T:2Hrs/wk, P:6Hrs/wk)

List of special equipment

1.	Student's Physiograph	3 nos
2.	Semi auto Analyzer	1 no
3.	Langendorf's Heart Perfusion Apparatus	2 nos
4.	Students Organ Bath (Temperature Controlled)	6 nos
5.	Elevated Plus Maze	1 no
6.	ECG Equipment for Rats	1 no
7.	Condon's Manometer (for rat BP)	3 nos

PAPER II. ADVANCED PHARMACOLOGY AND TOXICOLOGY

Revised Syllabus		Hours
GOAL: To understand the mechanism of drug action in detail and toxicity of drugs. OBJECTIVES: Upon completion of the course, the candidate shall be able to - know the chemical mediators and mechanisms by which the drugs act - know the drug therapy of certain disorders - understand gene therapy - understand different types of toxicities		
COURSE DESCRIPTION		
THEORY	50 Hours (2Hrs/wk)	
a. Molecular Mechanisms in Cell regulation b. Signaling molecules and their receptors: i. Molecules: Nitric oxide, carbon monoxide, neurotransmitters, cytokines, peptide hormones, growth factors and eicosanoids. ii. Receptors: 1. Cell surface Receptors: Ion channels, G-protein coupled receptors, tyrosine kinase receptors, cytokine receptors, non-receptor protein tyrosine kinases 2. Nuclear receptors: Steroid hormone receptors, thyroxine receptors, other nuclear receptor families c. Signal transduction: d. Intracellular signal transduction: cAMP, cGMP, IP3-DAG, calcium pathway, PI3K/Akt, m-TOR, MAPK, JAK/STAT, TGFβ/Smad, NFB signaling, Hedgehog-Wnt, Notch pathways including Adrenergic and cholinergic transmissions. Other peripheral mediators: 5-HT and Purines, Cannabinoids, Peptides and proteins i. Cytoskeleton signal transduction: Integrins and signal transduction, regulation of actin cytoskeleton		12
2. Chemical Mediators Biosynthesis, pathophysiological roles, receptors and drugs affecting the receptors for following a. Mediators of inflammation and allergy: Histamine, Bradykinin, PAF, Eicosanoids: prostaglandins, thromboxanes, leukotrienes and related compounds, EDRF and vascular substances, oxygen free radicals, Cytokines, Cox- 1 and Cox-2.		4
3. Pharmacotherapy [28 hrs] The student is expected to understand Pathophysiology, Pharmacotherapy and critical analysis of rational use of drugs in the following disorders. a. Introduction to Pharmacotherapeutics b. CVS: Hypertension, Ischaemic heart disease, CCF, Cardiac arrhythmias and dyslipidaemia. c. Respiratory: Asthma and COPD d. CNS: Parkinson's disease, Alzheimer's disease, Schizophrenia, Affective disorders, Epilepsy, insomnia, anxiety and pain management e. Musculoskeletal: Rheumatoid & Osteoarthritis, hyperuricaemia, Myasthenia gravis. f. GIT: Peptic ulcer, GERD, Inflammatory bowel diseases, constipation, diarrhoea. g. Endocrine: Obesity, Diabetes mellitus, Osteoporosis, Thyroid and parathyroid disorders, h. Infectious: UT infections, RT infections, GI infections (Bacterial and protozoal), Malaria, Tuberculosis, AIDS, Malignant: Leukaemia, Lymphomas and solid tumours.	4 1 2 3 4	28

8 hr

4. Toxicity studies: [6 Hours]

- a. Acute, sub-acute and chronic studies: Protocols, objectives, methods of execution and regulatory requirements.
- b. Reproductive toxicology assessment: Male reproductive toxicity, spermatogenesis, risk assessment in male reproductive toxicity, female reproductive toxicology, oocyte toxicity, alterations in reproductive endocrinology, relationship between maternal and developmental toxicity
- c. Mutagenicity: In vitro tests for gene mutations in bacteria, chromosome damage, gene mutations in vivo (micronucleus tests and metaphase analysis) in rodents.
- d. Carcinogenicity studies: In vivo and In vitro studies
- e. Toxicological requirements for biological and bio-tech products: Safety analysis, concept of safety Pharmacology, antibodies, transmission of viral infections, residual DNA

Text Books:

1. Goodman and Gilman's The Pharmacological Basis of Therapeutics. (International Edition) McGraw Hill, New York (2001), 10th Edition.
2. Pharmacology by Rang HP, Dale MM and Ritter JM. Churchill Livingstone, London, 6th Edition, 1999.
3. Basic and Clinical Pharmacology by Bertram G Katzung (International Edition) Lange Medical Book/McGraw-Hill, U.S.A. (2001) 8th Edition.
4. Clinical Pharmacy by D.R. Laurence, P.N. Bennett & Mi. Brown, 8th Edition Churchill Livingstone 1997.
5. Clinical pharmacy and therapeutics –Eric T, Herfindal, Williams and Wilkins Publications
6. Clinical pharmacy and therapeutics –Roger and Walker, Churchill Livingstone Publication
7. Experimental and surgical techniques in the rat, 2nd edition H.B. Waynforth and P.A Flecknell.

Reference Books:

8. Harrison's Principles of Internal Medicine. (2 Volumes 2001) by Braunwald, Fauci, Kasper, Hauser, Longo Jameson, McGraw Hill, New York, 15th Edition.
9. Pharmacotherapy; A pathophysiologic approach-Joseph T. Dipiro et.al Appleton and Lange
10. General and applied toxicology by B. Ballantyne, T. Marrs, P. Turner (Eds) The Macmillan Press Ltd, London.
11. Harrison's Principles of Internal Medicine. (2 Volumes 2001) by Braunwald, Fauci, Kasper, Hauser, Longo Jameson, McGraw Hill, New York, 15th Edition.

Journals:

1. Trends in Pharmacological Sciences. [Essential]
2. Indian Journal of Pharmacology [Essential]
3. Journal of Pharmacology and Experimental Therapeutics [Essential]
4. Indian Journal of Physiology and Pharmacology. (Desirable)
5. Annual Reviews of Pharmacology and Toxicology. [Desirable]
6. Pharmacological Reviews. [Desirable]
7. J-PET Journal of Pharmacology and experimental Therapeutics.

PRACTICALS

1. Animal house: Design and facilities to maintain the animals
2. Routes of administration of drugs like oral, intravenous, intraperitoneal, intramuscular, subcutaneous including conversion of human dose to animal

3. Anaesthetics for animals (isoflurane by inhalation, ketamine+xylazine by intraperitoneal)
4. Blood sampling methods in experimental animals (cardiac puncture, retroorbital, tail vein, cephalic, marginal ear vein)
5. To identify the cholinergic, adrenergic, serotonergic, vasodilator and cardiotonic drug /blockers using isolated mammalian heart preparation in Langendorff's setup.
6. To assess the effect of drugs on angiogenesis using chorio- allantoic membrane (CAM) assay
7. To identify the Anti-dysrhythmic activity in rats using ECG
8. To identify the effect of various autonomic drugs on rat blood pressure (carotid and jugular cannulation).
9. To identify the effect of various drugs on rabbit/rat/chick jejunum preparation.
10. To identify the Acetylcholine, noradrenaline, adenosine and serotonin like drug /blockers using rat anococcygeus muscle preparation.
11. To identify the following receptors by using suitable tissue preparations:
 - i. the alpha action of a drug
 - ii. the beta action of a drug
 - iii. the muscarinic action of a drug
 - iv. the nicotinic action of drug
 - v. the 5 HT action of a drug

Books for Practicals

1. Fundamentals of experimental pharmacology by M.N Ghosh, scientific book agency, Calcutta.
2. Hand book of experimental pharmacology by SK Kulkarni, Delhi, Vallabh Prakash
3. Short Protocols in Pharmacology and Drug Discovery edited by Enna SJ, et al., John Wiley & Sons Inc.
4. General and applied toxicology by B. Ballantyne, T. Marrs, P. Turner (Eds) The Macmillan Press Ltd, London.

PAPER III PHARMACOLOGICAL SCREENING METHODS & CLINICAL EVALUATION

Clinical Research: Introduction and Ethics [3 Hours]

- a. Definition and scope of clinical research. Role of sponsor, study director or principal investigator; Clinical Research Associate in conduct of Clinical Research
- b. Study design, ethics in patient selection and preserving their rights. Institutional Ethics Review committee its constituent members and its role in clinical research. Introduction to informed consent and its importance.

3**4. Phases of Clinical Trial and Clinical Trial Design [3 Hours]**

- a. Calculation of Human Equivalent Dose; Phase 0, Phase I, Phase II, Phase III, Phase IV and Phase V Clinical trial.
- b. Randomized Clinical Trial, Uncontrolled Trials, Protocol Development, End points, Patient Selection and blinding, special designs like cross over design, factorial design, Equivalence design, confounding in clinical trials and ways to minimize it, Missing data and its management, occurrence of ADRs, interim monitoring and stopping of trials,

5**5. Regulatory Affairs in Clinical Research [5 Hours]**

- a. Pharmacovigilance
- b. Laws governing Clinical Research: preparation of Drug master files (IND, NDA and ANDA) Schedule Y, Code of Federal Regulations (CFR-USFDA) CDSCO (ICMR), EMEA
- c. International Guidelines to meet the standards in Clinical Research: ICH guidelines for efficacy testing of drugs: clinical aspects and data management strategies (E1 – E14]

BOOKS:

1. Drug Discovery and Evaluation Pharmacological Assay by Vogel H G and Vogel W H (Springer publication)
2. Evaluation of drug activities Pharmacometrics by D R Laurence and A L Bacharach Vol. 1 and 2.
3. Drug Screening Methods by SK Gupta, Jaypee Brothers, New Delhi.
4. Alternatives to animals in toxicity testing. Scientific American 26:(1989), 16-22.
5. Remington's Pharmaceutical Sciences 24th edn.
6. Methods of clinical trials by Alan Spreit and Simon.
7. Clinical Pharmacology by P N Bennett and Brown
8. The Oxford textbook of Clinical Pharmacology and drug therapy by D.G. Graham-Smith and J.K.Aronson.
9. Modern Methods of Drug Discovery by Hillisch, A and Hilgenfeld, R

Reference Books:

1. Short Protocols in Pharmacology and Drug Discovery edited by Enna SJ, et al., John Wiley & Sons Inc.
2. Modern drug research- Paths to better and safe drugs (Medicinal Chemistry vol. 9) by Y C Martin, E. Kutter and V. Austel
3. Practical approaches in toxicity studies by Poole and Leslie
4. Pharmacological Experiments in Intact preparations, Edinburgh University Pharmacology staff, Livingstone, (1968)
5. Pharmacological Experiments on Isolated preparations, Edinburgh University Pharmacology staff, Livingstone, E & S Livingstone Edinburgh & London (1970).
6. Screening Methods in Pharmacology, Academic Press, New York and London (1965).
7. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, Lea and Febiger Book. 3rd Edition (1984).

Journals:

1. Indian Journal of Pharmacology [Essential]
2. British Journal of Pharmacology.

3. Drug Metabolism and Pharmacokinetics.

Practicals : [6 hours/week]

1. Bioassay of acetylcholine/histamine using guinea pig/rat ileum preparation.
2. Bioassay of oxytocin using rat uterine preparation.
3. PA_2 values of various antagonists using suitable isolated tissue preparations.
4. *In-vitro* Absorption study using Inverted rat intestine
5. Exercise on determination of pharmacokinetic parameters using UV/visible spectrophotometer/HPLC
6. Screening of anxiolytic drugs
7. Screening of antidepressant drugs
8. Antipyretic activity by yeast induced pyrexia in rats.
9. Anti-inflammatory activity by rat paw oedema method.
10. Analgesic by hot plate, tail flick, tail dip, paw pressure test, plantar test and/or writhing methods.
11. Skeletal muscle relaxant activity by rotarod method.
12. Anticonvulsant
13. Pole climbing
14. Actophotometer
15. Exercise on Biostatistics using software
16. Enzyme based *in vitro* bioassays (5-LO, COX, DPPH, AchE, hyaluronidase inhibition assays)
17. Antioxidant activity of Super oxide dismutase (SOD), Catalase, lipid peroxidation and Reduced glutathione in tissue homogenate

PAPER-IV. MOLECULAR BIOLOGY

Proposed	Hours
GOALS: To understand the cell biology & genetics that forms the basis for new drug discovery. OBJECTIVES: Upon completion of the course, the candidate is expected to know basic cell biology. Recombinant DNA technology, transfer of genes to mammalian cells. COURSE DESCRIPTION THEORY 1. Cellular structure and functions: (8 hours) a. Cell structure: cell wall, cytoplasm and its components, nucleus and its components b. Plasma membrane: Structure, transport of small molecules and drugs across it, endocytosis, transport proteins and their inhibitors c. Extra cellular matrix, cell signaling and communication between cells and their environment, ion-channels, Organization of signal transduction pathways, third messengers, d. Biosensors-introduction and applications. 2. Mechanisms of Cellular Regulation: (10 hours) a. Excitation, contraction and secretion b. Cell proliferation: Phases and checkpoints of Cell cycle, Positive and negative regulators of cell cycle c. Cell renewal: Stem cells and maintenance of adult tissues, proliferation of different stem cells, medical application of adult stem cells, embryonic stem cells, somatic cell nuclear transfer, induced pluripotent stem cells and their therapeutic applications in medicine. d. Cell death (Apoptosis): Events of apoptosis, regulators of apoptosis, intrinsic and death pathways of apoptosis. e. Animal cell culture 3. Gene manipulation and its applications (32 hours) a. Role of genes within cells, DNA- the primary genetic material, Elucidation of genetic code, Gene expression, Genetic elements that control gene expression, microarray. (5 hrs) b. Recombinant DNA Technology: Principles, process and applications. Gene cloning: Isolation, cloning vectors, enzymes used in molecular cloning, PCR (Polymerase chain reaction), LCR (Ligation chain reaction) and their applications. The formation and uses of RFLP's (Restriction Fragment Length Polymorphism). (8 hrs) c. Recombinant DNA / Human Genetics: DNA sequencing, Mapping and cloning of Human disease genes, DNA-Based diagnosis of genetic diseases. (4 hrs) d. Human genome project. (1 hrs) e. Gene therapy and Antisense technology (2 hrs). f. Biotechnology related techniques: Protein engineering, Peptide chemistry and peptidomimetics, Nucleic acid technologies, catalytic antibodies, glycobiology. (6 hrs) g. Principles of cell based assays and their application: MTT assay, COMET assay, DNA ladder, Radio-ligand binding assay, RT-PCR, Western blotting, Immunoblotting, Immunofluorescence, Flow cytometry. (6 hrs) BOOKS: 1. Molecular biology of the CELL. Alberts B. et.al (Eds). Garland Publishing Inc.	8 10 32

New York and London.

2. Pharmaceutical Biotechnology. Crommelin DJA and Sindelar RD. (Eds). Harward Academic Publishers, Australia, UK.
3. Biopharmaceuticals: Biochemistry & Biotechnology. Gary Walsh. (Eds). John Wiley and Sons.
4. Recombinant DNA. James D. Watson, Michael Gilman, Jan Witowski, Mark Zollet (Eds). Scientific American Books, New York
5. The Cell: A Molecular Approach. Geoffrey M Cooper and Robert E Hausman (Eds). 5th ed
6. S P Vyas and D V Kohli, Pharmaceutical Biotechnology
7. Kumarsan
8. Satynarayan

PRACTICALS

(6 Hrs/wk)

1. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
2. Drug mutagenicity study using mice bone-marrow micronucleus test.
3. Ame's test (Salmonella typhimurium)
4. Drug cytotoxicity using a cell line (MTT or any other assay)
5. Polyacrylamide Gel Electrophoresis
6. Western Blotting.
7. Isolation and estimation of DNA and RNA.
8. Restriction digestion of DNA.
9. Ligation of DNA.
10. Isolation of plasmids.
11. Estimation of proteins by Bradford /or Lowrays

Scheme or examination:

Synopsis	20 marks
Major experiment	35 marks
Minor experiment	25 marks
Viva-voce	20 marks
Total	100 marks

PAPER II. ADVANCE PHARMACEUTICAL CHEMISTRY

Goal: To make students acquainted with modern synthetic aspects of organic chemistry for those who take up drug synthesis as major field.

Objective: To impart necessary knowledge in organic synthesis and application.

Other activities: Seminar, journal club and workshop/Industrial visits.

COURSE DESCRIPTION

Theory

50 Hours (2hrs/wk)

Chapter 1. Principles of Organic Reactions

- 1.1 Types of Chemical Bonds and their Charge Distribution
- 1.2 Resonance and Inductive effect in organic molecule.
- 1.3 Hydrogen bonding.

4 hrs (10 marks)

Chapter 2. General Organic Reactions

- 2.1 Types of Organic reactions: Free radical reaction, substitution reaction, addition reaction, Elimination reaction, Rearrangement reaction, condensation reaction, molecular reaction, pericyclic reaction, oxidation reaction, reduction reaction.
- 2.2 Types of reagents used in organic Synthesis: Nucleophiles, Electrophiles, Catalysis-Hydrogenation using homogeneous and heterogeneous.
- 2.3 Reaction Intermediates: Generation, Stability, Structure and reactions of Carbonium ions, Free radicals, Carbenes, Nitrenes and Arenes.
- 2.4 Concept of Retrosynthesis, Thermodynamically and kinetically controlled processes
- 2.5 Microwave Irradiation Techniques.

6 hrs (20 marks)

Chapter 3. Reaction Mechanisms and their applications in Organic Synthesis

- 3.1 Friedel-Craft and Grignard Reactions
- 3.2 Condensation Reaction
- 3.3 Rearrangement Reaction
- 3.4 Oxidation-Reduction Reactions
- 3.5 Active methylene group Reactions
- 3.6 Preparation and Synthetic applications of Aceto-Acetate and Malonic Ester.

12 hrs (25 marks)

Chapter 4. Stereochemistry

- 4.1 Stereoisomerism and Optical Isomerism, Enantiomerism, diastereoisomerism, Meso compounds, Chiral centers.
- 4.2 Elements of symmetry, Racemic modification and Resolution of Racemic mixture
- 4.3 Configuration, specification of D & L Configuration.
- 4.4 Asymmetric synthesis and stereoselective and stereospecific reactions
- 4.5 Geometrical Isomerism and Its Nature of Formation, rotation about bonds, Nomenclature of isomers and determination of configuration.
- 4.6 Stereo-Chemistry of Biphenyls, Oximes and steroids.

14 hrs (20 marks)

Chapter 5. Heterocyclic Chemistry

- 5.1 Introduction, Classification, Nature and Nomenclature, Synthesis, Chemical and Physical Properties of active medicinal agents and their derivatives
- 5.2 Pyrrole, Furan and Thiophen
- 5.3 Indole, Benzothiophen and Benzofuran,
- 5.4 Pyridine and Piperidine
- 5.5 Quinoline, Isoquinoline and Acridine
- 5.6 Pyrazole, Imidazole, Oxazole and Isoxazole
- 5.7 Pyrimidine, Pyrazine, Pyridazine, Purine and Benzodiazepines
- 5.8 Miscellaneous: Benzthiadiazole, Benzothiazepines, Phenothiazines, Morpholine, Benzimidazoles, Quinazoline, Triazole, Tetrazole and Pencillin. 14 hrs (25 marks)

PRACTICALS

150 Hr. (6Hr/Week)

Part I. Quantitative Determination of Organic Compounds via Functional Groups (Any Four) (Minor expt)

1. Amino Group by Bromination method
2. Aminoacid by Formal titration Method
3. Carbonyl Group by Hydroxylamine hydrochloride-pyridine method
4. Determination of Acetone by Sodium hypoiodide method
5. Alcoholic group by Acetylation method
6. Carboxyl group by acid base method.

Part II. Qualitative Analysis: (Major expt)

A minimum of four Organic Binary mixtures should analyses systematically by ether separation technique with the preparation of at least one derivative of each compound.

Part III. Preparation of at least six compounds (Minor expt)

1. Parabromo aniline from acetanilide
2. Benzilic acid from Benzoin
3. Picric acid
4. Sulphanilic acid
5. Aminobenzene from Nitrobenzene
6. 2,5-Dimethylpyrole
7. 2-phenylindole
8. phenothiazine
9. Aminophenol from Nitrophenol
10. Coumalic acid.

Scheme of Examination

1. Synopsis	20 marks
2. Major expt	40 marks
3. Minor expt	20 marks
4. Viva voce	20 marks

Reference Book

1. I.L.Finar, Organic Chemistry Vol I & II 6th Edition, 2003, ELVS
2. Review of Organic Chemistry- Morrison, Robert Thornton, R.N.Boyd Prentice Hall India (P) Ltd.
3. B.S.Bhal and Arun Bhal, S. Chand, Advanced Organic Chemistry and Company, New Delhi 2001.
4. Modern Structural Theory of Organic Chemistry- Furguson, John Wiley and Sons , New York.
5. Principles of Organic Chemistry-Geissman T.A, W.H, Freeman & Co. San Francisco.
6. S.M.Mukerji and S.P. Sing, Reaction Mechanism in Organic Chemistry, 3rd Edition Macmillan Publication, 2001.
7. T.W.G. Solomans, Organic Chemistry, 6th Edition, John Wiley and Sons , New York. 1966.
8. Text Book Of Organic Reaction Mechanism- Tyagi and Yadav, Anmol Publication, New Delhi.
9. Advanced Organic Chemistry-Reaction Mechanism and Structure-Jerry March. Wiley Inter Science Publication New York.
10. Stereochemistry- Conformations and Mechanism- Kalsi P.S. New Age International (P) Ltd. New Delhi.
11. E.L.Eliel, John Wiley and Son, Stereochemistry of Organic Compounds, New York 1993.
12. Raj. K. Bansal. Heterocyclic Chemistry, New age International Ltd, New Delhi, Third Edition, 2001.
13. The logic of Synthesis- E.J.Corey, JohnWiley and Sons New York.
14. Organic Synthesis- Collective Volumes, JohnWiley and Sons New York.
15. A.I.Vogel, Elementary Organic Chemistry Part three , Quantitative Organic analysis, 2nd Edition, CBS Publication and Distributors, New Delhi 2000.
16. B.S. Furniss, A. J. Hannaford, P.W.G.Smith and A.R.Tathell, Vogel's Text Book of Practical Organic Chemistry, Edited, 5th edition, Addison Wesley Longman.
17. Mann and Saunders, Practical Organic Chemistry-ELBS and Long man Group Ltd.
18. D.L.Pavia, G.Lampman and G.D. Kriz. Introduction to Organic Laboratory Techniques.

Journals: (At least two international journals to be provided).

1. Journal of Heterocyclic chemistry.
2. Indian journal of Chemistry.
3. Indian journal of Heterocyclic Chemistry.
4. Journal of organic Chemistry.
5. Asian journal of Chemistry.

PAPER III. ADVANCE MEDICINAL CHEMISTRY

Goal: The goal of studying this paper is to train the candidate to ensure that he develops skill in the designing of target specific molecule and to train the candidate to isolate and identify the different principles from plant sources.

Objective: To train the candidates with different theoretical aspects involved in drug design, the candidates are trained to modify the chemical structure of the active constituents to improve their pharmacological activity and to impart through knowledge to the student about different medicinally active principles, their formation, isolation and identification.

Other activities: Seminar, journal club and workshop.

COURSE DESCRIPTION

Theory

50 Hours (2hrs/wk)

Chapter 1. Drug Discovery and Development

- 1.1 Introduction
- 1.2 How are the New Drugs Discovered
- 1.3 Requirements for an investigational drug to be tested in Human Volunteers
- 1.4 How are the Investigational Drugs Tested in Humans
- 1.5 How does Testing Continue after a New Drug is Approved
- 1.6 Procedures Followed in Drug Design. 4 hrs (10 marks)

Chapter 2. Principles of Drug Action and Drug Metabolism

- 2.1 Introduction
- 2.2 Physicochemical Properties and Drug Action
- 2.3 Bioisosteric Replacement
- 2.3 Drug-Receptor Bonding and G Protein-Coupled Receptors
- 2.4 Drug Metabolism, Prodrug. 5 hrs (10 marks)

Chapter 3. Computer-aided Drug Design

- 3.1 Introduction
- 3.2 CADD Methodology
- 3.3 Small Molecule-Based Drug Design
- 3.4 Macromolecule- Based Drug Design
- 3.5 Substituent's Constants Useful for QSAR Analysis. 4 hrs (10 marks)

Chapter 4. Sedatives, Hypnotics, and Anxiolytic Agents

- 4.1 Introduction
- 4.2 Classifications of sedative and Hypnotics and Synthesis of drugs
- 4.3 Barbiturates, Benzodiazepines, Benzodiazepines Antagonists, Miscellaneous
- 4.4 Anxiolytic agents and Newer Drugs. 4 hrs (5 marks)

Chapter 5. Anti-Epileptic Drugs

- 5.1 Introduction
- 5.2 Classification and Synthesis of drugs
- 5.3 Structural Requirements for Anticonvulsants Agents and Their SAR
- 5.4 Hydantoins and Oxazolidinediones and Succinimides and Benzodiazepines
- 5.5 Gaba Analogues and Miscellaneous and Newer Anticonvulsants. 4 hrs (10 marks)

Chapter 6. Antipsychotic Agents

- 6.1 Introduction
- 6.2 Classification, Mechanism of Action and SAR and Synthesis of drugs. 2 hrs (5 marks)

Chapter 7. Cardiovascular Agents

- 7.1 Introduction
- 7.2 Classification Mechanism of Action and Synthesis of drugs
- 7.3 Miscellaneous Drugs and Newer Drugs. 5 hrs (10 marks)

Chapter 8. Antibiotics

- 8.1 Introduction
- 8.2 β -Lactum Antibiotics and Tetracycline Antibiotics
- 8.3 Macrolide Antibiotics and Aminoglycoside Antibiotics
- 8.4 Miscellaneous Antibiotics and Newer Drugs and Synthesis of drugs. 5 hrs (10 marks)

Chapter 9. Cholinergic Agents

- 9.1 Introduction
- 9.2 Cholinomimetics and Anticholinesterases
- 9.3 Cholinergic Blocking agents and Newer drugs
- 9.4 Structure elucidation of Atropine and Synthesis of drugs. 4 hrs (5 marks)

Chapter 10. Adrenergic Agents

- 10.1 Introduction
- 10.2 Sympathomimetic agents and Adrenergic Blocking Agents, Newer drugs
- 10.3 Structure elucidation of Ephedrine and Synthesis of drugs. 4 hrs (5 marks)

Chapter 11 Hormones

- 11.1 Female and Male sex hormones and Development of antifertility agents
- 11.2 Adrenal cortex Hormones and their derivatives
- 11.3 Steroids/ triterpenoids-classification of plants steroids and triterpenoids. 4 hrs (10 marks)

Chapter 12 Purines and Pyrimidines

- 12.1 Metabolism of purines and pyrimidines
- 12.2 Antineoplastics agents
- 12.3 Antiparasitic purine and pyrimidine related agents
- 12.4 Antifungal agents. 5 hrs (10 marks)

PRACTICALS

150 Hr. (6Hr/Week)

Synthesis, Purification and identification of the following compounds employing micro-TLC and qualitative analysis.

A. Synthesis of the following (A minimum of Ten synthesis to be done) (Minor expt)

1. INH
2. Methaqualone
3. Chloramine T and Dichloromine T
4. Saccharin Sodium
5. 7-Hydroxy-4-methyl coumarin
6. Dapsone
7. Phenytoin from Benzaldehyde
8. Benzaldehyde
9. Benzophenone oxime
10. Sulfanilamide
11. Phenothiazine
12. 2,3 diphenyl quinoxaline
13. Benzimidazole
14. Phenyl urea and diphenyl urea
15. Benzofuran
16. Uramil

B. Isolation and Characterization of Natural Products (A minimum of 5 isolation to be done) (Major expt)

1. Caffeine from tea leaves
2. Starch from Potato
3. Sennosides from Senna
4. Eugenol from clove
5. Piperine from Blackpepper
6. Nicotine from Tobacco
7. Curcumin from Turmeric
8. Azylic acid from Castor oil
9. Pectin from Orange Peel
- 10 Lycopene from Tomato Peel.

Scheme of Examination

5. Synopsis	20 marks
6. Major expt	40 marks
7. Minor expt	20 marks
8. Viva voce	20 marks

References Books

1. A Biochemical Basis-Medicinal Chemistry by Thomas Nogrady.
2. Introduction to Quantitative Drug design by Y.C.Martin.
3. Selective Toxicity by/ Drein Albet.
4. Comprehensive Medicinal Chemistry- Corwin and Hansch, Pergamon Press New York.
5. Medicinal Chemistry by Burger, 4th edition, A Wiley- Interscience Publication, New York.
6. Principles of medicinal Chemistry by William O. Foey, 3rd Edition, Varghese Publication House Bombay.
7. Drug Design Volume Ariens.
8. Principles of Drug Design by Smith.
9. Strategy of drug Design by Brucell
10. The organic chemistry of the Drug design and drug Action by Richard B.Silverman.
11. Medicinal Chemistry by D.Sriram and P. Yogeewari, 2nd Edition, Dorling Kindersley.
12. Text Book of Organic Medicinal and Pharmaceutical Chemistry by Wilson and Gisvold's 8th Edition, Robert F. Doerge.
13. Modern Methods of Plant analysis- Peech and M.V. Tracey
14. Phytochemistry Vol-I and II by Miller, Jan Nostrant Rein Hold.
15. Organic Chemistry of Natural Products Vol-I and II Gurdeep Chatwal, Himalaya Publication House.

Journals: At least one international journals is to be subscribed.

1. Indian journal of Pharmaceutical science
2. Molecule journal
3. Journal of natural products
4. JMAPS.

PAPER IV. GOOD MANUFACTURING PRACTICES AND BULK DRUG TECHNOLOGY

Goal: To make the students aware of the extreme importance of quality consciousness and systematic scientific practices of documentation and performance and the syllabus is framed to give an insight to the medicinal chemist/production chemist working of bulk drug industry.

Objective: To give the necessary exposure to GMP and GLP concepts and applications and to provide essential infrastructure information about bulk drug industry and functioning.

Other activities: Seminar, journal club and workshop/Industrial visits.

COURSE DESCRIPTION

Theory

50 Hours (2hrs/wk)

Chapter 1. Good manufacturing Practices

- 1.0. Introduction to GMP
- 1.1 Philosophy and Concept of GMP
- 1.2 Applications of GMP and cGMP (Schedule M)
- 1.3 ICH Guidelines and WHO Guidelines
- 1.4 USFDA Guidelines. 4 hrs (10 marks)

Chapter 2. Personnel, Building and Facilities

- 2.0 Personal: Introduction, Qualification Experiences and Training
- 2.1 Responsibilities and Key Personnel, Personal Hygiene and Clothing
- 2.3 Legal aspects, Consultants, Documents and Formats.
- 2.4 Building and Facilities: Introduction, Principal area, Plumbing, Drainage System and
- 2.5 Lighting, Sewage, Refuse and Disposal of waste, Washing, Toilet Facilities,
- 2.6 Sanitation, Maintenances, Documents and Formats. 7 hrs (10 marks)

Chapter 3. Equipment

- 3.0 Introduction
- 3.1 Design, size, location and Construction of Equipments
- 3.2 Equipment identification and Equipment log
- 3.3 Cleaning and maintenances of Equipment
- 3.4 Automatic, Mechanical and Electronic Equipment
- 3.5 Planned Preventive Maintenances Programme 4 hrs (10 marks)

Chapter 4. Material Management

- 4.0 Introduction
- 4.1 Purchasing, Raw Material, Packing Material, Intermediate and Bulk Product
- 4.2 Finished Products, Rejected and Recovered Materials
- 4.3 Recalled Products and Returned goods
- 4.4 Waste Materials, References Standard and Miscellaneous Material. 5 hrs (10 marks)

Chapter 5. Quality Management

- 5.0 Introduction
- 5.1 Quality Assurance and Components of Q.A
- 5.2 Quality control and Components of QC
- 5.3 Computer applications in GMP
- 5.4 Patent act, trade mark act and monopoly restriction act. 4 hrs (10 marks)

Chapter 6. Manufacturing Operations and Control

- 6.1 Introduction
- 6.1 Sanitation of manufacturing premises, Mix-ups and Cross Contamination
- 6.2 Processing of Intermediates, Bulk product and I.P.Q.C
- 6.3 Packing operations and Releases of Finished product
- 6.4 Time limitation on production and Expiration Dating
- 6.5 Product record Review. 5 hrs (10 marks)

Chapter 7. Documentation and Record

- 7.0 Introduction
- 7.1 Specification
- 7.2 Master Production and Control Record
- 7.3 Batch Production and Control Record
- 7.4 Important SOPs and Records, Change Controls and Site Master file. 4 hrs (10 marks)

Chapter 8. Pharmaceutical Validation

- 8.0 Introduction
- 8.1 Validation of Building, Facilities and Equipment
- 8.2 Process Validation and Cleaning Validation
- 8.3 Validation of Analytical methods and Computer Systems
- 8.4 Validation of Specific Dosage Forms
- 8.5 Calibration Master plan and Validation Master plan,
ISO Standards 9000-9004, 14001 to 14010 and 14642 to 14644. 5 hrs (10 marks)

Chapter 9. Concept of Bulk Drug

- 9.0 Introduction (Concept of bulk drug Vs Formulation)
- 9.1 Historical development of Bulk Drug Industry in India
- 9.2 Recommendation of Hathi Committee
- 9.3 Estimated growth of selected bulk drug
- 9.4 Global scenario, Indian giant, Multinational companies,
- 9.5 GATT, Import-export, Exim policy TRIPS, IPR, NDE. 7 hrs (10 marks)

Chapter 10. Industrial Hazards and safety measures

- 10.1 Introduction.
- 10.2 Types of hazards
- 10.3 Industrial accidents and safety measures
- 10.4 Men's compensation Act. 5 hrs (10 marks)

PRACTICALS

150 Hr. (6Hr/Week)

A. Synthesis of the following (A minimum of Ten synthesis to be done) (Major expt)

1. Preparation of Aspirin
2. Preparation of Paracetamol, Phenacetin
3. Preparation of Phenytoin from Benzoin
4. Preparation of Niacinamide / Nicotinic acid
5. Preparation of Ibuprofen
6. Preparation of Benzocaine
7. Preparation of Schiff's base
8. Preparation of Mannich base
9. Preparation of Florescein
10. Preparation of Phenylbutazone
11. Preparation of Phenylbenzoate
12. Preparation of Analgin
13. Preparation of Antipyrine
14. Preparation of Chlorpropamide
15. Preparation of Dibenzylidene acetone

B. Documentation exercise on report making

1. Safety measures in handling hazardous chemicals in Bulk Drug industry
2. Plant location, layout and design
3. purification of organic solvents
4. Case study of equipment, reactors used in bulk drug industry
5. industrial visit report
6. An experiment on validation of apparatus / analytical instrument.
7. Reaction flow sheet of some important drugs.

C. Bulk drug Production techniques, Methodology, Reaction flow sheet, Equipments, Effluent treatment of selected drugs, process development, validation of selected drugs listed below:- (Minor expt)

Analgesic and Antipyretic: Paracetamol, Naproxen, Diclofenac, Nimesulide, Tramadol
Antitubercular: PAS, INH, Pyrazinamide, **Tranquilizer:** Diazepam,
Antileprotic: Dapsone, Clofazimine, **Anticonvulsant:** Phenytoin, Carbamazepine
Anthelmintics: Piperazine, Mebendazole, **Hypnotic & Sedative:** Phenobarbitones
Antihistamines: Chlorpheniramine, **Antifungal:** Clotrimazole, Ketokonazole,
Betablockers: Propanolol, Metoprolol, **Antidiabetic:** Glipizide
Antiallergic: Loratidine, **Antibiotics:** Quinolones (Ciprofloxacin)
Anticancer: Flutamide, Vincristine/Vinblastine.

Scheme of Examination

9. Synopsis	20 marks
10. Major expt	40 marks
11. Minor expt	20 marks
12. Viva voce	20 marks

References Books

1. Good Manufacturing Practices For Pharmaceuticals- Willing S.H., Marrcel DeCker New York.
2. GMP for Bulk Drug Manufacturing- Norms & Explanations
3. Pharmaceutical Process Validation-J.R.Berry
4. Good Laboratory Practices Regulation- Weinberg
5. SOP Validation Studies
6. Good Laboroatory Practice by Jurg P. Seiler
7. Pharmaceutical Quality Assurance by Manohar A. Potdar.
8. How to Practice GLP by P.P.Sharma.
9. Quality assurance of Pharmaceuticals Vol I & II by WHO Geneva, Published, Pharma Book Syndicate.
10. Unit Operations of Chemical Engg- W.L.McCabe etal. McGraw Hill Book Company.
11. Schedule M and Beyond-R.S.Iyer, IDMA.
12. Industrial Pollution-V.P.Kudesia.
13. Chemical Room Design- Whyte Carol and Desain
14. Chemical Engineer`s Hand Book-R.H.Perry-McGrow Hill Book Company
15. Drugs of future- J.R.Rouse Publishers, Barcelona.

Journals: At least two relevant journals to be provided.

1. Chemical weekly.
2. Indian Drug Review.
3. Indian Drugs.
4. Chemical Industry news.
5. IDMA Bulletin.

M.PHARM

PHARMACEUTICAL BIOTECHNOLOGY

GOALS: The course imparts knowledge in subjects “General Microbiology and immunobiotechnology, Bioprocess engineering and technology and Advanced Pharmaceutical Biotechnology so that the student is competent to work in pharmaceutical companies and R & D organizations to develop cost effective yet safe and quality biomedicines and pharmaceuticals.

OBJECTIVES: Postgraduates in Pharmaceutical Biotechnology are expected to:

- Identify appropriate sources of drugs/medical information
- Apply theoretical bases and practical applications of core pharmaceutical biotechnology subjects in concerned industries and organizations. Use the latest techniques for the search of new products from natural sources.
- Understand and analyze novel techniques of production, purification and characterization of enzymes, biotechnologically produced biomedicines and pharmaceuticals.
- Develop cost and time effective methods to produce safe and quality biomedicines.
- Understand and perform novel techniques of genetic engineering namely, recombinant DNA technology, enzyme immobilization, protoplast fusion etc.
- Develop skills in biotechnological techniques for obtaining and improving the quality of natural products.

a) Knowledge and understanding:

A postgraduate student should acquire detailed theoretical knowledge and practical techniques of the following during the period of his/her course. He/she should acquire thorough theoretical knowledge and practical skills in Microbial biochemistry and immunology, Bioprocess engineering and technology and Advanced pharmaceutical technology with special emphasis on design of bioreactors and fermentors. He/she should acquire adequate theoretical knowledge and practical skills on SDS PAGE electrophoresis techniques, biomass estimation, microbial assays, and bioautographic techniques. He/she should acquire adequate theoretical and practical knowledge about bacterial conjugation and transformation, immunodiagnostics and also on bioinformatics.

b) Attitude:

A postgraduate student must inculcate attitude for applying his acquired knowledge on biotechnological, bioengineering and immunobiotechnology. He/she has to maintain a high standard of professional ethics. He/she should continuously upgrade the acquired knowledge by keeping in touch with contemporary research through national and international journals and should be willing to participate in continuing education programs

Papers	Title of papers	Total hours	Hours per week	
			Theory	Practicals
Paper-I	Modern Pharmaceutical Analysis	75	3	6
Paper-II	General Microbiology and immunobiotechnology	50	2	6
Paper-III	Bioprocess engineering and technology	50	2	6
Paper-IV	Advanced Pharmaceutical Biotechnology	50	2	6

Paper-II
GENERAL MICROBIOLOGY AND IMMUNOBIOTECHNOLOGY
(50 Hrs, 2 Hrs/week)

GOALS:

1. To impart skills of Industrial methods for growth, isolation, screening techniques of micro-organisms and enzymes;
2. To understand and analyze metabolism and mechanism of resistance development in micro-organisms.
3. To train students in legal requirements and patents.

OBJECTIVES: Upon completion of the course, it is expected that students will be able to:

1. Identify, locate and isolate industrially useful micro-organisms and enzymes.
2. Perform screening techniques and assays of fermentation products independently.
3. Take part in production of industrially important solvents, fermentation and pharmaceutical effluent treatment.
4. Give appropriate recommendations for modification in the curriculum.

COURSE DESCRIPTION

THEORY

Total Hours: 50 (2 hr/week)	Examination Max Marks	Total Marks
	Annual	100
	Internal Assessment Exam:	30
	Seminar Evaluation:	20
	Total:	150

Chapter 1: Fundamental aspects of microbiology **10hrs (20 marks)**

- a. Morphology, ultra structure, cell organization and reproduction in microorganisms **06hrs**
- b. Molecular characterization and identification of microorganisms through techniques viz. 16s rRNA, ITS D1/D2 and phylogenic studies, tools and techniques to assess microbial diversity (Suggested version) **04hrs**

Chapter 2: Microbial nutrition and genetics **10hrs (20 marks)**

- a. Screening and isolation techniques, nutrition, cultivation and preservation of cultures **04hrs**
- b. Genetics of industrial microorganisms: Bacteria, Actinomycetes and Fungi, mutation (rational and random) in strain improvement, basic methods of gene transfer **06hrs**

Chapter 3: Microbial metabolism **10hrs (20 marks)**

Bioenergetics, important metabolic pathways in anabolism and catabolism correlating with biosynthesis of micromolecules

Chapter 4: Fundamental aspects of immunology **10hrs (20 marks)**

- a. Overview of innate and adaptive Immunity, cells and organs of immune system **02hrs**
- b. Detail study on humoral immunity and cell mediated immunity **08hrs**

Chapter 5: Applied Immunology **10hrs (20 marks)**

- a. Diagnostic applications: Cancer immunology and tumor markers, hybridoma technology and antibody engineering **05hrs**
- b. Therapeutic applications: Monoclonal antibody in drug delivery, therapeutic antibodies and cytokines **05hrs**

GENERAL MICROBIOLOGY AND IMMUNOBIOTECHNOLOGY
(150 Hrs, 6 Hrs/week)

Total Hours: 150 (6 hr/week)	Examination Max Marks	Total Hours: 150 (6 hr/week)
	Annual	100
	Internal Assessment Exam	30
	Practical record Evaluation	20
	Total	150

1. Isolation of bacteria, actinomycetes, fungi, yeasts from different sources
2. Isolation of bacteriophage
3. Study of morphological features of bacteria, actinomycetes, fungi, yeasts using staining, motility and biochemical characteristics.
4. Gradient plate technique
5. Replica plating
6. Determination of cell wall composition.
7. Bacterial conjugation.
8. Bacterial transformation.
9. Microbiological testing of water.
10. Double diffusion, immunoelectrophoresis and radial immune diffusion
11. Immunodiagnosics using commercial kits
12. ELISA
13. Bioconjugation.
14. Screening for microorganisms producing antibiotics, organic acids and pigments.
15. Practicals based on bioinformatics: Primer design and sequence analysis.

Any other practicals relevant to theory syllabus.

TEACHING AND LEARNING ACTIVITIES

Journal Club:

Each student is required to present any two recent articles relevant to the microbiology and immunobiotechnology from any of the journals in a year.

Seminars:

Each student is required to give two seminars relevant to the subject in a year.

Field/ Industrial Visits:

It is desirable to make to one visit to the relevant Laboratory / Industry in a year.

Conference / Meetings:

Each student has to be encouraged to attend at least one relevant national conference.

Scheme of Practical Examination

S.No	Synopsis	Major experiment	Minor experiment	Viva voce	Total
01	20	35	25	20	100

Text Books:

1. Microbiology, an Introduction; 8th Edition, Tortora, Funke and Case, Pearson Education, Singapore
2. Prescott's Microbiology, 4/e, Lasing Prescott, John Harley and Donald Klein, McGraw Hill
3. Introductory Mycology, CJ Alexopoulos, CW Mims, M Blackwell-John Wiley and Sons, Singapore

4. Kuby Immunology, Tomas J Kindt, Barbara A Osborne, Richard A Goldsby
5. Biopharmaceuticals: Biochemistry and Biotechnology, 2nd Ed, Gary Walsh, Wiley Publications.
6. Bioinformatics basics, Hooman H Rashidi, Lukas K Buehler.

Reference Books

1. General Microbiology, RY Stanier, John L Ingraham, ML Wheelis, PR Painter, 5th Ed, Macmillan Press, London
2. Microbial genetics, Jones and Bartlet Series in Biology, SR Maloy, John Jr. Cronan, David Freider
3. Topley & Wilson's Microbiology and Microbial infections
4. Essential fungal genetics, David Moore, Lily Ann, N Frazer
5. Immunobiology, the immune system in health and disease by Paul Travers, Mark Walport, J Donald Capra, Charles Janeway
6. Roitt's Essential Immunology (11th ed) Blackwell Publishers
7. Text book of Immunology, ST Banot, Mosby Publications
8. Text book of pharmaceutical biotechnology by .Kokate,Jalalpure and Hurakadle

Journals

- 1) Indian Journal Experimental Biology
- 2) Indian Journal of Biosciences
- 3) Indian Journal of genetics
- 4) Journal of Biological Chemistry
- 5) Journal of applied bacteriology
- 6) Journal of Immunology

Paper-III
BIOPROCESS ENGINEERING AND TECHNOLOGY

Theory

50 hrs (2hrs/wk)

GOALS:

1. To develop skills to modify, design and operate different types of fermenters and attachments.
2. To understand and implement various fermentation procedures.
3. To train students in scale up fermentation operations.

OBJECTIVES: Upon completion of the course, it is expected that students will be able to:

1. Describe the design and operation of various types of fermenters.
2. Elaborate the theoretical aspects and practical requirements for the growth of microorganisms in industries and R and D organizations.
3. Describe the theoretical basis of fermentation technology for industrial applications.
4. Understand and conduct fermentation process kinetics.

COURSE DESCRIPTION

THEORY

Total Hours: 50 (2 hrs/week)	Examination Max Marks	Total Marks
	Annual	100
	Internal Assessment Exam	30
	Seminar Evaluation	20
	Total	150

Chapter 1: Design features of bioreactors / fermenters

- a. Detailed study of design of microbial fermenters with an emphasis on agitators, aeration system, inoculation and sampling ports, pH, temperature and foam control devices, instrumentation and control.

6hrs

- b. A referral study on animal, plant and enzyme bioreactors. **4hrs**

Chapter 2: Fundamentals of bioprocess technology 10hrs (20 marks)

Microbial growth models with emphasis on Monod's kinetics, modes of fermentation, inocula preparation, turbidity analysis, cell yield determination and process economics

Chapter 3 : Principles underlying product formation 10hrs (20 marks)

Air and media sterilization, measurement of mass transfer coefficient, K_La and factors affecting K_La , power input, rheology of fermented broths and scale up studies.

Chapter 4: Principles underlying product recovery and purification 10hrs (20 marks)

Theory, equipment, design, operation and application of unit operations involved in recovery of microbial metabolites; filtration, centrifugation, cell disruption and precipitation, liquid-liquid extraction, ion exchange and affinity chromatography, membrane process and electrophoresis

Chapter 5: Large scale production of fermentation products 10hrs (20 marks)

- a. Organic solvents – Ethanol, acetone -butanol
- b. Organic acids – Citric acid and lactic acid
- c. Amino acids – Glutamic acid and tryptophan
- d. Vitamins – Vitamin B₂ and B₁₂
- e. Antibiotics – Penicillin, cephalosporin and griseofulvin
- f. Enzymes – Proteases and L-asparaginase

BIOPROCESS ENGINEERING AND TECHNOLOGY

PRACTICALS

150hrs (6hrs/wk)

Total Hours: 150 (6 hr/week)	Examination Max Marks	Total Marks
	Annual	100
	Internal Assessment Exam	30
	Practical record Evaluation	20
	Total	150

1. Study and operation of a laboratory fermentor.
2. Study of modes of fermentation (Batch and fed batch).
3. Construction of bacterial growth curve.
4. Study of diauxic growth.
5. Study and growth pattern of fungi and actinomycetia.
6. Biomass estimation and yield coefficient determination.
7. Thermal death kinetics.
8. Study of strain improvement by stress induced method.
9. Production and downstreaming process of an enzyme.
10. Effect of varying substrate concentration and metal ion concentration on enzyme production.
11. Effect of temperature and pH on enzyme production
12. Production and downstreaming process of an antibiotic.
13. Production and downstreaming process of an organic acid
14. Study of substrate inhibition on product formation.

15. Study of oxygen transfer rate, and $K_L a$ determination
16. Determination of respiratory quotient of microbial cells by Warburg-Respinometer.
17. Bioautographic techniques for identification of active metabolites.
18. Microbial assay of antibiotics and vitamins.

TEACHING AND LEARNING ACTIVITIES

Journal Club:

Each student is required to present any two recent articles relevant to the Bioprocess Engineering and Technology from any of the journals in a year.

Seminars:

Each student is required to give two seminars relevant to the subject in a year.

Field/ Industrial Visits:

It is desirable to make to one visit to the relevant Laboratory / Industry in a year.

Conference / Meetings:

Each student has to be encouraged to attend at least one relevant national conference.

Scheme of Practical Examination

S.No	Synopsis	Major experiment	Minor experiment	Viva voce	Total
01	20	35	25	20	100

TEXT BOOKS

1. Bioprocess engineering basic concepts by Michael L Shuler and Fikret Kargi. Pearson education publishers.
2. Principle of fermentation technology by P F Stanbury, A. Whitaker and S.J Hall. Butterworth, Heinemann, elisver publication.
3. Microbial technology-fermentation technology, vol-2 by H. J. Peppler and D.Pearlman. Academic press, Elsiver publication.
4. Biotechnology, A textbook of industrial microbiology, Wulf Crueger and Anneliese Crueger, Panima publishing coporation.
5. Industrial microbiology, L.E Cassida, Jr. New age international publishers, Bangalore.
6. Bioseperations science and engineering by Trevor G Day, Roger G Harison, Paul W Todd, Scott.R Rudge, Demetri petrides. Oxford university press.

REFERENCE BOOKS

1. Biochemical engineering – fundamentals, James E Bailey and David F Ollis. McGraw-Hill international edition.
2. Fermentation and biochemical engineering by Henry C Vogel. Noyes publishers.
3. Microbial biotechnology principles and applications, Lee Yuan Kun.
4. Principles and practice of Disinfection, Preservation and sterilization, A.D Russel (Editor), W B Hugo (Editor), G. A. J Aylifee (Editor).
5. Industrial microbiology by Prescott and Dunn,Agrobios (India), Jodhpur.
6. Pharmaceutical biotechnology by K Sambamurthy and A Kar.

Journals:

1. Indian journal of experimental Biology.
2. Indian journal of Biosciences.
3. Journal of Chemical technology and Biotechnology
4. Journal of Scientific instruments.

Paper-IV
ADVANCED PHARMACEUTICAL BIOTECHNOLOGY

Theory

50hrs (2hrs/wk)

GOALS:

1. To develop skills of advanced techniques of isolation and purification of enzymes.
2. To become well conversant with programmed fermentation process.
3. To train students how to use diagnostic kits for identification of infectious agents.
4. To enrich students about the current status of development of vaccines and economic importance of biotech products.

OBJECTIVES:

- Upon completion of the course, it is expected that students will be able to
1. Understand and perform advanced isolation and purification techniques in pharmaceutical and biotechnology industries.
 2. Identify appropriate sources of enzymes.
 3. Identify relevant tests for specific infectious disease states and interpret selected laboratory results.
 4. Understand and perform genetic engineering techniques in gene transfer, hybridization, protoplast fusion etc.
 5. Efficiently carryout tissue culture techniques to produce phytopharmaceuticals.

COURSE DESCRIPTION

THEORY

Total Hours: 50 (2 hrs/week)	Examination Max Marks	Total Marks
	Annual	100
	Internal Assessment Exam:	30
	Seminar Evaluation	20

	Total	150

CHAPTER 1: Genetic engineering: Tools and applications **10hrs (20 marks)**

Techniques of gene manipulation, basic tools used in r-DNA technology , cloning vectors, expression vectors and recombinant selection and screening, expression systems, in vitro gene amplification (PCR) , brief understanding of instruments involved in genetic engineering, production of recombinant insulin and hepatitis B vaccine.

Chapter 2: Enzyme technology **10hrs (20 marks)**

Sources of enzymes, production, isolation and purification of enzymes, applications of enzymes in therapeutics and clinical analysis. Immobilized enzyme engineering: different techniques of immobilization, kinetics of immobilized enzymes, design and operation of immobilized enzyme reactors, future of enzyme engineering.

Chapter 3: Immunological products **10 hrs(20 marks)**

Principles, production and storage aspects of conventional and modern vaccines such as DNA vaccines, anticancer vaccines, genetically improved live vaccines, genetically improved sub unit vaccines, synthetic peptide based vaccines and sera.

Chapter 4: “ Omic” technologies and molecular tools **10hrs(20 marks)**

- Overview of proteomics, genomics, pharmacogenomics and biomarkers.
- Application of biotechnology in pharmacokinetics and pharmacodynamics, in vitro expression of metabolic enzymes and their applications, isolation and characterization of receptors.

Chapter 5: Plant and animal cell biotechnology including regulatory aspects **(20 marks)**

- Plant tissue culture techniques, plant transformation and biotechnological production of plant secondary metabolites. **3hrs**

- b. Basic techniques, equipments, materials and media for animal cell culture, products and applications of animal cell biotechnology. **3hrs**
- c. Intellectual property rights (IPR), patent, types of patent applications, patent types: Conventional, divisional and patent of addition, specifications: provisional and complete forms and filing procedures. **4hrs**

ADVANCED PHARMACEUTICAL BIOTECHNOLOGY

Practical

150hrs (6hrs/wk)

Total Hours: 150 (6 hr/week)	Examination Max Marks	Total Marks
	Annual	100
	Internal Assessment Exam:	30
	Practical record Evaluation:	20
	Total:	150

1. Immobilization of enzymes and whole cells by using various immobilization methods.
2. Isolation of DNA from microbial , plant and animal sources
3. Isolation of RNA from yeast and plant sources.
4. Estimation of DNA and RNA
5. Restriction digestion.
6. Ligation and transformation
7. Isolation of plasmid DNA.
8. SDS PAGE
9. Agarose gel electrophoresis.

10. Induction of callus and cell suspension cultures.
11. Induction of hairy root culture.
12. Fumigation of laboratory.
13. Preparation of animal cell culture media.
14. Maintenance of cell cultures, passaging, trypsinization and preservation of cell cultures.
15. Cytotoxicity studies on cell lines by MTT assay using ELISA
16. In vitro antioxidant studies of different compounds.
17. Any other prevalent practical exercise based on theoretical topics.

TEACHING AND LEARNING ACTIVITIES

Journal Club:

Each student is required to present any two recent articles relevant to the Advanced Pharmaceutical Biotechnology from any of the journals in a year.

Seminars:

Each student is required to give two seminars relevant to the subject in a year.

Field/ Industrial Visits:

It is desirable to make to one visit to the relevant Laboratory / Industry in a year.

Conference / Meetings:

Each student has to be encouraged to attend at least one relevant national conference.

Scheme of Practical Examination

S.No	Synopsis	Major experiment	Minor experiment	Viva voce	Total
01	20	35	25	20	100

TEXT BOOKS

1. Molecular cell biology 5th edition. Lodish et.al. W. H Freeman and company, Newyork.
2. The cell, a molecular approach. G. M. Cooper, ASM press.
3. Molecular biology. David Freifelder.
4. Cell and molecular biology concepts and experiments Gerald Karp, John Wiley and sons.
5. Biopharmaceuticals: Biochemistry and Biotechnology, 2nd edition Gary Walls, Wiley publications.
6. Mol Bio, Upadhyaya and Nath.
7. Pharmaceutical biotechnology, Daan Crommelin, Robert D Sindelar, Routledge.
8. Biopharmaceuticals Drug Design and Development. Eds. Wu Pong Sussanna, 2nd edition, 2008, Human press book.
9. Medicinal plant biotechnology by Ciddi Veeresham.

REFERENCE BOOKS

1. Molecular biology of the gene 5th edition, James.D Watson,Tania A Baker, Stephen P Bell, Alexander Gann, Michael Levine, Richard Losick, Oxford university press.
2. Principles of microbiology ang immunology, Davis et.al Herper and group.
3. Molecular biology of the cell, Watson J D et.al, garland publishing InC.
4. Apotosis: The molecular biology of programmed cell death, Michael F Jacobson,NicolaMcCarthy.
5. Principles and techniques of biochemistry and molecular biology, Willson, Keith, Walker, John.
6. Cell cycle and growth control: Biomolecular regulation and cancer, Gary S Stein Arthur B Parde.

Journals:

1. Indian journal of Biosciences.
2. Indian journal of Genetics.
3. Journal of medical microbiology
4. Journal of Infectious disease.
5. Journal of Immunology.

M. Pharm

Pharmaceutical Analysis

A. Goals:

The goals of postgraduate training course in pharmaceutical analysis would be train a B. Pharm pharmacist who will:

- A. Control the quality of basic drugs, formulations, packing materials and additives in pharmaceutical formulations efficiently and effectively, backed by scientist knowledge and skill base
- B. Be careful in maintaining the official standards of pharmaceuticals and follow the directions given by various bodies like WHO in maintaining the standards of pharmaceuticals.
- C. Continue to evince keen interest in continuing education in pharmaceutical analysis irrespective of whether he is in a teaching institution or pharmaceutical industry.
- D. Be a motivated “teacher”- keen to share his knowledge and skills with a colleague or a junior or any learner.

B. Objectives

The following objectives are laid out to achieve the goals of the course. These objectives are to be achieved by the time candidate completes the course. The objectives may be considered under the subheadings

- a. Knowledge
- b. Skills
- c. Attitudes and communication abilities

2.1. Knowledge

A list of objectives related to knowledge and higher cognitive abilities that are expected to be achieved during the course is given

- Knowledge of basic chemical principles, theories and laboratory techniques as would be acquires through the successful completion of M. Pharm course in pharmaceutical analysis.
- Knowledge of use of common and more advanced instruments such as balances, pH meter, melting apparatus, refractometer, colourimeter, polarimeter, moisture balance required to be used in compendia methods in conformance with SOP, HPLC, GC, HPTLC, IR, FTIR, NMR and Mass spectrophotometer.

- Application of required quality assurance procedures.
- Adherence to established laboratory safety procedures.
- Knowledge of GMP/GLP.
- Knowledge of analysis of samples of pharmaceuticals (bulk and finished products) using established and validated analytical procedures.
- Development of new methods or revision of existing methods and validation of the methods so developed.
- Participation in collaborative studies at inter or intra-laboratory level.
- Planning of work for most efficient use of the resources.
- Knowledge of statistical methods for data evaluation.
- Supervision of the proficiency testing of the analysis.

2.2. Skills

- Knowledge of basic chemical principles, theories and laboratory techniques.
- Use of common and most modern instruments.
- Adequate knowledge of GMP/GLP.
- Establishing laboratory safety procedures.
- Communication of laboratory results in written reports.
- Development of analytical procedures is an important function of the laboratory in which all analysis should be involved to some extent.

2.3. Attitudes and Communications

- Possesses aptitude and attitude of mind to become competent analyst.
- Enjoys his assignment with pride.
- Punctual and disciplined
- Has pleasant personality, in humane and modest.
- Well organized and methodological

- Has initiative, drive, creative urge and ability to interact.
- Flexible and appreciates others view point.
- Imbibes confidence in his colleagues.
- Able to work independently and as member of a team.
- Plans his work for efficient use of time and resources.
- Can complete his assignment in a given time frame.
- Pays full attention to details.
- Can identify the cause and solve the problem.
- Able to think and evaluate scientifically and critically.
- Good presentations and communication skills.

M. Pharm. I	TITLES OF PAPERS	Total Hours	Hours per week	
			Theory	Practical
PAPER-I	Modern Pharmaceutical Analysis	75	3	6
PAPER-II	Pharmaceutical & Cosmetic AnalysisChemistry	50	2	6
PAPER-III	Instrumental Method of Analysis	50	2	6
PAPER-IV	Chemical& Biological Evaluaition	50	2	6
M. Pharm. II	Dissertation Work	One Year		

Paper II: Pharmaceutical And Cosmetic Analysis

THEORY

Goals:

To keep abreast with the developments in pharmaceutical and cosmetical analysis, to apply and adopt both conventional and non-conventional methods to own special needs.

Objectives:

On completion of the course in Pharmaceutical and Cosmetical Analysis, the candidates must be able to-

- Exten and improvise systems for quality control.

- Understand the latest internationally recognized standards, innovations and developments in the field of pharmaceutical and cosmetical analysis.
- Develop newer analytical methods for pharmaceutical and cosmetics.

Course Content

THEORY: 50 hr (2hr/week)

1. Titrimetric analysis:
 - b) Classification of reactions in titrimetric analysis, standard solutions, preparation of standard solutions, primary and secondary standard substances. Theory of acids-base titration. Neutralisation indicators, mixed and universal indicators, neutralization curves and displacement titrations. **4 hours (10-14 Marks)**
 - c) Non-aqueous titrations involving the following :
 1. Primary, secondary and tertiary amines
 2. Halogenated salts of bases
 3. Acidic substances
 4. Assay of official drugs in IP by non- aqueous titrimetry. **2 hours (05-07 Marks)**
 - d) Aquametry: Determination of water by titration with Karl Fischer Reagent (KFR) and other methods. **2 hours (05-07 Marks)**
2. Principles and pharmaceutical application of redox titrations involving:
 - a) Potassium Iodate/bromate titrations
 - b) Ceric ammonium sulphate titrations
 - c) Examples of assay of official drugs in IP. **2 hours (05-07 Marks)**
3. Principles and pharmaceutical applications of complexometric titrations involving:
 - a) Direct titration of polymetallic system with sodium editate
 - b) Residual titrations with sodium editate
 - c) Titration involving the displacement of one complex by another.
 - d) pM indicators
 - e) Examples of assays of official drugs in IP. **3 hours (08-10 Marks)**
4.
 - a) Principles and procedures involved in gravimetric and argentimetric analysis with examples
 - b) Diazotization titrations with at least 4 examples and applications. **3 hours (08-10 Marks)**
5. Thermo analytical methods of analysis: Application in cosmetics. **2 hours (05-07 Marks)**

6. Quality control of crude drugs- ash values, fiber content, powder analysis quantitative microscopy and microchemical tests, extractive values, arsenic and heavy metal analysis in crude drugs
4 hours (10-14 Marks)

7. Principles and pharmaceutical applications of electroanalytical methods.

- a) Potentiometry
- b) pH measurements
- c) Polarography and its types
- d) Amperometry
- e) High frequency titrations
- f) Conductometric titrations
- g) Advanced electro analytical methods

8 hours (20-24 Marks)

8. Identification and quantitative determination of preservatives, antioxidants, colouring materials, emulsifiers and stabilizers in pharmaceutical formulations and cosmetics.

4 hours (10-14 Marks)

9. Pharmaceutical methods for evaluation of tablets, capsules, liquid dosage forms, parenteral preparations, ointments and creams, suppositories and controlled release products as per IP.

5 hours (13-15 Marks)

10. Official evaluation methods of primary and secondary packaging pharmaceuticals.

3 hours (08-10 Marks)

11. a) Quality control of any four cosmetic products under each of the following categories - hair care products, skin care products, colour cosmetics, baby care products, colour makeup preparations, lipsticks, and eye shadows.

6 hours (16-20 Marks)

b) Safety and legislation for cosmetic products.

2 hours (05-07 Marks)

Practicals:

150 hr (6hr/week)

The following experiments or similar to be carried out and relevant documentation made.

- 1. Assay of Ibuprofen tablets, IP 1996
- 2. Assay of bisacodyl suppositories IP 1996
- 3. Assay of sodium diatrizoate injection IP 1996
- 4. Assay of ferrous sulphate tablets, IP 1996
- 5. Determination of moisture content in following drugs using Karl Fischer Reagent
 - a) Ampicillin Trihydrate

- b) Fructose
 - c) Gentamycin sulphate
 - d) Calcium lactate or gluconate/emitin dihydrochloride
6. Assay of cephalixin capsules, IP 1996
 7. Assay of calcium gluconate injection, IP 1996
 8. Assay of sodium aurothiomalate injection, IP 1996
 9. Quality control tests for tablets
 10. Quality control tests for capsules
 11. Quality control tests for paranteral preparations
 12. Quality control tests for ointments and creams
 13. Quality control tests for pessaries, suppositories and controlled release products.
 14. Detection and quantitative determination of preservatives
 15. Detection and quantitative determination of antioxidants
 16. Detection and quantitative determination of colouring materials.
 17. Quality control tests for some cosmetic preparations
 18. Quality control tests for pharmaceutical containers
 19. Evaluation of packing material by ATR data
 20. Determination of extractive values of crude drugs
 21. Quality control of secondary packaging materials.

Text Books

Practical Pharmaceutical Chemistry, by A. H. Beckett and J. B. Stenlake. 3rd Ed., Part I & II, 1997, CBS Publishers and Distributors, New Delhi.

G.H. Jeffery, J. Bassett, J. Mendham Vogel's Textbook of Quantitative Chemical Analysis
5th Edition and 6th Edition, 1989, ELBS

The Controller of Publications; New Delhi, Govt. of India, Indian Pharmacopoeia Vol I & II 1996

The Theory and Practice of *Industrial Pharmacy* by Leon Lachman

W.A. Poucher: Poucher's Perfumes, Cosmetics and Soaps: Vol 3, 9th Edition, Chapman and Hill, Landon.

R. J. Moore, J. B. Wilkinson: Harry's Cosmeticology 7th Edition: Lonagman Scientific & Technical Publishers, Singapore.

Reference Books

Text Books

P.D. Sethi; Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd Edition – 1997

Chatwal and Anand .Instrumental Methods of Chemical analysis 7th edition 1992 Publisher: Himalaya Publishing House. New Delhi

Alfonso R. Gennaro: Remington: the science and practice of pharmacy, Volume 1. By Joseph Price Remington, Lippincott Williams & Wilkins profile of Wolters Kluwer company Philaladelphia

Gilbert S. Banker, Christopher T. Rhodes Modern pharmaceutics 2nd Edition, Marcel Dekker Inc, New York

E G Thomson Modern Pharmaceutics 1985 Publisher: Universal Publishing Corporation, U.K

INSTRUMENTAL METHODS OF ANALYSIS

Theory:

Goals:

To keep abreast with instrumental analytical techniques.

Objectives:

At the end of the course, the candidate must be able to-

- Exten and improvise instrumental systems for quality control.

- Become skilled in application of instrumental methods in the development and use of medicines.
- Invent new analytical methods for quality control of pharmaceuticals.

Course Content

THEORY: 50 hr (2hr/week)

- a) Analysis of drugs and excipients in the solid state: Introduction, importance of particle size in various dosage forms, methods of particle size analysis, x-ray powder diffraction. Application of SEM & TEM in particle size analysis. **4 hours (10-14 Marks)**

22. Light scattering methods in quantitative analysis a) Turbidimetry b) Nephelometry
2 hours (05-07 Marks)

- b) Light emission methods in quantitative analysis: a) Fluorimetry b) Flame photometry c) Raman spectroscopy. Theory & Applications of Inductively Coupled Plasma – Optical Emission Spectrometers (ICP – OES) and Mass spectrometers (ICP – MS)
Atomic Absorption Spectrometry: Introduction, theory, instrumentation and applications.
6 hours (16-20 Marks)

- c) A detailed study of principles and procedures involved in various physico-chemical methods of analysis including instrumental methods of analysis of pharmaceutical dosage of any five official drugs from the following classes of drugs:
- Sulphonamides
 - Barbiturates
 - Adrenergic drugs
 - Anti-tubercular drugs
 - Diuretics
 - Anti-malarials
 - Local anaesthetics
 - General anaesthetics
 - Analgesics and anti-pyretics
 - Anthelmintics
 - Fluroquinolones
- 12 hours (32-38 Marks)**

- d) Principles and procedures involved in the analysis of pharmaceutical drugs and dosage forms containing the following groups of substances official in Pharmacopoea:
- Alkaloids
 - Glycosides
 - Vitamins
 - Antibiotics
 - Steroid hormones
- 6 hours (16-20 Marks)**

- e) Principles and procedures involved in the quantitative determination of the following groups:
- Hydroxyl
 - Carboxylic acid

- c. Carbonyl groups
- d. Methoxyl
- e. Ester
- f. Amine
- g. Nitrates

6 hours (16-20 Marks)

- f) Principles and procedures involved in the use of the following reagents in pharmaceutical analysis:
- a) MBTH (3-methyl-2-benzothiazolone hydrazone) reagent
 - b) FC (Folin ciocalteu) reagent
 - c) 1,2-naptha quinone-4-sulfonate reagent
 - d) 2,3,5-triphenyltetrazolium salt
 - e) PDAB (Paradimethyl amino benzaldehyde)
 - f) PDAC (Paradimethyl amino cinamaldehyde)
 - g) Ninhydrine reagent
 - h) Carr-price reagent
 - i) Bratton-marshall reagent
 - j) 2,6-dichloroquinone chlorimide

5 hours (13-16 Marks)

- g) Study of General Notices of IP 2007

3 hours (08-10 Marks)

23. Analytical method validation as per ICH guidelines

2 hours (05-07 Marks)

- h) Application of instrumental methods in product characterization for drug development, product development, production and pharmacopoeial controls, concept of analytical method development.

2 hours (05-07 Marks)

- i) Analysis of radiopharmaceuticals

2 hours (05-07 Marks)

Practicals:

150 hrs (6hrs/week)

1. Determination of chloride and sulphate in calcium gluconate by Nepheloturbidimetric analysis.
2. Estimation of any two drugs by fluorimetry a) doxazosin mesylate b) riboflavin c) thiamine d) terazocin
3. Study of quenching effect in fluorimetry-eg. Quenching of quinine fluorescence by iodide ions.
4. Determination of sodium/potassium by flame photometry.
5. Colourimetric estimation of sulphadiazine/ sulphacetamide using N-(1-naphthyl) ethylene diamine di hydrochloride.
6. Quantitative analysis of drugs in multicomponent dosage forms

- a) Diclofenac, Paracetamol & Chlorzoxazone
 - b) Mefenamic acid Paracetamol
 - c) Paracetamol & Diclofenac
 - d) Sulphamethoxazole & Trimethoprim
 - e) Nimesulide & Paracetamol
7. Quantitative determination of functional groups A) Hydroxyl B) Amine C) Aldehydes D) Esters E) Carbonyl and F) Methoxyl
 9. Quantitative colorimetric determination of any drug by using para dimethylamino cinnamaldehyde reagent.
 10. Quantitative colorimetric determination of any drug by MBTH reagent.
 11. Colorimetric estimation of ferrous ions using 1, 10-phenanthroline
 12. Assay of Adrenaline by metal-ligand complexation colourimetry.
 13. Assay of Paracetamol tablets IP.
 14. Assay of drugs by HPLC (5 Experiments)
 19. Assay of Alprazolam tablets IP.
 20. Assay of Atropine sulphate tablets IP.
 21. Assay of Benzhexol Hydrochloride tablets.
 22. Identification and verification of standards for a sample of castor oil IP.
 23. Identification and verification of standards for a sample of cetyl alcohol IP.
 24. Identification of drugs using IR spectra

Text books:

1. A.I Vogel: Text Book Of Inorganic Chemistry 4th edition, ELBS Publications, London
2. Beckett and Stenlake: Practical Pharmaceutical Chemistry, 3rd Edn. Vol. II and CBS Publishers, New Delhi.
3. K. A. Connors: A Textbook of Pharmaceutical Analysis, 3rd Edn. Wiley-Interscience Publication, New York.
4. Sydney, Siggia; Quantitative Organic Analysis, 4th edition, Wiley Interscience Publications, John Wiley and Sons New York, Toronto.

Reference books:

1. P.D Sethi: Quantitative Analysis of Drugs in Pharmaceutical Formulations, 2nd Edition, CBS Publisher
2. S. C Gupta, V.K Kapoor: Fundamentals of Applied Statistics
3. John H. Kennedy: Principles of Analytical Chemistry, 2nd Edition, Saunders College Publishing, New York.
4. Jorg Augstin, Barbara: Methods of Vitamin Assay, 4th Edition, Wiley Interscience Publications, John Wiley & Sons, New York.
5. David. G. Watson: Pharmaceutical Analysis, Churchill Livingstone, Edinburgh.
6. Indian Pharmacopoeia 1996.
7. Controller of Publications, Govt of India: Indian Pharmacopoeia, vol. I & II, III 2007.

8. Higuchi, Bechmman And Hassan: Pharmaceutical Analysis, 2nd Edition .John Wiley And Sons, New York.
9. British Pharmacopeia 2005.
10. United States Pharmacopeia.

Journals:

Indian Journal of Chemical Society.

Indian Drugs

CHEMICAL AND BIOLOGICAL EVALUATION

THEORY

GOALS

Achieve global standards in manufacture of drugs & pharmaceuticals and skills in biological evaluation.

Objectives

At the end of course in chemical and biological evaluation, the candidate must be able to –

- ❖ Answer various managerial problems and provide strategies needed to attain and hold quality leadership in an environment of continuous improvement.
- ❖ Identify and execute acquisition of control characteristics, process, inspection equipments, fixtures, total production resources and skills which may be needed to achieve required quality.
- ❖ Comprehend and document-design, production process, inspection and test procedures.
- ❖ Identify and prepare quality records.
- ❖ Evaluate biological preparations.

Course Content

THEORY: 50 hr (2hr/week)

1. Quality control, its procedure, responsibilities, good laboratory practices, Training, qualification of analytical instruments, Sampling techniques, specification, SOPs, Documentation review and batch release, Vendor and warehouse audit, Working references and Pharmacopoeial standards, Retention of active pharmaceutical ingredients and finished formulations and quality review, Schedule M of drug rules and WHO certification for export of pharmaceuticals, Salvaging of returned goods and reprocessing. **10 hours (26-32 Marks)**
2. Application of computers in quality control laboratory, Introduction to validation of computer systems and concepts of limbs. **2 hours (05-07 Marks)**
3. a) Validation: Cleaning validation, Personnel validation.
b) Calibration of following instruments 1) Analytical balance 2) UV-Visible spectrophotometer
3) FT-IR and 4) HPLC
c) Technology Transfer and method verification. **7 hours (18-22 Marks)**
4. Development of drug information profiles. **2 hours (05-07 Marks)**
5. Enzyme immune assay. Concepts and methodology. **3 hours (08-10 Marks)**
6. Microbiological validation, BET (Bacterial enumeration test) and sterility testing - methodology and interpretation **4 hours (10-14 Marks)**
7. Tests for effectiveness of antimicrobial preservatives. **2 hours (05-07 Marks)**
8. Detailed study of principles and procedures involved in the biological assays of the following:
a) Oxytocin
b) Streptokinase
c) Tetanus antitoxin
d) Tuberculin purified protein derivative **5 hours (13-16 Marks)**
9. Pyrogens- sources, chemistry and properties of bacterial pyrogens and endotoxins. Pyrogens testing: Official methods. Interpretation of data. **3 hours (08-10 Marks)**
10. Microbial assays of antibiotics zone of inhibition and vitamins zone of exhibition **3 hours (08-10 Marks)**

11. Chemical and bacteriological analysis of potable water, purified water and water for injection.
2 hours (05-07 Marks)
12. Stability studies and impurity profiling as per ICH Guidelines Q2, Q3 A, Q3B, and Q3C **3 hours (08-10 Marks)**
13. Biological sample preparation (protein precipitation, Liquid-Liquid extraction (LLE), Solid phase extraction (SPE), Solid phase micro extraction (SPME)) and Biological method validation as per ICH Guidelines.
4 hours (10-14 Marks)

Practical:

150 hrs (6hrs/week)

1. General requirement and URS for manufacturing area as per GMP.
2. General requirement and URS for QC Lab as per GMP.
3. Qualification of analytical instruments- UV,IR,HPLC
4. Qualification of pharmaceutical manufacturing machinery
5. a) Design of analytical method validation protocol
b) Execution of method validation using UV - Visible spectrophotometer.
6. Design of In-process testing parameters for different dosage form.
7. Calibration of volumetric glassware
8. Development of summary report for analytical method development.
9. Documentation for specification finalization
10. Quality control records
11. Standard operating procedures- for analytical instrumentation-UV-Visible Spectrophotometer
12. Standard operating procedures- for operating Dissolution test apparatus
13. Standard operating procedures- cleaning process of Tablet coating pan
14. Standard operating procedures- for Disintegration apparatus
15. Assay of amikacin sulphate injection, IP 1996
16. Assay of bacitracin zinc, IP 1996
17. Evaluation of preservatives in parenteral preparations
18. Development of analytical profiles for any two drugs
19. Estimation of paracetamol in Biological fluids
20. Test for pyrogens and abnormal toxicity

References:

Text Books

1. Kaushik Maitra and Sadhan K.Ghosh: A guide to total quality management, Oxford Publishing House, Calcutta.
2. M.L.Mehra: GMP, I Edition, University book agency, Allahabad.
3. P.P.Sharma: How to practice GMPs, Vandana Publications, Agra.
4. Sadhan K.Ghosh: Introduction to ISO 9000 and Total quality management, Oxford Publishing House, Calcutta.
5. Dr.A.Patani: The drug and cosmetics act 1940, Eastern book company, Lucknow.
6. Vijay Malik: The drug and cosmetics act 1940, Eastern book company, Lucknow.
7. D.H.Shah: SOP guidelines, 1st Edition, Business horizons, New Delhi.
8. R.S.Iyer: Schedule M and beyond good manufacturing practices, Indian Drug Manufacturers Association, Mumbai.

9. D.H.Shah: QA Manual, 1st Edition, 2000, Business horizons, New Delhi.
10. Controller of Publications, Govt of India: Indian Pharmacopoeia, vol.I & II, 1996.
11. Burn, Fininey and Godwin: Biological standardization, 2nd Edition, Oxford University Press, London.
12. British Pharmacopeia 2012

Reference Books:

1. Guidelines for developing national drug policies by WHO publications(1998)
2. Regulation of Pharmaceuticals in developing countries legal issues and approaches by D.C.Jeering WHO publications(1985)
3. The international pharmacopoeia Vol. 1, 2, 3 ,4; 3rd Edition, General methods of analysis and quality specifications for pharmaceutical substances, excipients, dosage forms.
4. Quality assurance of pharmaceuticals- A compendium of guidelines and related materials Vol.-1 (WHO publications)
5. Basic tests for pharmaceutical substances- WHO (1988)
6. Basic tests for pharmaceutical Dosage forms- WHO (1991)
7. WHO expert committee on 'Specifications for pharmaceutical preparations' 13th, 22nd, 23rd, 24th and 34th reports.
8. WHO expert committee on 'Biological standardizations' -37,38,39,40,41,42,43,44 and 45th report
9. Wilmer A, Jenkins & Kenton R Osborn: Packaging of drugs and Pharmaceuticals Technomic Publishing Company Inc.,Pennsylvania.
10. H.Lookhart and F.A. Paine: Packaging of Pharmaceuticals and Health care products.
11. M.Purkany: Quality assurance and TQM for analytical laboratories, the royal society of chemistry, Cambridge, London.
12. Donald C. Singer and Ronald P.Upton: Guide lines for laboratory quality auditing (Quality and Reliability Series No.39),1st Edition (1993), Marcel Dekker, New York.
13. Broton.J.Wright: Microbiological assays.

Journals

1. Indian Journals of Pharmaceutical Education.
2. Bulletin- Association Pharmaceutical Analysis
3. Pharma Times.

M. Pharm

Pharmaceutical Analysis

A. Goals:

The goals of postgraduate training course in pharmaceutical analysis would be train a B. Pharm pharmacist who will:

- A. Control the quality of basic drugs, formulations, packing materials and additives in pharmaceutical formulations efficiently and effectively, backed by scientist knowledge and skill base
- B. Be careful in maintaining the official standards of pharmaceuticals and follow the directions given by various bodies like WHO in maintaining the standards of pharmaceuticals.
- C. Continue to evince keen interest in continuing education in pharmaceutical analysis irrespective of whether he is in a teaching institution or pharmaceutical industry.
- D. Be a motivated “teacher”- keen to share his knowledge and skills with a colleague or a junior or any learner.

B. Objectives

The following objectives are laid out to achieve the goals of the course. These objectives are to be achieved by the time candidate completes the course. The objectives may be considered under the subheadings

- a. Knowledge
- b. Skills
- c. Attitudes and communication abilities

2.1. Knowledge

A list of objectives related to knowledge and higher cognitive abilities that are expected to be achieved during the course is given

- Knowledge of basic chemical principles, theories and laboratory techniques as would be acquires through the successful completion of M. Pharm course in pharmaceutical analysis.
- Knowledge of use of common and more advanced instruments such as balances, pH meter, melting apparatus, refractometer, colourimeter, polarimeter, moisture balance required to be used in compendia methods in conformance with SOP, HPLC, GC, HPTLC, IR, FTIR, NMR and Mass spectrophotometer.

- Application of required quality assurance procedures.
- Adherence to established laboratory safety procedures.
- Knowledge of GMP/GLP.
- Knowledge of analysis of samples of pharmaceuticals (bulk and finished products) using established and validated analytical procedures.
- Development of new methods or revision of existing methods and validation of the methods so developed.
- Participation in collaborative studies at inter or intra-laboratory level.
- Planning of work for most efficient use of the resources.
- Knowledge of statistical methods for data evaluation.
- Supervision of the proficiency testing of the analysis.

2.2. Skills

- Knowledge of basic chemical principles, theories and laboratory techniques.
- Use of common and most modern instruments.
- Adequate knowledge of GMP/GLP.
- Establishing laboratory safety procedures.
- Communication of laboratory results in written reports.
- Development of analytical procedures is an important function of the laboratory in which all analysis should be involved to some extent.

2.3. Attitudes and Communications

- Possesses aptitude and attitude of mind to become competent analyst.
- Enjoys his assignment with pride.
- Punctual and disciplined
- Has pleasant personality, in humane and modest.
- Well organized and methodological

- Has initiative, drive, creative urge and ability to interact.
- Flexible and appreciates others view point.
- Imbibes confidence in his colleagues.
- Able to work independently and as member of a team.
- Plans his work for efficient use of time and resources.
- Can complete his assignment in a given time frame.
- Pays full attention to details.
- Can identify the cause and solve the problem.
- Able to think and evaluate scientifically and critically.
- Good presentations and communication skills.

M. Pharm. I	TITLES OF PAPERS	Total Hours	Hours per week	
			Theory	Practical
PAPER-I	Modern Pharmaceutical Analysis	75	3	6
PAPER-II	Pharmaceutical & Cosmetic AnalysisChemistry	50	2	6
PAPER-III	Instrumental Method of Analysis	50	2	6
PAPER-IV	Chemical& Biological Evaluaition	50	2	6
M. Pharm. II	Dissertation Work	One Year		

Paper II: Pharmaceutical And Cosmetic Analysis

THEORY

Goals:

To keep abreast with the developments in pharmaceutical and cosmetical analysis, to apply and adopt both conventional and non-conventional methods to own special needs.

Objectives:

On completion of the course in Pharmaceutical and Cosmetical Analysis, the candidates must be able to-

- Exten and improvise systems for quality control.

- Understand the latest internationally recognized standards, innovations and developments in the field of pharmaceutical and cosmetical analysis.
- Develop newer analytical methods for pharmaceutical and cosmetics.

Course Content

THEORY: 50 hr (2hr/week)

1. Titrimetric analysis:
 - b) Classification of reactions in titrimetric analysis, standard solutions, preparation of standard solutions, primary and secondary standard substances. Theory of acids-base titration. Neutralisation indicators, mixed and universal indicators, neutralization curves and displacement titrations. **4 hours (10-14 Marks)**
 - c) Non-aqueous titrations involving the following :
 1. Primary, secondary and tertiary amines
 2. Halogenated salts of bases
 3. Acidic substances
 4. Assay of official drugs in IP by non- aqueous titrimetry. **2 hours (05-07 Marks)**
 - d) Aquametry: Determination of water by titration with Karl Fischer Reagent (KFR) and other methods. **2 hours (05-07 Marks)**
2. Principles and pharmaceutical application of redox titrations involving:
 - a) Potassium Iodate/bromate titrations
 - b) Ceric ammonium sulphate titrations
 - c) Examples of assay of official drugs in IP. **2 hours (05-07 Marks)**
3. Principles and pharmaceutical applications of complexometric titrations involving:
 - a) Direct titration of polymetalic system with sodium editate
 - b) Residual titrations with sodium editate
 - c) Titration involving the displacement of one complex by another.
 - d) pM indicators
 - e) Examples of assays of official drugs in IP. **3 hours (08-10 Marks)**
4.
 - a) Principles and procedures involved in gravimetric and argentimetric analysis with examples
 - b) Diazotization titrations with at least 4 examples and applications. **3 hours (08-10 Marks)**
5. Thermo analytical methods of analysis: Application in cosmetics. **2 hours (05-07 Marks)**

6. Quality control of crude drugs- ash values, fiber content, powder analysis quantitative microscopy and microchemical tests, extractive values, arsenic and heavy metal analysis in crude drugs
4 hours (10-14 Marks)
7. Principles and pharmaceutical applications of electroanalytical methods.
a) Potentiometry
b) pH measurements
c) Polarography and its types
d) Amperometry
e) High frequency titrations
f) Conductometric titrations
g) Advanced electro analytical methods
8 hours (20-24 Marks)
8. Identification and quantitative determination of preservatives, antioxidants, colouring materials, emulsifiers and stabilizers in pharmaceutical formulations and cosmetics.
4 hours (10-14 Marks)
9. Pharmaceutical methods for evaluation of tablets, capsules, liquid dosage forms, parenteral preparations, ointments and creams, suppositories and controlled release products as per IP.
5 hours (13-15 Marks)
10. Official evaluation methods of primary and secondary packaging pharmaceuticals.
3 hours (08-10 Marks)
11. a) Quality control of any four cosmetic products under each of the following categories - hair care products, skin care products, colour cosmetics, baby care products, colour makeup preparations, lipsticks, and eye shadows.
6 hours (16-20 Marks)
- b) Safety and legislation for cosmetic products.
2 hours (05-07 Marks)

Practicals:

150 hr (6hr/week)

The following experiments or similar to be carried out and relevant documentation made.

1. Assay of Ibuprofen tablets, IP 1996
2. Assay of bisacodyl suppositories IP 1996
3. Assay of sodium diatrizoate injection IP 1996
4. Assay of ferrous sulphate tablets, IP 1996
5. Determination of moisture content in following drugs using Karl Fischer Reagent
 - a) Ampicillin Trihydrate

- b) Fructose
 - c) Gentamycin sulphate
 - d) Calcium lactate or gluconate/emitin dihydrochloride
6. Assay of cephalixin capsules, IP 1996
 7. Assay of calcium gluconate injection, IP 1996
 8. Assay of sodium aurothiomalate injection, IP 1996
 9. Quality control tests for tablets
 10. Quality control tests for capsules
 11. Quality control tests for paranteral preparations
 12. Quality control tests for ointments and creams
 13. Quality control tests for pessaries, suppositories and controlled release products.
 14. Detection and quantitative determination of preservatives
 15. Detection and quantitative determination of antioxidants
 16. Detection and quantitative determination of colouring materials.
 17. Quality control tests for some cosmetic preparations
 18. Quality control tests for pharmaceutical containers
 19. Evaluation of packing material by ATR data
 20. Determination of extractive values of crude drugs
 21. Quality control of secondary packaging materials.

Text Books

Practical Pharmaceutical Chemistry, by A. H. Beckett and J. B. Stenlake. 3rd Ed., Part I & II, 1997, CBS Publishers and Distributors, New Delhi.

G.H. Jeffery, J. Bassett, J. Mendham Vogel's Textbook of Quantitative Chemical Analysis
5th Edition and 6th Edition, 1989, ELBS

The Controller of Publications; New Delhi, Govt. of India, Indian Pharmacopoeia Vol I & II 1996

The Theory and Practice of *Industrial Pharmacy* by Leon Lachman

W.A. Poucher: Poucher's Perfumes, Cosmetics and Soaps: Vol 3, 9th Edition, Chapman and Hill, London.

R. J. Moore, J. B. Wilkinson: Harry's Cosmeticology 7th Edition: Lonagman Scientific & Technical Publishers, Singapore.

Reference Books

Text Books

P.D. Sethi; Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd Edition – 1997

Chatwal and Anand .Instrumental Methods of Chemical analysis 7th edition 1992 Publisher: Himalaya Publishing House. New Delhi

Alfonso R. Gennaro: Remington: the science and practice of pharmacy, Volume 1. By Joseph Price Remington, Lippincott Williams & Wilkins profile of Wolters Kluwer company Philaladelphia

Gilbert S. Banker, Christopher T. Rhodes Modern pharmaceutics 2nd Edition, Marcel Dekker Inc, New York

E G Thomson Modern Pharmaceutics 1985 Publisher: Universal Publishing Corporation, U.K

INSTRUMENTAL METHODS OF ANALYSIS

Theory:

Goals:

To keep abreast with instrumental analytical techniques.

Objectives:

At the end of the course, the candidate must be able to-

- Exten and improvise instrumental systems for quality control.

- Become skilled in application of instrumental methods in the development and use of medicines.
- Invent new analytical methods for quality control of pharmaceuticals.

Course Content

THEORY: 50 hr (2hr/week)

- a) Analysis of drugs and excipients in the solid state: Introduction, importance of particle size in various dosage forms, methods of particle size analysis, x-ray powder diffraction. Application of SEM & TEM in particle size analysis. **4 hours (10-14 Marks)**

22. Light scattering methods in quantitative analysis a) Turbidimetry b) Nephelometry
2 hours (05-07 Marks)

- b) Light emission methods in quantitative analysis: a) Fluorimetry b) Flame photometry c) Raman spectroscopy. Theory & Applications of Inductively Coupled Plasma – Optical Emission Spectrometers (ICP – OES) and Mass spectrometers (ICP – MS)
Atomic Absorption Spectrometry: Introduction, theory, instrumentation and applications.
6 hours (16-20 Marks)

- c) A detailed study of principles and procedures involved in various physico-chemical methods of analysis including instrumental methods of analysis of pharmaceutical dosage of any five official drugs from the following classes of drugs:
- Sulphonamides
 - Barbiturates
 - Adrenergic drugs
 - Anti-tubercular drugs
 - Diuretics
 - Anti-malarials
 - Local anaesthetics
 - General anaesthetics
 - Analgesics and anti-pyretics
 - Anthelmintics
 - Fluroquinolones
- 12 hours (32-38 Marks)**

- d) Principles and procedures involved in the analysis of pharmaceutical drugs and dosage forms containing the following groups of substances official in Pharmacopoea:
- Alkaloids
 - Glycosides
 - Vitamins
 - Antibiotics
 - Steroid hormones
- 6 hours (16-20 Marks)**

- e) Principles and procedures involved in the quantitative determination of the following groups:
- Hydroxyl
 - Carboxylic acid

- c. Carbonyl groups
- d. Methoxyl
- e. Ester
- f. Amine
- g. Nitrates

6 hours (16-20 Marks)

- f) Principles and procedures involved in the use of the following reagents in pharmaceutical analysis:
- a) MBTH (3-methyl-2-benzothiazolone hydrazone) reagent
 - b) FC (Folin ciocalteu) reagent
 - c) 1,2-naptha quinone-4-sulfonate reagent
 - d) 2,3,5-triphenyltetrazolium salt
 - e) PDAB (Paradimethyl amino benzaldehyde)
 - f) PDAC (Paradimethyl amino cinamaldehyde)
 - g) Ninhydrine reagent
 - h) Carr-price reagent
 - i) Bratton-marshall reagent
 - j) 2,6-dichloroquinone chlorimide

5 hours (13-16 Marks)

- g) Study of General Notices of IP 2007

3 hours (08-10 Marks)

23. Analytical method validation as per ICH guidelines

2 hours (05-07 Marks)

- h) Application of instrumental methods in product characterization for drug development, product development, production and pharmacopoeial controls, concept of analytical method development.

2 hours (05-07 Marks)

- i) Analysis of radiopharmaceuticals

2 hours (05-07 Marks)

Practicals:

150 hrs (6hrs/week)

1. Determination of chloride and sulphate in calcium gluconate by Nepheloturbidimetric analysis.
2. Estimation of any two drugs by fluorimetry a) doxazosin mesylate b) riboflavin c) thiamine d) terazosin
3. Study of quenching effect in fluorimetry-eg. Quenching of quinine fluorescence by iodide ions.
4. Determination of sodium/potassium by flame photometry.
5. Colourimetric estimation of sulphadiazine/ sulphacetamide using N-(1-naphthyl) ethylene diamine dihydrochloride.
6. Quantitative analysis of drugs in multicomponent dosage forms

- a) Diclofenac, Paracetamol & Chlorzoxazone
 - b) Mefenamic acid Paracetamol
 - c) Paracetamol & Diclofenac
 - d) Sulphamethoxazole & Trimethoprim
 - e) Nimesulide & Paracetamol
7. Quantitative determination of functional groups A) Hydroxyl B) Amine C) Aldehydes D) Esters E) Carbonyl and F) Methoxyl
 9. Quantitative colorimetric determination of any drug by using para dimethylamino cinnamaldehyde reagent.
 10. Quantitative colorimetric determination of any drug by MBTH reagent.
 11. Colorimetric estimation of ferrous ions using 1, 10-phenanthroline
 12. Assay of Adrenaline by metal-ligand complexation colourimetry.
 13. Assay of Paracetamol tablets IP.
 14. Assay of drugs by HPLC (5 Experiments)
 19. Assay of Alprazolam tablets IP.
 20. Assay of Atropine sulphate tablets IP.
 21. Assay of Benzhexol Hydrochloride tablets.
 22. Identification and verification of standards for a sample of castor oil IP.
 23. Identification and verification of standards for a sample of cetyl alcohol IP.
 24. Identification of drugs using IR spectra

Text books:

1. A.I Vogel: Text Book Of Inorganic Chemistry 4th edition, ELBS Publications, London
2. Beckett and Stenlake: Practical Pharmaceutical Chemistry, 3rd Edn. Vol. II and CBS Publishers, New Delhi.
3. K. A. Connors: A Textbook of Pharmaceutical Analysis, 3rd Edn. Wiley-Interscience Publication, New York.
4. Sydney, Siggia; Quantitative Organic Analysis, 4th edition, Wiley Interscience Publications, John Wiley and Sons New York, Toronto.

Reference books:

1. P.D Sethi: Quantitative Analysis of Drugs in Pharmaceutical Formulations, 2nd Edition, CBS Publisher
2. S. C Gupta, V.K Kapoor: Fundamentals of Applied Statistics
3. John H. Kennedy: Principles of Analytical Chemistry, 2nd Edition, Saunders College Publishing, New York.
4. Jorg Augstin, Barbara: Methods of Vitamin Assay, 4th Edition, Wiley Interscience Publications, John Wiley & Sons, New York.
5. David. G. Watson: Pharmaceutical Analysis, Churchill Livingstone, Edinburgh.
6. Indian Pharmacopoeia 1996.
7. Controller of Publications, Govt of India: Indian Pharmacopoeia, vol. I & II, III 2007.

8. Higuchi, Bechmman And Hassan: Pharmaceutical Analysis, 2nd Edition .John Wiley And Sons, New York.
9. British Pharmacopeia 2005.
10. United States Pharmacopeia.

Journals:

Indian Journal of Chemical Society.

Indian Drugs

CHEMICAL AND BIOLOGICAL EVALUATION

THEORY

GOALS

Achieve global standards in manufacture of drugs & pharmaceuticals and skills in biological evaluation.

Objectives

At the end of course in chemical and biological evaluation, the candidate must be able to –

- ❖ Answer various managerial problems and provide strategies needed to attain and hold quality leadership in an environment of continuous improvement.
- ❖ Identify and execute acquisition of control characteristics, process, inspection equipments, fixtures, total production resources and skills which may be needed to achieve required quality.
- ❖ Comprehend and document-design, production process, inspection and test procedures.
- ❖ Identify and prepare quality records.
- ❖ Evaluate biological preparations.

Course Content

THEORY: 50 hr (2hr/week)

1. Quality control, its procedure, responsibilities, good laboratory practices, Training, qualification of analytical instruments, Sampling techniques, specification, SOPs, Documentation review and batch release, Vendor and warehouse audit, Working references and Pharmacopoeial standards, Retention of active pharmaceutical ingredients and finished formulations and quality review, Schedule M of drug rules and WHO certification for export of pharmaceuticals, Salvaging of returned goods and reprocessing. **10 hours (26-32 Marks)**
2. Application of computers in quality control laboratory, Introduction to validation of computer systems and concepts of limbs. **2 hours (05-07 Marks)**
3. a) Validation: Cleaning validation, Personnel validation.
b) Calibration of following instruments 1) Analytical balance 2) UV-Visible spectrophotometer
3) FT-IR and 4) HPLC
c) Technology Transfer and method verification. **7 hours (18-22 Marks)**
4. Development of drug information profiles. **2 hours (05-07 Marks)**
5. Enzyme immune assay. Concepts and methodology. **3 hours (08-10 Marks)**
6. Microbiological validation, BET (Bacterial enumeration test) and sterility testing - methodology and interpretation **4 hours (10-14 Marks)**
7. Tests for effectiveness of antimicrobial preservatives. **2 hours (05-07 Marks)**
8. Detailed study of principles and procedures involved in the biological assays of the following:
a) Oxytocin
b) Streptokinase
c) Tetanus antitoxin
d) Tuberculin purified protein derivative **5 hours (13-16 Marks)**
9. Pyrogens- sources, chemistry and properties of bacterial pyrogens and endotoxins. Pyrogens testing: Official methods. Interpretation of data. **3 hours (08-10 Marks)**
10. Microbial assays of antibiotics zone of inhibition and vitamins zone of exhibition **3 hours (08-10 Marks)**

11. Chemical and bacteriological analysis of potable water, purified water and water for injection.
2 hours (05-07 Marks)
12. Stability studies and impurity profiling as per ICH Guidelines Q2, Q3 A, Q3B, and Q3C **3 hours (08-10 Marks)**
13. Biological sample preparation (protein precipitation, Liquid-Liquid extraction (LLE), Solid phase extraction (SPE), Solid phase micro extraction (SPME)) and Biological method validation as per ICH Guidelines.
4 hours (10-14 Marks)

Practical:

150 hrs (6hrs/week)

1. General requirement and URS for manufacturing area as per GMP.
2. General requirement and URS for QC Lab as per GMP.
3. Qualification of analytical instruments- UV,IR,HPLC
4. Qualification of pharmaceutical manufacturing machinery
5. a) Design of analytical method validation protocol
b) Execution of method validation using UV - Visible spectrophotometer.
6. Design of In-process testing parameters for different dosage form.
7. Calibration of volumetric glassware
8. Development of summary report for analytical method development.
9. Documentation for specification finalization
10. Quality control records
11. Standard operating procedures- for analytical instrumentation-UV-Visible Spectrophotometer
12. Standard operating procedures- for operating Dissolution test apparatus
13. Standard operating procedures- cleaning process of Tablet coating pan
14. Standard operating procedures- for Disintegration apparatus
15. Assay of amikacin sulphate injection, IP 1996
16. Assay of bacitracin zinc, IP 1996
17. Evaluation of preservatives in parenteral preparations
18. Development of analytical profiles for any two drugs
19. Estimation of paracetamol in Biological fluids
20. Test for pyrogens and abnormal toxicity

References:

Text Books

1. Kaushik Maitra and Sadhan K.Ghosh: A guide to total quality management, Oxford Publishing House, Calcutta.
2. M.L.Mehra: GMP, I Edition, University book agency, Allahabad.
3. P.P.Sharma: How to practice GMPs, Vandana Publications, Agra.
4. Sadhan K.Ghosh: Introduction to ISO 9000 and Total quality management, Oxford Publishing House, Calcutta.
5. Dr.A.Patani: The drug and cosmetics act 1940, Eastern book company, Lucknow.
6. Vijay Malik: The drug and cosmetics act 1940, Eastern book company, Lucknow.
7. D.H.Shah: SOP guidelines, 1st Edition, Business horizons, New Delhi.
8. R.S.Iyer: Schedule M and beyond good manufacturing practices, Indian Drug Manufacturers Association, Mumbai.

9. D.H.Shah: QA Manual, 1st Edition, 2000, Business horizons, New Delhi.
10. Controller of Publications, Govt of India: Indian Pharmacopoeia, vol.I & II, 1996.
11. Burn, Fininey and Godwin: Biological standardization, 2nd Edition, Oxford University Press, London.
12. British Pharmacopeia 2012

Reference Books:

1. Guidelines for developing national drug policies by WHO publications(1998)
2. Regulation of Pharmaceuticals in developing countries legal issues and approaches by D.C.Jeering WHO publications(1985)
3. The international pharmacopoeia Vol. 1, 2, 3 ,4; 3rd Edition, General methods of analysis and quality specifications for pharmaceutical substances, excipients, dosage forms.
4. Quality assurance of pharmaceuticals- A compendium of guidelines and related materials Vol.-1 (WHO publications)
5. Basic tests for pharmaceutical substances- WHO (1988)
6. Basic tests for pharmaceutical Dosage forms- WHO (1991)
7. WHO expert committee on 'Specifications for pharmaceutical preparations' 13th, 22nd, 23rd, 24th and 34th reports.
8. WHO expert committee on 'Biological standardizations'-37,38,39,40,41,42,43,44 and 45th report
9. Wilmer A, Jenkins & Kenton R Osborn: Packaging of drugs and Pharmaceuticals Technomic Publishing Company Inc.,Pennsylvania.
10. H.Lookhart and F.A. Paine: Packaging of Pharmaceuticals and Health care products.
11. M.Purkany: Quality assurance and TQM for analytical laboratories, the royal society of chemistry, Cambridge, London.
12. Donald C. Singer and Ronald P.Upton: Guide lines for laboratory quality auditing (Quality and Reliability Series No.39),1st Edition (1993), Marcel Dekker, New York.
13. Broton.J.Wright: Microbiological assays.

Journals

1. Indian Journals of Pharmaceutical Education.
2. Bulletin- Association Pharmaceutical Analysis
3. Pharma Times.

REVISED FINAL SYLLABUS FOR M.PHARM (QA)
(15TH MARCH 2013)

M PHARM--QUALITY ASSURANCE

GOALS

To equip a post- graduate in Quality Assurance to:

- Achieve comprehensive understanding and competency in quality assurance systems and regulatory requirements.
- Develop and implement a robust quality assurance system in an organization towards quality excellence

COMPONENTS OF THE PG QUALITY ASSURANCE CURRICULUM

- Theoretical knowledge.
- Practical skills.
- Training in research methodology.
- Training in thesis writing.

SUBJECTS/ CURRICULUM:

M Pharm (Previous):

TITLE OF PAPERS

PAPER I: Modern Pharmaceutical Analysis	(T: 3HRS/WK, P: 6HRS/WK)
PAPER II: Quality Assurance	(T: 2HRS/WK, P: 6HRS/WK)
PAPER III: Pharmaceutical Technology & Validation	(T: 2HRS/WK, P: 6HRS/WK)
PAPER IV: Analytical Assurance	(T: 2HRS/WK, P: 6HRS/WK)

List of Equipment:

- 1) Double beam UV-Visible Spectrophotometer.
- 2) Gas Chromatograph.
- 3) HPLC.
- 4) FTIR.
- 5) Electronic balance (0.01mg sensitivity).

PAPER II: QUALITY ASSURANCE

GOAL:

- To equip student to be professionally competent to achieve global quality standards in the pharmaceutical industry.

OBJECTIVES:

On completion of the course in Quality Assurance, the candidate must be able to:

- Acquire knowledge on various quality assurance systems, processes and current regulatory guidelines related to manufacturing and distribution.
- Address quality issues and provide solutions needed to attain Quality leadership in an environment of continual improvement.
- Understand the importance of effective documentation.

COURSE DESCRIPTION

THEORY

50hrs (2hrs/week)

1. Concept and evolution of Quality Assurance and Quality Control, cGMP, TQM (2hr)
2. **Overview of ICH Guidelines** - QSEM, with special emphasis on Q-series guidelines(2hr)(Unit 1&2-20marks
3. **cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention(PIC) and EMEA covering: (70marks)**
 - a. **Organization and Personnel** : Responsibilities, training, hygiene(2hr)
 - b. **Premises**: Location, design, plan and layout, construction, maintenance and sanitation, environmental control – sterile and non-sterile areas, prevention and containment of contamination.(2hr)
 - c. **Equipment**: Material Make, Selection process through vendor evaluation, purchase specifications, maintenance, Preventive Maintenance Protocol, Automation (2hr)
 - d. **Raw materials**: Purchase specifications, maintenance of stores, vendor qualification and evaluation. (2hr)
 - e. **Manufacture and controls of various dosage forms**: Various tiers of documents pertaining to Manufacturing documents, master formula record, and batch manufacturing

- record, standard operating procedures for various operations - cleaning, filling, drying, compression, coating, disinfection and sterilization. **(3hr)**
- f. **In-process quality controls:** For sterile and non-sterile dosage forms **(2hr)**
 - g. **Packaging material controls:** Packaging materials and control of packaging materials **(1hr)**
 - h. **Quality control laboratory responsibilities:** GLP protocols on non-clinical testing control on animal house, data generation, integration and storage, standard test procedure, retention of sample records. CPCSEA guidelines. **(5hr)**
 - i. **Finished product release:** Quality review and batch release document. **(1hr)**
 - j. **Warehousing:** Good warehousing practices, cold chain management and materials management. **(1hr)**
 - k. **Distribution:** Distribution records, handling of returned goods, recovered materials and reprocessing. **(2hr)**
 - l. **Complaints and recalls:** Evaluation of complaints, recall procedure and documentation. **(2hr)**
 - m. **Waste and scrap disposal:** Storage and management of scrap, recycling practices, Disposal procedures and records. **(1hr)**
 - n. Change management, annual product quality review and parametric release **(2hr)**
 - o. **Audits:** Types of audits, quality audits of manufacturing processes and facilities, audits of quality control **(3hr)**
 - p. **Documentation** - Good documentation practices, root cause analysis, corrective action preventive action (CAPA), out of specifications (OOS) and out of trend (OOT) **(3hr)**
- 4. **Clinical studies-** ICH GCP (E6) guidelines, post marketing surveillance, pharmacovigilance, BABE (bioavailability and bioequivalence) studies. **(2hr)**
 - 5. Concepts and management of contract manufacturing (European guidelines) **(2hr)(Unit 4&5-20marks)**
 - 6. Introduction, scope and importance of IPR. Concept of trade mark, copyright and patents **(2hr)**
 - 7. Product registration guidelines – CDSCO, USFDA. **(2hr)(Unit 6&7-15marks)**
 - 8. Concept of ISO 9001:2008, 14000, OSHAS guidelines **(2hr)**
 - 9. Brief concept of IND, NDA, ANDA, SNDA and PAT **(2hr)(Unit 8&9-15marks)**

PRACTICALS

150hrs (6hrs/wk)

The following exercise to be worked upon along with documentation.

1. Drawing and discussion on plant layouts.
2. Preparation of Master Formula Record.
3. Preparation of Batch Manufacturing Record.
4. Preparation of Quality control records for dosage forms (3Expts)
5. Quality control tests and interpretation of results according to pharmacopoeial specifications and alerts for tablets, capsules, semisolids and parenterals. (6Expts)
6. Standard operating procedures- for operation and calibration of analytical instrument.(5Expts)
7. Standard operating procedures- for operating pharmaceutical machinery. (3Expts)
8. Verification of compendial methods (3Expts)
9. Case studies: IPQA Failure, Deviation OOS, market recalls, complaints investigation, scale up, Corrective action preventive action (CAPA) (any 4Expts)

SCHEME OF EXAMINATION

INTERNAL ASSESMENT:

There shall be a total of three sessionals conducted in theory and two in practicals for 30 marks separately. The average of best of two sessionals should be considered as the internal assessment marks for theory and practicals separately.

FINAL EXAMINATION PRACTICALS:

Scheme for university practical examination

Synopsis	Major Experiment	Minor Experiment (group discussion/ topic presentation/case study)	Viva-Voce	Total
20	35	25	20	100

REFERENCES :

1. Sharp J. Good Pharmaceutical Manufacturing Practice: Rationale and Compliance. CRC Press; 2005.
2. Chow SC. Encyclopedia of Biopharmaceutical Statistics. Marcel Dekker; 2003.

3. McCormick K. Quality (Pharmaceutical Engineering Series). Butterworth-Heinemann; 2002.
4. Gad SC. Pharmaceutical Manufacturing Handbook: Production and Processes. John Wiley & Sons; 2008.
5. Willig SH, Stoker JR. Good manufacturing practices for pharmaceuticals: a plan for total quality control. Marcel Dekker; 1997.
6. Signore AA, Jacobs T. Good Design Practices for GMP Pharmaceutical Facilities. Taylor & Francis Group; 2005.
7. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
8. Haider SI. Pharmaceutical Master Validation Plan: The Ultimate Guide to FDA, GMP, and GLP Compliance. St. Lucie Press; 2002.
9. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
10. Kolman J, Meng P, Scott G. Good Clinical Practice: Standard Operating Procedures for Clinical Researchers. Wiley; 1998.
11. Waller P. An Introduction to Pharmacovigilance. John Wiley & Sons; 2011.
12. Mann RD, Andrews EB. Pharmacovigilance. John Wiley & Sons; 2007.
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21. Chalmers AA. International Pharmaceutical Registration. Interpharm Press; 2000.
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1. <http://www.ich.org/>
2. <http://www.ich.org/about/organisation-of-ich.html>
3. <http://www.ich.org/about/process-of-harmonisation.html>
4. <http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html>
5. [http://cdsco.nic.in/html/gmp/schedulem\(gmp\).pdf](http://cdsco.nic.in/html/gmp/schedulem(gmp).pdf)
6. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=210>
7. http://ec.europa.eu/health/documents/eudralex/vol-4/index_en.htm
8. http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step_4/E6_R1_Guideline.pdf
9. <http://ori.hhs.gov/documents/WHOHandbookonGCP04-06.pdf>

Journals:

- 1) Indian drugs.
- 2) International Journal of Pharmaceutical Quality Assurance.
- 3) Journal of Pharmaceutical Quality Assurance
- 4) Pharma Pulse.
- 5) The Quality Assurance Journal.
- 6) Pharmaceutical Engineering, International Society of Pharmaceutical Engineers.

PAPER III: PHARMACEUTICAL TECHNOLOGY AND VALIDATION

GOAL:

- To consistently achieve excellence in the field of drugs and pharmaceuticals with a thorough understanding of current global industrial requirements.

OBJECTIVES:

On completion of the course in Pharmaceutical technology and validation, the student must be able to -

- Gain a thorough understanding of all aspects related to development, manufacturing and evaluation of pharmaceuticals.
- Acquire adequate understanding of process design of pharmaceuticals.
- Understand the principles of validation in pharmaceutical industry

COURSE DESCRIPTION

THEORY

50hrs (2hrs/week)

1. **Preformulation Studies:** Understanding concepts of physicochemical and biopharmaceutical characteristics in preformulation. Compatibility studies, protocol for product development. **(5hr)(20marks)**
2. **Dissolution Studies:** Biopharmaceutical Classification System (BCS) and its relevance to drug development, Factors affecting dissolution, Pharmacopoeial dissolution testing models, *In vitro* – *in vivo* correlation (IVIVC), Biowavers, Similarity factors. **(5hr)(20marks)**
3. **Drug Stability:** ICH guidelines for stability testing of drug substances and drug products. **(5hr)(15marks)**
4. Concepts of Pilot plant scale up and technology transfer, scale up and post approval changes (SUPAC) and bulk active chemicals post approval changes (BACPAC). **(5hr)(15marks)**
5. **Packaging of Pharmaceutical Products (Parenterals and Non - Parenterals):** Objectives, Types of packaging, Containers and closures, Quality control testing of primary and secondary packaging materials. Packaging of solid, semisolid and liquid dosage forms. Innovative packaging technologies. Product-package compatibility. **(5hr)(15marks)**
6. **Validation:** **(25hr)(55 marks)**
 - Introduction to calibration of instruments and its guidelines.
 - Introduction to Qualification and Validation,
 - Importance and scope of Validation.
 - Types of Validation,
 - Validation master plan.

- Process Validation of different dosage forms - solid, semisolids and parenterals
- Qualification of equipment: DQ, IQ, OQ and PQ(Validation of critical equipment - mixer, compression machine, fluidized bed dryer (FBD), filling equipment, sterilization tunnel.)
- Sterile equipment train Validation, Validation of HVAC systems including clean room concepts, air handling equipment and water supply systems (purified, distilled and water for injection).
- Cleaning Validation.
- Understanding of computer system validation (electronic records and digital signature- 21 CFR Part 11) concept of firmware, Commercial off the Shelf (COTS) and GAMP 5

PRACTICALS

150hrs (6hrs/wk)

1. Evaluation of marketed solid, semisolid and liquid dosage form as per Pharmacopeia. (3Expts)
2. Drug - drug and drug - excipients compatibility studies by TLC, FTIR and DSC. (3Expts)
3. Comparative dissolution study with interpretation of similarity factor f1 and f2 for drugs belonging to BCS class I and III drugs. (2Expts)
4. Determination of shelf life for a formulation based on ANCOVA. (Analysis of Covariance).
5. Preparation and execution of stability protocol for a pharmaceutical dosage form as per ICH guidelines.
6. Investigation of a case study based on Pilot plant scale up.
7. Quality control testing of primary and secondary packaging materials.
8. Evaluation of container closure integrity.
9. Determination of compatibility between drug substances and packaging material.
10. Qualification of Pharma Equipment (Tablet compression machine, Stability chamber, Mixer). (3Expts)
11. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester). (3Expts)

SCHEME OF EXAMINATION

INTERNAL ASSESEMENT:

There shall be a total of three sessionals conducted in theory and two in practicals for 30 marks separately. The average of best of two sessionals should be considered as the assessment marks for theory and practicals separately.

FINAL EXAMINATION (PRACTICAL)

Scheme for university practical examination

Synopsis	Major Experiment	Minor Experiment	Viva-Voce	Total
20	35	25	20	100

REFERENCES:

1. Niazi SK, Niazi S. Handbook of Preformulation: Chemical, Biological and Botanical Drugs. CRC Press; 2007.
2. AbdouHM. Dissolution Bioavailability and Bioequivalence, Mack Publishing Company, Eastern Pennsylvania.
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4. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
5. Milo Gibaldi, Text book of Bio-Pharmaceuticals and Clinical Pharmokinetics, 3rd Edn, Lea &Febriger, Philadelphia.
6. Chow S-C. Encyclopedia of Biopharmaceutical Statistics. Marcel Dekker; 2003.
7. Dressman JB, Kramer J. Pharmaceutical Dissolution Testing. Taylor & Francis; 2005.
8. Chilukuri DM, Sunkara G, Young D. Pharmaceutical Product Development: In Vitro-In Vivo Correlation. Informa Healthcare; 2007.
9. Niazi S. Handbook of Bioequivalence Testing. CRC Press; 2007.
10. Sunesen VH. Biorelevant Dissolution Media to Simulate in Vivo Dissolution of Poorly Soluble Drugs. Danish University of Pharmaceutical Sciences; 2003.
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12. Chow SC. Encyclopedia of Biopharmaceutical Statistics. Marcel Dekker; 2003.
13. Paulson DS. Handbook of Regression and Modeling: Applications for the Clinical and Pharmaceutical Industries. CRC Press; 2007.
14. Huynh BK. Handbook of Stability Testing in Pharmaceutical Development: Regulations, Methodologies, and Best Practices. Springer; 2009.
15. Huynh BK. Pharmaceutical Stability Testing to Support Global Markets. Springer; 2010.
16. Swarbrick J. Encyclopedia of Pharmaceutical Technology. Informa Healthcare; 2007.
17. Levin M. Pharmaceutical Process Scale-Up. CRC Press; 2001.
18. Piringer OG, Baner AL. Plastic Packaging: Interactions with Food and Pharmaceuticals. John Wiley & Sons; 2008.
19. Jenke D. Compatibility of Pharmaceutical Solutions and Contact Materials: Safety Assessments of Extractable and Leachable for Pharmaceutical Products. John Wiley & Sons; 2009.
20. Theobald N, Winder B. Packaging Closures and Sealing Systems. John Wiley & Sons; 2009.
21. Bauer E. Pharmaceutical Packaging Handbook. Informa Healthcare; 2009.
22. Dean DA, Evans R, Hall I. Pharmaceutical Packaging Technology. Taylor & Francis; 2000.
23. Calver G. What Is Packaging Design? Rotovision; 2007.
24. Haider SI. Pharmaceutical Master Validation Plan: The Ultimate Guide to FDA, GMP and GLP Compliance. St. Lucie Press; 2002.
25. Wrigley GC. Facility Validation: Theory, Practice, and Tools. CRC Press; 2004.
26. Haider SI, Asif ES. Cleaning Validation Manual: A Comprehensive Guide for the Pharmaceutical and Biotechnology Industries. CRC Press; 2010.
27. Segalstad SH. International IT Regulations and Compliance: Quality Standards in the Pharmaceutical and Regulated Industries. John Wiley & Sons; 2008.
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29. Ira R. Berry and Robert A. Nash, Pharmaceutical process validation (Drugs and Pharmaceutical Series), Marcel Dekker Inc. New York.
30. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare; 2007.
31. Agalloco JP, Carleton FJ. Validation of Pharmaceutical Processes. CRC Press; 2008.
32. Qiu Y, Chen Y, Zhang GGZ, Liu L, Porter W. Developing Solid Oral Dosage Forms: Pharmaceutical Theory and Practice. Academic Press; 2009.

33. Haider SI. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, And Biotech Industries. CRC Press; 2006.
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35. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press; 2000.

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1. <http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html> (ICH Stability guidelines Q1A-F)
2. <http://apps.who.int/medicinedocs/documents/s19638en/s19638en.pdf>(WHO Guidelines on packaging for pharmaceutical Products)
3. <http://www.fda.gov/downloads/Drugs/Guidances/UCM070640.pdf> (US FDA, Scale-Up and Post approval Changes: Chemistry, Manufacturing, and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation)
4. <http://www.validation-online.net/pharmaceutical-validation.html> (Sample validation documents)

Journals:

1. Indian Journal of Pharmaceutical Sciences.
2. Indian drugs
3. Journal of Validation Technology.
4. Pharmaceutical Engineering, International Society of Pharmaceutical Engineers.

PAPER IV: ANALYTICAL ASSURANCE

GOAL:

To equip students with comprehensive knowledge on regulatory aspects of analytical techniques.

OBJECTIVES:

On completion of the course in analytical assurance and regulatory compliance, the candidate must be able to-

- Develop and validate analytical and bioanalytical methods for pharmaceuticals vis-a-vis regulatory compliance.
- Understand the latest internationally recognized standards and developments in analytical assurance.

COURSE DESCRIPTION

THEORY

50hrs (2hrs/week)

1. **Analytical method development and validation-** Introduction, method development for assay of API and dosage forms using UV - Visible Spectroscopy, LC and GC. Validation of analytical method as per ICH guidelines and USP.**(6hr)(20marks)**
2. **Bioanalytical method validation** – Introduction, sample preparation and validation parameters as per USFDA.**(3hr)(15marks)**
3. **Impurity profiling and validation** – Types and sources - metal impurities, biological impurities, residual solvents and related substances. Identification, characterization and quantification by LC-MS/MS, GC-MS, AAS/ICPMS. Harmonized methods for microbiological limit tests. Validation as per ICH guidelines.**(7hr)(20marks)**
4. **Stability indicating assay** – Types of stability indicating assay method (SIAM), forced degradation studies, SIAM development and validation.**(5hr)(15marks)**
5. **Standardization of herbal substances, preparations and products**–As per WHO and EU requirements with special emphasis on microbial, heavy metals and pesticide residues.**(5hr)(15marks)**
6. **Immunological assay** - Principle, methods and application – Enzyme Linked Immunosorbent Assay and Radio Immunoassay.**(2hr)(10marks)**

7. **Bioassay** – Overview, types – direct, indirect and assay based on quantal responses, parallel line bioassays, bench top and primary bioassay screening, high-throughput screening, statistical principles in bioassay- randomization, replication and elimination of variation. **(6hr)(15marks)**
8. **Pyrogens** – Production, chemistry and properties of bacterial pyrogens and endotoxin. Bacterial endotoxin challenge testing: IP, BP and USP methods. Interpretation of data comparison with other pyrogen tests. **(3hr)**
9. **Sterility testing**- methodology and interpretation. **(2hr)**
10. Preservative efficacy or antimicrobial effectiveness testing as per USP. **(1hr)(Unit 8,9&10-10marks)**
11. **Advanced techniques**- principles and applications of Near Infra Red spectroscopy, Scanning Electron Microscopy, Transmission Electron Microscopy. **(5hr)(5marks)**
12. **Qualification of analytical instruments** - HPLC, UV-Visible Spectrometer, GC and FTIR. **(5hr)(15marks)**

PRACTICALS

150hrs (6hrs/wk)

1. Analytical method validation for the parameters accuracy, precision, repeatability, specificity, system suitability, selectivity and robustness for the following drugs/formulations by UV-Visible Spectroscopy and HPLC. (7Expts)
 - a. Paracetamol tablets
 - b. Diclofenac sodium gel.
 - c. Cetirizine syrup.
 - d. Metronidazole infusion.
 - e. Chloramphenicol capsules.
 - f. Ibuprofen and Paracetamol tablets
 - g. Paracetamol and Diclofenac sodium tablets.
2. Identification of impurities in drug substances by TLC and LC method - Aspirin, Paracetamol and Ranitidine HCl. (3Expts)
3. Stability indicating assays for Ranitidine HCl and Aspirin by LC method. (2Expts)
4. Limit test for heavy metals of herbal preparations - Arsenic, lead, cadmium and mercury. (2Expts)
5. Determination of residual solvents by GC. (2Expts)

6. Qualification of analytical instruments – UV- Visible spectrometer, FTIR, Colorimeter, pH meter, HPLC. (4Expts)

SCHEME OF EXAMINATION

INTERNAL ASSESEMENT:

There shall be a total of three sessionals conducted in theory and two in practicals for 30 marks separately. The average of best of two sessionals should be considered as the assessment marks for theory and practicals separately.

FINAL EXAMINATION PRACTICALS

Scheme for university practical examination

Synopsis	Major Experiment	Minor Experiment	Viva-Voce	Total
20	35	25	20	100

REFERENCES:

1. Riley CM, Rosanske TW. Development and Validation of Analytical Methods. Elsevier; 1996.
2. Chow S-C. Encyclopedia of biopharmaceutical statistics. Marcel Dekker; 2000.
3. Snyder LR, Kirkland JJ, Glajch JL. Practical HPLC Method Development. Wiley; 1997.
4. Ahuja S, Dong M. Handbook of Pharmaceutical Analysis by HPLC. Elsevier; 2005.
5. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare; 2007.
6. Braithwaite A, Smith FJ. Chromatographic Methods Fifth Edition. Chapman and Hall; 1996.
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8. Chan CC, Lee YC, Lam H, Zhang X-M. Analytical Method Validation and Instrument Performance Verification. John Wiley & Sons; 2004.
9. Bliesner DM. Validating Chromatographic Methods: A Practical Guide. John Wiley & Sons; 2006.
10. Mikkelsen SR, Cortón E. Bioanalytical Chemistry. John Wiley & Sons; 2004.
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24. Deshpande SS. Enzyme Immunoassays: From Concept to Product Development. Springer; 1996.
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2. <http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html>
3. http://www.uspbpep.com/usp31/v31261/usp31nf26s1_c51.asp
4. http://ec.europa.eu/health/documents/eudralex/vol-4/index_en.htm
5. <http://www.sciencedirect.com/science/article/pii/S073170850200047X>

Journals:

- 1) Indian drugs.
- 2) Indian Journal of Pharmaceutical Sciences.
- 3) Indian Journal of Chemical Society.
- 4) Journal of Chromatography.
- 5) Journal of Pharmaceutical and Biomedical Analysis.

M. PHARM.
PHARMACEUTICAL MARKETING AND MANAGEMENT

GOAL:

To make the candidate an innovative, skillful and effective professional, who can raise industry standards, bring profits and name to the nation.

OBJECTIVE:

Upon completion of the course the candidate:

- Will gain specialized knowledge in marketing of pharmaceutical products.
- Will become a skilled profit making marketer with adequate knowledge of financial management.
- Will be a skilled leader in a pharmaceutical company.
- Will be able to raise standards of the pharmaceutical industry in the current global scenario.

TITLE OF PAPERS:

PAPER I : Pharmacological Basis of Disease Management	(T: 3hrs/wk, P: 6 hrs/wk)
PAPER II : Pharmaceutical Marketing	(T: 2hrs/wk, P: 6 hrs/wk)
PAPER III : Pharmaceutical Management	(T: 2hrs/wk, P: 6 hrs/wk)
PAPER IV : Production Management and Regulatory Affairs	(T: 2hrs/wk, P: 6 hrs/wk)

PAPER I: PHARMACOLOGICAL BASIS OF DISEASE MANAGEMENT

GOAL: To help the students to identify and understand the need gap in disease management.

OBJECTIVES: Upon completion of the course the candidate will be able to:

- Discuss the standard guidelines of top therapy areas
- Acquire skills to analyze the need gap in disease management
- Identify the USP of drugs
- Develop the ability to impart / exchange scientific knowledge with Sales personnel, Doctors and Higher Management.

COURSE DESCRIPTION

THEORY

75 Hours (3Hrs/ wk.)

1. ICD - CURRENT GUIDELINES ON DISEASES (1hr.)
2. BASIC PHARMACOLOGY
 - I. Introduction.
 - II. Drug receptor binding, ion channels and G-protein coupled receptors, secondary messenger systems (5hrs.)
 - III. Basics of pharmacodynamics and pharmacokinetics and drug bio-transformation. (5 hrs.)
 - IV. Clinical interpretation of drug concentration. (2 hrs.)
 - V. Basic and clinical evaluation of new drugs. (2 hrs.)
3. Key therapy areas to be focused with respect to the guidelines, class of drugs, and the differentiating points between the inter class and intra class of drugs.
 - I. INFECTIOUS DISEASES (6hrs.)
 - II. NEOPLASTIC DISEASES (6 hrs.)
 - III. BLOOD DISORDERS. (2 hrs.)
 - a. ANEMIA
 - b. COAGULATION DISORDERS
 - IV. METABOLIC DISORDERS. (4hrs.)
 - a. DIABETES MELLITUS
 - b. HYPERLIPIDEMIA
 - V. MENTAL AND BEHAVIOURAL DISORDERS. (8 hrs.)
 - a. ANXIETY
 - b. SCHIZOPHRENIA
 - c. AFFECTIVE DISORDERS
 - d. DEMENTIA
 - e. PARKINSONISM

VI.	CARDIAC DISEASES.	(6hrs.)
	a. HYPERTENSION	
	b. ISCHEMIC HEART DISEASES	
	c. CONGESTIVE CARDIAC FAILURE	
VII.	GASTROINTESTINAL DISORDERS.	(4 hrs.)
	a. PEPTIC ULCER	
	b. GERD	
VIII.	RESPIRATORY AND ALLERGIC DISEASES	(4 hrs.)
	a. ASTHMA	
	b. COPD	
IX.	GENITOURINARY DISEASES	(6 hrs.)
	a. KIDNEY DISEASES	
	b. UROLITHIASIS	
	c. GENITAL DISEASES	
X.	SKIN DISEASES	(4hrs.)
	a. BULLOUS DISORDERS	
	b. DERMATITIS AND ECZEMA	
	c. URTICARIA AND ERYTHEMA	
XI.	MUSCULOSKELETAL SYSTEM DISEASES.	(6 Hrs.)
	a. OSTEO ARTHRITIS	
	b. GOUT	
	c. SPONDYLITIS	
	d. OSTEOPOROSIS	
XII.	MISCELLANEOUS:	(4 Hrs.)
	a. GLAUCOMA	
	b. OTITIS	

PRACTICALS:

150 hrs. (6 Hrs/wk.)

1. Identification of USP to switch over from one product to another.
 - a. Data collection.
 - b. Write up.
 - c. Visual Aid.
 - d. Training Slides
 - e. Medico Marketing Aids
2. Current Guidelines Discussion of Top Therapy Areas.
3. Handling Scientific Objections: Doctor Query Management/ Case Situation.

TEXT BOOKS:

1. Pharmacology 3rd edition, Rang. H. P., Dale M.M. And Ritter J.M 1995 Churchill Living Stone.
2. Basic and Clinical Pharmacology, 5th edition, Katzung B.G (editor), 1992 Mcgraw Hill.
3. Oxford Handbook of Clinical Medicine, 5th revised edition, Longmore M, Hope R.A , Ian Wilkinson I, Torok E. Oxford University Press Inc, 2001.
4. Davidson's Principles and Practice of Medicine, 21 edition, Colledge N.R, Walker B.R, H. Ralston S.H, Churchill Livingstone, 2010.

REFERENCE BOOKS:

1. Goodman and Gilman's the Pharmacologicals Basis of Therapeutics, 10th edition, Hardman J.D. and Limbird L.E (Editor –in Chief), 2001 Mcgraw- Hill (Medical Publishing Division)
2. Clinical Pharmacy and Therapeutics, 3rd edition, Walker R, Edwards C.R.W, Churchill Livingstone, 2002.
3. Braunwald's Heart Disease: A Textbook of Cardiovascular Medicine, 9th edition, Bonow, R.O, Douglas L., Zipes D.P, Libby P., 2011, Saunders.
4. Joslin's Diabetes Mellitus, 14th Edition, Kahn C.R, Weir G , King G, Jacobson A, Smith R, Moses A, (editors) Lippincott Williams & Wilkins, 2004
5. Cancer: Principles and Practice of Oncology , 9th north American edition, Vita d, Hellman, Rosenberg, Lippincott Williams & Wilkins, 2011.

WEB REFERENCES:

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2. <http://www.heart.org> (AHA)
3. <http://www.diabetes.org> (Diabetes association)
4. <http://www.escardio.org> (ESC)
5. <http://emedicine.medscape.com>
6. <http://www.hon.ch>(HONCODE SITE)
7. <http://apps.who.int/classifications/icd10/browse/2010/en#/XIII>(ICD GUIDELINES)

JOURNALS:

1. JAMA (Journal Of American Medical Association)
2. NEJM (New England Journal Of Medicine)
3. BMJ (British Medical Journal)
4. LANCET
5. JAPI (Journal Of Association Of Physician Of India)

SCHEME OF ANNUAL PRACTICAL EXAMINATION:

1. Synopsis	20 Marks
2. Major Experiment:	35 Marks
Switching Doctors from X to Y drug based on USP's of the given drugs.	
3. Discussion on the guidelines of the given therapy class.	25 Marks
4. Viva voce	20 Marks
TOTAL	100 Marks

PAPER II. PHARMACEUTICAL MARKETING

GOAL: To prepare the candidate to acquire sufficient knowledge in marketing management principles so that he/ she can handle product management, field management, training the field force, market research, industrial business, institutional business and international business, effectively, efficiently and profitably.

OBJECTIVES: Upon completion of course the candidate shall

- **Gain knowledge in Product Management of Pharmaceutical Products**
- **Gain knowledge of Marketing Management and Sales Management**
- **Acquire skills in Brand Planning**
- **Acquire skills to Launch a Product**
- **Raise Product Management standards**

COURSE DESCRIPTION

THEORY

50 Hours (2 Hrs/wk)

1. Marketing Concepts

(04 Hours)

- a. Global Pharmaceutical Industry scenario
- b. Indian Pharmaceutical Industry scenario
- c. Specificities of Pharmaceutical Marketing
- d. Role of Marketing in today's organization
- e. Identifying and classifying markets.
- f. Tasks of Marketing and Planning

2. Understanding Consumer Behavior

(03 Hours)

- a. Differentiating between consumer and customer in Pharmaceutical Marketing
- b. Consumer behavior models
- c. Physician's prescribing habits
- d. Rational and emotional decision making

3. Market Segmentation, Targeting and Positioning

(08 Hours)

i. Market Segmentation

- a. Definition and approaches to segmenting a market
- b. Bases for segmenting a pharmaceutical market
- c. Advantages and drawbacks of segmentation

ii. Market Targeting

- a. Evaluation of Market Segments
- b. Target Market Selection

iii. Product Positioning

- a. Definition, types of positioning
- b. Positioning Strategies

4. Product

(07 Hours)

- a) Concept of Product Management
- b) Understanding the Product Manager's role
- c) Understanding the Product, and its market
- d) SWOT analysis, Porter's Five Forces analysis, BCG Matrix(Portfolio analysis), Ansoff's Matrix
- e) Product financial justification (Profit and Loss, cash flow analysis)
- f) New Product Launch Strategy
- g) Product Life Cycle Management for Pharmaceutical Products
- h) Branding and Brand Management.

5. Place

(02 Hours)

- a) Study of Distribution Channels in Pharmaceutical industry
- b) Role of Carrying and Forwarding agents, Wholesalers, Stockists and Retailers

6. Price

(02 Hours)

- a) Pricing strategies
- b) Bases of Pricing
- c) Drug Price Control Order
- d) National Drug Policy

7. Promotion

(06 Hours)

- a) Verbal and Non verbal communication
- b) Elements of Promotion mix
- c) Medico Marketing aids
 - Written aids- Leave behind literature, visual aids
 - Digital aids- Slide kits, Flash presentations
 - Event Management- Continuing Medical Education, Key opinion Leaders(International and National)
- d) Promotional budget

8. Competitor Analysis

(02 Hours)

- a) Competitive Intelligence
- b) Competitive Advantages

9. Marketing Strategies

(04 Hours)

- a) Understanding Strategy, Tactics and Objectives
- b) Types of Marketing Strategies
- c) Product Strategies
- d) Promotional Strategies
- e) Sales Strategies
- f) Distribution Strategies
- g) Pricing Strategies
- h) Differentiation Strategies

10. Marketing Research

(03 Hours)

- a) Primary and Secondary Research
- b) Sampling Techniques-Probability and Non Probability
- c) Questionnaire Design
- d) Data Collection
- e) Data Analysis

11. International Marketing**(03 Hours)**

- a) Factors to be considered in International Marketing of Pharmaceutical Products
- b) Understanding the impact of the following factors in International Marketing:
 - Political Environment
 - Economical Environment
 - Social Environment
 - Technological Environment
 - Regulatory Environment
 - Cultural Environment
- c) Study of Marketing Mix elements and Market Entry strategies for regulated and semi-regulated markets.
- d) Foreign Trade Policy (EXIM Policy)

12. Pharmaceutical Marketing Codes**(02 Hours)**

- a. OPPI Code
- b. Uniform Codes of Pharmaceutical Marketing Practice

13. Field Personnel Training**(02 Hours)**

- a. Communication on product.
- b. How, when why, what to communicate?

14. Industrial Marketing**(02 Hours)**

- a. Comparison between Consumer Marketing and Industrial Marketing
- b. Marketing Mix Decisions with reference to Industrial Products.

PRACTICALS

150 Hours (6 Hrs/wk)

- i. Case studies (15), group discussions (10) and 2 role plays.
- ii. Preparation and presentation of campaigns.
- iii. Market survey and short term project
- iv. News capsule
- v. Preparation and submission of marketing plan for a given Molecule/Product.

SCHEME OF ANNUAL PRACTICAL EXAMINATION:

1. Synopsis	20 marks
2. Case study	15 marks
3. Group discussion	15 marks
4. Brand Plan for given Drug / Product	30 marks
5. Viva voce	20 marks

TOTAL

100 marks

Text Books :

1. Marketing Management by Philip Kotler, Kevin Lane Keller, Abraham Koshy, Mithileshwar Jha (Latest Edition), Published by Prentice-Hall Pvt Ltd.
2. A Framework for Marketing Management by Philip Kotler, Kevin Lane Keller (Latest Edition), Published by Prentice-Hall Pvt. Ltd.
3. Principles Of Marketing by Philip Kotler, Gary Armstrong (Latest Edition), Published by Prentice-Hall Pvt. Ltd.
4. Pharmaceutical Marketing In India: Concepts, Strategy, Cases by Subba Rao Chaganti (Latest Edition), Published by Pharma Book Syndicate.
5. Principles of Pharmaceutical Marketing by Mickey C Smith (Latest Edition), Published by CBS Publishers & Distributors.
6. Pharmaceutical Marketing in 21st Century by Mickey C Smith (Latest Edition), Published by Viva Books Pvt. Ltd. ,New Delhi-2.

Reference Books :

1. Essentials of Human Resource Management and Industrial Relations by Subbarao.P (Latest Edition), Published by Himalaya Publishing House.
2. Marketing Research : An Applied Orientation by Naresh K Malhotra (Latest Edition), Published by Prentice-Hall Pvt Ltd.
3. Pharmaceutical Marketing : A Practical Guide by Dimitris Dogramatz (Latest Edition), Published by CRS Press.
4. Marketing Warfare : How to use Military Principles to develop Marketing Strategies by Al Ries, Jack Trout (Latest Edition), Published by Listen USA.
5. Positioning : The Battle for your Mind by Al Ries, Jack Trout, Philip Kotler (Latest Edition), Published by McGraw-Hill.
6. Marketing Planning for the Pharmaceutical Industry by John Lindstone, Janice MacLennan (Latest Edition), Published by Gower Pub Co..
7. Revitalizing the Pharmaceutical Business : Innovative Marketing Approaches by R.B. Smarta (Latest Edition), Published by Response Books (Sage Publications).
8. Brand Positioning : Strategies for Competitive Advantage by Subroto Sengupta (Latest Edition), Published by Tata McGraw-Hill.

Journals:

1. Pharma Pulse
2. IDMA Bulletin
3. Harvard Business Review
4. 4Ps
5. Pharma Executive
6. Indian Journal of Marketing

PAPER III. PHARMACEUTICAL MANAGEMENT

GOAL: To prepare candidates in General Management and inculcate the Managerial Skills.

OBJECTIVES: At the end of the course, the candidate will :

- Gain knowledge in General Management
- Learn about Organizational Behavior, HRM, Financial Management, Operations Management and Quality Management.
- Gain skills in Distribution Management.
- Learn about Corporate Governance, Ethics, Shareholders value creation and Corporate Social Responsibility (CSR)
- Bring awareness about Quality and Productivity Tools: Enterprise Resource Planning (ERP), Material Resource Planning (MRP), Total Quality Management (TQM) and Kaizen.

COURSE DESCRIPTION

THEORY

50 Hours (2Hrs/wk)

1. Introduction to Management Aspects

(05 Hours)

- Concept, Nature and purpose of Management.
- Professional Managers- Tasks, Responsibilities and Skills needed.
- Leadership styles.
- Decision Making- Types, Procedures, Evaluation and Selection of Alternatives.
- Decision Making under various situations.
- Types of organization structure and map : Pharmaceutical Company as a model.
- Organizational Culture.

2. Organizational Behavior

(07 Hours)

- Meaning.
- Foundation of Organizational Behavior.
- Perceptions, Motivation, Emotions.
- Foundation of Group Behavior.
- Communication skills.
- Conflict Management.
- Foundation of Organizational Structures.

3. Human Resource Management (HRM)

(06 Hours)

- Human resource planning.
- Recruitment and Interviewing.
- Human skills evaluation through various instruments : Job Description, Job Evaluation, Role Clarity.
- Performance Appraisal Methods, Rewards and Incentives, Career Planning.
- Theories of Motivation, Motivational Techniques.
- Group Dynamics.
- Interpersonal Skills.

4. Operations Management

(08 Hours)

- Project Management.
- Product Design.
- Importance of Processes.
- Process Capabilities and Statistical Quality Control.
- Planning and controlling the supply chain: Forecasting, Aggregate Sales and Operations Planning, Inventory Control, Material Requirement Planning, Operation scheduling.
- Productivity Tools: ERP, MRP.

5. Financial Management

(06 Hours)

- Overview and introduction
- Financial statements: Taxes and Cash Flow
- Break Even Analysis
- Techniques of Capital Budgeting

6. Quality Management

(06 Hours)

- Introduction to statistical Methods
- Statistical Quality Control Tools
- Statistical Tools for Decision making
- Total Quality Management/ Kaizen: Six Sigma, Quality Circle.
- CPM

7. Distribution Management

(05 Hours)

- Managing Retailing, Wholesaling and Logistics

8. Corporate Governance

(05 Hours)

- Ethics.
- Shareholders Value Creation.
- Corporate Social Responsibility (CSR)

9. Systems Management

(02Hours)

- Management Information System (MIS)
- Database Management System (DBMS)

PRACTICALS

150 Hours (6Hrs/wk)

Student shall submit a journal consisting a write-up on Job description of different levels of employees each from different function and give employee evaluation controls (e.g. one for distribution dept., one for finance dept, one in administration, one in marketing & production dept.)

Student shall also submit a journal consisting a write-up on case studies and their analysis covering the various principles outlined in theory

- **Case Studies-** 15 Cases shall be analyzed based on topics of Principles of Management, Organizational behaviour and HRM, globalization- Mergers and acquisitions
- **Group Discussions** -10 based on problem –solving areas
- 2 role plays , movie presentations, video clips
- Problem solving to decide upon project choices and investment decisions

SCHEME OF ANNUAL PRACTICAL EXAMINATION

1. Synopsis	15 marks
2. Case study	30 marks
3. Group discussion	20 marks
4. Problem solving to decide upon project based on Choices and Investment decisions (Quantitative techniques)	15 marks
5. Viva voce	20 marks

TOTAL

100 marks

Text Books:

1. Management - A Global Perspective by Heinz Weirich, Harold Koontz (Latest Edition), Published by McGraw-Hill.
2. Management : Tasks, Responsibilities, Practices by Peter F. Drucker (Latest Edition), Published by Harpar Business.
3. Organizational Behavior by Stephen Robins (Latest Edition), Published by Prentice-Hall Pvt Ltd.
4. A textbook of Human Resource Management by C B Mamoria, S.V.Gankar (Latest Edition), Published by Himalaya Publishing House.
5. Financial Management: Theory and Practice By Prasanna Chandra (Latest Edition), Published by Tata McGraw-Hill.
6. Operations Management: A Competitive Advantage by Richar B Chace, F Robert Jacobs, Nicholas Aquilano (Latest Edition), Published by Tata McGraw-Hill.
7. HRD Audit By T V Rao (Latest Edition), Published by Sage Publication Pvt Ltd.
8. Sales Management- Decisions Strategies and Cases by Richard R Still, Edward W. Cundiff, Norman A.P. Govoni (Latest Edition), Published by Prentice-Hall Pvt Ltd.

Reference Books:

1. Human Resource Management and Industrial Relations by S .V.Subba Rao (Latest Edition), Published by Himalaya Publishing House.
2. Quantitative Techniques by C.R.Kothari (Latest Edition), Published by Vikas Publishing House Pvt Ltd.
3. Organizational Behaviour by Dr. K. Aswathappa (Latest Edition), Published by Himalaya Publishing House.
4. Productions and Operations Management by Dr. K. Aswathappa, K. Shridhara Bhat (Latest Edition), Published by Himalaya Publishing House.
5. Organisational Behaviour by Fred Luthans (Latest Edition), Published by Mc-Graw Hill International Edition

JOURNALS:

1. Pharmaceutical Executive
2. IDMA Bulletin
3. Pharma Biz
4. Pharma Pulse
5. The Pharma Review

PERIODICALS / JOURNALS / MANAGEMENT

1. HBR
2. Indian Journal Of Management

PAPER IV. PRODUCTION MANAGEMENT AND REGULATORY AFFAIRS

GOAL: To make the candidate completely familiar with statutory plant design, production planning, statutory regulations of production, formulation techniques.

OBJECTIVES: Upon completion of study candidate shall be able to

- Thoroughly understand the rules and regulations related to the manufacture and sale of drugs, understand and evaluate quality
- Attain an in-depth understanding knowledge about pharmaceutical service, facilities, material handling, and safety aspects
- To gain awareness in developing formulations as per statutory requirements.
- To gain knowledge in production planning, inventory control and forecasting.
- Exposure to industrial aspects of Pharmaceutical manufacture.

COURSE DESCRIPTION

THEORY

50 Hours (2Hrs/wk)

1. Dosage Form Manufacturing

(06 Hours)

Sterile and Non Sterile Dosage Forms

Introduction to Pilot plant scale- up techniques

Packaging

2. Validation and Quality Management

(09 Hours)

- Basics of validation, Concept, merits, types
- Concept of Quality Assurance, Quality Control, GMP, cGMP
- Lean Manufacturing, Just in Time, 5S, Kanban system
- Introduction to ISO 9000 & 18000 series,
- ICH guidelines with respect to API and formulations pertaining to Quality, safety and efficacy .

3. Intellectual Property Management (06 Hours)

Intellectual property Rights (Patents, Trademark and Copyrights), Patents: types, filing procedure, infringement issues, Hatch Waxman act, PCT Filing.

4. Supply Chain Management (04 Hours)

Supply Chain Design, Supply Chain Strategy and Logistic management

5. Production Planning, Scheduling and Forecasting (06 Hours)

Production planning and inventory control management, vendor development, assessment of production rate changes.

6. New Drug Discovery and Development (08 Hours)

Brief introduction of Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA).

7. Overview of Current Pharmaceutical Policy (03 Hours)

8. Various regulatory agencies worldwide like (08 Hours)

USFDA, TGA, MHRA, EMEA, MCC, ANVISA, SFDA, MHLW and CDSCO

PRACTICALS

100 Hours (6 Hrs/wk)

1. CASE STUDIES related to IPR infringement issues, Supply Chain management, Drug approval procedures and Production problems. Total 8 Case Studies (Major)
2. Comparative evaluation of Packaging guidelines of various regulatory agencies. (Minor)
3. Comparative evaluation of Labeling guidelines of various regulatory agencies (Minor)
4. Formulation of solid dosage forms and evaluation of excipients used in its formulation. (Major)
5. Formulation of liquid dosage forms and evaluation of excipients used in its formulation. (Major)
6. Formulation of semisolid dosage forms and evaluation of excipients used in its formulation. (Major)
7. Evaluation of Packaging Materials: Glass, Metal and Rubber (Minor)

Text Books:

1. The Theory and Practice of Industrial Pharmacy Leon Lachman, Ph.D., Lachman Consultant Services, Inc. Garden City, New York. Herbert A. Lieberman, Ph.D., H.H. Lieberman Associates, Inc. Consultant Services, Livingston, New Jersey. Joseph L. Kanig, Ph.D, Kanig Consulting and Research Associates, Inc. Ridgefield, Connecticut. Third Edition (Indian Edition) Varghese Publishing House, Hind Rajasthan Building, Dadar Bombay 400 0 14. 1987.
2. Pharmaceutical Dosage Forms and Drug Delivery System Fifth Edition Howard C. Ansel, Ph.D., Professor and Dean, College of Pharmacy, The University of Georgia. Nicholas G Popovich, Ph.D., Professor, School of Pharmacy and Pharmaceutical Sciences, Purdue University. Published by Lea & Febiger, Philadelphia. London. 1990.
3. Drugs and Cosmetics Act, Vijay Malik, Latest edition. Eastern Publishers.
4. FDA regulatory affairs: A guide for prescription drugs, medical devices and biologics by Douglas J. Pisano and David S Mantus Publisher: CRC press
5. IPR handbook for Pharma students and researchers by Parikshit Bansal. Publisher: Pharma Book Syndicate

6. Production Planning and control- Text and cases by S K Mukhopadhyaya Publisher: Prentice Hall India
7. New Drug Approval Process by Richard A Guarino M. D. Publicer: Informa Health Care
8. Rohilla, Dhulichand; Dureja, HarishDr., New Drug Approval Process: Regulatory View, Pharmainfo.net, 2010.
9. Governement and regulatory bodies around the world, pharmweb.net/pwmirror/pwk/pharmwebk.html.
10. Meadows, M. The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective (2002). fda.gov/fdac/features/2002/402_drug.html
11. Rusell, R.S. & Taylor, B.W., "Operations Management, WSE, 5th Ed., 2006
12. Adam, E.E and Ebert, R.J., Production & Operations Management, 5th Ed., PHI, 1993.
13. Piringer OG, Baner AL. Plastic Packaging: Interactions with Food and Pharmaceuticals. John Wiley & Sons; 2008.
14. Jenke D. Compatibility of Pharmaceutical Solutions and Contact Materials: Safety Assessments of Extractables and Leachables for Pharmaceutical Products. John Wiley & Sons; 2009.
15. Theobald N, Winder B. Packaging Closures and Sealing Systems. John Wiley & Sons; 2009.
16. Bauer E. Pharmaceutical Packaging Handbook. Informa Healthcare; 2009.
17. Dean DA, Evans R, Hall I. Pharmaceutical Packaging Technology. Taylor & Francis; 2000.
18. Calver G. What Is Packaging Design? Rotovision; 2007.
19. http://www.iso.org/iso/home/standards/management-standards/iso_9000.htm
20. http://www.isohelpline.com/iso_ohsas_18000_18001_2007_document_manual.htm
21. www.ich.org/
22. www.ich.org/products/guidelines/quality.html

Reference Books:

1. Modern Pharmaceutics, Second Edition, Revised & Expanded (Volume 40) Edited by Gilbert S. Banker'; University of Minnesota, Minneapolis, Minnesota; ChristopherT. Rhodes, University of Rhode Island, Kingston, 1990 Marcel Dekker Inc., 270 Madison Avenue, New York 10016.
2. Controlled Drug Delivery (Volume 29) Fundamentals & Applications Second Edition, Revised and Expanded Edited by Joseph R. Robinson, School of Pharmacy, University of Wisconsin, Madison, Wisconsin; Vincenth L. Lee, School of Pharmacy, University of Southern California, Los Angeles, California, 1987 Marcel Dekker, Inc., 270 Madison Avenue, New York, New York 10016.
3. Remington's Pharmaceutical Sciences, 20th Edition - 2001 Editors: Atthur Osol, Grabton D. Chase, Alfonso R. Gennaro, Melvin R. Gibson, C. Boyd Granberg, Stewart C. Harvey, Robert E. King, Alfred N. Martin, EwartA. Swinyard, Gilbert L. Zink Published in the 160th year of the Philadelphia College of Pharmacy and Science.
4. Pharmaceutical Dosage Forms - Tablets: Second Edition, Revised and Expanded in three volumes Volume - 3 Edited by Herbert A. Lieberman, H.H. Lieberman Associates, Inc., Consultant Services, Livingston, New Jersey. Leon Lachman, Lachman Consultant Services, Westbury, New York. Joseph B. Sch)Vartz, Philadelphia College of Pharmacy and Science, Philadelphia, Pennsylvania. 1990 by Marcel Dekker, Inc., 270 Madison Avenue, New York 10016.
5. Pharmaceutical Dosage Forms - Disperse Systems Edited by Herbert A. Lieberman . Rieger and Gilbert S. Banker, 1989, Marcel Dekker, Inc. 270 Madison Avenue, New York 10016.
6. Material Management by K.K. Ahuja, Published by: CBS Publishers and Distributors, 1992

JOURNALS

1. Indian Journal of Pharmaceutical Sciences
2. IDMA Bulletin
3. Pharma Biz
4. Indian Drugs

SCHEME OF ANNUAL PRACTICAL EXAMINATION:

1.Synopsis	20 Marks
2 Major Experiment (Case Study Presentation or Laboratory Experiment)	40 Marks
3. Minor Experiment (Case Study Presentation or Laboratory Experiment)	20 Marks
4.Viva	20 Marks
TOTAL:	100 Marks

Note: Case study presentation should be the part of examination as either major or minor experiment.

M.PHARM PHARMACOGNOSY

GOALS: To impart advanced level training in the field of Pharmacognosy, Phytochemistry and Biotechnology so as to meet the industrial, research and academic standards.

OBJECTIVES: On completion of the course the candidate shall be able to:

- Explore the advanced techniques for the search of new products from natural sources.
- Achieve a high degree of proficiency and develop competence in isolation and estimation of phytoconstituents from herbs.
- Understand industrial requirements for quality control and quality assurance of herbal drugs. Formulate and standardize various herbal products
- Understand the biotechnological techniques for obtaining and improving the quality of natural products.
- Develop skills in presenting research methods, scientific writing etc.

a) Knowledge and understanding:

A postgraduate student should acquire detailed theoretical knowledge and practical techniques of the following during the period of his/her course. He/she should acquire thorough theoretical knowledge and practical skills in Pharmacognosy, Phytochemistry and Biotechnology with special emphasis on all modern analytical instruments and techniques. He/she should acquire adequate theoretical knowledge and practical skills in isolation, characterization of various types of plant secondary metabolites. He/she should acquire adequate theoretical and practical knowledge about structure elucidation of natural products of therapeutic interest and also alternative sources for novel active metabolites from natural origin.

b) Attitude:

A postgraduate student must inculcate attitude for applying his acquired knowledge on isolation of phytoconstituents and their biological evaluation, standardization of herbal products as per international standards. He/she has to maintain a high standard of professional ethics. He/she should continuously upgrade the acquired knowledge by keeping in touch with contemporary research through national and international journals and should be willing to participate in continuing education programs

Papers	Title of papers	Total hours	Hours per week	
			Theory	Practicals
Paper-I	Modern Pharmaceutical Analysis	75	3	6
Paper-II	Advanced Pharmacognosy and Phytochemistry	50	2	6
Paper-III	Industrial Pharmacognosy	50	2	6
Paper-IV	Medicinal Plant Cultivation and Biotechnology	50	2	6

List of Equipments

1. Extraction units
2. Distillation units
3. Flash evaporator
4. Columns
5. Heating mantles
6. Vacuum pumps
7. TLC unit
8. pH meter
9. UV Spectrophotometer
10. HPTLC
11. HPLC
12. IR
13. GC
14. Centrifuge
15. Muffle furnace
16. Oven
17. Incubator
18. Laminar flow unit
19. Desiccators
20. Electronic balances
21. Electric shakers
22. Electrophoresis
23. Biofermenters
24. Trinocular microscope

Paper-II
ADVANCED PHARMACOGNOSY AND PHYTOCHEMISTRY (THEORY)
(50 hrs: 2 hrs/week)

Goal: To give latest update on developments in the field of Pharmacognosy and Phytochemistry

Objectives: By the end of the course the student shall be able to

- Explore advanced techniques in natural product research
- Screen herbal extracts/preparations for various biological/pharmacological activities.
- Develop skills in presenting research methods, scientific writing etc.

Course description

Total Hours:50 (2 hrs/week),	Examination	Max Marks
	Annual	100
	Internal Assessment Exam	30
	Seminar Evaluation	20
	Total	150

CHAPTER 1: Extraction technology for medicinal and aromatic plants

08 hrs (16 marks)

- a. Overview of various extraction techniques for medicinal and aromatic plants. Different types of extracts. Factors affecting choice of extraction. Role of process simulation in extraction technology.
- b. Methods of extraction, isolation, purification, identification and estimation of: Alkaloids, Glycosides, Steroids, Terpenoids, and Volatile oils.
- c. Applications of chromatography in isolation, identification and purification of phytoconstituents.

CHAPTER 2: Chemistry of natural products

05 hrs (10 marks)

Chemistry of following classes of secondary metabolites, their biogenesis and methods of extraction and estimation

- Alkaloids
- Glycosides

- Coumarins
- Polyphenols
- Steroids and Terpenes.

CHAPTER 3: Natural products as lead compounds for drug discovery

08 hrs (16 marks)

- Introduction to natural products as leads to design new drugs for CNS, Anticancer, Antidiabetic and Cardiovascular drugs.
- Reverse pharmacology process for drug development from natural leads.
- High throughput screening (HTS).
- Ethnomedicine approach for drug discovery
- Role of Complementary Alternative Medical (CAM) systems for search of new drugs.

CHAPTER 4: Advances in natural product research

08 hrs (16 marks)

- Nutraceuticals – Antioxidants, Vitamins Supplements, Dietary fibres, PUFA
- Bitters, colouring agents and sweetening agents
- Potentials of Marine pharmacognosy and Zoo pharmacognosy in natural product research.
- Secondary metabolites for various biological / pharmacological activities from endophytes
- Methods of authentication of plants. Microtechnique and microscopy. Macerate and staining techniques. Preparation of herbarium and herbal database.

CHAPTER 5: Phytopharmacology

12 hrs (24 marks)

- a. General concept of pharmacological screening.
- b. Bioavailability and pharmacokinetic significance for herbal drugs with examples of clinically used herbal drugs. Clinical trials for herbal drugs.
- c. Different models for screening of the following pharmacological activities of herbal drugs including *in-vitro* and enzyme bioassays.
 - Adaptogens
 - Anti cancer
 - Antidiabetics & Hypolipidaemics

- Hepatoprotective and Anti hepatotoxics
 - Anti microbial
 - Cardiovascular
 - Antioxidants
 - Anti- inflammatory and antiulcer
- d. Use of cell line cultures and enzymes for screening of anti cancer, cytotoxic, antidiabetic and adaptogenic activities

CHAPTER 6: Pharmacovigilance for herbal drugs 04 hrs (08 marks)

- WHO Guidelines on safety monitoring of herbal medicines in pharmacovigilance systems. Safety monitoring of herbal medicines.
- Interaction of herbs with other herbs, food and allopathic drugs (Herb- drug Interaction, Herb-Herb Interaction, Herb- Food Interaction) with suitable examples.

CHAPTER 7: Research Methodology and Scientific writing 5 hrs (10 marks)

- a. Basic concepts of research and fundamentals in research process. Formation of research problem. Analysis of data.
- b. Biomedical literature-searching, reviewing and referencing. Study of information and retrieval methods of natural plants and herbal databases.
- c. Writing protocols, synopsis, dissertations, grants and research paper.

ADVANCED PHARMACOGNOSY AND PHYTOCHEMISTRY (PRACTICALS)

(150 hrs: 6 hrs/week)

Total Hours: 150 (6 hrs/week),	Examination	Max Marks
	Annual	100
	Internal Assessment Exam	30
	Practical record evaluation	20
	Total:	150

1. Herbarium preparation of some medicinal plants.
2. Preparation of extracts and enriched extracts
3. TLC/HPTLC finger printing of Kalmegh and Ashwagandha extracts from different sources/ accessions
4. Phytochemical screening of extracts: Curcuma, Gaduchi and Gymnema .
5. Isolation of:

- Quinine from cinchona/extract
- Glycyrrhizin
- Curcumin
- Piperine
- Hesperidin
- Rutin
- Clove oil
- Eugenol

6. Determination of

- i) Total Phenolic content in plant extract
- ii) Total Alkaloid content in plant extract
- iii) Total Saponin content in plant extract
- iv) Total bitter content in plant extract

7. Evaluation of herbal drugs (*In Vitro* methods) for following activities

- i) Antioxidant(Free radical scavenging, DPPH, Reducing power assay)
- ii) Anti-inflammatory
- iii) Antiuro lithiatic
- iv) Antimitotic
- v) Anti microbial

8. Bioautography of extracts

9. Extraction of volatile oil –clove, eucalyptus

10. Characterization of volatile oil constituents by Gas Chromatography (GC)

11. Column chromatography using silica gel, reverse phase silica gel and sephadex.

12. Isolation of bacterial and fungal endophytes

13. *In vitro* assays- amylase, α glucose-oxidase

14. MTT assay technique for cell lines

(Any other relevant practical exercise based on theoretical aspects)

TEACHING AND LEARNING ACTIVITIES

Journal Club:

Each student is required to present any two recent articles relevant to the Advanced Pharmacognosy and Phytochemistry from any of the journals in a year.

Seminars:

Each student is required to give two seminars relevant to the subject in a year.

Field/ Industrial Visits:

It is desirable to make to one visit to the relevant Laboratory / Industry in a year.

Conference / Meetings:

Each student has to be encouraged to attend at least one relevant national conference.

Scheme of Practical Examination

S.No	Synopsis	Major experiment	Minor experiment	Viva voce	Total
01	20	35	25	20	100

REFERENCE BOOKS

- 1) Trease and Evans Pharmacognosy by W C Evans, 15th edition W.B Saunders Edinburgh New York
- 2) Text Book of Pharmacognosy and Phytochemistry by Biren shah and A K Seth, Elsevier 2010.
- 3) Natural products: A lab guide by Raphael Ikan 2nd edition Academic Press 1991
- 4) Pharmacology and Pharmco biotechnology by Ashutosh Khar New Age International (P) Publisher 2003
- 5) Pharmacognosy and Phytochemistry of medicinal plants by Jean Brunton, Technique and documentation-Lavoiser, 1995.
- 6) Text book of Pharmacognosy by C. K. Kokate, Purohit, Gokhale 4th edition, Nirali Prakashan, 2010.
- 7) Extraction Technologies for Medicinal and Aromatic Plants by Sukhdev Swami Handa, Suman Preet Singh Khanuja, Gennaro Longo, Dev Dutt Rakesh International Centre for Science and High Technology Trieste, 2008
- 8) Drug Discovery and Development, Traditional Medicinal and Ethano pharmacology, by Bhushan Patwardhan, NIPA (New India publishing agency). 2007.
- 9) The Process of New Drug Discovery and Development 2nd Edition Edited by Charles G. Smith James T. O'Donnell. Informa Healthcare USA 2006
- 10) Medicinal natural products (a biosynthetic approach), 1st edition, by Paul M. Dewick, John Wiley & Sons Ltd, England, 1998.
- 11) Phytochemical methods-A guide to modern techniques of plant analysis by J B Harborne, 3rd Edn. Springer, 2005.

- 12) Natural Products from Plants, 1st edition, by Peter B.Kaufman,CRC press, New York,1998
- 13) Glimpses of Indian Ethano Pharmacology by P. Pushpangadam, Ulf Nyman, V George Tropical Botanic Garden & Research Institute, 1995
- 14) General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine WHO/EDM/TRM/2000.1
- 15) WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems WHO 2004
- 16) Biomedical Research by Dr. G. Jagadeesh, Wolters Publisher 2009.
- 17) Chemistry of Natural Products by S V Bhat, B A Nagasampagi, M Shiv kumar; Narsa publishing House, Delhi.
- 18) Bioactive marine natural products by Bhakuni and Rawat, Anmaya publishers, New Delhi. 2005.
- 19) Microbial Endophytes, Charles W. Bacon, James Francis White, CRC Press, 2000
- 20) Microbial Root Endophytes, Barbara J. E. Schulz, Christine J. C. Boyle, Thomas N. Sieber, Springer, 2006

Web articles from scientific journals

Journals:

- 1) Phytochemistry
- 2) Planta Medica
- 3) Pharmaceutical Biology
- 4) Journal of Ethanopharmacology

Paper-III
INDUSTRIAL PHARMACOGNOSY (THEORY)
(50 hrs: 2 hrs/week)

Goal: To make students understand the technological aspects herbal based preparations and their commercial potential.

Objectives: By the end of the course the student shall be able to

- Isolate and estimate various secondary metabolites from natural source.
- Develop skills for the quality control of herbal raw materials and formulations.

- Understand Intellectual property rights and regulatory affairs for herbal products.

Course description

Total Hours: 50 (2 hrs/week),	Examination	Max Marks
	Annual	100
	Internal Assessment Exam	30
	Seminar Evaluation	20
	Total	150

Chapter 1: Herbal Drug Industries

06 hrs (12 marks)

- Introduction to Herbal Drug Industries their scope and applications. Study of infrastructure for different types of industries involved in making standardized extracts and various dosage forms including traditional Ayurvedic and modern dosage forms.
- Quality assurance in herbal drug industry. Concept of GMP, GLP and HACCP
- Drug Regulatory Aspects– Indian drug regulatory authorities, Central and State regulatory bodies. General regulatory requirements under USFDA
- Drugs and Cosmetics Act and Rules with latest Amendments. Special emphasis – Schedule M and Y and various licenses.

CHAPTER 2: Isolation and estimation of phytopharmaceuticals

10 hrs (20 marks)

Different methods for isolation and estimation of phytoconstituents from the following drugs (with special emphasis on HPLC & HPTLC)

- *Adhatoda vasica*-vasicine
- *Andrographis paniculata*-andrographolides
- *Coleus forskoli*-forskolin
- *Commiphora mukul*- guggulsterone
- *Curcuma longa*-curcumin
- *Glycyrrhiza glabra*- glycyrrhizin
- *Gymnema sylvestre*-gymnemic acid
- *Piper nigrum/longum*-piperine
- *Tinospora cordifolia*- cordifoliocide

- *Withania somnifera*-withanolides

CHAPTER 3: Characterization of phytoconstituents

07 hrs (14 marks)

- General methods for identification and characterization of following class of compounds
 - Alkaloids
 - Glycosides
 - Flavonoids
 - Steroids and Terpenoids
- Applications of UV, IR, NMR, ¹HNMR, ¹³CNMR and Mass spectroscopy for structural elucidation of phytoconstituents.
- Structural elucidation of following class of phytoconstituents
 - Alkaloids- vasicine, caffeine, taxol
 - Flavonoids- quercetin, rutin
 - Steroids and Tri terpenoids – lupeol, β-sitosterol.

CHAPTER 4: Quality control of herbal drugs (crude drugs, extracts and formulations).

8 hrs (16 marks)

- Quality control methods for medicinal plant materials. Evaluation and standardization of herbal drugs according to WHO guidelines.
- Standardization requirements of herbal medicines and traditional preparations: their quality, safety and efficacy assessment. Quality control of single and multicomponent classical Ayurvedic and Unani formulations by study of HPTLC and HPLC fingerprints.
- Role of marker compounds for analysis of drugs (specified in chapter 2), finger printing, phytoequivalence studies in herbal drug standardization
- Importance of monographs of medicinal plants, their comparative study as per- Indian Pharmacopoeia, Indian Herbal Pharmacopoeia, API, Ayurvedic formulary of India, Chinese Pharmacopoeia, United States Pharmacopoeia, British Herbal Pharmacopoeia, European Pharmacopoeia, American Herbal Pharmacopoeia.

CHAPTER 5: Intellectual property rights and regulatory affairs

07 hrs (14 marks)

- Indian and international patents laws and procedures. Latest Indian patent guidelines for herbal drugs. Patent processing and application, copyright and trademarks
- Regulating authorities in India
- Biological diversity act 2002, rules 2004, geographical indications, bioprospecting and biopiracy

- Objectives and guidelines of USFDA, WHO and ICH for herbal drugs, AYUSH guidelines for herbal drugs, Food safety Act 2006, rules 2011.
- Plant breeder's and Farmer's rights.

CHAPTER 6: Herbal Formulations 07 hrs (14 marks)

- Study of traditional formulations as per Ayurvedic formulary of India.
- Shelf life study- protocols to study stabilization of herbal based products. Assessment of physical, physico-chemical and chemical parameters at different stages
- Novel drug delivery systems for plant actives and extracts and their applications.
- Nanotechnology in natural product research-Introduction to nanotechnology, applications, types of nano formulations. Preparation and characterization of nano formulations for plant secondary metabolites.

CHAPTER 7: Herbal Cosmetics 05 hrs (10 marks)

- Raw materials of herbal origin and their uses in cosmetics: oil, waxes, gums, colors, perfumes, protective agents, bleaching agents, preservatives, antioxidants and other ancillary agents.
- Formulation and standardization of herbal cosmetics like skin care preparations, deodorants, anti perspirants and hair care preparations.
- Regulatory aspects of safety as per BIS standards (Bureau of Indian Standards)

INDUSTRIAL PHARMACOGNOSY (PRACTICALS)

(150 hrs: 6 hrs/week)

Total Hours: 150 (2 hr/week),	Examination	Max Marks
	Annual	100
	Internal Assessment Exam	30
	Practical record evaluation	20
	Total:	150

1. Monograph analysis of crude drugs : Ashwagandha, Vasaka, Kalmegh
2. Preparation of monograph of any one plant.
3. Determination of extractive values
4. Determination of ash values

5. Determination of moisture content by two different methods.
 6. Estimation of marker compounds by HPLC/ HPTLC: Andrographolide, berberine and piperine.
 7. Spectral analysis (UV, IR, ^1H , ^{13}C NMR and Mass) of phytoconstituents: caffeine, vasicine.
 8. Preparation of Herbal formulations and herbal cosmetics.
 9. Standardization of marketed herbal formulations using physical, chemical and chromatographic methods.
 10. Determination of alcohol content in *Asava* and *Arista* preparations.
 11. Determination of total microbial content in drugs and formulations
 12. Separation and identification of aflotoxins in Crude drugs.
 13. Preparation and evaluation of phytosomes.
 14. Estimation of isolated compounds by
 - a) Spectroscopic methods- berberine, curcumin, caffeine
 - b) HPLC/ HPTLC methods – gallic acid, reserpine, rutin,
- (Any other relevant practical exercise based on theoretical aspects)**

TEACHING AND LEARNING ACTIVITIES

Journal Club:

Each student is required to present any two recent articles relevant to the Industrial Pharmacognosy from any of the journals in a year.

Seminars:

Each student is required to give two seminars relevant to the subject in a year.

Field/ Industrial Visits:

It is desirable to make one visit to the relevant Laboratory / Industry in a year.

Conference / Meetings:

Each student has to be encouraged to attend at least one relevant national conference.

Scheme of Practical Examination

S.No	Synopsis	Major experiment	Minor experiment	Viva voce	Total
01	20	35	25	20	100

REFERENCE BOOKS

1. Herbal Drug Industry by R.D. Choudhary, 1st edition, Eastern Publisher, New Delhi, 1996
2. Herbal Drug Technology by S.S Agarwal and M Paridhavi, 2nd edition ,Univdersities Press 2007
3. Quality Control of Herbal Drugs by Pulok K. Mukherjee,1st edition, Business Horizons Pharmaceutical Publisher, New Delhi, 2005
4. Trease and Evans Pharmacognosy by W C Evans, 15th edition W.B Saunders Edinburgh NewYork.
5. Controlled and novel drug delivery systems by N K Jain, CBS publishers, New Delhi, 2009.
6. Introduction to novel drug delivery systems By N K Jain, Ist Edn. Vallabh publishers, 2010.
7. Targeted and controlled drug delivery novel carrier systems by S P Vyas, R K Khar, Ist Edn. CBS publishers, New Delhi, 2010.
8. IPRS and Pharmaceuticals by Abhinav Agarwal Ist Edn. Vallabh publishers, 2011.
9. WTO concept: Challenges and global developments by N K Jain, Regal publishers New Delhi, 2008.
10. Guidelines for the Assessment of herbal medicines-WHO Report, Geneva, 1991,
11. WHO guidelines for assessing quality of herbal medicines with reference to contaminants and residues. World Health Organization 2007
12. WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems WHO 2004
13. Quality Control Methods for Medicinal Plant material, WHO Updated edition 1998
14. WHO monographs of selected herbs.WHO 1999
15. Indian Herbal Pharmacopoeia, Vol.1&2,RRL, IDMA,1998,2000
16. Indian Pharmacopieia 2010
17. USP
18. Ayurvedic Formulary
19. Standardization of Botanicals by V. Rajpal, Vol.1 Eastern publishers, New Delhi,2002
20. The Handbook of Clinically Tested Herbal Remedies *Volume I* Marilyn Barrett, PhD The Haworth Press 2004
21. Evaluation of herbal Medicinal Products, Peter J Houghton and Mukherjee PK 2008, Pharmaceutical Press, UK

22. PDR of Herbal Medicines , 2nd edition, Medicinal Economic Company, New Jersey, 2000
23. Botanicals, A Phytocosmetic Desk Ref by Frank S D Amelio Sr CRC Press, 1999.
24. Harry's cosmeticology by J B Wilkinsson.
25. Poucher's perfumes, cosmetics and soaps by W A Poucher.

Web articles from scientific journals

JOURNALS:

1. Indian Journal of Natural Products
2. Phytochemistry
3. Fitoterapia
4. International journal of Pharmaceutics
5. Phytomedicine
6. Web articles

Paper-IV **MEDICINAL PLANT CULTIVATION AND BIOTECHNOLOGY** **(THEORY)**

(50 Hrs: 2 Hrs/week)

Goal: To impart acquaint students about commerce and trade of medicinal and aromatic plants and biotechnological aspects of natural product research.

Objectives: By the end of the course the student shall be able to

- Obtain knowledge on the production and management of medicinal and aromatic plants.
- Understand genetics and biotechnology with reference to plants
- Understand the biotechnology techniques involved in herbal drug research

Course description

Total Hours: 50 (2 hr/week),	Examination	Max Marks
	Annual	100
	Internal Assessment Exam	30

	Seminar Evaluation	20
	Total:	150

CHAPTER 1: Production and management of commercially useful plants

10 hrs (20 Marks)

- Commerce and production of crude drugs; Technology for commercial scale cultivation of medicinal and aromatic plants; General understanding of good agricultural and collection practices (GACP).
- National and international trade in medicinal and aromatic plants. Export potential of phytopharmaceuticals.
- Disease management of medicinal and aromatic plants. Weed and pest control. Study of natural pesticides.
- Profile for commercial cultivation technology and post harvest care of following medicinal and aromatic plants - Ashwagandha, Guggul, Senna, Isapgol, Piper, Lemon Grass, Amla, Ginkgo.
- *In situ* conservation of medicinal plants. Mutation breeding.

CHAPTER 2: Plant Tissue culture

10 hrs (20 marks)

- Principal, techniques and applications of tissue culture: organogenesis, embryogenesis, haploid culture, endosperm culture, nucellus culture, ovary and embryo culture, floral bud culture, shoot primordial, stem and root culture, protoplast isolation, fusion and somatic hybridization.
- Suspension Culture; Production of secondary metabolites by various techniques. Strategies involving culture conditions, elicitors, precursors, biotransformation, immobilization and hairy root cultures for enhancement of secondary metabolites in tissue culture. Production of shikonin. Hairy root culture and their applications. Advances in plant stem cell research
- Bioreactors for pilot and large scale cultures of plant cells. Immobilization techniques. Immobilized plant cell culture systems and their applications

CHAPTER 3: Germplasm Storage and Cryopreservation

05 hrs (marks)

- Importance of *in-vitro* conservation and cryopreservation. Medium term conservation by slow growth. Long term conservation by cryopreservation. Organ, tissue and meristem culture for conservation of somaclonal and gametoclonal variations.
- Recalcitrant seeds; Conservation of rare germplasms. Cryobanking of plant germplasma

CHAPTER 4: Gene transfer in plants

10 hrs (20 marks)

5. Micropropagation of –Brahmi, *Alpinia galanga* and Vasaka
6. Evaluation of secondary metabolites in micropropagated plants.
7. Development of synthetic seed by immobilization
8. Isolation of enzyme- papain and bromelain
9. Immobilization of cells-yeast
10. Immobilization of enzymes-invertase and catalase
11. Agrobacterium mediated transformation of plant tissue
12. Isolation of protoplast
13. Isolation of DNA and RNA from plant sources
14. Electrophoresis
15. Estimation of DNA and RNA
16. Determination of mitotic index on onion shoot tip.

(Any other relevant practical exercise based on theoretical aspects)

TEACHING AND LEARNING ACTIVITIES

Journal Club:

Each student is required to present any two recent articles relevant to the Biotechnology of Natural Products from any of the journals in a year.

Seminars:

Each student is required to give two seminars relevant to the subject in a year.

Field/ Industrial Visits:

It is desirable to make to one visit to the relevant Laboratory / Industry in a year.

Conference / Meetings:

Each student has to be encouraged to attend at least one relevant national conference.

Scheme of Practical Examination

S.No	Synopsis	Major experiment	Minor experiment	Viva voce	Total
01	20	35	25	20	100

REFERENCE BOOKS:

1. Cultivation and Utilization of Medicinal and Aromatic plants by Farooqui A.A, Sreeramu B.S. University Press 2001
2. Cultivation of medicinal and aromatic crops, 1st edition, by S.N by Yoganarsimhan, Interline Publishing Pvt. Ltd., 2000

3. Pharmaceutical biotechnology S.P. Vyas and V.K. Dixit CBS Publishers and distributors, 2001.
4. Medicinal Plant Biotechnology by Veeresham CBS publication 2008
5. Plant propagation by tissue culture by Edwin F. George, Michael A. Hall and Geert-Jan De Klerk Springer 2008
6. Role of Biotechnology in Medicinal and Aromatic Plants Vol. I & II by Irfan A Khan and Atiya Khanum, Ukaoz Publications. 1998
7. Plant Chromosome analysis, manipulation and engineering by Arun and Archana Sharma 1st Edition Harwood Academic Publishers 1999
8. Staba, E.J., Applied and Fundamental Aspect and Plant Cell, Tissue and organ culture (Reivert J. and Y.P.S. Bajaj Ed.), Berlin.
9. Plant Tissue Culture and its Biotechnological Application by Tabata, M., Springer, Berlin.
10. Plant Biotechnology and Transgenic Plants (CRC Press) By Oksman-Caldente
11. Transgenic Plants By R Ranjan Agarobotanica.1999.
12. Pharmacognosy and Pharmacobiotechnology by Ashutosh Khar New Age International Publishers 2003
13. Herbal Drug Technology SS Agarwal and M Paridhavi Univdersities Press 2007
14. Introduction to Plant Tissue culture, Razdan, M.K., Oxford & IBH Publishing Co. Pvt. Ltd., New Delhi.
15. A text book of pharmaceutical biotechnology, C K Kokate, Sunil Jalalpure, and Pramod Harakadle, Elsevier publications 2012.
16. Enzyme Technology (Springer) edited by Ashok Pandey, Colin Webb, Carlos Ricardo Soccol, Christian Larroch
17. A Practical Guide to Assay Development and High-Throughput Screening in Drug (CRC) By Taosheng Chen

Web articles from scientific journals

JOURNALS:

1. Journal of plant biochemistry and biotechnology
2. Current Science

ONE DAY PRE–WORKSHOP

ON

**Revision of syllabus and Curriculum Content of
M. Pharm (Pharmacy Practice)**

**Hosted by Sri Adi Chunchanagiri College of Pharmacy
B.G Nagara, Karnataka – 571448**

**In Association with Rajiv Gandhi University of Health
Sciences, Karnataka
Bangalore – 560027**

09/03/2013

A Report Submitted To

**Rajiv Gandhi University of Health Sciences,
Bangalore**

**Dr. B Ramesh
Chairman, BOS PG Pharmacy, RGUHS**

PAPER I. CLINICAL PHARMACY PRACTICE

GOALS:

1. To develop skills to provide clinical pharmacy services
2. To gain knowledge in conduct of clinical research
3. To train the students in comprehensive patient care management

OBJECTIVES:

Upon completion of the course, it is expected that students will be able to:

1. Understand and perform the daily activities of clinical pharmacist
2. Identify relevant tests for specific disease states and interpretation of selected laboratory results (as monitoring parameters in therapeutics)
3. Identify appropriate sources of drug/poison information in answering the clinical queries.
4. Efficiently retrieve relevant and current literature and evaluate them (i.e. use databases)
5. Describe the theoretical basis for TDM services and other applications of Pharmacokinetics
6. Give appropriate recommendations for clinical dosing of specific drugs
7. Understand the conduct of clinical trials and use of statistical tests

SCHEME OF EXAMINATION:

THEORY

MAXIMUM MARKS: 150

i. INTERNAL ASSESSMENT

MAX MARKS: 50

- Written exam:----- 30 marks
- Seminar:----- 20 marks

ii. ANNUAL EXAMINATION:

MAX MARKS: 100

PRACTICAL:

MAXIMUM MARKS: 150

i. INTERNAL ASSESSMENT:

MAX MARKS: 50

- Practical exam:----- 30 marks
- Record:----- 20 marks

ii. ANNUAL EXAMINATION:

MAX MARKS: 100

- Synopsis:----- 15 marks
- Lab Data Evaluation:----- 40 marks
- Answering Drug Information Queries/Assessment of ADRs:---- 30 marks
- Viva:----- 15 marks

COURSE DESCRIPTION

THEORY

75 Hours (3 Hrs/wk)

- 1. Definition, Development and Scope of Clinical Pharmacy** **1 Hour**
- 2. Introduction to daily activities of a clinical pharmacist – Roles & Responsibilities** **6 Hours**
 - Drug therapy monitoring (medication chart review, clinical review, clinical pharmacist interventions)
 - Ward round participation
 - Medication history
 - Pharmaceutical care
- 3. Drug & Poison information** **10 Hours**
 - Introduction to drug information resources available
 - Systemic approach in answering DI queries
 - Critical evaluation of drug information and literature
 - Preparation of written and verbal reports
 - Establishing a Drug Information Centre
 - Poison information – organization & information resources
- 4. Pharmacovigilance** **10 Hours**
 - Basics of Adverse Drug Reactions(ADRs): Definition, Types and Risk Factors
 - Assessment of ADRs (Causality, Preventability, Predictability, Severity)
 - Spontaneous Reporting System
 - National Pharmacovigilance Programme of India: Structure, Operational Modality and functions.
- 5. Drug Utilization Evaluation (DUE) and Drug Utilization Review (DUR) – Definition and Cycle** **2 Hours**
- 6. Patient data analysis**
 - The patient's case history, its structure and use in evaluation of drug therapy & understanding common medical abbreviations and terminologies used in clinical practice **2 Hours**
 - Clinical laboratory tests used in the evaluation of disease states and interpretation of test results **12 Hours**
 - Haematological examination, Liver function tests, Renal function tests, Thyroid function tests
 - Pulmonary function tests
 - Tests associated with cardiac disorders
 - Fluid and electrolytic balance
 - Microbiological culture sensitivity tests
- 7. Clinical Pharmacokinetics and its Applications** **16 Hours**
 - Pharmacokinetic models
 - Compartment, Non-compartment and Physiological models
 - One and two compartment models – Oral and I V.

- Pharmacokinetic parameters like K_a , K_e , $t_{1/2}$, AUC, t_{max}
- Volume of distribution and Clearance– Renal & Non-renal
- Bioavailability and Bioequivalence studies — Design and conduct
- Multiple dosing — I V and oral-steady state
- Calculation of loading and maintenance doses
- Dose adjustment in renal failure, hepatic dysfunction, geriatric and paediatric patients
- Therapeutic Drug Monitoring (General aspects)

8. Clinical Applications of Statistical Analysis

6 Hours

- Parametric & Non-parametric tests
- Sample size calculation
- Tests of significance-chi square test, t-test and ANOVA
- Use of excel spreadsheet for data entry, execution of statistical tests and graphical presentation of results

9. Research Design & Conduct of Clinical Trials

10 Hours

- Good Clinical Practice guidelines (ICH & CDSCO)
 - Historical perspectives
 - Roles and responsibilities of sponsor, investigator and ethics committee
- Indian Clinical trial legislation (Schedule Y of Drugs and Cosmetics Act 1940 and Rules 1945)
- Quality Control and Assurance in Clinical Trials (Monitoring, Auditing, Inspections).

PRACTICALS

150 Hours (6 Hrs/wk)

Patient medication history interview, answering drug information questions, patient counseling, participation in ward rounds: General Medicine Department compulsory and minimum of three of the other departments viz. Paediatrics, Dermatology, OBG, Surgery and others.

1. Answering drug information queries (4)

(Queries related to Dosage, administration, Contraindications, Adverse drug reactions, Drug Interactions, drug use in pregnancy and lactation, Paediatrics and geriatrics, drug profile, efficacy and safety)

2. Case studies related to laboratory investigations (4)

3. Patient medication chart review and history interview (2)

4. Detection and assessment of adverse drug reactions and their documentation (3)

ASSIGNMENTS

Each student must submit any three of the following assignments:

1. Problem solving in Clinical Pharmacokinetics.
2. Literature evaluation pertaining to therapeutic range used in therapeutic monitoring of any two drugs frequently subjected for TDM.
3. Critical appraisal of two recently published articles in the biomedical literature, which deals with a drug or therapeutic issue.
4. Use of excel spreadsheets for data entry (Dummy) calculation and graphs.
5. Preparation of informed consent form for a study.

REFERENCES:

1. Basic skills in interpreting laboratory data – Scott LT, American Society of Health System Pharmacists Inc.
2. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.1997
3. Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
4. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall Publication
5. Relevant review articles from recent medical and pharmaceutical literature.
6. A Textbook of Clinical Pharmacy Practice - G. Parthasarathi, Karin Nyfort-Hansen, Milap C Nahata. Universities Press India Ltd.
7. Clinical Guidelines: Diagnosis & treatment Manual - MSF

JOURNALS:

1. Pharmaceutical Journal, Royal Pharmaceutical Society, London
2. Journal of Pharmacy Practice and Research, Society of Hospital Pharmacists of Australia
3. International Journal of Pharmacy Practice, United Kingdom
4. Hospital Pharmacist, UK
5. Indian Journal of Hospital Pharmacy
6. Indian Journal of Pharmacy Practice

PAPER II. PHARMACOTHERAPEUTICS - I

GOALS:

1. To train the students in drug therapy management of different diseases
2. To develop skills in students to identify and resolve any drug related problems
3. To appreciate the quality use of medicines and to follow evidence based medicine.

OBJECTIVES:

Upon completion of the course, it is expected that students will be able to:

1. Describe the pathophysiology of selected disease states and explain the rationale for drug therapy.
2. Summarize the therapeutic approach to management of these diseases including reference to the latest available evidence.
3. Use standard clinical guidelines as part of evidence based medicine.
4. Discuss the preparation of individualized therapeutic plans.
5. Identify the patient-specific parameters relevant in initiating drug therapy and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse outcomes)

SCHEME OF EXAMINATION:

THEORY

MAXIMUM MARKS: 150

i. INTERNAL ASSESSMENT

MAX MARKS: 50

- Written exam:----- 30 marks
- Seminar:----- 20 marks

ii. ANNUAL EXAMINATION:

MAX MARKS: 100

PRACTICAL:

MAXIMUM MARKS: 150

i. INTERNAL ASSESSMENT:

MAX MARKS: 50

- Practical exam:----- 30 marks
- Record:----- 20 marks

ii. ANNUAL EXAMINATION:

MAX MARKS: 100

- Synopsis:----- 15 marks
- Major case:----- 40 marks
- Minor case:----- 30 marks
- Viva:----- 15 marks

COURSE DESCRIPTION

THEORY

50 Hours (2Hrs/wk)

1. Pathophysiology and pharmacotherapy of diseases associated with following systems/diseases.

1.1 Cardiovascular system 10 Hours

- Hypertension, Congestive cardiac failure, Ischemic heart disease, Myocardial infarction, Arrhythmias, Hyperlipidaemias [2+2+2+2+1+1]

1.2 Respiratory system 5 Hours

- Asthma, Chronic obstructive airway disease, Drug induced pulmonary diseases [2+2+1]

1.3 Haematological diseases 3 Hours

- Anaemia, Deep vein thrombosis, Drug induced haematological disorders [1.5+1+0.5]

1.4 Rheumatic diseases 5 Hours

- Rheumatoid arthritis, Osteoarthritis, Gout, Systemic lupus erythematosus [2+1+1+1]

1.5 Gastrointestinal system 8 Hours

- Peptic ulcer disease, Reflux oesophagitis, Inflammatory bowel diseases, Hepatitis, Jaundice & Cirrhosis, Diarrhoea and constipation, Drug-induced liver diseases [2+1+1+2+1+2+1]

1.6 Skin and sexually transmitted diseases 4 Hours

- Psoriasis, Eczema and scabies, Syphilis and Gonorrhoea, Drug related skin reactions [1+0.5+1+1.5]

1.7 Pain management 4 Hours

- Pain pathways, Analgesics and NSAIDs, Neuralgias including post herpetic, trigeminal and glossopharyngeal neuralgia, Palliative care [0.5+1+1+0.5+1]

1.8 Immunology 3 Hours

- Autoimmunity – Definition, Classification, Mechanism of Autoimmune disease, Pathogenesis of autoimmunity, Immunoglobulins [2+1]

2. General Prescribing guidelines for 3 Hours

2.1 Paediatric patients

2.2 Geriatric patients

2.3 Pregnancy and breast feeding [1+1+1]

3. Introduction to rational drug use 5 Hours

3.1. Definition and scope

3.2. Irrational drug use and its impact, factors responsible for irrational drug use and strategies to improve rational drug use

3.3. Concept of essential drug list

3.4. Evidence based medicine

PRACTICALS

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow-up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 10 cases should be presented and recorded covering most common diseases. The list of clinical cases should include follow-up of the clinical cases mentioned below from the day of admission till discharge. The same cases should be entered in the practical records following SOAP [Subjective, Objective, Assessment, Plan] format for cases in clinical pharmacy setting and FARM [Findings, Assessment, Resolution, Monitoring] format for cases in community pharmacy settings which involve treating patients with non-prescription drugs in minor ailments.

1. Hypertension
2. Heart failure
3. Myocardial infraction
4. Coronary heart disease
5. Asthma
6. Chronic obstructive pulmonary disease
7. Anaemia
8. Osteoarthritis
9. Rheumatoid arthritis
10. Gout
11. Peptic ulcer
12. Gastro oesophageal reflux disease
13. Hyperlipidaemia
14. Neuralgias
15. Psoriasis
16. Hepatitis

ASSIGNMENTS

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500-2000 words] should be submitted for evaluation.

MODEL ASSIGNMENTS

1. Management of idiopathic thrombolytic purpura
2. Therapy of Helicobacter pylori infection
3. Role of oral corticosteroids in chronic obstructive pulmonary disease

TEXT BOOKS:

1. Clinical Pharmacy and therapeutics – Roger and Walker, Churchill Livingstone publication.
2. Pharmacotherapy: A Pathophysiologic approach – Joseph T. Dipiro et al. Appleton & Lange.

REFERENCE BOOKS:

1. Pathologic basis of disease – Robins SL, W.B Saunders publication.
2. Pathology and therapeutics for Pharmacist: A basis for clinical pharmacy practice – Green and Harris, Chapman and Hall publication.
3. Clinical pharmacy and therapeutics – Eric T Herfindal, Williams and Wilkins and Wilkins Publication.
4. Applied therapeutics: the clinical use of drugs. Lloyd Young and koda-kimble MA [ISBN 0-33365881-7].
5. Avery's drug treatment, 4th edn, Adis International Limited.
6. Relevant review articles from recent medical and pharmaceutical literature.
7. Harrison's Principles of Internal Medicine — Dan L. Longo, Anthony S. Fauci, Dennis L. Kasper, Stephen L. Hauser, J. Larry Jameson, Joseph Loscalzo, Eds., McGraw Hill Publication.

JOURNALS:

1. British Medical Journal
2. Annals of Pharmacotherapy
3. New England Journal of Medicine
4. Lancet
5. Indian Journal of Medical Research

PAPER III. PHARMACOTHERAPEUTICS-II

GOALS:

1. To train the students in drug therapy management of different diseases
2. To develop skills in students to identify and resolve any drug related problems
3. To appreciate the quality use of medicines and to follow evidence based medicine.

OBJECTIVES:

Upon completion of the course, it is expected that students will be able to:

1. Describe the pathophysiology of selected disease states and explain the rationale for drug therapy.
2. Summarize the therapeutic approach to management of these diseases including reference to the latest available evidence.
3. Use standard clinical guidelines as part of evidence based medicine.
4. Discuss the preparation of individualized therapeutic plans.
5. Identify the patient-specific parameters relevant in initiating drug therapy and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse outcomes).

SCHEME OF EXAMINATION:

THEORY

MAXIMUM MARKS: 150

iii. INTERNAL ASSESSMENT

MAX MARKS: 50

- Written exam:----- 30 marks
- Seminar:----- 20 marks

iv. ANNUAL EXAMINATION:

MAX MARKS: 100

PRACTICAL:

MAXIMUM MARKS: 150

iii. INTERNAL ASSESSMENT:

MAX MARKS: 50

- Practical exam:----- 30 marks
- Record:----- 20 marks

iv. ANNUAL EXAMINATION:

MAX MARKS: 100

- Synopsis:----- 15 marks
- Major case:----- 40 marks
- Minor case:----- 30 marks
- Viva:----- 15 marks

COURSE DESCRIPTION

THEORY:

50 Hours (2 Hrs/wk)

Pathophysiology and pharmacotherapy of disease associated with following systems/diseases

1.1 Renal system

4 Hours

- Acute renal failure, Chronic renal failure, Renal dialysis and transplantation, Drug induced renal diseases.

[1+1+1+1]

1.2 Endocrine system

6 Hours

- Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis.

[2+1+1+1]

1.3 Nervous system

7 Hours

- Epilepsy, Parkinson's disease, Stroke and Transient ischemic attacks, Headache.

[2+1+1+2]

1.4 Psychiatric disorders

5 Hours

- Schizophrenia, Depression, Anxiety & Sleep disorders. Drug induced psychosis.

[1+2+1+1]

1.5 Ophthalmology

1 Hour

- Glaucoma, Eye infections

1.6 Infectious diseases

22 Hours

- General guidelines for the rational use of antibiotics. Meningitis, Respiratory tract infections, Gastroenteritis, Bacterial endocarditis, Septicaemia, Otitis media, Urinary tract infections, Tuberculosis, Leprosy, Malaria, Helmentiasis, HIV and opportunistic infections, Fungal infections, Rheumatic fever.

[1+1+3+1+1+1+1+2+2+1+2+1+3+1+1]

1.7 Oncology

5 Hours

- General principles of cancer chemotherapy, Commonly used cytotoxic drugs, Chemotherapy of lung cancer, haematological malignancies, Management of nausea and vomiting

[1+1+1+1+1]

PRACTICALS

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow-up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 10 cases should be presented and recorded covering most common diseases. The list of clinical cases should include follow-up of the clinical cases mentioned below from the day of admission till discharge. The same cases should be entered in the practical records following SOAP [Subjective, Objective, Assessment, Plan] format for cases in clinical pharmacy setting and FARM [Findings, Assessment, Resolution, Monitoring] format for cases in community pharmacy settings which involve treating patients with non-prescription drugs in minor ailments.

1. Type 1 Diabetes mellitus
2. Type 2 Diabetes mellitus
3. Hypothyroidism
4. Hyperthyroidism
5. Acute renal failure
6. Chronic renal failure
7. Schizophrenia
8. Depression
9. Anxiety
10. Epilepsy
11. Parkinson's disease
12. Stroke
13. Infectious diseases [any five].

ASSIGNMENTS

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments (1500-2000 words) should be submitted for evaluation.

MODEL FOR ASSIGNMENTS

1. Management of Multidrug resistant tuberculosis
2. Use of antiplatelet in the secondary prevention of stroke
3. Secondary failure to oral hypoglycaemic agents and its management

TEXT BOOKS:

1. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication
2. Pharmacotherapy : A Pathophysiological approach – Joseph T. Dipiro et al. Appleton& Lange

REFERENCE BOOKS:

1. Pathologic basis of disease – Robins SL, W.B Saunders publication.
2. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice – Green and Harris, Chapman and Hall publication.
3. Clinical Pharmacy and Therapeutics-Eric T. Herfindal, Williams and Wilkins Publication.
4. Applied Therapeutics: The clinical use of drugs. Lloyd Young and Koda – Kimble MA (ISBN 0-333-65881-7).
5. Avery's drug treatment, 4th edn, 1997, Adis International Limited.
6. Relevant review articles from recent medical and pharmaceutical literature.
7. Harrison's Principles of Internal Medicine, —Dan L. Longo, Anthony S. Fauci, Dennis L. Kasper, Stephen L. Hauser, J. Larry Jameson, Joseph Loscalzo, Eds., McGraw Hill Publication.

JOURNALS:

1. British Medical Journal
2. Annals of Pharmacotherapy
3. New England Journal of Medicine
4. Lancet
5. Indian Journal of Medical Research

PAPER IV. HOSPITAL & COMMUNITY PHARMACY

GOALS:

1. To train the students in the management of hospital and community pharmacy services.
2. To train the students to conduct pharmacoepidemiological and pharmacoeconomic studies.

OBJECTIVES:

Upon completion of the course, it is expected that students will be able to:

1. Manage drug distribution system in the hospital setup
2. Develop skills in maintaining community pharmacy
3. Participate in health screening services
4. Participate in the pharmacoepidemiological and pharmacoeconomic studies

SCHEME OF EXAMINATION:

THEORY

MAXIMUM MARKS: 150

i. INTERNAL ASSESSMENT

MAX MARKS: 50

- Written exam:----- 30 marks
- Seminar:----- 20 marks

ii. ANNUAL EXAMINATION:

MAX MARKS: 100

PRACTICAL:

MAXIMUM MARKS: 150

i. INTERNAL ASSESSMENT:

MAX MARKS: 50

- Practical exam:----- 30 marks
- Record:----- 20 marks

ii. ANNUAL EXAMINATION:

MAX MARKS: 100

- Synopsis:----- 15 marks
- Major case (Inventory control)----- 40 marks
- Minor case (Patient counseling):----- 30 marks
- Viva:----- 15 marks

COURSE DESCRIPTION

THOERY:

50 Hours (2 Hrs/wk)

A. HOSPITAL PHARMACY

1. Professional Role of Hospital Pharmacist

1 Hour

The role of the hospital pharmacy department and its relationship with other hospital departments and staff.

2. Hospital drug policy

3 Hours

- Drugs & Therapeutics Committee, Formulary and guidelines, Other hospital committees such as Infection Control Committee and Research and Ethics Committee.

3. Hospital pharmacy management

5 Hours

- Organization of Hospital Pharmacy: Staff (professional and non-professional), materials (drugs, non-drug consumables), financial (drug budget, cost centers, source of revenue, revenue collection), infrastructure requirements (building, furniture and fittings, specialized equipment, maintenance and repairs).

4. Drug Supply Chain Management

7 Hours

- Purchasing (Vendor selection), warehousing (storage conditions, expiry date control, recycling of drugs, stock taking, drug recalls), Inventory control principles and methods, Drug distribution methods (ward stock, individual patients dispensing, unit dose), specific requirements for in-patients, out-patients, casualty/emergency, operation theatres, ICU/CCU, Management of controlled drugs, Hospital waste management.

5. Hospital Pharmacy Preparations

6 Hours

- **Parenterals:** Total parental nutrition, Large volume parenterals, Preparation of IV admixtures, Cytotoxic drugs
- **Non-Parenterals:** Oral solid dosage forms, oral liquid dosage forms, topical preparations.
- Radio pharmaceuticals
- Unit doses
- Labeling of preparations
- Quality control

6. Education and training

2 Hours

- Training of technical staff, Training and continuing education for pharmacists, Pharmacy students, Medical staff and students, Nursing staff and students, Formal and informal meetings and lectures, Drugs and therapeutics newsletter, Patient information leaflets- Content, Layout, Design, evaluation and cautionary labels.

B. COMMUNITY PHARMACY

1. Professional Role & Responsibilities of Community Pharmacist	1 Hour
The role of community pharmacy and its relationship with other local health care providers.	
2. Prescribed medication order - Interpretation and legal requirements (Good Prescription and dispensing Practices)	1 Hour
3. Communication skills – communication with prescribers and patients including counseling techniques	2 Hours
4. Over the counter (OTC) medication – Definition, role of pharmacist in dispensing the OTC medicines, drug interactions of OTC drugs.	1 Hour
5. Primary health care in community pharmacy	3 Hours
Family planning, first aid, participation in National Health Programs, (immunization, NRHM programs, DOTS, HAART etc.) smoking cessation, Health Screening Programs.	
6. Services to nursing home/clinics	1 Hour
7. Community pharmacy management	6 Hours
Financial, materials, staff, infrastructure requirements, drug information resources, computers, Schedule in Drugs Control Act, Pharmacy layout, Consumerisation, Softwares used in community pharmacy, Indirect taxes associated with sale of pharmaceuticals (Brief overview of Value Added Tax, Service Tax, Sales Tax), Pharmacy Licensing Procedures (Brief overview of licenses related to Drugs Control Department, Food Safety Authority of India, State Government Excise & Labour Act).	
8. Code of ethics for community pharmacist	1 Hour
9. Pharmacoepidemiology	5 Hours
Definition, scope and study designs	
10. Pharmacoeconomics	3 Hours
Definition and scope, Types of pharmacoeconomic evaluation	
11. Pharmaceutical Care Principles – Good Pharmacy Practice	2 Hours

TEXT BOOKS (LATEST EDITION):

1. Hospital pharmacy – Hassan WE. Lec and Febiger publication
2. Text book of hospital pharmacy – Allwood MC and Blackwell
3. A Textbook of Pharmacy Practice – Dr. B. D. Miglani, K. G. Revikumar. Career Publication

REFERENCES BOOKS (LATEST EDITION):

1. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited
2. Remington Pharmaceutical Sciences
3. Relevant review articles from recent medical and pharmaceutical literature
4. International society for pharmacoepidemiology (<http://www.pharmacoepi.org/>) & International society for pharmacoeconomics and outcomes research (<http://www.ispor.org/>) websites.

JOURNALS:

1. Hospital Pharmacist, U.K.
2. Indian Journal of Hospital Pharmacy
3. Indian Journal of Pharmacy Practice
4. Pharmacoepidemiology and Drug Safety
5. Value in Health

OTHERS:

- www.mohfw.nic.in/

PRACTICALS

1. Patient medication counseling for common diseases like Diabetes, Asthma, Hypertension, Tuberculosis (TB), Chronic Obstructive Pulmonary Disease (COPD), Anemia, Dyslipidemia etc. (8)
2. Inventory control using ABC analysis (3) and VEN analysis. (2)
3. Unit dose preparation and labeling for Pediatrics, Oncology, Cardiology etc. in Hospitals. (2)

ASSIGNMENTS FOR COMMUNITY PHARMACY

1. Critical study of two community pharmacies in the neighborhood for schedule M compliance
2. Comparison of prescription handling in two community pharmacies
3. Audit of OTC sales over a 24 hour period in a local community pharmacy
4. Role of community pharmacists in health education, family planning, first aid, smoking cessation
Health screening programs, immunization, etc.
5. Finance and material management in community pharmacies
6. Critical study of two community pharmacies in large hospitals
7. Code of ethics for community pharmacies

8. Summary of the advice and recommendations which should be provided to the following customers at a community pharmacy.
 - A 57 year old woman who requests a cough mixture. She has no other associated symptoms, and is being treated for diabetes and hypertension.
 - A young mother requesting an anti-diarrheal medication for her 18 month old son
 - A patient with confirmed anemia who has been advised by their Doctor to take Global TM
 - A 25 year old man who wishes to purchase medication for temporary relief of myalgia and fever
9. Collection and completion of licensing forms associated with the licensing process of community pharmacy from various government departments

ASSIGNMENTS FOR HOSPITAL PHARMACY

1. You have been asked to establish a drug information centre in a 1200 bed teaching hospital. Prepare a written report for the hospital's administration summarizing the resources you will need to do this, including a budget for both initial and ongoing expenditure.
2. Select a new drug, which has recently been marketed in India for the first time. Prepare a report for a hospital's Drug and Therapeutics committee, and make a case either for or against the addition of this new drug on the hospital's formulary. Issues, which you may need to cover, include the drug's pharmacology, its clinical use, the opinions of relevant hospital consultants and a cost comparison with existing therapies for the same condition for which the new drug is indicated.
3. Describe and evaluate the layout and workflow patterns in the dispensary of a local hospital. Include in your report any improvements, which you would recommend to achieve more efficient work practices.
4. Examine and report on the drug distribution methods used in a local hospital.
5. Prepare one inventory for the following:
 - a. Drugs and Surgical, based on ABC and VED Analysis.
 - b. Injection ASV
 - c. Injection Adrenaline
 - d. Injection Deriphylline
 - e. Injection Garamycin
 - f. Bandage cloth, vasofix
 - g. Disposable Syringes
 - h. Antacid Tablets
 - i. Tablet Erythromycin
 - j. Vitamin tablets
6. Study the Store Management in Teaching/ District/Mission hospitals for the following aspects:
 - a) Receipt of stores b) Storage c) Issue d) Documentation.
7. Procurements and storage of vaccine, sera and biological preparations in District Health office.

SECTION 1: REGULATIONS FOR THE M. PHARM DEGREE
RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCE, KARNATAKA,
ORDINANCE FOR THE GRADUATE COURSE LEADING MASTER'S DEGREE IN
PHARMACY

1.1 ELIGIBILITY:

A candidate who has passed B. Pharm degree examination of Rajiv Gandhi University of Health Science, or B. Pharm Examination of any other recognized Indian University established by law in India or any other degree courses in Pharmacy recognized as equivalent by RGUHS or Pharmacy Council of India (PCI) and / or All India Council of Technical Education (A.I.C.T.E) for this purpose and who has secured not less than 55% of the maximum marks (aggregate of four years prescribed for the qualification examination shall be eligible for the admission to the M. Pharm course.

Further, Pharmacy teachers having recognized B. Pharm qualification and with minimum of five years of teaching experience in an institution approved by A.I.C.T.E and PCI will be eligible provided they have scored not less than 50% of the maximum marks (aggregate of four years in B. Pharm)

For SC/ST (Karnataka) Category-I candidates the prescribed percentage of marks will be 50% of the maximum marks in the qualifying examinations.

1.2 DURATION:

The course of study including submission of dissertation of the topic registered shall be of 24 months (two years) duration from the commencement of academic term.

The study of M. Pharm course shall be of annual system that includes M. Pharm part-I, extending for twelve months from the commencement of academic term and M. Pharm part-II of twelve months duration.

At the end of M. Pharm part-I, there shall be an university examination of M. Pharm Part-I. At the end of M. Pharm Part-II, the candidate shall submit a dissertation on the topic approved by the university.

1.3 COURSE OF STUDY

During the course of study, candidates of M. Pharm Part-I, shall undergo a compulsory course in Current Good Manufacturing Practices (cGMP) and Documentation, Pharmaceutical Validation, Quality Management systems, Pharmaceutical Regulatory Requirements in Drug regulatory affairs. The subject of Pharmacy Ethics shall be studied by candidates belonging to all branches. The syllabus for Pharmacy Ethics is given in Section V. There shall be three specialized subjects in each branch of M. Pharm course in addition to the common subject mentioned earlier.. The subjects for study under Drug regulatory affairs specialization are listed in the Table II.

Table-1: M. Pharm in Drug regulatory affairs

1	Drug regulatory affairs

Table II: Subjects to be studied in Drug regulatory affairs

Sl.No	Branch	Paper	Name of subject
1	Drug Regulatory Affairs	I	Current Good Manufacturing Practices (cGMP) and Documentation
		II	Pharmaceutical Validation
		III	Quality Management systems
		IV	Pharmaceutical Regulatory Requirements

1.4 Attendance and Monitoring Process of Studies

Attendance:

- i. A candidate pursuing M. Pharm course shall study in the concerned department of the institution for the entire period as full time student. No. candidate is permitted to work in any laboratory / college /industry/pharmacy, etc., while studying postgraduate course. No candidate should join any other course of study or appear for any other examination conducted by this university or any other university in India or abroad during the period of registration
- ii. Each year shall be taken as a unity for the purpose of calculating attendance.
- iii. Every student shall attend symposia, seminars, conferences, journal review meetings and lectures during each year as prescribed by the department/college/university and not absent him/her without valid reasons.
- iv. Candidate who has put in a minimum of 80% of attendance in theory and practical assignments separately shall be permitted to appear for M. Pharm part-I examination.
- v. Candidate who has put in a minimum of 80% of attendance in M. Pharm part-II shall only be eligible to submit the dissertation.
- vi. Any student who fails to complete the course in the manner stated above shall not be permitted to appear for the University examinations.

Monitoring Progress of Studies

Every candidate shall maintain a work diary and record of his/her participation in the training programmes conducted by the department such as journal reviews, seminars, etc. (please see Chapter IV for model checklists and logbook specimen copy). The work diary shall be scrutinized and certified by the Head of the Department and Head of the Institution, and presented in the University practical examination if called for. Special mention may be made of the presentations by the candidate as well as details of experiments or laboratory procedures, conducted by the candidate. The presentations will be assessed by the faculty members and peers using relevant checklists given in the Section IV.

1.5 EXAMINATION

There shall be an examination for M. Pharm part-I at the end of an academic year for M. Pharm part-II, the examination shall be an evaluation of dissertation and Viva-Voce at the end of twelve months (one Year) after commencement of M. Pharm Part-II course.

1.6 SCHEME OF EXAMINATION

A. Sessional Examination:

There shall be minimum of two sessional examinations in each subject of specialization conducted by the colleges at regular interval at the end of First term and Second term respectively both in theory and in practical which include seminars.

The sessional marks shall be awarded out of a maximum of 50 for theory and practical as follows:

Theory		Practical	
a)	Written examination (average of two) 30 marks	a)	Practical Examination (average of two) 30 marks
b)	Seminar 20 Marks	b)	Lab work 20 marks
Total Marks 50 marks		Total Marks 50 Marks	

B. University Examination (M. Pharm Part-I)

There shall be two university examinations annually conducted at an interval of not less than four months. There shall be four theory papers in the university examination. Each theory paper shall be

of 3 hours duration carrying 100 marks each. In each paper, there shall be two long essay questions of 20 marks each, five short essay questions of ten marks each and two short notes of five marks each. Zone of the short not questions would be on Pharmacy Ethics in Paper I. The particulars of marks of Papers I, II, III and IV for all the branches are given in Table-III.

There shall be four practical examinations in all the respective branches. The duration of each practical examination is of six hours which carries 100 marks each.

C. Criteria for Pass

M. Pharm Part-I

A candidate who secures 50% of marks in each subject in theory and practical separately including sessional marks and university examination marks together shall be declared to have passé in M. Pharm part-I examination, provided the candidate secures a minimum of 40% marks (excluding sessionals) in theory & practical separately. Candidate, who fails in theory or practical exam kin a subject, shall appear for both theory and practical in the subsequent examination in the subject.

Those candidates who fail in one or more subjects shall have to appear only in the subjects so failed, in the subsequent examinations.

Re-sessional examination:

Candidates who want to improve their sessional marks may be permitted to take re-sessional examination after the announcement of results only once in one or more theory/practical papers. In respect of practical re-sessional, the marks, scored by the candidate, earlier in the laboratory work remains unchanged (out of 20 marks).

Candidate who fail in M. Pharm part-I examination shall be permitted to continue M. Pharm part-II course. However, such candidate shall not be permitted to submit the dissertation unless the candidate completes M. Pharm part-I examination and passes both theory and practical at a time together.

M. Pharm. Part -II

Dissertation

- i. Every candidate pursuing M. Pham course is required to carry out work on a selected research project under the guidance of a recognized postgraduate teacher. The results of such work shall be submitted in the form of a dissertation.
- ii. The dissertation is aimed to train a postgraduate student in research methods and techniques. It includes identification of the problem, formulation of a hypothesis, review of literature, getting acquainted with recent advances, designing of a research study, collection of data, critical analysis, and comparison of results and drawing conclusions.
- iii. The dissertation should be writer under the following headings
 1. Introduction
 2. Aims or Objectives of study
 3. Review of Literature
 4. Material and Methods
 5. Results
 6. Discussion
 7. Conclusion
 8. Summary
 9. References
 10. Tables
 11. Annexure

- iv. The written text dissertation shall be not less than 50 pages shall not exceed 150 pages excluding references, tables, questionnaires and other annexure. It should be neatly typed with double line spacing on one side of the bond paper (A 4 size 8. 27" x 11.69) and bound properly. Spiral binding should be avoided. The dissertation shall be certified by the guide and co-guide if any, Head of the Department and Head of the Institution. The dissertation shall be submitted at least two month before the end of M. Pharm part II term.
- v. A guide shall be a full time post graduate teacher of an institution affiliated to RGUHS and recognized by RGUHS as a guide for supervision of dissertation work. However a co guide can be opted wherever required. The co-guide shall also be a postgraduate teacher recognized by RGUHS as guide.
- vi. **Synopsis.** A candidate shall submit synopsis to the Registrar, RGUHS of the intended project work through the guide, HOD and Head of the institutions, not later than nine months from the date of admission to M. Pharm part I on or before the date specified by RGUHS.

1.6. SUBMISSION OF DISSERTATION:

Three copied of the dissertation duly certified by the Guide, Head of the Department and the Principal shall be submitted to the Register , evaluation, RGUHS, through the principal two months before the final examination notified by RGUHS.

1.7. VIVA-VOCE EXAMINATION:

The Viva-Voce examination shall aim at assessing the depth of knowledge, logical reasoning, confidence and oral communication skills.

The Viva Voce examination shall be held after the submission of dissertation. If any candidate fails to submit the dissertation on or before the date prescribed, him/her Viva Voce shall be conducted during the subsequent examination which shall not be earlier than six months from the date fixed in the first instance.

Examiners: There shall be at least two examiners in each branch / specialization, out of them one shall be external examiner and the other one shall be the internal examiner. The internal examiner ordinarily be the guide. The qualification and teaching experience for appointment as examiner shall be as given in section No. 1.12

a. DISTRIBUTION OF MARKS FOR M. PHARM PART-II EXAMINATION

Total 200 marks, Dissertation-150 marks, and Viva Voce-50 marks.

The dissertation viva voce shall be valued, by the examiners together appointed by the university.

Scheme of evaluation of M. Pharm. Dissertation

The minimum marks for pass in M. Pharm part II shall be 50% of the marks of dissertation and viva and an aggregate of 100 marks out of 200 marks.

1.9 Class shall be declared on the basis of the aggregate of marks scored in M. Pharm Part I and part II as follows:

(1) 75% and above	- Distinction
(2) 60% & above but less than 75%	- First class
(3) 50% & above but less than 60%	-Second class

1.10 The candidate shall not take more than double the number of years prescribed for the course (i.e., 4 years) for passing. Otherwise the candidate should seek readmission.

TABLE III: Drug Regulatory Affairs

Theory						Practical			
Subjects	No of papers	Duration of paper (Hours)	Maximum marks for written exam	Sessional maximum marks	Total	Duration of paper (Hours)	Maximum marks for written exam	Sessional maximum marks	Total
Paper I Current Good Manufacturing Practices (cGMP) and Documentation	1	3	100	50	150	6	100	50	150
Paper II	1	3	100	50	150	6	100	50	150
Paper III	1	3	100	50	150	6	100	50	150
Paper IV	1	3	100	50	150	6	100	50	150
Total					600				600

Table IV: Consolidated Marks for Part I & Part II

Part I	Part II	Grand Total
1200	200	1400

1.11. M Pharm Qualification required to Teacher of Drug Regulatory affairs

Sl No	Name of the subject	M Pharm Qualification
1	Drug Regulatory Affairs	Any M Pharm with 6 six years experience

1.12 Qualification and experience required for postgraduate Teacher, Guide and Examiner:**Qualification and experience required for teaching M. Pharm**

M. Pharm with a minimum of five years teaching experience for B. Pharm degree course after obtaining M. Pharm degree. He/she should have taught the subjects of his/her PG any specialization

OR

M. Pharm the subject of specialization concerned and Ph. D with one year teaching experience for B. Pharm degree course in any specialization

OR

One year research experience or Pot Doctoral Experience after Ph. D course in Pharmacy after obtaining M. Pharm degree

B. qualification and experience required to be a PG guide

He /She shall be M. Pharm with minimum of Six years of teaching experience for B. Pharm degree course out of which two years teaching experience of PG course in Pharmacy after obtaining M. Pharm degree.

OR

He / She shall be M. Pharm with minimum of Six years of teaching experience in B. Pharm and should have published at least two peer reviewed papers in scientific journals of Pharmacy or allied branches as first or second author.

OR

M. Pharm in any specialization and Ph. D with two years teaching experience for B. Pharm or PG Pharm course in the any specialization.

Number of candidates per guide

An approved post graduate guide can guide a maximum of Five M. Pharm students in one academic year,

Examiner

To be eligible to become PG examiner, he / she should have been a recognized as a PG guide in Pharmacy by RGUHS for at least two years.

1.13 Co-guide

The qualification and experience required for a co-guide is the same as that prescribed for a PG guide (sec1.14B) However,

- i. For the subject of Industrial pharmacy, the qualification and experience required for a person working in a pharmaceutical industry to be appointed as co-guide shall be M. Pharm or Ph. D degree from a recognized university established by law and at least 10 years of experience in manufacturing or in R & D quality control in a reputed pharmaceutical industry recognized by DST.
- ii. For the subject of Pharmacy Practice, the requirement for a co-guide is that he/she should be a recognized PG teacher of RGUHS belonging to any faculty of health sciences from any affiliated colleges having approved postgraduate courses.

A. Co guide can guide a maximum of two students at a time.

MASTER OF PHARMACY

M.Pharm-Drug Regulatory Affairs

Goal: It is very essential for the pharmacists to have a thorough knowledge and understanding of the regulatory requirement of pharmaceutical industry. Students will be trained in areas of CGMP, Documentation, drug discovery and development process, validation, GCP, GLP and quality management system.

Regulatory requirement for drug development, product approval, pre clinical and clinical trials and patent laws will be studied in detail.

- CGMP, Drug laws, Drug discovery and development process
- Process validation of APIs and finished products, water, sterile and non sterile facility, medical devices, analytical methods.
- Concept of TQM, regulatory audits, ICH Process, GLP, GCP
- Stability testing
- Generic drug development process
- Non clinical drug development
- Clinical trials

SYLLABUS

M. Pharm – Drug Regulatory Affairs

Paper	Subject
I	Current Good Manufacturing Practices (cGMP) and Documentation
II	Pharmaceutical Validation
III	Quality Management systems
IV	Pharmaceutical Regulatory Requirements

PAPER - I
Current Good Manufacturing Practices (cGMP) and Documentation

Goals:

To impart in depth study of good manufacturing practices in an industrial set up including drug laws, drug discovery and development process

THEORY	75 HOURS
1. cGMP of Pharmaceutical manufacturing · Evolution and Principles of cGMP, Schedule-M, WHO-GMP requirements, European Union (EU) and United States Food and Drug Administration (USFDA) guidelines on Pharmaceutical manufacturing.	15 Hrs 20 Marks
2. Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.	10 Hrs 20 Marks
3. Packaging of Dosage Forms: cGMP complied packaging and documentation Labeling requirements of various regulated and non-regulated markets for Tablets, Capsules, Liquid Orals, Parenterals/ Injectables, and Semisolids.	06 Hrs 10 Marks
4. Equipments selection & purchase specifications, maintenance, clean in place, purchase specifications and maintenance of stores for raw materials.	06 Hrs 10 Marks
5. In process quality control and finished products quality control for following formulation in Pharma industry: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products.	10 Hrs 10 Marks
6. Documentation in pharmaceutical industry: Batch Formula Record, Master Formula Record, Distribution records. Common Technical Document and Drug Master Files., Medical Devices, Electronic Common Technical Documentation	10 Hrs 10 Marks
7. An introductory study of following laws with regard to drug product design, manufacture and distribution in India (with latest amendments) : a. Drugs and Cosmetics Act 1940 and its rules 1945 b. National Pharmaceutical Pricing Authority (NPPA) c. The Environmental Protection Act-1986 & Occupational Safety and Health Administration (OSHA) d. Consumer Protection Act-1986 e. Factories Act-1948 and Pollution control Act-1989 f. Law of Contracts (Indian contract Act-1872) g. Monopolistic & Restrictive Trade Practices Act-1969 h. Law of Torts i. Pharmaceutical inspection convention guide for cGMP	10 Hrs 10 Marks
8. Drug discovery and development process: Principles of Drug discovery and development. Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), handling of Orange book, Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up	08 Hrs 20 Marks

Post approval changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC). Post marketing surveillance, Current Biopharmaceutical regulations and in particular related to Cell Therapy and regenerative medicine.

RECOMMENDED BOOKS

1. Good Manufacturing Practice Rationale and compliance by John Sharp
2. Pharmaceutical master validation plan: The ultimate guide to FDA, GMP and GLP Compliance by Syed Imitiaz Haider
3. Pharmaceutical dosage forms: Parenterals Vol-2, II Edition, by Kenneth EA and Leon Lachman
4. Packaging and Pharmaceuticals and health care products by H. Lockhart, Frank A. Paine
5. The process of new drug discovery and development. I and II Edition by Charles G. Smith, James T and O. Donnell.
6. Establishing a CGMP laboratory audit system- A Practical guide by David M. Bliesner.
7. J.F.Hanlon: Hand book of package engineering :Mac-Grawhill company
8. Good manufacturing practices: A plan total quality control: S.H.Wilhing, M.M. Tuckerman, S.Hitchings, Marcel Deckker, Inc. Yew york.
9. Cell therapy, CGMP, Facilities and Manufacturing, Springer

PRACTICALS :

(6 Hours per week)

Twenty Assignments to be carried out and submitted on the aforementioned theoretical aspects like

1. **Documentation** for in process and finished products Quality control tests for Solid, Semisolid and Sterile preparations.
2. **Protocol** preparation for purchase of manufacturing equipments and raw materials.
3. **Protocol** preparation for documentation of various types of records (BFR, MFR, DR, etc.)
4. **Labeling** comparison between brand & generics. (Review of Promotion Materials)

PAPER - II
Pharmaceutical Validation

Goals:

To develop competency in international guidelines in the area of validation methods, processes, equipments etc.

THEORY

50 HOURS

1.	An Introduction to the Basic Concepts of Process Validation & How it Differs from Qualification (Installation Qualification (IQ), Operational Qualification (OQ) & Performance Qualification (PQ) Procedures, Validation master plan (VMP)	07 Hrs 10 Marks
2.	A Review of Prospective, Concurrent, Retrospective Validation & Revalidation including the use of Statistical Process Control (SPC)	04 Hrs 10 Marks
3.	Planning & Managing a Validation Program including Change Control, Scale-Up and Post-Approval Changes (SUPAC), Pre Approval Inspections (PAI) & Technology Transfer Issues	08 Hrs 20 Marks
4.	Validation of Water (Demineralised, Distilled and Water for Injection) & Thermal Systems, including Heat Ventilation and Air conditioning (HVAC), Facilities & Cleaning Validation	03 Hrs 10 Marks
5.	Process Validation of Active Pharmaceutical Ingredients (APIs) and finished products. Data generation and storage, quality control documents, retention samples, records and audits of quality control facilities. Finished products release, quality review, quality audits, batch release document	07 Hrs 10 Marks
6.	Validation of Sterile and Non-Sterile Facility	08 Hrs 20 Marks
7.	Medical Device, <i>In Vitro</i> Diagnostics & Packaging Validation Issues	03 Hrs 10 Marks
8.	Validation of Analytical Methods, Automated Systems, International Conference on Harmonization (ICH) and World Health Organization (WHO) Guidelines for calibration of equipments, Validation of process: mixing, granulation, drying, compression, filtration, filling, Validation of sterilization methods and equipments: dry heat sterilization, autoclaving, membrane filtration. Validation of analytical procedures, Validation of air handling equipments and facilities in sterile and non sterile areas.	10 Hrs 20 Marks

RECOMMENDED BOOKS

1. Pharmaceutical Process Validation, 3rd Edition, Edited by Robert Nash and Alfred Wachter, Marcel Dekker
2. Good Manufacturing Practices for Pharmaceuticals: A Plan for Total Quality Control from Manufacturer to Consumer, Sidney J. Willig, Marcel Dekker, 5th Ed.
3. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
4. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
5. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
6. Pharmaceutical Quality Assurance by Manohar A. Potdhar, 2nd edition, Nirali Prakashan.

PRACTICALS: (6 Hours per week)

Twenty Assignments to be carried out and submitted on the aforementioned theoretical aspects like

- Preparation of protocols on various validation requirements
- Validation of machines & analytical instruments used for Pharmaceutical formulations.
- Process Validation of various pharmaceutical dosage forms.
- Validation of medical devices.(viz., Nebulizers, Inhalers, Infusion pump, Insulin pens)
- Cleaning Validation
- Analytical methods Validation

PAPER – III
Quality Management systems

Goals:

Learning the system of quality audit, regulatory requirements, quality evaluation, GLP, GCP concepts etc.

THEORY

50 HOURS

1.	Concept of Quality, Total Quality Management. Quality by design, six sigma concept	06 Hrs 10 Marks
2.	Auditors, Auditing strategies and preparation of audits, Quality audit & audit check lists and Auditing of manufacturing facilities by International regulatory agencies. Conducting and Handling of internal/Domestic/International Regulatory Audits/ Customer specific audits /Pre approval inspections,	07 Hrs 10 Marks
3.	Harmonization of regulatory requirements-The International Conference on Harmonization (ICH) process, guidelines to establish quality, safety and efficacy of drug substances and products. Study of ICH common technical documents, harmonization of pharmacopoeial standards The International Organization for Standardization (ISO) 9000 series of quality systems standards, ISO 14000	10 Hrs 20 Marks
4.	Quality evaluation and batch release: Change Control, Deviation-(planned and unplanned), Corrective Action and Preventive Action (CAPA), Handling of non-conformance, Vendor evaluation process, Out of specification (OOS), batch reconciliation and finished goods release, Market recalls & Market complaints.	07 Hrs 20 Marks
5.	Good Laboratory Practices (GLP): Scope of GLP, Quality assurance unit, Standard operating procedures (SOP), protocols for conduct of non clinical testing, control on animal house, report preparation and documentation.	04 Hrs 10 Marks
6.	National Accreditation Board for testing and Calibration Laboratory (NABL) certification and accreditation procedure	03 Hrs 10 Marks
7.	Stability testing: ICH and WHO guidelines, Photostability studies	07 Hrs 10 Marks
8.	Good Clinical Practices (GCP): International regulatory requirements for pharmaceutical development regarding clinical research practices. Current issues in GCP; standards for design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials. Schedule Y of Indian Drugs and Cosmetics Act 1940, Role of Regulatory affairs in Product development, Clinical phase, Preclinical Phase, Manufacturing phase and Marketing Phase. Indian Council of Medical Research (ICMR) Guidelines for Ethics in Biomedical Research.	06 Hrs 20 Marks

RECOMMENDED BOOKS

1. Quality planning and Analysis by JM Juran and FM Gryna, Tata McGrawHill- India.
2. Total Quality Management, Dale H. Besterfield, Pearson Education, 3rd Ed., 2003.
3. Total Quality Management, Principles, Implementation & Cases, Sharma D.D., Sultan Chand & Sons, New Delhi, 2000.
4. Fundamentals of Total Quality Management, Process Analysis and Improvement by Jens.J Daulgard, Kai Kriestensen and Gopal K.Kanji. Taylor and Francis
5. Total Quality Management, Organization, and Strategy, James R. Evans, Thomson, 4th Ed., 2007.
6. Quality Control, Besterfield, D.H., Pearson, 7th Ed., 2004.
7. Implementing ISO 14000: a practical, comprehensive guide to the ISO 14000 environmental management standards, Authors: Tom Tibor, Ira Feldman , Editors: Tom Tibor, Ira Feldman, Irwin Professional Pub., 1997.
8. Establishing A cGMP Lab; Audit System- A practical guide, David M.Bleisner, Wiley Interscience.
9. The manager's guide to ISO 9000, Kenneth L. Arnold, Free Press, 1994.
10. How To Practice GLP, Good Laboratory Practice, Sharma PP, Vandana Publications
11. GLP Essentials: A Concise Guide to Good Laboratory Practice, Second Edition, Milton A. Anderson, Informa Healthcare.
12. GLP Quality Audit Manual, Milton A. Anderson, Third Edition, Informa Healthcare.
13. Laboratory Auditing for Quality and Regulatory Compliance, by Donald C.Singer, Stefan and Stedan, Drugs and Pharmaceutical Sciences, Vol.150
14. Handbook of Stability Testing in Pharmaceutical Development: Regulations, Methodologies, and Best Practices, Huynh-Ba, Kim, Springer.
15. International Stability Testing, Mazzo J. Mazzo, David J. Mazzo, Informa Healthcare Pharmaceutical Stability Testing To Support Global Markets (biotechnology: Pharmaceutical Aspects), Kim Huynh-ba, Springer.
16. Good Laboratory Practice Regulations, Third Edition, Revised and Expanded Edited by Sandy Weinberg
17. Handbook of Stability Testing in Pharmaceutical Development: Regulations, Methodologies, and Best Practices, Kim Huynh-ba, Springer.
18. Good Clinical Practice: Standard Operating Procedures for Clinical Researchers, Wiley.
19. Laboratory Auditing for quality and regulatory compliance, Donald C. Singer, Taylor and Francis.
20. Current Good Manufacturing Practices, MA Potdhar, BS Publications.

PRACTICALS:

(6 Hours per week)

Twenty Assignments to be carried out and submitted on the aforementioned theoretical aspects like

1. Preparation of SOPs for various equipments and manufacturing processes as per ISO requirements.
2. Quality control tests on Solid, liquid, semisolid and sterile dosage forms
3. Accelerated and Photostability studies on dosage forms as per ICH Guidelines
4. Preparation of final clinical trial report (Phase I,II and III) for submission to regulatory authorities.
5. Documentation for audits and inspection of manufacturing facilities.
6. Report preparation of GLP for non-clinical testing

PAPER – IV

Pharmaceutical Regulatory Requirements

Goals:

To develop competency in product development, regulatory requirement for product approval, FDA regulations and guidelines, preclinical and clinical trial regulations and requirements.

THEORY

50 HOURS

1. Generic Drug Product development: Introduction, Quality Control and Quality Assurance (QC &QA), Hatch-Waxman update, Drug product performance- *in vitro*, ANDA Regulatory Approval Process, Bioequivalence and Drug Product Assessment- *in vivo*, Scale up Post approval changes, Post marketing surveillance, Outsourcing Bioavailability and Bioequivalence studies to Contract Research organizations. Formats for marketing authorization submission to US, EU, Asia-PAC (includes countries of East Asia, southeast Asia, Australasia, Oceania) etc., Data privacy Protection and Intellectual property, patents, Pharmaceutical Labeling, Advertising and Promotion, Risk Management in regulatory affairs
10 Hrs
20 Marks
2. Regulatory requirements for product approvals: Active Pharmaceutical Ingredients, Biologics, Novel therapies, special categories [Over the counter (OTCS), herbal medicines and Homeopathic] obtaining New Drug Application (NDA), Abbreviated New Drug Application (ANDA) for generic drugs, ways and means of US Registration for foreign drugs, Chemistry, Manufacturing and controls (CMC), Post approval Regulatory affairs, Regulation for combination products (Controlled release systems), medical device, Environmental concerns and regulations
08 Hrs
20 Marks

21 Code of Federal Regulations (CFR) Part 11 and LIMS (Laboratory information Management System).
3. FDA Approvable indications and other considerations: Data procession for Global submission, Text and Tabular exposition- Common Technical Document (CTD)/ electronic Common Technical Document (eCTD) Format, working with contract Research Organization (CRO), Industry and FDA Liaison, Role of European Commission Competent Authorities and Notified Bodies and USFDA Authorities
08 Hrs
20 Marks
4. Nonclinical drug development: Global submission of Investigational New Drug application (IND), New Drug application (NDA), Abbreviated New Drug Application (ANDA), Investigation medicinal product Dossier (IMPD) & Investigator Brochure (IB), New product Applications for Global Pharmaceutical Product approvals, US NDA vs Global CTD Formats, ANDA & Supplemental Abbreviated New Drug Application (SNDAs), CTD and eCTD for registration of pharmaceuticals for Human use, combination products (Controlled release systems).
08 Hrs
20 Marks
5. Clinical trials: Developing clinical trial protocols, Institutional Review Board/ Independent Ethics committee-formation and working procedures, Informed consent-process and procedures, HIPAA- A new requirement to clinical study process, Code of Federal Regulations (CFR)/ International Conference on Harmonization (ICH)/EU GCP obligations of Investigators, sponsors & Monitors, Importance of Quality Assurance in clinical trials, Managing and Monitoring clinical trials, European clinical trials (CT) directives-implementation and update., Pharmacovigilance-safety monitoring in clinical
08 Hrs
10 Marks

- trials.
6. International legal consideration: BXA (Bureau of export administration), EAR (Export administration regulation), ECCN (Export control classification number), STELA (System for tracking export license application), FCPA (Federal corrupt practice act), EPA (Environmental protection agency regulation), SFD (Securities & exchange commission).

08Hrs
10 Marks

RECOMMENDED BOOKS

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series, Vol.144
3. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185 Informa Health care Publishers.
4. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
5. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
6. FDA regulatory affairs : a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
8. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD
9. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
10. Drugs: From Discovery to Approval, Second Edition By Rick Ng
11. New Drug Development: A Regulatory Overview, Eighth Edition By Mark Mathieu
12. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
13. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema
14. Medical Device Development: A Regulatory Overview By Jonathan S. Kahan
15. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices By John J. Tobin and Gary Walsh

PRACTICALS :

(6 Hours per week)

Twenty Assignments to be carried out and submitted on the aforementioned theoretical aspects like

- Preparation of regulatory compliance checklist tabulating cGMP requirements as per 21 CFR 210 and 211.
- Preparation of global list of documents for registration of IND, NDA, ANDA as per ICH CTD format.
- Preparation of Annual report for regulatory on approved ANDA
- Case studies on response with scientific rationale to USFDA Warning Letter
- Preparation of an IMPD for EU submission.
- Preparation of a Clinical Trial Protocol for submission to Regulatory.
- Preparation of regulatory compliance requirements for BA/BE study.
- Preparation and documentation for Indian Patent.
- Patent challenge / non infringement (Para IV) case studies.

- Preparation of Annual Product Quality Review (APQR).
- Preparation of Periodic Safety Update Report (PSUR).
- Comparison of key GMP requirements of India, US, EU and Japan of a dosage form.
- Comparison of Clinical Trial Application Requirements of India, US, EU and Japan of a dosage form.
- Fast track approval in different countries considering different class of drugs (e.g. Anti HIV and anticancer), therapeutic area (rare diseases) etc.
- Annotated side by side comparison of labels, Prescribing Information and Patient Information Leaflet.
- Preparation of generic product registration application as per Association of South East Asian Nations [ASEAN] CTD (ACTD)

Preparation of a marketing authorization application for OTC, homeopathic and Herbal Medicinal Product.

*Rajiv Gandhi University of Health Sciences,
Karnataka, Bangalore*

**Revised Syllabus of Bachelor of
Pharmacy (B. Pharm) Degree Course**

**For the Academic Year 2014-15 and
onwards**

**REVISED ORDINANCE GOVERNING
BACHELOR OF PHARMACY (B. PHARM.)
DEGREE COURSE**

2014



**Rajiv Gandhi University of Health Sciences, Karnataka
4th 'T' Block, Jayanagar, Bangalore – 560 041**

**Revised Ordinance Governing
Bachelor of Pharmacy (B. Pharm.)
Degree Course**

This book can be had from:

**Director
Prasaranga
Rajiv Gandhi University of Health Sciences, Karnataka
4th 'T' Block, Jayanagar, Bangalore – 560 041
Web:www.rguhs.ac.in**

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Rajiv Gandhi University of Health Sciences, Karnataka, Bangalore

4th F Block, Jayanagar, Bangalore - 560 041

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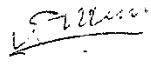
NOTIFICATION

- Sub: Revised Ordinance pertaining to B.Pharm Degree Course
Ref: 1) Minutes of the 108th meeting of Syndicate held on 14.08.2014
2) Recommendations of Academic Council in its meeting held on 19/06/2014.

In exercise of the powers conferred under section 35 of RGUHS Act, 1994 the Syndicate is pleased to approve the Revised Ordinance pertaining to B.Pharm Degree Course as shown in the annexure appended herewith.

The Revised Ordinance as above shall come into effect from the academic year 2014-2015 onwards.

By Order,


REGISTRAR

To

All Principals of the colleges conducting B.Pharm Course.

Copy to:

1. The Secretary to Governor, Governor's Secretariat, Raj Bhavan, Bangalore - 560 001.
2. The Principal Secretary to Government, Health & Family Welfare Department, (Medical Education), Vidhana Soudha, Bangalore - 560 001.
3. The Director, Department of Medical Education, Anand Rao Circle, Bangalore - 560 009
4. PA to Vice-Chancellor / Registrar / Registrar (Eva) / Finance Officer.
5. Director, Curriculum Development Cell.
6. Public Information Officer.
7. The Home Page of RGUHS Website
8. Guard File / Office Copy.

SECTION I

GOALS OF EDUCATION AND TRAINING IN PHARMACEUTICAL SCIENCES OF RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES, KARNATAKA

The pharmacy curriculum shall be oriented towards educating students of B.Pharm course to:

1. Imbibe the concept of better patient health care at every face of Health related activities.
2. Should be capable of functioning independently in both rural and urban environment.
3. Appraise fellow professionals in Hospitals, Community and Industry of newer developments in pharmacy.
4. Be a part of all National & International sponsored health education programmes.
5. Educate the community about disease prevention measures, community hygiene and better health.
6. Inculcate critical thinking, clarity of expression, independent thinking and scientific temperament.
7. Encourage active learning methods like group discussions, Seminars, peer interactions etc., which would enable students to develop discipline, personality, communicating skills, and other qualities, which are necessary.
8. Be able to produce and market dosage forms and be responsible in minimizing the pollution hazards, by using proper scientific and logical techniques.

Regular periodic assessment shall be done throughout the course. Examinations shall be designed with a view to assess not merely the knowledge but also practical skills, habits and values which are necessary for a pharmacy graduate to carry out the professional obligations competently.

Towards achieving these goals every pharmacy College should:

- Evolve institutional objectives, which would be in consonance with the national goals and health policies.
- Shift the role of pharmacy teachers from merely imparting knowledge to that of facilitator and motivator of student learning.
- Establish an institution for faculty development, preparation of learning resource materials and for improving evaluation methods.
- Encourage and facilitate for industry-Academic interaction.

SECTION II

AIMS AND OBJECTIVES OF B.PHARM COURSE

Aims:

Pharmacy graduates are required to learn and acquire adequate knowledge, necessary skills to practice the profession of pharmacy including thorough and exhaustive knowledge of synthesis and assay of Medicinal agents including mode of action, drug interactions and Patient counseling and professional information exchange with Physicians and other paramedicos. The graduates are required to acquire an in-depth knowledge of formulation, storage and analysis of various pharmaceutical dosage forms including herbal medicines required for both large scale commercial production & research. The graduates should understand the concept of Community Pharmacy and be able to participate in rural and urban health care projects of State and Central government. The graduate is also required to detail the physicians and community' and market the medicinal agents for diagnosis, prevention and therapeutic purposes. The pharmacist should act as bridge between Physicians and Patients and strive for better healthcare.

Objectives:

The objectives are covered under three headings namely:

- (a) Knowledge and understanding
- (b) Skills and
- (c) Attitude

(a) KNOWLEDGE & UNDERSTANDING

The graduate should acquire the following during their four year B Pharm course

1. Adequate knowledge and scientific information regarding basic principles of Pharmaceutical chemistry, Pharmaceutics including cosmetics, Pharmacology/ and Pharmacognosy including Herbal drugs
2. Adequate knowledge of practical aspects of synthesis, formulation and analysis of various pharmaceutical and Herbal medicinal agents
3. Adequate knowledge of practical aspects of delivering a quality assured product as per pharmacopoeia, WHO and ISO standards
4. Adequate knowledge of practical aspects of pharmacological screening, biological standardization and *in-vivo* drug interactions.
5. Adequate knowledge of clinical studies for patient counseling leading to physical and social well being of patients.

6. Adequate knowledge of practical aspects of product detailing and marketing of Pharmaceutical products.

(b) SKILLS

A graduate should be able to demonstrate the following skills necessary for practice of a pharmacy.

1. Able to synthesize, purify, identify and analyze medicinal agents.
2. Able to formulate, store, dispense, analyze the prescriptions and / or manufacture the medicinal agents at commercial level.
3. Able to learn and apply the quality assurance principles including legal and ethical aspects involving drugs.
4. Able to extract, purify, identify and know the therapeutic value of herbal / crude / natural products.
5. Able to screen various medicinal agents using animal models for pharmacological activity.

(C) ATTITUDES

The graduate should develop the following attitudes during their four year B.Pharm course.

1. Willing to apply the current knowledge of pharmacy in the best interest of patients and the community.
2. Maintain a high standard of professional ethics in discharging professional obligations.
3. Continuously upgrade professional information and be conversant with latest advances in Pharmacy field to serve the community better.
4. Willing to participate in continuing education programmes of PCI and AICTE to upgrade knowledge and professional skills.
5. To help and to participate in the implementation of National Health programs.

Section III

REGULATIONS

I. Minimum qualification for admission to the course

1. Candidates who have passed two years P.U.C. examination of Karnataka P.U.C. Board or an equivalent examination of any other approved Board or university with not less than 40% marks in any combination comprising P.C.M. or P.C.B. or P.C.M.B. or P.C. and Computer Science (P.C.CS.) or P.C. and Electronics (P.C.E.) or P.C. and Information Science (P.C.IS.) or P.C. and Biotechnology (P.C.Bt.).

Note: In respect of candidates who have taken P.C.M.B. combination the aggregate of P.C.M. or P.C.B. whichever is higher shall be considered for the purpose of admission.

2. In case of students belonging to SC/ST or category-I/OBC, the minimum percentage of marks for admission to B. Pharm. course shall be not less than 35% in P.U.C. or its equivalent examination of any other approved Board or university in any combination comprising P.C.M. or P.C.B. or P.C.M.B. or P.C. and Computer Science (P.C.CS.) or P.C. and Electronics (P.C.E.) or P.C. and Information Science (P.C.IS.) or P.C. and Biotechnology (P.C.Bt.) and D.Pharm.
3. Candidates who have passed D. Pharm. course approved by Pharmacy Council of India shall also be eligible to this course and shall be admitted directly to II B. Pharm. course 10% over and above the sanctioned intake and shall have to study Mathematics, Computer Sciences, and Statistics of I B. Pharm. in addition to the II B. Pharm. subjects.

II. Age:

Minimum age for entry to I B. Pharm. course shall be 17 years as on 31st December of that year.

III. Duration of the course

The course of study for B. Pharm. shall extend over a period of four academic years and three academic years for those admitted to second B. Pharm. directly. The curricula and syllabii for the course shall be prescribed from time to time.

IV. Medium of Instruction and Examinations

Medium of Instruction and Examination shall be English.

V. Attendance and Progress

A candidate is required to put in atleast 80% attendance in theory and practical subjects separately in a recognized institution approved by and affiliated to Rajiv Gandhi University

of Health Sciences, Karnataka. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

VI. Course of study

The course of study for B. Pharm. I, II, III, and IV year shall include the respective Theory & Practical subjects as given in Tables - I, II, III, and IV respectively. The number of hours to be devoted to each Theory and Practical subject in an academic year shall not be less than that shown in the respective tables.

VII. Approval of institution conducting the course of study

The regular course for B. Pharm. I, II, III, and IV year under clause VI shall be conducted by an institution approved by All India Council for Technical Education, Pharmacy Council of India and affiliated to Rajiv Gandhi University of Health Sciences, Karnataka. The approval and affiliation will be granted only if adequate arrangements for teaching-infrastructure facilities, accommodation, equipments, chemicals, glassware, library, and teaching non-teaching staff are provided as required under the norms of Rajiv Gandhi University of Health Sciences, Karnataka.

VIII. Academic Work

A regular record of attendance both in theory and practicals shall be maintained by the teaching staff of respective subjects.

Internal Assessment Marks:

- A. Theory:** Three sessional examinations evenly spread during the academic year shall be conducted by the affiliated colleges. The average marks of the best two examinations shall be computed out of a maximum of 30 marks and shall constitute the sessional award in theory. Provided further the colleges may conduct one special theory sessional examination towards the end of the academic session for those who might have missed any one of the regular sessional examination on the genuine grounds. For special theory sessional exam, the portion prescribed shall be the entire syllabus of the subject.
- B. Practical:** Students are expected to perform the number of experiments listed in the respective syllabus. The number of experiments are also listed. Marks shall be awarded out of a maximum of 10 to each of the practical exercise and an average of those shall be computed out of maximum of 10 marks. In addition, three practical sessional examinations evenly spread during each academic year shall be conducted. The average marks of the best two practical examinations shall be computed out of a maximum of 20 marks. A total of 30 marks shall constitute the sessional award in practical. While awarding the sessional marks for practical experiments, the following considerations should be taken into account.

1. Preparation of the candidate.
2. Manipulative skills.

3. Results of the experiment.
4. Knowledge of the experiment.
5. Viva voce pertaining to the experiments only.

The college shall maintain the sessional books of the students and the record of sessional award of the students.

A regular record of both theory and practical class work and sessional examinations conducted in an institution imparting the course shall be maintained for each student in the institution. Marks shall be awarded as per the schemes given in the tables V, VI, VII and VIII.

IX. Examinations

There shall be four examinations namely, First year, Second year, Third year, and Final year B. Pharm. examination. The details regarding the duration of papers, maximum marks for each paper including the sessional marks allotted to each subject are given in the tables V, VI, VII and VIII.

X. Criteria for pass

- a) Candidates who have secured a minimum of 50% marks in the Theory (including sessionals) and Practical (including sessionals) separately in any subject or subjects shall be declared to have passed in that subject/s and exempted from appearing in that subject/s at subsequent examination.
- b) Theory and Practical of a particular subject are considered as individual subjects for the purpose of pass criteria.

XI. Conditions under which candidates are permitted to proceed to next higher class:

- a) Out of nine subjects to be studied at I. B. Pharm course, there shall be an examination conducted by the college in respect of the following subjects.
 1. Mathematics - theory.
 2. Biology - theory and practical.
 3. Computer Science & Statistics theory and practical for the candidates admitted on PUC/12th Standard/ Equivalent qualifications and for the candidates admitted to II. B. Pharm., admitted on the basis of D. Pharm.
 4. Indian Constitution - theory
 5. Kannada subject for the students belonging to other than Karnataka state
- b) The candidates are required to score a minimum of 50% marks of the total marks prescribed for pass in all the above subjects both in theory and practical separately including their sessional marks for a pass.

c) Candidates of I B. Pharm. are permitted to carryover all the failed subjects to II B. Pharm. and appear for II B. Pharm. examination concurrently along with failed subjects of I B. Pharm. However, these candidates have to pass all the failed subjects of I B. Pharm. to become eligible to proceed to III B. Pharm.

d) Similarly, candidates of II B. Pharm. who have completely passed all the subjects of I B. Pharm. but have failed in II B. Pharm. are permitted to carryover all the failed subjects of II B. Pharm. to III B. Pharm. and appear for III B. Pharm. concurrently along with failed subjects of II B. Pharm. However, these candidates have to pass all the failed subjects of II B. Pharm. to become eligible to proceed to IV B. Pharm.

e) Candidates of III B. Pharm. who have completely passed all the subjects of II B. Pharm. but have failed in III B. Pharm. are permitted to carryover all the failed subjects of III B. Pharm. and appear for IV B. Pharm. examination concurrently along with failed subjects of III B. Pharm.

f) The final B. Pharm. candidates can appear for all the subjects of IV B. Pharm. along with the failed subjects of III B. Pharm. However, they have to pass all the subjects of III B. Pharm. before the announcement of IV B. Pharm. results.

g) However in case of In-service candidates (those who are Registered Pharmacists and have put in minimum of 5 years working experience in either Government or Private sector), they are permitted to take admission into final year B. Pharm even if he/she is having a carryover of II year and III year B. Pharm. subjects but he/she cannot appear for final B. Pharm. examination till he/she passes all the subjects of II year B. Pharm.

h) A candidate who has passed in all the subjects of IV B. Pharm. will be eligible for the award of B. Pharm. degree, provided he/she has passed in all the III B. Pharm. subjects also in the case of carryover and he/she has satisfactorily completed the practical training as mentioned under clause XIV.

XII. Improvement of sessional marks

Candidates who wish to improve the sessional marks only in theory subjects can do so by appearing in the special resessional examinations conducted by the college. A minimum of two and maximum of three sessional examinations shall be conducted by the college out of which the average marks of the best two of the three special resessional examination shall be forwarded to the university at least 15 days prior to the commencement of the next university examination. In case the marks scored by the students in the resessional examination are less than regular sessional examination, the Head of the Institution shall forward the marks whichever is higher (Resessional/Regular Sessional). The resessional/regular sessional marks shall be sent to the University at least 15 days prior to the next university examination.

XIII. Declaration of Class

Class shall be awarded at the end of I, II, III, and final year of B. Pharm. examination as shown below:

- 1) Distinction 75% and above
- 2) First Class 60% and above and less than 75%
- 3) Second Class 50% and above and less than 60%

Pass class shall be awarded to such of the candidates who would have passed the examination in more than one attempt. However, this shall not be applicable to candidates who are exempted in Introductory Biology and Introductory Mathematics by the RGUHS Karnataka, Bangalore.

Note: The carryover facility; full carryover till final year but has to pass all subjects before taking final year Notification syn/ORD-B.Pharma/739/2004-05 dated 04-03-2005. This is applicable for OS/RS/RS2 batch of i.e. admitted up to 2003-04.

XIV. Every candidate shall undergo practical training in Pharmaceutical Manufacturing House/ Approved Hospital/ CSIR research labs for a period of not less than one hundred and fifty hours to be covered in not less than 45 days after completing III B. Pharm. or IV B. Pharm. course.

Candidate should submit two copies of the training report duly certified by the authorities of the training center in which he/she has undergone training duly accepted and certified by the Head of the Institution.

XV. Industrial Tour

Candidates studying in final year of the course shall visit several pharmaceutical manufacturing houses as a supplement to their academic training and submit a report to the satisfaction of the Head of the institution where he/she has studied.

XVI. Duration of the course: Maximum duration to complete the course shall be EIGHT years from the year of admission.

XVII. Tutorials to be fixed at one hour per batch per subject.

XVIII. Award of Ranks

Ranks and Medals shall be awarded on the basis of aggregate of all the four university examinations of Rajiv Gandhi University of Health Sciences, Karnataka, Bangalore. However, candidates who fail in one or more subjects during the B. Pharm. courses shall not be eligible for award of ranks.

Moreover, the candidates should have completed the B. Pharm. course in minimum prescribed number of years, for the award of ranks.

XIX. Award of Degree

Candidates who fulfill the requirements mentioned in XI(h) and XVI will be eligible for award of degree during the ensuing convocation.

XX. Migration & Transfer:

For Guidelines see PCI letter 12:07:84 PCI 662-2/87 dated: 12:06:2001/ applicable from 12:06:2001 onwards only.

Both colleges should be recognized by PCI. Total intake including transfer should not exceed 5% of sanctioned intake.

Courses of Study for B. Pharm

(See Clause VI)

Table I: First Year B. Pharm

Sl.No.	Subject	Theory Hours/ Week	Practical Hours/ Week	Tutorials per batch of 20 students Hours/ Week
1.1	Human Anatomy & Physiology	03	03	01
1.2	Pharmaceutics	02	03	01
1.3	Pharmacognosy	02	03	01
1.4	Pharmaceutical Organic Chemistry-I	03	03	01
1.5	Pharmaceutical Inorganic Chemistry	03	03	01
1.6	*Mathematics or *Biology	03/02	00/02	Nil
1.7	*Computer Science and Statistics	03	02	Nil
1.8	*Kannada	01	00	Nil
1.9	*Indian Constitution	01	00	Nil

*College Exams only

Table II: Second Year B. Pharm

Sl.No.	Subject	Theory Hours/ Week	Practical Hours/ Week	Tutorials per batch of 20 students Hours/ Week
2.1	Physical Pharmaceutics	03	03	01
2.2	Pharmaceutical Microbiology & Biotechnology	03	03	01
2.3	Pathophysiology	03	00	01
2.4	Applied Biochemistry	03	03	01
2.5	Pharmaceutical Organic Chemistry – II	03	03	01
2.6	Environmental Science*	02	00	00

*College Exams only

Note: Maths/Biology and Computer Science for D. Pharm students (ER91) for PCB/PCM candidates only. In addition they have to study Kannada and Indian Constitution also.

Table III: Third Year B. Pharm

Sl.No.	Subject	Theory Hours/ Week	Practical Hours/ Week	Tutorials per batch of 20 students Hours/ Week
3.1	Medicinal Chemistry – I	03	03	01
3.2	Pharmaceutical Jurisprudence	02	00	01
3.3	Pharmacognosy & Phytochemistry	03	03	01
3.4	Pharmaceutical Engineering	03	03	01
3.5	Pharmacology	03	03	01
3.6	Pharmaceutical Marketing	02	00	01

Table IV: Fourth Year B. Pharm

Sl.No.	Subject	Theory Hours/ Week	Practical Hours/ Week	Tutorials per batch of 20 students Hours/ Week
4.1	Pharmaceutical Technology & Biopharmaceutics	03	03	01
4.2	Instrumental & Biomedical Analysis	03	03	01
4.3	Pharmacology & Toxicology	03	03	01
4.4	Medicinal Chemistry – II	03	03	01
4.5	Industrial Pharmacognosy	02	03	01
4.6	Advanced Industrial Pharmacy	02	00	01

Scheme of Study and Examination for B. Pharm. Course

Table V: Scheme of Study and Examination for First Year B. Pharm Course

Subject	THEORY					PRACTICALS				
	No. of Papers	Duration of examination (Hrs)	Sessional Maximum Marks	Max. Marks for written papers	Total Marks	Duration of examination (Hrs)	Sessional Maximum Marks	Max. Marks for practical papers	Total Marks	Grand Total
1.1 Human Anatomy & Physiology	1	03	30	70	100	04	30	70	100	200
1.2 Pharmaceutics	1	03	30	70	100	04	30	70	100	200
1.3 Pharmacognosy	1	03	30	70	100	04	30	70	100	200
1.4 Pharmaceutical Organic Chemistry – I	1	03	30	70	100	04	30	70	100	200
1.5 Pharmaceutical Inorganic Chemistry	1	03	30	70	100	04	30	70	100	200
1.6 Mathematics*	1	03	30	70	100	No Practicals				
Or Biology*	1	03	30	70	100	04	30	70	100	
1.7 Computer Science & Statistics*	1	03	30	70	100	04	30	70	100	
1.8 Kannada*	1	03	30	70	100	No Practicals				
1.9 Indian Constitution*	1	03	30	70	100	No Practicals				

Total: Theory 500; Practicals 500; Grand Total 1000 (*for the subjects 1.6 to 1.9 examination is conducted by the college)

Table VI: Scheme of Study and Examination for Second Year B. Pharm Course

Subject	THEORY					PRACTICALS				
	No. of Papers	Duration of examination (Hrs)	Sessional Maximum Marks	Max. Marks for written papers	Total Marks	Duration of examination (Hrs)	Sessional Maximum Marks	Max. Marks for practical papers	Total Marks	Grand Total
2.1 Physical Pharmaceutics	1	03	30	70	100	04	30	70	100	200
2.2 Pharmaceutical Microbiology & Biotechnology	1	03	30	70	100	04	30	70	100	200
2.3 Pathophysiology	1	03	30	70	100	No Practicals				100
2.4 Applied Biochemistry	1	03	30	70	100	04	30	70	100	200
2.5 Pharmaceutical Organic Chemistry-II	1	03	30	70	100	04	30	70	100	200
*2.6 Environmental Science	1	03	30	70	100	No Practicals				

Total: Theory 500; Practicals 400; Grand Total 900 (*for the subject 2.6 examination is conducted by the college)

Table VII: Scheme of Study and Examination for Third Year B. Pharm Course

Subject	THEORY					PRACTICALS				
	No. of Papers	Duration of examination (Hrs)	Sessional Maximum Marks	Max. Marks for written papers	Total Marks	Duration of examination (Hrs)	Sessional Maximum Marks	Max. Marks for practical papers	Total Marks	Grand Total
3.1 Medicinal Chemistry – I	1	03	30	70	100	04	30	70	100	200
3.2 Pharmaceutical Jurisprudence & Ethics	1	03	30	70	100	No Practicals				100
3.3 Pharmacognosy & Phytochemistry	1	03	30	70	100	04	30	70	100	200
3.4 Pharmaceutical Engineering	1	03	30	70	100	04	30	70	100	200
3.5 Pharmacology	1	03	30	70	100	04	30	70	100	200
3.6 Pharmaceutical Marketing	1	03	30	70	100	No Practicals				100

Total: Theory 600; Practicals 400; Grand Total 1000

Table VIII: Scheme of Study and Examination for Fourth Year B. Pharm Course

Subject	THEORY					PRACTICALS				
	No. of Papers	Duration of examination (Hrs)	Sessional Maximum Marks	Max. Marks for written papers	Total Marks	Duration of examination (Hrs)	Sessional Maximum Marks	Max. Marks for practical papers	Total Marks	Grand Total
4.1 Pharmaceutical Technology & Biopharmaceutics	1	03	30	70	100	04	30	70	100	200
4.2 Instrumental & Biomedical Analysis	1	03	30	70	100	04	30	70	100	200
4.3 Pharmacology & Toxicology	1	03	30	70	100	04	30	70	100	200
4.4 Medicinal Chemistry-II	1	03	30	70	100	04	30	70	100	200
4.5 Industrial Pharmacognosy	1	03	30	70	100	04	30	70	100	200
4.6 Advanced Industrial Pharmacy	1	03	30	70	100	No Practicals				100

Total: Theory 600; Practicals 500; Grand Total 1100

I B. PHARM SYLLABUS

1.1 HUMAN ANATOMY AND PHYSIOLOGY (THEORY)

75 Hours; 3 hours/week

1. **Scope of Anatomy & Physiology.** Basic Terminologies Used: Directional Terminologies, Plains & Sections and Body Cavities. **1 hour; 2 marks**
2. **Structure of the Cell:** Structure & Function of Plasma Membrane, Cell Cycle and Transport of Substances across Cell Membrane. **1 hour; 2-5 marks**
3. **Tissues:** Definition, Classification of Tissues, Location, Characteristics and Function of Epithelial, Connective, Muscular & Nervous Tissues. Definitions of Malignant & Benign Tumors **2 hours; 5-7 marks**
4. **Osseous System:** Structure & Composition of Bone. Functions of Skeleton. Classification of Joints. Definition of Disorders: Osteoporosis, Arthritis, Rickets & Gout **2 hours; 5-7 marks**
5. **Haemopoietic System :** Composition & Functions of Blood. Haemopoiesis. Blood Grouping. Mechanisms of Blood Clotting. Definitions of Disorders: Anaemias, Polycythaemia, Leukopenia, Leukocytosis, Leukaemia, Thrombocytopenia & Haemophilia. **6 hours; 8-10 marks**
6. **Lymphatic System :** Composition, Formation, Circulation & Functions of Lymph. Structure & Functions of Lymph Node, Spleen and Thymus Gland. Definitions of Disorders: Lymphoedema, Elephantiasis & Splenomegaly. **3 hours; 2-5 marks**
7. **Cardiovascular System:** Anatomy of Heart. Structure of Blood Vessels. Circulation: Pulmonary, Systemic (Coronary & Portal). Conduction System of the Heart, Cardiac Cycle & ECG. Blood Pressure: Mechanism of regulation, Factors determining Blood Pressure. Definitions of Disorders: Congestive Heart Failure, Cardiac Arrhythmias, Angina Pectoris, Myocardial Infarction, Atherosclerosis, Rheumatic Heart Disease, Hypertension & Hypotension. **9 hours: 8-10 marks**
8. **Respiratory System:** Anatomy & Functions of Respiratory Organs. Mechanisms of regulation of Respiration. Transport of Respiratory Gases. Definitions of Lung Volume & Capacities, Hypoxia and Resuscitation. Definitions of Disorders: Asthma, COPD, Tuberculosis & Pneumonia **5 hours: 4-6 marks**
9. **Digestive System :** Anatomy & Functions of Salivary Gland, Stomach, Intestine, Liver, Gall Bladder and Pancreas. Digestion & Absorption. Definitions of Disorders: Peptic Ulcer, Constipation, Diarrhea, Emesis, Liver Cirrhosis, Hepatitis, Anorexia & GERD. **6 hours: 4-6 marks**
10. **Nervous Systems:** Classification of Nervous System. Meninges & Cerebrospinal Fluid. Functional Areas of Brain: Cerebrum, Cerebellum, Pons & Medulla, Thalamus & Hypothalamus and Basal Ganglia. Spinal Cord: Structure & Reflexes. Cranial Nerves &

their Functions. Autonomic Nervous System: Anatomy & Functions of Sympathetic and Parasympathetic Nervous System. Somatic Nervous System. Definitions of Disorders: Epilepsy, Parkinson's Disease, Depression, Insomnia, Anxiety, Schizophrenia, Migraine & Alzheimer's Disease. **12 hours; 8-10 marks**

11. **Urinary System:** Parts of Urinary System: Structure & Functions of Kidney and Structure of Nephron. Mechanism of Urine Formation & Acid-Base Balance. Micturition Reflex & Renal Function Test. Definitions of Disorders: Renal Calculi, Cystitis, Glomerulonephritis Renal Fibrosis & Urinary Incontinence. **5 hours; 5-7 marks**
12. **Endocrine System:** Structure, Secretions & Functions of Hypothalamus & Pituitary Gland, Thyroid & Parathyroid Gland, Adrenal Gland, Pancreatic Islets. Definitions of Disorders: Hypothyroidism, Hyperthyroidism, Cushing's Syndrome, Addison's Disease, Diabetes Mellitus, Pheochromocytoma, Gigantism, Acromegaly, Diabetes insipidus & Dwarfism. **4 marks; 5-7 marks**
13. **Reproductive System:** Structure, Functions & Hormones of Male & Female Reproductive System. Physiology of Menstruation, Spermatogenesis & Oogenesis. Pregnancy & its maintenance and Parturition. Definitions of Disorders: Infertility, Polycystic Ovarian Disease, Erectile Dysfunction & AIDS. **5 marks; 5-7 marks**
14. **Sense Organs:** Structure and Functioning of Eye, Ear, Skin, Taste & Smell. Definitions of Disorders: Glaucoma, Cataract, Conjunctivitis, Psoriasis & Tinnitus. **6 hours; 5-8 marks**
15. **Skeletal Muscles:** Physiology of Muscle Contraction. Neuro-muscular Junction. Properties of Skeletal Muscles. Muscles in Exercise. Definitions of Disorders: Muscular Dystrophy, Myasthenia Gravis. **3 hours; 2-4 marks**

HUMAN ANATOMY AND PHYSIOLOGY (PRACTICALS)

75 Hours; 3 hours/week

1. Determination of Hemoglobin content of Blood**
2. Determination of R.B.C. count of Blood**
3. Determination of W.B.C. count of Blood**
4. Determination of Differential W.B.C count of Blood**
5. Determination of Blood Groups*
6. Determination of Erythrocyte Sedimentation Rate (ESR)*
7. Recording of Human Body Temperature*
8. Recording of Human Heart Rate & Pulse Rate*
9. Determination of Blood Pressure & To study the effect of Posture & Exercise on Blood Pressure*
10. Determination of Bleeding time & Clotting time*
11. Determination of Vital Capacity*
12. Understanding of ECG: PQRST Waves & its Significance*
13. Study of various Models & Specimens of Vital organs & Systems*
14. Study of Skeleton & Bones*
15. Study of Histology slides of different tissues/organs*
16. Study of different Family Planning Appliances*
17. Understanding of Pregnancy Diagnosis Tests*

Note: ** Denotes major experiments

*** Denotes minor experiments**

SCHEME OF EXAMINATION

1. Identification	-	10 Marks
2. Synopsis	-	10 Marks
3. Major Experiment	-	25 Marks
4. Minor Experiment	-	15 Marks
5. Viva	-	10 Marks
Total	-	70 Marks

HUMAN ANATOMY AND PHYSIOLOGY TEXT BOOKS

1. Anne W, Allison G. Ross and Wilson Anatomy and physiology in health and illness. 11th ed. Edinburgh:Churchill Livingstone;2010.
2. Chatterjee CC. Human physiology (Vol. I & II). 11th ed. Calcutta:Medical Allied Agency;1985.
3. Sujit KC. Concise medical physiology. 6th ed. Calcutta:New Central Book Agency; 2008.
4. Thakore B, Gandhi P, Harit RD. Elements of human anatomy physiology and health education. 4th ed. Ahmedabad:B.S. Shah Publishers;1991.
5. Goyal RK, Patel NM. Practical anatomy physiology and biochemistry. 11th ed. Ahmedabad:B.S. Shah Prakashan;2008.

HUMAN ANATOMY AND PHYSIOLOGY REFERENCE BOOKS

1. Gerard JT, Bryan HD. Principles of anatomy and physiology. 13th ed. New York: John-Wiley & Sons;2012.
2. Douglas EK, Richard LW, Allen CE. Bailey's text book of microscopic anatomy. 18th ed. London:Williams & Wilkins Publishers;1984.
3. Inderbir S. Text book of human histology with colour atlas. 6th ed. New Delhi:Jaypee Brothers Medical Publishers;2011.

LIST OF MINIMUM EQUIPMENT REQUIRED

(For a batch of 20 students)

1. Compound Microscopes with oil immersion lens	20 nos
2. Haemocytometers	20 nos
3. Sahli's Haemometers	20 nos
4. Glass Slides	80 nos
5. Westergren's ESR apparatus	05 nos
6. Clinical Thermometers	05 nos
7. Sphygmomanometers	05 nos
8. Stethoscopes	05 nos
9. Hutchinson's Spirometer	01 no
10. Permanent slides for various tissues & organs	(One pair for each tissue /organ)
11. Specimens for various organs	(One specimen for each organ)
12. Models for various organs & systems	(One model for each organ system)
13. Skeleton & Bones	(One set of skeleton and one spare set of bones)
14. Family planning appliances	(One set)

1.2 PHARMACEUTICS (THEORY)

50 Hours; 2 hours/week

1. **Historical background** and development of profession of pharmacy. **Development of Indian pharmacopoeia** and introduction to other pharmacopoeias such as B.P, U.S.P, European pharmacopoeia, Extra pharmacopoeia and Indian National Formulary. **4 hours; 6-8 marks**
2. **Weights and measures:** Different types of weights and measures, modern methods of weighing, errors in weighing. Calculations involving percentage of solutions, allegation method, proof spirit, isotonic solutions. **4 hours; 6-8 marks**
 - a) **Prescription:** Definition, parts of prescription, handling and sources of errors.
 - b) **Posology:** Definition, factors affecting dose selection, calculation of child and infant doses.
 - c) **Incompatibility:** Introduction to physical and chemical incompatibility. Discussion of therapeutic incompatibility with examples. **5 hours; 8-10 marks**
3. **Introduction to dosage forms:** Classification and definitions. Theoretical aspects including commonly used vehicles, essential adjuvants like stabilizers, colorants and flavourants with relevance to monophasic liquid dosage forms. **6 hours; 10-12 marks**
4. **Biphasic liquid dosage forms:**
 1. **Suspensions:** Definition, classification, advantages and disadvantages. Study of diffusible and in-diffusible solids, flocculated and deflocculated suspension. Settling in suspension, discussion on wetting, controlled flocculation and flocculation in structured vehicles.
 2. **Emulsions:** Definition, classification and identification of types of emulsion, mechanism of action of emulsifying agents, theories of emulsification. Formulation of emulsion; stability of emulsions. **8 hours; 13-15 marks**
5. **Powders and granules:** Classification, advantages and disadvantages and methods of mixing of powders. Preparation of simple powders, compound powders, insufflations, dusting powders, Eutectic powders. Study of effervescent granules. **4 hours; 6-8 marks**
6. **Semi solid dosage forms:** Definition, types, semi-solid bases, their selection. Formulation of semi solids such as ointments, creams, pastes, gels, suppositories, packaging, and their evaluation. **8 hours; 13-15 marks**
7. **Galenicals:** Definition of infusion, decoction and expression. Detailed study of maceration and percolation and Soxhlet extraction. **4 hours; 6-8 marks**
8. **Surgical Aids:** Study of surgical dressings namely bandages, absorbent cotton and POP. Definition and types of surgical sutures and ligatures. Manufacturing, standardization and sterilization of surgical catgut. **4 hours; 6-8 marks**
9. **Radiopharmaceuticals:** Uses in diagnosis and treatment, methods of preparations, handling and safety precautions. **3 hours; 5-7 marks**

PHARMACEUTICS (PRACTICALS)

75 Hours; 3 hours/week

1. **Syrups:**
 - a) Simple syrup IP *
 - b) Syrup of ephedrine hydrochloride NF*
2. **Elixirs:**
 - a) Piperazine citrate elixir BP*
 - b) Paracetamol paediatric elixir BPC*
3. **Linctuses:**
 - a) Simple linctus BPC*
 - b) Paediatric compound tolu linctus*
4. **Solutions:**
 - a) Solution of cresol with soap IP**
 - b) Aqueous iodine solution IP*
 - c) Strong ammonium acetate solution IP**
5. **Galenicals:**
 - a) Tincture of benzoin*
 - b) Spirit of camphor USP*
6. **Gargle:**
 - a) Potassium chlorate gargle*
7. **Mouth wash:**
 - a) Antiseptic mouth wash*
8. **Enema:**
 - a) Glycerin enema*
9. **Liniments:**
 - a) Liniment of turpentine IP**
 - b) Liniment of camphor BPC**
10. **Lotions:**
 - a) Calamine lotion IP**
 - b) Benzyl benzoate lotion USP*
11. **Suspensions:**
 - a) Magnesium hydroxide mixture BP**
 - b) Preparation of deflocculated and flocculated suspensions and their evaluation**
12. **Emulsions:**
 - a) Cod liver oil emulsion**
 - b) Liquid paraffin emulsion. Preparation and evaluation**
13. **Powders:**
 - a) Eutectic powder*
 - b) Dusting powder*
 - c) Effervescent granules**
14. **Semi solids:**
 - a) Simple ointment*
 - b) Zinc and Salicylic acid paste*
 - c) Diclofenac gel**
 - d) Boric acid suppository**
 - e) Lactic acid pessaries**

Note: ** Denotes major experiments

*** Denotes minor experiments**

SCHEME OF EXAMINATION

1. Synopsis	-10 Marks
2. Major experiment (indicated by **)	-30 Marks
3. Minor experiment (indicated by *)	-20 Marks
4. Viva voce	-10 Marks
Total	<u>=70 Marks</u>

PHARMACEUTICS REFERENCE BOOKS

1. Aulton ME. Pharmaceutics, The science of dosage form design. 2nd ed. Edinburgh:Churchill Livingstone;2002.
2. Bharat S. Pharmaceutics. New Delhi:Dorling Kindersley (India) Pvt Ltd;2013.
3. British Pharmacopoeia (BP), United States Pharmacopoeia (USP), Extra Pharmacopoeia, Merck Index, and British Pharmaceutical Codex (BPC).
4. Carter SJ. Cooper and Gunn's Dispensing for pharmaceutical students. 12th ed. New Delhi:CBS Publishers;2000.
5. Carter SJ. Cooper and Gunn's Tutorial pharmacy. 6th ed. New Delhi:CBS Publishers;2000.
6. Gennaro AL. Remington: The science and practice of pharmacy, Vol I and II. 20th ed. Philadelphia:Lippincott Williams and Wilkns;2000.
7. Indian Pharmacopoeia. Delhi:The Controller of Publications;1966, 1977, 1985, 1996, 2007, 2014.
8. Loyd VA, Nicholas GP, Howard CA. Ansel's pharmaceutical dosage forms and drug delivery systems. 8th ed. Noida: BI Publications Pvt Ltd;2005.
9. Mehta RM. Dispensing Pharmacy. Delhi:Vallabh Prakashan;2013.
10. Mehta RM. Pharmaceutics I. Delhi:Vallabh Prakashan;2014.
11. Mitchell JS, Howard CA. Pharmaceutical calculations. 10th ed. New Delhi:BI Waverley Pvt Ltd;1996.
12. Rawlins EA. Bentley's textbook of pharmaceutics. 8th ed. New Delhi:Reed Elsevier India Pvt Ltd;2010.
13. Subrahmanyam CVS. Textbook of physical pharmaceutics. 2nd ed. Delhi:Vallabh Prakashan;2003.

LIST OF MINIMUM EQUIPMENTS REQUIRED

1.Electronic balances	02 nos.
2.Homogeniser	02 nos.
3.Mechanical stirrers	10 nos.
4. Oven	01 no.
5.pH meter	01 no.
6.Suppository moulds	20 nos.

1.3 PHARMACOGNOSY (THEORY)

50 hours; 2 Hours/week

1. Definition, History and Scope of Pharmacognosy. **2 hours; 2-5 marks**
2. **Plant Taxonomy:** Study of the following families with special reference to medicinally important plants - Apocynaceae, Solanaceae, Umbelliferae, Leguminosae, Rubiaceae, Liliaceae. **3 hours; 2-5 marks**
3. **Classification of Crude drugs:** Alphabetical, Morphological, Chemical, Pharmacological and Taxonomical methods. General aspects of Chemotaxonomy **5 hours; 5-10 marks**
4. **Medicinal Plants Cultivation:** a) Cultivation, collection, Processing and storage of crude drugs: Factors influencing the cultivation of medicinal plants. b) Detailed method of cultivation for the following drugs: i) Senna ii) Isapgol iii) Opium, iv) Cinchona v) Clove c) Conservation of medicinal plants. **8 hours; 7-17 marks**
5. **Study of Natural Pesticides:** Pyrethrum, Neem and Tobacco. **2 hours; 2-5 marks**
6. Study of different types of adulteration in crude drugs with examples. **2 hours; 2-5 marks**
7. Brief study of various plant constituents and ergastic cell inclusions. **2 hours; 2-5 marks**
8. **Study of morphology and microscopy of different plant parts with the specific examples given below:** i. Leaf: Datura, ii. Bark: Cinnamon (Cassia), iii. Rhizome: Ginger, iv. Stem: Ephedra, v. Root: Rauwolfia, , i. Wood: Quassia, vii. Flower: Clove viii. Fruit: Fennel, ix Seed: Nux-Vomica. **10 hours; 10-17 marks**
9. **Carbohydrates:** Biological source, method of production, chemical constituents, identification tests and uses of the following carbohydrates and related products i) Isapgol, ii) Guar gum, iii) Honey, iv) Acacia, v) Agar, vi) Tragacanth, vii) Pectin, viii) Sterculia gum. **5 hours; 5-10 marks**
10. **Lipids:** Biological source, method of production, chemical constituents, identification tests and uses of the following oils and fats i) Castor oil, ii) Cod liver oil, iii) Chaulmoogra oil, iv) wool fat, v) Bees wax vi) Kokum butter, vii) Olive oil , viii) Linseed oil **5 hours; 5-10 marks**
11. **Resins:** a) Natural occurrence, properties, classification and method of production of Resins b) Sources, diagnostic characters, active constituents and uses of: (i) Podophyllum (ii) Ginger (iii) Benzoin (iv) Asafoetida (v) Myrrh **4 hours; 5-8 marks**
12. **Study of plant and animal fibers:** Cotton, Wool, Jute, Silk, Hemp **2 hours; 2-5 marks**

PHARMACOGNOSY (PRACTICALS)

75 Hours; 3 hours/week

1. General morphological study of different parts of the plants*

- a) Leaf: Datura
- b) Bark: Cinnamon (Cassia),
- c) Rhizome: Ginger,
- d) Stem: Ephedra
- e) Root: Rauwolfia,
- f) Wood: Quassia
- g) Flower: Clove
- h) Fruit: Fennel,
- i) Seed: Nux Vomica

2. Transverse section of the drugs mentioned in 1**

3. Chemical tests for the identification of following drugs and their adulterants

- a) Acacia b) Agar c) Tragacanth d) Honey

4. Chemical tests for the identification of following oils and fats and their adulterants

- a) Castor oil b) Cod Liver oil c) Wool fat d) Bee's wax

5. Chemical tests for the identification of following resins and their adulterants

- a) Asafoetida b) Benzoin c) Myrrh

Note: ** Denotes major experiments * Denotes minor experiments

SCHEME OF EXAMINATION

1. Synopsis	10 marks
2. Major Experiment T S**	25 marks
3. Minor Experiment* Morphology	10 marks
4. Minor experiment* Chemical Test	15 marks
5. Viva-Voce	10 marks

Total

70 marks

PHARMACOGNOSY REFERENCE BOOKS

1. Evans WC. Trease and Evans Pharmacognosy. 15th ed. Philadelphia:Elsevier Science Ltd;2002.
2. Kokate CK, Purohit AR, Gokhale SB. Pharmacognosy. 45th ed. Pune:Nirali Prakashan;2010.
3. Shah BS, Qadry JS. Pharmacognosy. 12th ed. Ahmedabad:BS Shah Prakashan;2005.
4. Wallis TE. Textbook of pharmacognosy. 5th ed. London:JA Churchill Limited;1985.
5. Biren SN, Seth AK. Textbook of pharmacognosy and phytochemistry. 1st ed. New Delhi: A Division of Read Elsevier India Private Ltd;2010.
6. Yoganarsimhan SN. Cultivation of medicinal & aromatic crops. 1st ed. Bangalore:Interline Publishing Private Ltd;2000.
7. The Wealth of India. A dictionary of Indian raw materials and industrial products (All Volumes). New Delhi:NISCAIR, CSIR; 2000.
8. Kokate CK. Practical Pharmacognosy. 4th ed. New Delhi:Vallabh Prakashan;1994.
9. Khandelwal KR. Practical pharmacognosy techniques and experiments. 16th ed. Pune;Nirali Prakashan;2006.
10. Iyengar MA, Nayak SGK. Anatomy of crude drugs. 8th ed. Manipal:Manipal Power Press; 2001.

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Microscope with Stage	20
2. Balance	5
3. Reflux flask with condenser	5
4. Heating mantle	5
5. Water bath	10

1.4 PHARMACEUTICAL ORGANIC CHEMISTRY - I (THEORY)

75 Hours; 3 hours/week

1. **Nomenclature of aliphatic and aromatic organic compounds belonging to the following classes:** alkanes, alkenes, dienes, alkynes, alcohols, aldehydes, ketones, amides, amines, phenols, alkyl halides, carboxylic acids, esters, acid chlorides and cycloalkanes. **8 hours; 7-8 marks**
2. **Structure and physical properties:**
 - a) Polarity and Dipolemoment, Hydrogen bonding and its applications, Inductive effect Mesomeric effect, Protic and aprotic solvents.
 - b) An introduction to Isomerism- Definition, Classification of structural and stereo isomerism **2 hours; 1-2 marks**
3.
 - a) Definition, formation, classification, and stability of free radicals.
 - b) Free radical chain reactions of alkanes-mechanism, relative reactivity and stability. **4 hours; 3-4 marks**
4.
 - a) **Alicyclic compounds:** Preparation of cycloalkanes, Bayer's strain theory, theory of Strainless ring, molecular orbital concept.
 - b) Concept of aromaticity (Huckel's rule). Definition, classification, Methods of synthesis (Haworth's and Diel's Alder), Properties and Reaction of Poly nuclear hydrocarbons Such as Naphthalene, Anthracene and Phenanthrene.
 - c) Attacking reagents- Electrophiles and Nucleophiles Definition with examples. **5 hours; 4-5 marks**
5.
 - a) Definition ,formation, classification and stability of carbocations.
 - b) Nucleophilic aliphatic substitution mechanism: nucleophiles, and leaving groups, kinetics of second and first order reaction. Mechanism and Stereochemistry of SN_2 reaction, Mechanism and Stereochemistry of SN_1 reaction. Rearrangement of carbocation, SN_2 versus SN_1 reactions, Reactivity of alkyl halides in SN_2 and SN_1 , Factors affecting SN_2 and SN_1 reaction. **8 hours; 7-8 marks**
6. **Elimination reactions:** Dehydrohalogenation of alkyl halides: 1, 2 elimination, kinetics, E_2 and E_1 mechanisms, E_2 versus E_1 , elimination versus substitution. Dehydration of alcohols and its mechanism, orientation and reactivity in E_1 and E_2 reactions, Saytzeff 's and Hoffman's elimination. **7 hours; 6-7 marks**
7. **Electrophilic addition:** a) Reactions at carbon-carbon double bond, hydrogenation and its mechanism Markovnikov's rule, addition of hydrogen halides, Addition of hydrogen bromides-peroxide effect. Electrophilic addition mechanism.
b) Definition, formation, classification and stability of carbenes, Mechanism of cycloaddition reactions with examples. Addition of carbenes to alkenes, Diel's Alder reaction. **5 hours; 4-5 marks**
8. **Theory of resonance:** Allyl radical as a resonance hybrid, stability, and orbital picture. Resonance stabilization of Allyl cations: hyper conjugation, stability of conjugated dienes, mechanisms of 1,2 and 1,4-additions with examples **6 hours; 5-6 marks**

- 9. Electrophilic aromatic substitution;** Definition and classification of electrophiles, effect of substituent groups, determination of orientation, and of relative reactivity, classification of substituent groups, mechanism of nitration, sulphonation, halogenation, Friedel Craft's alkylation and Friedel Craft's acylation, Reactivity and orientation, activating and deactivating (o, m, p, directing) groups, orientation and synthesis. Orientation in disubstituted benzenes, theory of reactivity and orientation, effects of halogens and Suzuki coupling reaction. **10 hours; 9-10 marks**
- 10.** a) Definition, formation, classification and stability of carbonanions.
b) Nucleophilic additions in aldehydes and ketones, mechanisms with examples. Reactions of Grignard reagent. Aldol and crossed Aldol condensation, Claisen condensation, Cannizaro and crossed Cannizaro reaction, Benzoin's, Perkins, Knoevenagels and Reformatsky reactions. **7 hours; 6-7 marks**
- 11. Carboxylic acids -** Ionization of carboxylic acids, acidity of constant, acidity of carboxylic acids, structure of carboxylate ion, effect of substituents on acidity of carboxylic acids, Conversion of carboxylic acids into acid chloride, ester, amide, anhydrides and Hatu coupling. **6 hours; 5-6 marks**
- 12. Amines –** a) Basicity of Amines, effect of substituents on basicity of aliphatic and aromatic amines
b) Definition, formation, classification, stability and reactivity of nitrenes. Hofmann's, Beckmanns, Curtius, Smith, rearrangement with their mechanism
c) Diazotisation and its mechanism, Sandmeyer's and Gattermann reaction, coupling reaction of Diazonium salts with phenols and amines **5 hours; 4-5 marks**
- 13. Phenols –** Acidity of phenols, effect of substituent on acidity of phenols. Kolbe's reaction, Reimer - Tiemann reaction, Fries rearrangement and Williamson's synthesis. **2 hours; 1-2 marks**

PHARMACEUTICAL ORGANIC CHEMISTRY I (PRACTICALS)
75 Hours; 3 hours/week

1. Introduction to the various laboratory techniques through demonstrations involving synthesis of the following compounds *

- a) Acetanilide / Aspirin (acetylation)
- b) Benzanilide / Phenyl benzoate (Benzoylation)
- c) p-Bromo acetanilide / 2,4, 6 Tribromo aniline. (Bromination)
- d) Dibenzylidene acetone (condensation)
- e) 1-Phenylazo-2-naphthol (Diazotisation)
- f) Benzoic acid / Salicylic acid (hydrolysis of ester)
- g) m-Dinitro benzene (nitration)
- h) Oxidation of Toluene to benzoic acid
- i) Benzophenone oxime (oxime formation)
- j) Benzyl benzoate and Sodium benzoate from Benzaldehyde (Cannizzaro's reaction)

2. Identification of organic compounds belonging to the following classes by systematic qualitative organic analysis including physical constant and preparation of their derivatives.**

1. Phenols, 2. Amides, 3. Carbohydrates, 4. Amines, 5. Carboxylic acids, 6. Aldehydes and ketones, 7. Alcohols, 8. Esters, 9. Hydrocarbons, 10. Anilides, 11. Nitro compounds.

3. Introduction to the use of stereo models

1. Methane, 2. Ethane, 3. Ethylene, 4. Acetylene, 5. cis-Alkene, 6. trans-Alkene, 7. Inversion of configuration

4. Determination of melting point and boiling point for some important pharmaceutical Organic compounds.

Note: ** Denotes major experiments * Denotes minor experiments

SCHEME OF EXAMINATION

1. Synopsis	-	10 Marks
2. Major Experiment (Experiments indicated by **) (Systematic Qualitative Analysis)	-	35 Marks
3. Minor Experiment –I (Experiments indicated by)* (Preparation of Simple Organic Compound)	-	15 Marks
4. Practical viva voce	-	10 Marks
Total	-	70 Marks

PHARMACEUTICAL ORGANIC CHEMISTRY I TEXT BOOKS (THEORY)

1. Morrison TR, Boyd R. Text of organic chemistry. 6th ed. New Delhi;Prentice Hall of India Pvt. Ltd.
2. Finar IL. Organic chemistry, the fundamentals of chemistry, vol 1. 6th ed. Longman Publishers.
3. Bhal A, Bhal BS. A textbook of organic chemistry. Revised ed. S.Chand & Company Pvt Ltd.
4. Atherden LM. Bentley and Driver's textbook of pharmaceutical chemistry. 8th ed.

PHARMACEUTICAL ORGANIC CHEMISTRY I REFERENCE BOOKS (THEORY)

1. Graham STW. Fundamentals of organic chemistry. 5th ed. USA:John Wiley & Sons Inc.
2. Catm JM, Carm DJ. Organic chemistry. 13th ed. Saunders College of Publishing.
3. Brown, Organic chemistry.
4. Indian Pharmacopoeia. All editions. Delhi: The Controller of Publications, Ministry of Health and Family welfare, Govt. of India.
5. Jerry, March. Advanced organic chemistry. 4th ed. New Delhi;Wiley Eastern Limited.
6. Cram, Hammer. Pine Hendrickson organic chemistry.
7. Alinger, Cava, Dejongh. Organic chemistry.
8. Neckers, Doyle. Organic chemistry.
9. Agronnonov et. al., Problems and exercises in organic chemistry.
10. Man & Sounders. Practical organic chemistry.
11. Ahluwalia. Practical organic chemistry.
12. Pandey OP. Practical oraganic chemistry. S.Chand Publications.

PHARMACEUTICAL ORGANIC CHEMISTRY I REFERENCE BOOKS (Practicals)

1. Vogel AI. Elementary practical organic chemistry. London;ELBS and Longman Group Ltd.
2. Mann, Sounders. Practical organic chemistry. ELBS and Longman Group Ltd.
3. Pavia DL, Lampman G, Kriz GD. Introduction to organic laboratory techniques.
4. Indian Pharmacopoeia. All editions. Delhi: The Controller of Publications, Ministry of Health and Family welfare, Govt. of India.
5. Vogel. Textbook of practical organic chemistry. 4th ed. London;ELBS Longman.

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Melting Point Apparatus	10 nos
2. Triple beam balances	10 nos
3. Physical balances	05 nos
4. Suction Pumps	01 no
5. Water Baths	10 nos
6. Hot Plates	01 no
7. Oven	01 no
8. Refrigerator	01 no
9. Distillation Unit	01 no

1.5 PHARMACEUTICAL INORGANIC CHEMISTRY (THEORY)

75 Hours; 3 hours/week

1. Sources and effects of impurities in Pharmacopoeial substances, importance of limit test, general principles and procedures for limit tests for chloride, sulphate, iron, arsenic, lead and heavy metals. Modified procedures for limit tests for chlorides and sulfates in Potassium permanganate, sodium bicarbonate and sodium salicylate.

10 hours; 12-13 marks

2. General methods of preparation, assays (marked by *), storage condition and medicinal uses of inorganic compounds belonging to the following classes.

2.1 Medicinal Gases: Oxygen, Nitrous oxide, Carbon dioxide

2 hours; 2-3 marks

2.2 Gastrointestinal agents

Acidifiers: dilute HCl, ammonium chloride

Antacids: Classification of antacids, Ideal properties of antacids, combination therapy, Aluminium hydroxide gel*, Calcium carbonate, Sodium bicarbonate* Magnesium trisilicate, Magnesium carbonate (light and heavy), Magnesium hydroxide mixture*

Protective and adsorbents: Kaolin and Talc,

Laxatives, Purgatives and Cathartics: Magnesium sulphate and Sodium sulphate.

10 hours; 12-13 marks

2.3 Topical agents and Dermatological preparations:

Protective: Talc, Zinc oxide*, Zinc stearate,

Antimicrobials: Potassium Permanganate*, Chlorinated lime*, Iodine preparations, Boric acid*, Borax Hydrogen peroxide*

6 hours; 7-8 marks

- 2.4 **Dental products:** Dentifrices, anticaries agents, desensitizing agents, calcium carbonate, sodium fluoride, Stannous fluoride, Zinc chloride, Zinc eugenol cement.

3 hours; 4-5 marks

2.5 Miscellaneous agents:

Expectorants: Ammonium chloride* (Formal method), Potassium iodide.

Haematinics: Ferrous sulfate*, Ferrous gluconate, Ferrous Fumarate, Iron dextran injection, Iron and Ammonium citrate.

Emetics: Copper sulphate*

Antidotes: Definition, classification and mode of action-Sodium thiosulphate, Charcoal, (activated)

Pharmaceutical Aids: Definition and classification Bentonite, Barium sulphate, Magnesium stearate, Phenylmercuric acetate, Sodium benzoate

Antioxidants: definition, sodium metabisulphite.

6 hours; 7-8 marks

- 2.6 Major intra and extra cellular electrolytes, major physiological ions and electrolytes used for replacement therapy, physiological acid base balance, electrolyte combination therapy, ORS, Sodium chloride injection*, Dextrose and Sodium chloride injection, Calcium gluconate injection*

6 hours; 7-8 marks

3. Sources and types of errors, methods of minimizing errors, accuracy, precision

5 hours; 6-7 marks

4. Fundamentals of volumetric analysis

- 4.1 Definition of titration, titrant, titrand, equivalence point, end point, indicators, Equivalent weight, primary standard substances and their properties. Various methods of expressing concentration of primary and secondary standard substance **4 hours; 5-6 marks**
- 4.2 **Neutralisation titrations:** Examples of neutralization titrations, indicators choice of indicators, theory of indicators, neutralization curves, method of preparation, Standardization and Storage of oxalic acid, sodium hydroxide, hydrochloric acid
- 4.3 Theory of non aqueous titrations, classification of solvents used in non aqueous titrations, their leveling and differentiating effects. Estimation of Sodium Benzoate by non aqueous titrations **4 hours; 5-6 marks**
- 4.4 Redox titrations: Principle of redox titrations, Concepts of oxidation and reduction. Redox reactions, strength and equivalent weights of oxidizing and reducing agents, Preparation, standardization and storage of various volumetric solutions such as sodium thiosulfate, potassium permanganate and Iodine solution, theory of iodometry, iodimetry, bromometry, titrations with potassium iodate, potassium bromate, 2,6-dichlorophenol indophenols . **9 hours; 11-12 marks**
- 4.5 Principles of precipitation titrations, different methods-Mohr's, Modified Mohr's, Volhard's, Modified Volhard's, Fajan's with example. Estimation of sodium chloride. **5 hours; 6-7 marks**
- 4.6 **Complexometric titrations:** Ligands and their classification, principles of complexometric titrations, indicators, different types of complexometric titrations, estimation of calcium gluconate. **5 hours; 6-7 marks**

PHARMACEUTICAL INORGANIC CHEMISTRY (PRACTICALS)
75 Hours; 3 hours/week

(Following experiments to be covered in 25 practical classes)

1. Limit tests (7 exercises)

1. Limit test for chlorides*
2. Limit test for sulphate*
3. Limit test for Iron*
4. Limit test for heavy metals*
5. Limit test for Arsenic
6. Modifications in limit tests* for chloride and sulphates in potassium permanganate, sodium bicarbonate, sodium benzoate

2. Assay of the following compounds including standardisation**

1. Ammonium chloride-acid base titration (Formal titration)
2. Ferrous sulphate- (redox) Cerimetry
3. Copper sulphate- (redox) Iodometry
4. Calcium gluconate-complexometry
5. Hydrogen peroxide- (redox) Permanganometry
6. Sodium benzoate-nonaqueous titration
7. Sodium chloride-Modified Volhard's method
8. Assay of KI-KIO₃ titration
9. Assay of Zinc oxide (acid base) back titration

3. Test for identity for the following (3 exercises)

1. Sodium bicarbonate
2. Ferrous sulphate
3. Potassium chloride
4. Calcium chloride

4. Test for purity for the following (2 exercises)*

1. Swelling power of Bentonite
2. Ammonium salts in Potash alum.
3. Presence of Iodates in Potassium iodide

5. Preparation of inorganic pharmaceuticals (2 exercises)*

1. Boric acid
2. Potash alum
3. Magnesium hydroxide.
4. Magnesium sulphate

Note: ** Denotes major experiments

*** Denotes minor experiments**

SCHEME OF EXAMINATION: Practical and Viva Voce

1. Synopsis	10 Marks
2. Major Experiment	25 Marks
3. Minor Experiments	
a) Limit Test	13 Marks
b) Test for Purity or Preparation	12 Marks
4. Practical viva voce	10 Marks
Total	<u>70 Marks</u>

PHARMACEUTICAL INORGANIC CHEMISTRY TEXT BOOKS

1. Schroff ML. Inorganic pharmaceutical chemistry. Bombay;Five star publications.
2. Atherden LM. Bentely and Driver's textbook of pharmaceutical chemistry.
3. Block JH, Roche EB, Soine TO, Wilson CO. Inorganic medicinal and pharmaceutical chemistry.
4. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry Vol I & II. 4th ed. London;Stahlone Press of University of London.
5. Pandey OP, Bajpai DN, Giri S. Practical Chemistry. S Chand Publishers.
6. Shah, Qadry. Textbook of inorganic pharmaceutical chemistry.

PHARMACEUTICAL INORGANIC CHEMISTRY REFERENCE BOOKS

1. Lee JD. Concise inorganic chemistry. 4th ed.
2. Discher CA. Modern inorganic pharmaceutical chemistry.
3. Indian Pharmacopoeia. 3rd & 4th eds. Delhi: The Controller of Publications, Ministry of Health and Family welfare, Govt. of India;1985 and 1996
4. Ayers. Quantitative chemical analysis.
5. John HK. Analytical chemistry-principles. 3rd ed. New York:Sunders College Publication.
6. Hargis, Larry. Analytical chemistry- principles and techniques.
7. Skoog DA, West DM. Fundamental of analytical chemistry. 6th ed.
8. Walton. Principles and methods of chemical analysis.

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Analytical Balance	10 nos
2. Physical Balance	05 nos
3. Suction Pump	03 nos
4. Muffle Furnace	01 no
5. Oven	01 no
6. Hot Plate	05 nos
7. Water Bath	10 nos
8. Distillation Unit	01 no

1.6 MATHEMATICS (THEORY)

75 Hours; 3 Hours/week

1. Matrices: Definition of matrices, addition, subtraction, multiplication of matrices. Determinants of order two and three examples pharmaceutical applications of determinants, solution of simultaneous linear equations by Cramer's rule. **8 hours; 14 marks**

2. Trigonometry: Relation between the sides and angles of a triangle. Inverse trigonometric functions **6 hours; 12 marks**

3. Analytical Geometry: Point – Distance – Examples. Straight line: - General form of the Equation of a straight line, slope of the line, slope point form. Condition for two lines to be parallel and perpendicular, Perpendicular distance from the point to the line, angle between two lines. Circle: General Equation of a circle, finding centre and radius of the circle. **6 hours; 10 marks**

4. Differential Calculus: Limit of a function, derivative of a function. Differentiation of a sum, product and quotient. Differentiation of composite functions, parametric functions, exponential functions, inverse trigonometric functions, Logarithmic differentiation. **10 hours; 19 marks**

5. Integral Calculus: Indefinite integrals, integration by substitution and integration by parts important properties of definite integrals. **8 hours; 16 marks**

6. Differential Equations: Definition formation of differential equations, differential equations of the first order and first degree. Methods of solving ordinary differential equations: variables separable, homogenous, linear, differential equations and equations reducible to these forms, linear differential equations with constant coefficients (higher order), homogeneous linear differential equations, simultaneous linear differential equations of the first order, Pharmaceutical applications. **12 hours; 19 marks**

MATHEMATICS REFERENCE BOOKS

1. Differential calculus – Shantinakaran
2. Integral calculus –Shantinakaran
3. Integral calculus - Golden Series
4. Engineering Mathematics – Grewaf
5. Trigonometry Part – I - S.L. Loncy
6. A Text Book of Mathematics for second year Pre-university - Prof. B.M. Sreenivasa Rao and S. Nagaraj
7. College Mathematics - G.K. Ranganath
8. Differential Equations - Golden Series

1.6 BIOLOGY (THEORY)
50 Hours; 2 hours/week

PART A. BOTANY

1. General organisation of the plant and plant cell and its inclusion **2 hours; 4 marks**
2. The plant tissues (Meristematic & Permanent) **2 hours; 4 marks**
The broad classification of plant kingdom
3. Morphology of plant parts like roots, stem and leaf and their modifications **2 hours; 4 marks**
4. Inflorescence, flower and its pollination **2 hours; 4 marks**
Morphology of fruits and seeds **2 hours; 4 marks**
Plant taxonomy: Study of different families viz. Leguminaceae, Umbelliferae, Solanaceae, Liliaceae, Zingiberaceae, Rubiaceae with special reference to medicinal plants. **6 hours; 12 marks**
5. **Plant physiology:** Transpiration, Photosynthesis, Respiration, Growth **4 hours; 8 marks**
The study of: 1) Fungi: eg. Yeast, Penicillin 2) Bacteria **6 hours; 12 marks**

PART B. ZOOLOGY

1. The study of Animal cell, Animal Tissue, Differences between plant and animal cell. **4 hours; 8 marks**
2. The detailed study of frog. The study of representatives of Pisces, Reptiles and Aves with special reference to the medicinal values. **6 hours; 12 marks**
3. General organisation of a mammal **5 hours; 10 marks**
4. The study of poisonous animals. **5 hours; 10 marks**

BIOLOGY (PRACTICALS)
50 Hours; 2 hours/week

PART A. Botany

1. The general organization of a typical plant and morphological study of plant parts studied in theory (Roots, Stem, Leaves and their modifications) *
2. Inflorescence and Flower *
3. Fruits and seeds (Identification) *
4. Plant tissues through permanent slides * and Histological preparations of roots, stems, leaves by eosin or Saphranian stain **
5. Simple experiments on plant physiology *
6. Identification of cell inclusions *

Part – B : Zoology

1. The study of animal tissues through permanent slides *
2. The study of various systems of frog using charts and models **
3. Identification of poisonous animals *
4. Demonstration of dissection in rats *
5. Identification of representatives of animals phyla like Fish, Frog, Reptile and Mammal *

Note: ** Denotes major experiments

*** Denotes minor experiments**

SCHEME OF EXAMINATION

1. Synopsis	-	10 marks
2. Study of any one system of frog	-	15 marks
3. Transfer section of leaf root or stem	-	15 marks
4. Minor experiment 1	-	10 marks
5. Minor experiment 2	-	10 marks
6. Viva voce	-	10 marks
Total		70 marks

BIOLOGY REFERENCE BOOKS

1. Dutta AC. A class book of botany.
2. Ekkambernath I. Outlines of zoology.
3. Tayler, Weber. Functional anatomy of a mammal.
4. Atwood. Comparative anatomy.
5. Prasad SN. A textbook of vertebrate zoology .
6. Ekkambernath I. Vertebrate zoology vol. II

1.7 COMPUTER SCIENCE AND STATISTICS (THEORY)

75 hours ; 3 hours/week

PART A: STATISTICS

1. Definition, data frequency, distribution, Classification of data. General graphical representation of the data: histogram, Frequency curve and frequency polygon and Ogive. Semilog line graph. Use of semilog scale-examples. **8 hours; 10 marks**
2. Measures of central tendency: Arithmetic mean, geometric mean and harmonic mean. Median, Mode, Calculation of quartiles and percentiles deciles. **8 hours; 10 marks**
3. Measures of dispersion: Range, quartile deviation, Mean deviation, Standard deviation, variance, coefficient of variation, skewness and kurtosis. **7 hours; 9 marks**
4. Correlation, Regression: Linear correlation, coefficient of correlation: Karl Pearson's formula, Spearman's rank method, curve fitting by the method of least squares: Fitting a straight line $y=a+bx$, Fitting a power curve $y=ax^b$, Fitting an exponential curve $y=abx$, $y=aebx$, Regression analysis for lines. **12 hours; 14 marks**
5. Definition of probability: Random experiment, sample space, Addition and multiplication laws of probability (without proof), probability distribution: binomial, Poisson's normal and chi-square, Student test and Pharmaceutical examples. **10 hours; 12 marks**

PART B : COMPUTER SCIENCE

1. a) Computer Fundamentals **6 hours; 8 marks**
Introduction, Classification of Computers (Based on all Criteria), Functional Units, Evaluation of Computer Languages, Assembler, Compiler, Interpreter.
b) Number Systems **4 hours; 4 marks**
Introduction to Number Systems - Numeric and Non-Numeric Representation of Data, Decimal, Binary (Addition, Subtraction, Multiplication, Division) and Hexadecimal Number Systems.
2. a) Introduction to Networks **3 hours; 3 marks**
i) Network Topologies - Linear, Ring, Star, Mesh, Hybrid, Types of Network - Lan, Man, Wan
ii) Internet and Intranet, Protocols (TCP, IP, SMTP, FTP, HTTP etc.),
iii) Web pages, Browsers, Search Engines
b) Introduction to DBMS **5 hours; 6 marks**
Data and Information, Database Users, Characteristics of the Database Approach, Advantages of using DBMS, Data Models, Schemas and Instances, Database Languages (DML, DDL)
3. a) Introduction to OS **2 hours; 2 marks**
Definition and Types of Operating Systems (Unix, Windows, Mac OS)
b) Introduction to Office Packages **6 hours; 7 marks**
Microsoft Word, Microsoft Excel, Microsoft PowerPoint

4. Introduction to Programming Languages – C **4 hours; 5 marks**
Features and Applications of C, Character Set, Definitions and Declarations of Identifiers, Variables, constants, Keywords, Data types, Operators and Expressions, Operator Precedence
Various types of standard input and output statements.

COMPUTER SCIENCE AND STATISTICS (PRACTICALS)
50 hours ; 2 hours/week

CYCLE – I

1. **MS-Word** **6 hours**
Creating Document, Letters, Banners, Pamphlets, Newspapers, Alignment of Paragraphs and Fonts, Page Settings, Mail Merge, Creating Tables, Header Footers, Inserting Images, Files.
2. **MS-Excel** **8 hours**
Creating Salary Slips, Creating Marks Cards, Creating Student/Employee Complete Data
Creating Different Graphs with respect to the given data eg. Salary Slip, Employee Performance. Students Marks Cards, Calculating Sum, Average - Manual and Automatic by using tools.
3. **MS-PowerPoint** **6 hours**
Creating Colorful Slides with respect to any given data or to the subject using audio and video files

CYCLE – II

4. **C Programming Lab** **15 hours**
 1. Program to Find sum of even and odd numbers separately in the given list of numbers
 2. Program to find the largest and smallest of N numbers
 3. Given two numbers, program to perform arithmetic operations using switch statement.
 4. Program to generate Fibonacci Series upto N numbers using Do-while loop
 5. Program to generate Prime Numbers using for loop.
 6. Program to check whether the given number is factorial or not.
 7. Program to insert a sub-string into a given string
 8. Program to add, subtract and Multiply two MxN matrices
 9. Program to swap two numbers using functions.
 10. Program to create a simple marks card assuming appropriate conditions

CYCLE – III

5. Oracle / MS SQL **15 hours**
6. Create a Database of any Size
7. Create 6 Tables with respect to any subject
8. Use Script language SQL / PL SQL
9. Using script commands, SELECT, INSERT, UPDATE, DELETE, DROP, CREATE, RENAME
10. JOIN, LEFT JOIN, RIGHT JOIN, INNER JOIN
11. Create a customized report with respect to the subject assigned.
12. Introduction to PERL Scripting

STATISTICS REFERENCE BOOKS

1. Steven PM, Andreas K. Applied statistics in the pharmaceutical industry. 2001.
2. Munrao BH. Statistical methods for health care research. 4th ed. Lippincott Company Publication;2000.
3. Pagano M, Kimberlee, Gauvreau. Principles of biostatistics. 10th ed. Lib of American Publication;2000.
4. Gotteti BK, Patricia KS. Statistics. London;Jones and Bartlet Publication;1994.

COMPUTER SCIENCE REFERENCE BOOKS

1. Thomas CB. Digital Computer Fundamentals. Tata Mc Graw Hill Publishing.
2. Sinha. Fundamentals of computers.
3. Ramez E, Shamkanth BN. Fundamentals of database systems.
4. IVAN Bayross, SQL, PL/SQL The programming Language of Oracle.

1.8 KANNADA (THEORY)

25 Hours; 1 hour/week

ಕನ್ನಡ : ಒಂದು

ಪಠ್ಯಕ್ರಮದ ರೂಪರೇಖೆ

ಸ್ಥಾನ : ಬಿ. ಫಾರ್ಮಸಿ ಮೊದಲ ವರ್ಷ

ಸಮಯ : 15 ಘಂಟೆಗಳು (ಹದಿನೈದು ಘಂಟೆಗಳು)

ಪಠ್ಯಕ್ರಮ : ವಿದ್ಯಾರ್ಥಿ/ ವಿದ್ಯಾರ್ಥಿನಿಯರು ದಿನನಿತ್ಯ ಸಂಪರ್ಕಿಸಬಹುದಾದ ಜನಸಾಮಾನ್ಯರೊಡನೆ ಔಷಧಿಗೆ ಸಂಬಂಧಿಸಿದಂತೆ ಕನ್ನಡದಲ್ಲಿ ಸಂಭಾಷಣೆ ಮಾಡಲು ಹಾಗೂ ತಿಳುವಳಿಕೆ ನೀಡಲು ಸಹಕಾರವಾಗುವಂತೆ ಪಠ್ಯಕ್ರಮದ ಮಾದರಿಯನ್ನು ಅಳವಡಿಸುವುದು.

ಉದ್ದೇಶ : 1. ದಿನಬಳಕೆಯ ವ್ಯವಹಾರದಲ್ಲಿ ಔಷಧಿಗೆ ಸಂಬಂಧಪಟ್ಟಂತೆ ಕನ್ನಡ ಭಾಷೆಯ ಅಳವಡಿಕೆ.

2. ಕನ್ನಡೇತರರಿಗೆ ಕನ್ನಡ ಭಾಷೆಯ ಪರಿಚಯ ಮಾಡಿಕೊಡುವುದು.

ಪಠ್ಯಕ್ರಮದ ವಿವರ

ಘಟಕ ಒಂದು : (ಅ) ಅಕ್ಷರಮಾಲೆ, ಸ್ವರಗಳು, ವ್ಯಂಜನಗಳು

(ಆ) ಪದ್ಯ ಪದಪುಂಜ, ವಾಕ್ಯ ರಚನೆ, ಪತ್ರಲೇಖನ, ಪ್ರಬಂಧರಚನೆ

(ಪ್ರಾರಂಭದ, ಸಮಯವನ್ನು ಅಭ್ಯಾಸ, ಚರ್ಚೆ, ಮೌಕಿಖ ಪ್ರಯತ್ನಕ್ಕಾಗಿ ಮೀಸಲಿಡಬೇಕು)

ಎರಡು : ಔಷಧಿಗಳಿಗೆ ಸಂಬಂಧಿಸಿದ ಪದಗಳು (ಇಂಗ್ಲೀಷಿನಿಂದ ಕನ್ನಡಕ್ಕೆ ಔಷಧಿಗಳ ಸಾಮಾನ್ಯಬಳಕೆಗೆ ಸಂಬಂಧಪಟ್ಟಂತೆ)

ಮೂರು: ರೋಗಿ ಹಾಗೂ ಔಷಧ ತಜ್ಞರ ನಡುವೆ ಸಾಮಾನ್ಯವಾಗಿ ನಡೆಯುವ ಸಂಭಾಷಣೆ

(ಅ) ಪ್ರಶ್ನಾರ್ಥಕ ಸಲಹೆ ಕೊಡುವ ವಾಕ್ಯಗಳು

(ಆ) ವೈದ್ಯರೊಂದಿಗೆ ಹಾಗೂ ಇತರೆ ಸಹಚರರೊಂದಿಗೆ ವ್ಯವಹರಿಸಲು, ಸಂಭಾಷಣೆ ನಡೆಸಲುಬೇಕಾದ ವಾಕ್ಯಗಳು.

ಅಧ್ಯಯನಕ್ಕೆ ಶಿಫಾರಸ್ಸು ಮಾಡಲಾಗಿರುವ ಗ್ರಂಥಗಳು

1. ಕನ್ನಡ ವ್ಯಾಕರಣ (8, 9 ಮತ್ತು 10ನೇ ತರಗತಿಗಳಿಗೆ ಕರ್ನಾಟಕ ಸರ್ಕಾರ, ಪಠ್ಯಪುಸ್ತಕಗಳ ಇಲಾಖೆ)
2. ವ್ಯವಹಾರಿಕ ಕನ್ನಡ : ಹೆಚ್. ಎಸ್. ಕೆ.
3. ಪತ್ರ ಲೇಖನ : ಕನ್ನಡ ಸಾಹಿತ್ಯ ಪರಿಷತ್ತು
4. ಲೇಖನ ಕಲೆ : ಎನ್. ಪ್ರಹ್ಲಾದ್‌ರಾವ್
5. ಆರೋಗ್ಯ ಮತ್ತು ಇತರೆ ಪ್ರಬಂಧಗಳು : ಡಾ|| ಪಿ.ಎನ್. ಶಂಕರ್
6. ವೈದ್ಯ ಪದಗಳ ಹುಟ್ಟು ರಚನೆ : ಡಾ|| ಡಿ. ಎನ್. ಶಿವಪ್ಪ

ಕನ್ನಡ : ಎರಡು

ಪಠ್ಯಕ್ರಮದ ರೂಪರೇಖೆ

ಸ್ಥಾನ	:	ಬಿ. ಫಾರ್ಮಸಿ ಮೊದಲ ವರ್ಷ
ಸಮಯ	:	10 ಘಂಟೆಗಳು (ಹತ್ತು ಘಂಟೆಗಳು)
ಉದ್ದೇಶ	:	ಜನಾರೋಗ್ಯದ ಬಗ್ಗೆ ಜನಸಮುದಾಯಕ್ಕೆ ತಿಳುವಳಿಕೆ ಕೊಡುವುದು.

ಪಠ್ಯಕ್ರಮದ ವಿವರ

ಘಟಕ ಒಂದು	:	ಜನಾರೋಗ್ಯದಲ್ಲಿ ಬಳಸುವ ಔಷಧಗಳ ಬಗ್ಗೆ ಮಾಹಿತಿ, ಸಂದರ್ಶನ ಮಹತ್ವ, ಸಂದರ್ಶನದ ಗುಣಗಳು, ಅನುಸರಿಸಬೇಕಾದ ನಿಯಮಗಳು ಅವ್ಯಯ ಮಾಹಿತಿಗಳ ಸಂಗ್ರಹ, ಸಂದೇಹಗಳು (ಶಂಕೆಗಳು) ಕುಟುಂಬ ಸಂಪರ್ಕ, ಸಂದರ್ಶಕ ಭಾಷೆಯಾಗಿ ಕನ್ನಡ ಬಳಕೆ

ಎರಡು	:	ವೈಯಕ್ತಿಕ ಆರೋಗ್ಯ
ಮೂರು	:	ನೈಸರ್ಗಿಕ ನೈರ್ಮಲ್ಯ
ನಾಲ್ಕು	:	ಸಾಂಕ್ರಾಮಿಕ ರೋಗಗಳು ಮತ್ತು ಅವುಗಳ ತಡೆಗಟ್ಟುವಿಕೆ
ಐದು	:	ಆಹಾರ ಮತ್ತು ಆರೋಗ್ಯ
ಆರು	:	ತಾಯಿ ಮತ್ತು ಮಗುವಿನ ಆರೋಗ್ಯ
ಏಳು	:	ಕುಟುಂಬಕಲ್ಯಾಣ ಯೋಜನೆ, ಅದರ ಉದ್ದೇಶ ಮತ್ತು ಲಾಭಗಳು

ಅಧ್ಯಯನಕ್ಕೆ ಶಿಫಾರಸ್ಸು ಮಾಡಲಾಗಿರುವ ಗ್ರಂಥಗಳು

1. ಸಮಾಜ ಆರೋಗ್ಯ : ಡಾ|| ಎಸ್. ಎ. ನಾರಾಯಣ್
2. ತಾಯಿ ಮಗು : ಡಾ|| ಅನುಪಮ ನಿರಂಜನ್
3. ಪರಿಸರ ಮಲಿನತೆ: ಕರ್ನಾಟಕ ರಾಜ್ಯ ವಿಜ್ಞಾನ ಪರಿಷತ್ತಿನ ಪ್ರಕಟಣೆಗಳು

1.9 INDIAN CONSTITUTION (THEORY)

25 Hours; 1 hour/week

1. Meaning of the term “Constitution” making of the Indian Constitution 1946-49.
2. The democratic institution created by the Constitution Bicameral system of Legislature at the Centre and in the States.
3. Fundamental Rights and Duties...Their content and significance.
4. Directive Principles of States Policies ...The need to balance Fundamental Rights with Directive Principles.
5. Special Rights created in the Constitution for: Dalits, Backwards, Women and Children and the Religious and Linguistic Minorities.
6. Doctrine of Separation of Powers-----Legislative, Executive and Judicial and their functioning in India.
7. The Election Commission and State Public Service Commissions.
8. Method of amending the Constitution.
9. Enforcing rights through Writs: Certiorari, Mandamus, Quo warranto and Habeas Corpus.
10. Constitution and Sustainable Development in India.

CONSTITUTION OF INDIA REFERENCE BOOKS

1. J.C. Johari: The Constitution of India—A Politico-Legal Study— Sterling Publication Pvt. Ltd. New Delhi.
2. J.N Pandey: Constitution Law of India, Allahabad, Central Law Agency, 1998.
3. Granville Austin: The Indian Constitution—Corner Stone of a Nation— Oxford, New Delhi, 2000.
4. <http://india.gov.in/my-government/constitution-india>.

SYLLABUS FOR II YEAR B.PHARM

2.1 PHYSICAL PHARMACEUTICS (THEORY)

75 hours ; 3 hours/week

1. **Distribution law:** Explanation, limitations and applications. **4 hours; 6-8 marks**
2. **Kinetics & drug stability:** Rates and molecularity of a reaction, determination of order, factors influencing rate of reactions, stabilization of drugs, applications of chemical kinetics to the stability testing of pharmaceuticals. Simple numerical problems. Stabilization of medicinal agents against common reactions like hydrolysis and oxidation. Accelerated stability testing in dating of pharmaceutical dosage forms by ICH guidelines. **8 hours; 13-15 marks**
3. **Interfacial phenomenon:** Liquid interfaces, adsorption at liquid/solid interfaces, adsorption isotherms, concept of contact angle, hydrophile lipophile balance, spreading coefficient, Gibb's adsorption equation and electrical properties of interfaces. **6 hours; 10-12 marks**
4. **Diffusion and dissolution:** Steady state diffusion, types of diffusion, diffusion equation, diffusion cells, dissolution of tablets and capsules, Hixon-Crowell cube root law, dissolution apparatus; factors affecting dissolution. **5 hours; 8-10 marks**
5. **Rheology:** Newtonian and Non-Newtonian systems, thixotropy, determinations of rheological properties (single and multipoint instruments). Applications to pharmacy. Rheological consideration, preparation, physical stability and evaluation of suspensions. Rheology of emulsions, micro-emulsions, multiple emulsions. **9 hours; 13-15 marks**
6. **Micrometrics:** Particle size distribution, methods for determining particle size, shape and surface area. Derived properties of powders. Simple numerical problems. **5 hours; 8-10 marks**
7. **Colloids:** Definition, types, preparation, purification, stabilization of colloids, properties, optical properties, kinetic properties, electrical properties, Donnan membrane phenomenon. **5 hours; 8-10 marks**
8. **Complexation:** Types of complexes, metal complexes, organic molecular complexes, inclusion compounds, methods of analysis of complex. **5 hours; 8-10 marks**
9. **Analytical techniques :** Brief introduction and applications of newer analytical techniques – DSC, X-Ray Diffraction, X-Ray Crystallography, SEM, TEM. **3 hours; 5-7 marks**

PHYSICAL PHARMACEUTICS (PRACTICALS)
75 hours ; 3 hours/week

1. Determination of viscosity of liquids using Ostwald's viscometer.*
2. Determination surface tension of liquid by drop weight method.*
3. Study of flow properties of granules viz., rate of flow, angle of repose, bulk density.*
4. Preparation, stabilization and evaluation of hydrophobic colloids.**
5. Determination of partition coefficient of benzoic acid between benzene and water.**
6. Determination of HLB number of surfactants by Griffins method.**
7. Determination of shelf life using accelerated stability studies.**
8. Determination of rate constant for first order reactions.**
9. Determination of rate constant for second order reactions.**
10. Study of particle size distribution by optical microscopy.*
11. Determination of required HLB number for the oil phase to be presented as an emulsion. Formulation and evaluation of emulsion.**
12. Determination of constants of Freundlich and Langmuir adsorption for adsorptions of acetic acid on activated charcoal.**
13. Determination of stability constant of glycine-copper complex by pH titration method.**
14. Construction of rheograms and study of rheological behaviour of biphasic systems employing multipoint viscometers. (For demonstration)

Note: ** Denotes major experiments * Denotes minor experiments

SCHEME OF EXAMINATION

1. Synopsis	-10 Marks
2. Major experiment (indicated by **)	-30 Marks
3. Minor experiment (indicated by *)	-20 Marks
4. Viva voce	-10 Marks
Total	= 70 Marks

PHYSICAL PHARMACEUTICS REFERENCE BOOKS

1. Carter SJ. Cooper and Gunn's Tutorial pharmacy. 6th ed. New Delhi: CBS Publishers; 2000.
2. Gennaro AL. Remington: The science and practice of pharmacy Vol I and II. 20th ed. Philadelphia: Lippincott Williams and Wilkins; 2000.
3. Martin A, Bustamante P, Chun AHC. Physical pharmacy. 4th ed. New Delhi: BI Waverly Pvt Ltd; 1995.
4. Rawlins EA. Bentley's textbook of pharmaceuticals. 8th ed. New Delhi: Reed Elsevier India Pvt Ltd; 2010.
5. Subrahmanyam CVS. Essentials of physical pharmacy. Delhi: Vallabh Prakashan; 2003.
6. Subrahmanyam CVS. Textbook of physical pharmaceuticals. 2nd ed. Delhi: Vallabh Prakashan; 2003.
7. Willard HH, Meritt LL, Dean JA, Settle FA. Instrumental methods of analysis. 7th ed. New Delhi: CBS Publishers & Distributors; 1986.

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Brookfield's viscometer	01 no.
2. Digital electronic balances	03 nos.
3. Digital pH meters	01 no.
4. Microscopes	05 nos.
5. Ostwald's Viscometers	15 nos.
6. Stage and eye piece micro meters	05 nos.
7. Stalagmometers	15 nos.

2.2 PHARMACEUTICAL MICROBIOLOGY AND BIOTECHNOLOGY (THEORY)

75 hours ; 3 hours/week

1. Introduction, a brief history of microbiology (spontaneous generation, theory of biogenesis, germ theory of disease, contributions of Antony Van Leeuwenhoek, Edward Jenner, Robert Koch, Louis Pasteur and Alexander Fleming), pharmaceutical importance of microorganisms. **4 hours; 2-5 marks**
2. Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, culture media with emphasis on special purpose media, growth curve, continuous growth, synchronous growth, isolation and preservation [space] methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count), identification of bacteria using colony characters, staining techniques (simple, Gram's & Acid fast staining) and biochemical tests (IMViC). **12 hours; 12-17 marks**
3. Study of morphology, classification, reproduction/replication and cultivation of Fungi and Virus. **4 hours; 2-5 marks**
4. Study of principle, procedure, merits, demerits and applications of thermal, radiation, gaseous (ethylene oxide), filtration methods of sterilization. Brief study on sterilization indicators. Study of general methods of sterility testing including interpretation of its results. **12 hours; 10-15 marks**
5. Ideal properties, classification and factors affecting the action of disinfectants. Mode of action and uses of phenols, halogens, metallic salts and aldehydes. Evaluation of bacteriostatic, bactericidal (phenol coefficient methods) properties of disinfectants and preservatives. **8 hours; 5-9 marks**
6. Types of immunity, antigens and antigenic determinants, structure and formation of antibodies, classification of immunoglobulins, antigen-antibody reactions (precipitation and agglutination reactions), Types of vaccines, difference between vaccine & sera, killed vaccine & attenuated vaccine, preparation of BCG vaccine, Tetanus toxoid and Polio vaccine, immunization program and importance of booster dose, diagnostic tests viz. ELISA, Western blot, Widal and Mantoux. **12 hours; 12-17 marks**
7. Introduction to fermentation technology, design and operation of a fermenter, production of streptomycin and vitamin B₁₂. Principles and methods of microbiological assays with reference to streptomycin and vitamin B₁₂. **8 hours; 7-10 marks**
8. Introduction to recombinant DNA technology, tools and techniques of gene manipulation, production of recombinant insulin and hepatitis B vaccine. **5 hours; 5-7 marks**
9. Types of cell lines, basic requirements, advantages, disadvantages and applications of animal cell culture. Production and applications of monoclonal antibodies. **5 hours; 5-7 marks**

10. Study of causative organism, mode of transmission, signs and symptoms, treatment and prevention of microbial diseases like cholera, typhoid, tuberculosis, AIDS, malaria and dengue. **5 hours; 5-7 marks**

PHARMACEUTICAL MICROBIOLOGY AND BIOTECHNOLOGY (PRACTICALS)

75 hours ; 3 hours/week

1. Study of apparatus used in experimental microbiology.
2. Sterilisation of glassware, preparation and sterilisation of media.
3. Staining techniques – Simple staining*, Gram's staining. **
4. Motility testing*
5. Total and viable count*.
6. Isolation and maintenance of pure culture*.
8. Sensitivity testing.*
9. Microbiological assay of antibiotics by cup plate method**.
10. Sterility testing by direct transfer and membrane filtration technique*.
11. Initiation of callus culture*
12. Estimation of DNA by spectroscopic method.**
13. Estimation of RNA on spectroscopic method. **

Note: ** Denotes major experiments

*** Denotes minor experiments**

SCHEME OF EXAMINATION

1. Synopsis	-10 Marks
2. Major experiment**	-25 Marks
3. Minor experiment*	-15 Marks
4. Minor experiment*	-10 Marks
5. Viva-Voce	-10 Marks
Total	- 70 Marks

PHARMACEUTICAL MICROBIOLOGY REFERENCE BOOKS

1. *Hugo and Russell's Pharmaceutical Microbiology* (2004), 7th Ed, Blackwell Publishing Ltd, 9600 Garsington Road, Oxford OX4 2DQ, UK
2. *Microbiology: an introduction* (2010) by Gerard J. Tortora, Berdell R. Funke, Christine L. Case, 10th ed., Pearson Education, Inc., San Francisco, CA 94111
3. Prescott, Harley and Klein's *Microbiology* 2 Ed, W. C Brown Publishers, 1993.
4. Pelczar Reid, *Microbiology*, 5th Ed, Tata MC Graw- Hill Publishers company, 1993.
5. Ananthnarayan and Pannicker, *Text Book of Microbiology*, 6 Ed, Orient-longman, Chennai, 1995.
6. S.P. Vyas and Dixit *Pharmaceutical Biotechnology*, 1 Ed, CBS Publishers & distributors, NewDelhi, 1998.
7. S.S Kori *Pharmaceutical Biotechnology, .Fundamentals and Applications*, 1 Ed Vallabh Prakashan, New Delhi.
8. *Microbiology: A Laboratory Manual* By Cappuccino, Pearson Education India, 2005
9. Frobisher M, *Fundamentals of Microbiology*,9 Ed, Toppan Company Ltd. Tokyo. Japan.
10. Collins C.H. *Microbiological Methods*. 6 Ed, Butterworth, London. 1989.
11. Stanier, Ingraham, *General Microbiology* 5 Ed., Wheelies and Painter. 1987.
12. Cooper & Gunn's – *Tutorial Pharmacy*, 9 Ed, CBS Publisher and Distribution, 1986.
13. Roitt, *Immunology*, 4 Ed , Harwood academic publishers, Mosby, London.1997.
14. Bentley's *Text Book of Pharmaceutics* by Rawlins 8 Ed, ELBS publication, 1984.
15. *Pharmacopoeia of India* Govt. of India

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Autoclave	02 nos
2. Hot air oven	01 no
3. B.O.D. Incubator	01 no
4. Refrigerator	01 no
5. Laminar air flow	01 no
6. Colony counter	02 nos
7. Zone reader	01 no
8. Spectrophotometer	01 no
9. Microscope with stage	20 nos
10. Sterility testing unit	01 no

2.3 PATHOPHYSIOLOGY (THEORY)

75 hours ; 3 hours/week

1. a) Definition of pathology, health and disease. Terminologies used in pathology. b) Basic principles of cell injury and adaptation: Causes, pathogenesis and morphology of cell injury, Cellular adaptation's-physiologic and pathologic adaptations, Cellular ageing and death, Antioxidant enzymes-superoxide dismutase, catalase and glutathione peroxidase.

6 hours; 10-12 marks

2. **Inflammation:**a) Definition, causes, signs ,types of inflammation and chemical-mediators. b) Pathogenesis of acute inflammation (vascular events, Cellular events, transdate, exudate, edema, phagocytosis). c) Pathogenesis of chronic-inflammation and difference between acute and chronic inflammation. d) Tissue renewal and repair: regeneration healing and fibrosis. e) Wound healing: process of wound healing, types of cells, factors influencing healing of wounds.

12 hours; 10-12 marks

3. **Diseases of Immunity:** Components of the immune system: Cells involved in immune response- T and B cells, Macrophages, Dendritic cells and Natural killer cells. MHC proteins or transplantation antigens. Immune Tolerance.

A) Hypersensitivity: Hypersensitivity type I, II, III, IV. Biological significance of hypersensitivity. Allergy due to food, chemicals and drugs. **B) Auto-immunity:** Mechanism of Autoimmunity. Classification of autoimmune diseases in man. Transplantation rejection (types and mechanisms). **C) Acquired Immune Deficiency Syndrome (AIDS) D) Amyloidosis.**

12 hours; 10-12 marks

4. **Cancer:** General aspects of neoplasia, Definition, terminology, Differences between benign and malignant tumors. Etiology and pathogenesis of cancer. General biology and classification of malignant tumors. Invasions and metastasis of cancer.

10 hours; 6-10 marks

5. **Shock:** Types, mechanism, stages and Management

2 hours; 2-5 marks

6. **Biological effects of radiation:** Introduction on radiation, strength of radiation, mechanism of action of ionizing and non-ionizing radiations and their toxic effects.

1 hour; 2-4 marks

7. **Environment and Nutritional diseases:**Obesity, Malnutrition, Pathogenesis of deficiency diseases with special reference to vitamins and minerals, Air pollution and smoking — SO₂, NO and CO.

4 hours; 2-4 marks

8. **Pathophysiology (etiology, pathogenesis, signs and symptoms) of common diseases/disorders:** Peptic ulcer and inflammatory bowel disease, Gastritis, Hypertension, Angina, Myocardial Infarction, Congestive cardiac failure, Atherosclerosis, Stroke (Ischemic and Hemorrhage), Diabetes Mellitus, Hypo and hyperthyroidism, Cirrhosis and Alcoholic liver diseases, Asthma and chronic obstructive airway diseases, Parkinsonism, Schizophrenia, Depression and Mania, Alzheimer's disease, Acute and chronic renal failure.

16 hours; 16-18 marks

9. **Pathophysiology (causative organisms, mode of transmission, pathogenesis, signs and symptoms) of infectious diseases:** Hepatitis - infective hepatitis, Sexually transmitted

diseases (Syphilis, Gonorrhea), Pneumonia, Typhoid, Urinary tract infections, Tuberculosis, Leprosy, Malaria, Dysentery (Bacterial and amoebic), Dengue and Chikungunya.

13 hours; 6-8 marks

10. Genetics and chromosomal disorders: Mendelian disorders, Cytogenic disorders (Karyotypic abnormalities)

3 hours; 6-8 marks

PATHOPHYSIOLOGY TEXT BOOKS

1. Kumar V., Abbas A.K. and Aster J., Robbins Basic Pathology, 9th Edition, Elsevier, 2012.
2. Mohan H., Textbook of Pathology, 6th Edition , Jaypee Brothers, Medical Publishers, 2010.

PATHOPHYSIOLOGY REFERENCE BOOKS

1. Kumar V., Abbas A.K., Fausto N. and Aster J., Robbins and Cotran Pathologic Basis of Disease, 8th Edition , Saunders, 2009.
2. Mitchell R., Kumar V., Fausto N., Abbas A.K. and Aster J., Pocket comparisons to Robbins Pathologic Basis of Disease, 8th Edition, Saunders, 2011.
3. Kumar, Cotran, Robbins. Robbin's Basic pathology. 7th edition. Elsevier.

2.4 APPLIED BIOCHEMISTRY (THEORY)

75 hours ; 3 hours/week

1. Bio energetics **3 hours; 4-5 marks**

- a) Concept of free energy and its determination; redox potential
- b) Energy rich compounds; ATP; Cyclic AMP; their biological significance

2. Biological Oxidation **5 hours; 6-7 marks**

- a) Electron transport chain (its mechanism and role)
- b) Inhibitors and Uncouplers of ETC
- c) Oxidative phosphorylation
- d) Substrate level phosphorylation and oxidative phosphorylation

3. Proteins **2 hours; 2-3 marks**

Definition, classification, biological significance, properties viz, denaturation, isoelectric point

4. Enzymes and Coenzymes **13 hours; 16-17 marks**

- a) Definition ; Nomenclature ; IUB Classification
- b) Properties of enzymes;
- c) Factors effecting enzyme activity;
- d) Enzyme kinetics (Michaelis plot ; Line Weaver Burke plot)
- e) Enzyme Inhibition (with examples)
- f) Iso-enzymes
- g) Enzyme Induction; repression
- h) Applications of enzymes
- i) Coenzymes, categories of reactions requiring coenzymes;
- j) Structure of coenzymes, and their biochemical role
- k) Vitamins - water soluble, fat soluble

5. Carbohydrate metabolism **13 hours; 16-17 marks**

- a) Introduction: Definition, classification and biological significance
- b) Glycolysis along with significance and energetics
- c) Glycogenesis glycogenolysis,
- d) TCA cycle; (Amphibolic nature of TCA cycle) along with significance and energetics
- e) Gluconeogenesis and its significance
- f) Various shuttle systems (glycerol phosphate; Malate aspartate)
- g) HMP Shunt Pathway and its significance
- h) Uronic acid pathway and galactose metabolism
- i) disorders of carbohydrate metabolism: glycogen storage diseases, Diabetes mellitus
- j) Hormonal regulation of carbohydrate metabolism
- k) Glucose tolerance test and blood glucose regulation.

6. Lipid metabolism

10 hours; 12-13 marks

- a) Introduction: Definition, classification, essential fatty acids
- b) Oxidation of saturated (palmitic acid) fatty acids
- c) Oxidation of unsaturated fatty acids (-linolenic acid)
- d) Oxidation of odd numbered fatty acids
- e) Formation and fate of ketone bodies
- f) Cholesterol metabolism,
- g) Biosynthesis of fatty acids (de novo)
- h) Phospholipids and sphingolipids.

7. Amino acid metabolism

12 hours; 14-15 marks

- a) Amino acids definition, classification and significance
- b) General reactions of amino acids: Transamination, deamination and decarboxylations of amino acids
- c) Urea cycle, deficiency symptoms of urea cycle enzymes
- d) Metabolism of sulphur containing amino acids
- e) Catabolism of tyrosine, tryptophan, phenylalanine, phenyl ketonurea alkaptonurea
- f) Synthesis & significance of biologically important substances: creatine, histamine, 5-HT, dopamine, noradrenaline, adrenaline.
- g) Porphyrins, Bile Pigments; Hyperbilirubinemia

8. Nucleotides and Nucleic acids

12 hours; 14-15 marks

- a) Introduction: Structure and numbering of purine and pyrimidine nucleus
- b) Purine nucleotides biosynthesis
- c) Pyrimidine nucleotides biosynthesis
- d) Catabolism of purines and pyrimidines
- e) DNA structure, significance as genetic material
- f) RNA types, structure and significance
- g) DNA replication
- h) Mutation and repair of DNA
- i) Transcription or RNA synthesis
- j) Genetic code
- k) Translation or protein synthesis and its Inhibition

9. Principles and significance for following Biochemical tests

5 hours; 6-7 marks

- a) Kidney function tests
- b) Liver function tests
- c) Lipid profile
- d) Gastric function test

APPLIED BIOCHEMISTRY (PRACTICALS)
75 hours ; 3 hours/week

- 1. Identification of carbohydrates (Scheme and identification)**
(glucose, fructose, lactose, maltose, sucrose)
- 2 Identification of proteins (Scheme and identification)**
(casein, albumin, gelatin, peptone)
- 3. Quantitative estimation of carbohydrates (any one method)**
DNS reagent
Anthrone Reagent
- 4. Quantitative estimation of proteins (any one method): Biuret Reagent, Lowry's Reagent**
- 5. Qualitative analysis of Urine**
 - a) For Normal constituents
 - b) Abnormal constituents
- 6. Quantitative Urine analysis**
 - a. Titrable acidity and ammonia
 - b. Estimation of reducing sugars in urine (Benedict's method)
 - c. Estimation of chlorides in urine
 - d. Estimation of Creatinine in urine
 - e. Estimation of calcium in urine
- 7. Quantitative analysis of blood**
 - a. Estimation of glucose in blood (Folin-Wu method)
 - b. Estimation of creatinine in blood
 - c. Estimation of cholesterol in blood
 - d. Estimation of urea in serum
 - e. Estimation of SGOT in serum
 - f. Estimation of SGPT in serum
- 8. Enzyme**
 - a. Salivary amylase activity
 - b. Effect of temperature on enzyme (amylase) activity
 - c. Effect of pH on enzyme (amylase) activity

SCHEME OF EXAMINATION

1. Synopsis	10 Marks
2. Urine Analysis	15 Marks
3. Titrimetric Experiment	20 Marks
4. Colorimetric Experiment	15 Marks
5. Viva	10 Marks

Total

70 Marks

APPLIED BIOCHEMISTRY TEXT BOOKS

- 1) Pharmaceutical Biochemistry – KN Jayaveera et al, S Chand publishers
- 2) Textbook of Biochemistry – Harron and Mazur
- 3) Textbook of Biochemistry – Varun Kumar Malhotra
- 4) Fundamentals of Biochemistry- JL Jain et al, S Chand publishers

APPLIED BIOCHEMISTRY REFERENCE BOOKS

- 1) Harpers Review of Biochemistry – Martin
- 2) Text book of Biochemistry – Lehninger
- 3) Outlines of Biochemistry – Conn and Stump
- 4) Hawk's Physiological Chemistry- Oser
- 5) Hand Book of Basic Pharmacokinetics- Pitachel

LIST OF MINIMUM EQUIPMENTS REQUIRED

1) Colorimeter	01
2) Centrifuge	01
3) Electronic Balance	01
4) Physical/Chemical Balance	01
5) pH meter	01
6) Water bath	05
a) Temperature controlled	01
b) Ordinary	01
7) Volumetric flask	60
8) Pipette	20
a) Graduated	10
b) Bulb	10
9) Burettes	20
10) Conical flask	20
11) China dish	20
12) Burner	20
13) Glass wares such as measuring cylinders, reagent bottles, glass rods, tubes etc.	
14) Folin-Wu tube	120

2.5 PHARMACEUTICAL ORGANIC CHEMISTRY-II (THEORY)

75 hours ; 3 hours/week

The subject is to be treated in the light of modern perspective giving stress wherever possible on the following aspects-structure, nomenclature, preparation, properties, energy of activation, transition state, resonance, stereochemistry, optical isomerism, Geometric isomerism and mechanism of reaction.

I. Stereochemistry:

14 hours;17-18 marks

- a) Stereo isomerism, classification of stereoisomers tetrahedral optical activity, enantiomerism, diastereoisomerism, meso structures, elements of symmetry, chirality, chiral centers, configuration, specification of D and L configuration, R and S configuration. Racemic modification and resolution of racemic mixture, conformational isomers, asymmetric synthesis, Reaction of chiral molecules
- b) Stereo selective and stereospecific reactions with examples. 2 hours;3-4 marks
- c) Geometrical isomerism, its nature of formation, rotation about bonds: nomenclature of isomers, determination of configuration, Nature of E and Z forms 5 hours; 6-7 marks
- d) Stereochemistry of alicyclic compounds, allenes and biphenyls, stereochemistry of oximes 3 hours; 4-5 marks

II. Heterocyclic Chemistry:

27 hours; 34-36 marks

General classification of heterocyclic compounds, nature and nomenclature. reactions, synthesis and properties of the following heterocyclic systems and their derivatives.

- a) Pyrrole, Furan and Thiophene
- b) Indole, Benzofuran and Benzothiophene
- c) Pyridine
- d) Quinoline, Isoquinoline, acridine
- e) Pyrazole, Imidazole, Oxazole, Isoxazole and Thiazole
- f) Pyrimidine, Pyrazine, Pyridazine, Purine, benzodiazepine and phenothiazine

III Chemistry of bio molecules of pharmaceutical importance:

1. Carbohydrates:

9 hours; 11-12 marks

Introduction, Definition, Classification, Nomenclature, Structural determination of Glucose and Fructose. Stereoisomers of monosaccharides, reactions, conversions, configuration, cyclic structures of glucose, determination of ring size in Glucose. Fischer projection formulae, and conformations. Disaccharides and polysaccharides. Chemical nature of maltose, lactose, sucrose, starch and cellulose, derivatives used in pharmacy.

2. Fats and Oils:

4 hours; 5-6 marks

Chemistry of fats oils and waxes. Occurrence and composition. Hydrolysis of fats, Fats as sources of pure acids and alcohols. Analytical constants of fats and oils such as Saponification value, Iodine value, Acid value and Unsaponifiable matter and methods of their determination and significance. Rancidity of oils, hardening of oils, hydrogenation of oils, drying, semidrying and nondrying oils with example.

3. Proteins and Amino acids:

4 hours; 5-6 marks

Introduction, definition, classification of proteins and amino acids their properties Zwitterions. Isoelectric point and its significance. reactions, synthesis of amino acids (Gabriel's Phthalimide synthesis, Strecker's synthesis, Knoop's and Erlenmeyer's azalactone

synthesis) and reactions. Peptide linkages, Peptide synthesis, solid phase synthesis structures of proteins, C-terminal and N-terminal analysis.

4. Protection and De-protection of groups:

3 hours; 4-5 marks

Introduction to protection and deprotection of functional groups examples of two protective agents each for amino, hydroxyl and carbonyl groups with their significance in organic synthesis.

5. A study and specific uses of the reagents in organic synthesis including their mechanism

4 hours; 5-6 marks

- a) Aluminium isopropoxide – Meerwein –Ponndorf- Verley reduction, Oppenauer oxidation.
- b) Aluminium tertiary butoxide – Allylic bromination
- c) Lithium aluminium hydride – Reduction of carboxylic acid
- d) Periodic acid – Oxidation of 1,2 – diol to carbonyl compound
- e) Sodamide – Chichibian reaction
- f) Sodium borohydride – Reduction of aldehyde carbonyl group
- g) Metachloro peroxybenzoic acid – Beyer – villegier oxidation (oxidation of ketone to esters)
- h) Diazo methane – Buchaner – Curtius – Schlotterbeck reaction (Aldehydes to methyl ketones)

PHARMACEUTICAL ORGANIC CHEMISTRY-II (PRACTICALS)
75 hours ; 3 hours/week
(Following experiments to be carried out in 25 classes)

I. Quantitative determination of organic compounds via functional groups **

1. Phenolic group by bromination method
2. Alcoholic group by acetylation method
3. Carbonyl group by hydroxylamine hydrochloride-pyridine method
4. Aldehyde group by sodium sulphite-sulphuric acid procedure
5. Carboxyl group by acid-base method
6. Determination of acetone by sodium hypoiodide method
7. Amino group by bromination method
8. Amino acid Formal titration method

II. Analysis of oils and fats: (I.P. Method)*

1. Acid value
2. Saponification value
3. Iodine value

III. Synthesis/ preparation involving more than one step*

1. p-bromoaniline from acetanilide
2. p-Nitroaniline from acetanilide
3. p-Nitrophenyldrazine from p-nitroaniline
4. 3-methyl-1-phenyl-5-pyrazole from ethyl acetoacetate
5. Benzilic acid from benzoin
6. Pthalimide from benzophenone
7. Pthalimide from phthalic acid
8. Synthesis of 2, 3-Diphenyl quinoxaline
9. Benzimidazole Orthophenylene Diamine

Note: ** Denotes major experiments * Denotes minor experiments

SCHEME OF EXAMINATION

1 Synopsis	10 Marks
2 Major Experiment (**)	30 Marks
3 Minor Experiment (*or oil analysis)	20 Marks
4 Viva	10 Marks
Total	70 Marks

PHARMACEUTICAL ORGANIC CHEMISTRY-II TEXT BOOKS (THEORY)

1. E. L. Eliel, John Wiley and Son, Stereochemistry of Organic Compounds. New York, 1993.
2. I. L. Finar, Organic Chemistry Vol. I and II, Sixth Edition, 2003, ELBS.
3. A text book of Organic Chemistry Arun Bhal and B.S., Bhal, S. Chand Publishers revised edition.
4. Raj K. Bansal, Heterocyclic Chemistry, New age international Ltd., New Delhi, Third Edition, 2001.
5. B. S. Bhal and Arun Bhal, S. Chand, Advanced Organic Chemistry and Company, New Delhi, 2001.
6. T. W. G. Solomans, Organic Chemistry, Sixth Edition, , John Wiley and Son, New York, 1996.

PHARMACEUTICAL ORGANIC CHEMISTRY-II REFERENCE BOOKS (Theory)

1. R.O.C Norman and J. M. Conon, Principals of Organic Synthesis, Third Edition, 1995, ELBS,
2. R. J. Morrison and R. N. Boyd Organic Chemistry, Fifth Edition, Prentice Hall of India Pvt. Ltd., New Delhi.
3. J. A. Joule and L. K. Mills, Heterocyclic Chemistry Fourth edition, Blackwell Science Publisher, 2000.
4. S. M. Mukherji and S. P. Singh, Reaction Mechanisms in Organic Chemistry, Third Edition Macmillan publishers, 2001.
5. I. P. 1996, Govt. of India, Ministry of Health and Family Welfare, All edition including latest.
6. A. I. Vogel, Elementary Organic Chemistry, Part-3, Quantitative Organic Analysis, second edition, CBS Publishers and Distributors, New Delhi, 2000.
7. B. S. Furniss, A. J. Hannaford, P.W.G. Smith and A. R. Tatchell, Vogel's Text Book of Practical Organic Chemistry, Edited, Fifth Edition, Addison Wesley Longman, England, 1998.
8. Chemistry and Natural Products by Chatwal Vol. 1 & 2
9. Reaction and reagents O P Agrawal, Goel Publishing House, Subhash Bazar, Meerut (U.P) India

PHARMACEUTICAL ORGANIC CHEMISTRY-II REFERENCE BOOKS (Practical)

1. A.I. Vogel, Elementary Practical organic chemistry, ELBS and Longman group Ltd., London.
2. Mann and Sounders, Practical Organic Chemistry-ELBS and Longman group Ltd.,
3. D.L. Pavia, G. Lampman and G.D. Kriz. Introduction to Organic Laboratory Techniques.
4. I.P., Govt. of India, Ministry of Health and Family welfare, 3rd Edition (1985), 4th Edition (1996).
5. A. I. Vogel, Text Book of practical organic chemistry, ELBS Longman, London, 4th edition.

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Suction Pump	01
2. Analytical Balance	01
3. Physical Balance	05
4. Triple Beam Balance	Adequate
5. Water Baths, Reflux flask and condenser	10
6. Hot Plate	Adequate
7. Mechanical Stirrer	Adequate
8. Magnetic Stirrers with Thermostat	Adequate
9. Distillation Unit	01
10. Refrigerator	01
11. Oven	01

2.6 ENVIRONMENTAL SCIENCE (THEORY)

50 hours ; 2 hours/week

Unit 1 : Multidisciplinary nature of environmental studies ; Definition, scope and importance **2 hours;2-5 marks**

Unit 2 : Natural Resources : Renewable and non-renewable resources :

Natural resources and associated problems.

- a) Forest resources : Use and over-exploitation, deforestation, case studies. Timber extraction, mining, dams and their effects on forest and tribal people.
 - b) Water resources : Use and over-utilization of surface and ground water, floods, drought, conflicts over water, dams-benefits and problems.
 - c) Mineral resources : Use and exploitation, environmental effects of extracting and using mineral resources, case studies.
 - d) Food resources : World food problems, changes caused by agriculture and overgrazing, effects of modern agriculture, fertilizer-pesticide problems, water logging, salinity, case studies.
 - e) Energy resources : Growing energy needs, renewable and non renewable energy sources, use of alternate energy sources. Case studies.
 - f) Land resources : Land as a resource, land degradation, man induced landslides, soil erosion and desertification. • Role of an individual in conservation of natural resources.
- Equitable use of resources for sustainable lifestyles. **8 hours;5-10 marks**

Unit 3 : Ecosystems

- Concept of an ecosystem.
 - Structure and function of an ecosystem.
 - Producers, consumers and decomposers.
 - Energy flow in the ecosystem.
 - Ecological succession.
 - Food chains, food webs and ecological pyramids.
 - Introduction, types, characteristic features, structure and function of the following ecosystem :-
 - a. Forest ecosystem
 - b. Grassland ecosystem
 - c. Desert ecosystem
 - d. Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)
- 6 hours;5-10 marks**

Unit 4 : Biodiversity and its conservation

- Introduction – Definition : genetic, species and ecosystem diversity.
- Biogeographical classification of India
- Value of biodiversity : consumptive use, productive use, social, ethical, aesthetic and option values
- Biodiversity at global, National and local levels.
- India as a mega-diversity nation
- Hot-spots of biodiversity.
- Threats to biodiversity : habitat loss, poaching of wildlife, man-wildlife conflicts.
- Endangered and endemic species of India
- Conservation of biodiversity: In-situ and Ex-situ conservation of biodiversity.

8 hours; 5-10 marks

Unit 5 : Environmental Pollution

Definition

- Cause, effects and control measures of :-
 - a. Air pollution
 - b. Water pollution
 - c. Soil pollution
 - d. Marine pollution
 - e. Noise pollution
 - f. Thermal pollution
 - g. Nuclear hazards
- Solid waste Management: Causes, effects and control measures of urban and industrial wastes.
- Role of an individual in prevention of pollution.
- Pollution case studies.
- Disaster management: floods, earthquake, cyclone and landslides.

8 hours;5-10 marks

Unit 6 : Social Issues and the Environment

- From Unsustainable to Sustainable development
- Urban problems related to energy
- Water conservation, rain water harvesting, watershed management
- Resettlement and rehabilitation of people; its problems and concerns. Case Studies
- Environmental ethics : Issues and possible solutions.
- Climate change, global warming, acid rain, ozone layer depletion, nuclear accidents and holocaust. Case Studies.
- Wasteland reclamation.
- Consumerism and waste products.
- Environment Protection Act.
- Air (Prevention and Control of Pollution) Act.
- Water (Prevention and control of Pollution) Act
- Wildlife Protection Act
- Forest Conservation Act
- Issues involved in enforcement of environmental legislation.
- Public awareness.

7 hours;5-10 marks

Unit 7 : Human Population and the Environment

- Population growth, variation among nations.
- Population explosion – Family Welfare Programme.
- Environment and human health.
- Human Rights.
- Value Education.
- HIV/AIDS.
- Women and Child Welfare.
- Role of Information Technology in Environment and human health.
- Case Studies.

6 hours;5-10 marks

Unit 8 : Field work

(Field work Equal to 5 Hrs)

- Visit to a local area to document environmental assets river/ forest/grassland/hill/mountain
- Visit to a local polluted site-Urban/Rural/Industrial/Agricultural
- Study of common plants, insects, birds.
- Study of simple ecosystems-pond, river, hill slopes, etc

Teaching Methodologies

The core Module Syllabus for Environment Studies includes class room teaching and Field Work. The syllabus is divided into eight units covering 50 lectures. The first seven units will cover 45 lectures which are class room based to enhance knowledge skills and attitude to environment. Unit eight is based on field activities which will be covered in five lecture hours and would provide student first hand knowledge on various local environmental aspects. Field experience is one of the most effective learning tools for environmental concerns. This moves out of the scope of the text book mode of teaching into the realm of real learning in the field, where the teacher merely acts as a catalyst to interpret what the student observes or discovers in his/her own environment. Field studies are as essential as class work and form an irreplaceable synergistic tool in the entire learning process. Course material provided by UGC for class room teaching and field activities be utilized. The universities/colleges can also draw upon expertise of outside resource persons for teaching purpose. Environmental Core Module shall be integrated into the teaching programmes of all undergraduate courses.

Exam Pattern : In case of awarding the marks, the question paper should carry 100 marks. The structure of the question paper being :

Part-A, Short answer pattern	- 15 marks
Part-B, Essay type with inbuilt choice	- 40 marks
Part-C, Field Work	- 15 marks

Total	70 Marks

ENVIRONMENTAL SCIENCE REFERENCE BOOKS

- a) Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.
- b) Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380 013, India, Email:mapin@icenet.net (R)
- c) Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
- d) Clark R.S., Marine Pollution, Clanderson Press Oxford (TB)
- e) Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumabai, 1196p
- f) De A.K., Environmental Chemistry, Wiley Eastern Ltd.
- g) Down to Earth, Centre for Science and Environment (R)
- h) Gleick, H.P. 1993. Water in crisis, Pacific Institute for Studies in Dev., Environment & Security. Stockholm Env. Institute Oxford Univ. Press. 473p
- i) Hawkins R.E., Encyclopedia of Indian Natural History, Bombay Natural History Society, Bombay (R)
- j) Heywood, V.H & Waston, R.T. 1995. Global Biodiversity Assessment. Cambridge Univ. Press 1140p.

- k) Jadhav, H & Bhosale, V.M. 1995. Environmental Protection and Laws. Himalaya Pub. House, Delhi 284 p.
 - l) Mckinney, M.L. & School, R.M. 1996. Environmental Science systems & Solutions, Web enhanced edition. 639p.
 - m) Mhaskar A.K., Matter Hazardous, Techno-Science Publication (TB)
 - n) Miller T.G. Jr. Environmental Science, Wadsworth Publishing Co. (TB)
 - o) Odum, E.P. 1971. Fundamentals of Ecology. W.B. Saunders Co. USA, 574p
 - p) Rao M N. & Datta, A.K. 1987. Waste Water treatment. Oxford & IBH Publ. Co. Pvt. Ltd. 345p.
 - q) Sharma B.K., 2001. Environmental Chemistry. Geol Publ. House, Meerut
 - r) Survey of the Environment, The Hindu (M)
 - s) Townsend C., Harper J, and Michael Begon, Essentials of Ecology, Blackwell Science (TB)
 - t) Trivedi R.K., Handbook of Environmental Laws, Rules Guidelines, Compliances and Stadards, Vol I and II, Enviro Media (R)
 - u) Trivedi R. K. and P.K. Goel, Introduction to air pollution, Techno-Science Publication (TB)
 - v) Wanger K.D., 1998 Environmental Management. W.B. Saunders Co. Philadelphia, USA 499p
- (M) Magazine (R) Reference (TB) Textbook

SYLLABUS FOR III YEAR B. PHARM

3.1 MEDICINAL CHEMISTRY – I (THEORY)

75 hours ; 3 hours/week

I Basic Principles of Medicinal Chemistry

12 hours;15-16 marks

- History and development of Medicinal Chemistry, definition of hit, lead and drug.
- Effects of the following physicochemical properties of drug molecules on biological activity: Ionisation, hydrogen bonding, solubility, partition coefficient, logP, logD, protein binding, chelation and polar surface area.
- Receptor and drug receptor interactions.
- Drug metabolism: Biotransformation, sites of biotransformation, General pathways of drug biotransformation, role of cytochrome P-450 and monoaminoxygenase in oxidative biotransformation, oxidative, reductive, hydrolytic and conjugation reactions with examples.

A study of development of the following classes of drugs including structure activity relationship (SAR), mechanism of action, synthesis of compounds superscribed by 's', chemical nomenclature, generic names, brand names (a few important marketed products) and side effects.

II Central nervous system depressants

16 hours;20-21 marks

- General Anaesthetics: Definition, mode of action
 - Inhalation anaesthetics: Halothane^s, Methoxyflurane, Nitrous oxide
 - Ultra short acting barbiturates: Methohexital sodium^s, Thiopental sodium
 - Dissociative anaesthetics: Ketamine hydrochloride
- Tranquilizers, sedatives and hypnotics
 - Major tranquilizers*: SAR of Phenothiazines, Promethazine HCl, Chlorpromazine HCl^s, Prochlorperazine, thioridazine HCl
Thioxanthenes: Chlorprothixene, thiothixine, clozapine
Fluorobutyrophenones: Haloperidol^s, Risperidone
Beta amino ketones: Molindone HCl, Benzamide surpierre
Minor tranquilizers: SAR of Benzodiazepines, Chlordiazepoxide, Diazepam^s, Orazepam, Chlorazepam, Lorazepam, Flurazepam, Alprazolam^s, Triazolam^s
 - Barbiturates: Classification and SAR, Barbitol^s, Methobarbital^s, Phenobarbital, Amobarbital^s, Butarbital, Pentobarbital, Secobarbital
 - Miscellaneous sedative hypnotics:
 - Amides and imides: Glutethimide^s, Methypylon, Methaqualone^s
 - Alcohols and their carbamate derivatives: Ethchlorvynol, Ethinamate, Meproamate^s
 - Aldehydes and their derivatives: Chloral hydrate, Paraldehyde
- Skeletal muscle relaxants: Chlorphenesin^s, Methocarbamol, Chlorzoxazone
- Drugs used in spasticity: Baclofen, Buspirone
- Anticonvulsants: Structural requirement for anticonvulsant activity, mechanism of anticonvulsant action
 - Barbiturates: Phenobarbitone, Mepobarbitone
 - Hydantoins: Phenytoin sodium^s, Ethotoin, Mephenytoin
 - Oxazolindiones: Trimethadione^s, Paramethadione
 - Succinimides: Phensuximide^s, Methsuximide, Ethsuximide
 - Urea and monoacyl ureas: Phenacemide, Carbamazepine^s

6. Benzodiazepines: Clonazepam^s,
7. Miscellaneous: Primidone, Valproic acid

III Adrenergic agents

9 hours;11-12 marks

A. Adrenergic neurotransmitters and their biosynthesis and metabolism, adrenergic receptors their distribution and actions mediated by them

B. Sympathomimetics

1. Direct acting: SAR, Endogenous catecholamines,
 - a) Alpha adrenergic agonists: Phenylephrine^s, Methoxamine, Naphazoline, Xylometazoline^s, Oxymetazoline, Clonidine^s, Guanabenz, Methyldopa
 - b) Dual agonist/antagonist: Dobutamine
 - c) Beta adrenergic agonists: Isoproterenol^s, Metaproterenol, Terbutalin^s, Albuterol, Salbuterol, Bitolterol, Ritodrine
2. Indirect acting: Hydroxyamphetamine, Propylhexedrine
3. Mixed acting: Ephedrine, Metaraminol

C. Adrenolytics:

1. Alpha blockers:
 - a) Non selective: Tolazoline
 - b) Irreversible blockers: Phenoxybenzamine^s
 - c) Alpha1 blockers: Prazosin^s, Doxazosin, Tamsulosin
 - d) Alpha2 blockers: Yohimbine, Coryanthine
2. Beta blockers: SAR
 - a) Non selective blockers: Propranolol^s, Nadolol, Pindolol, Timolol, Sotalol
 - b) Beta1 blockers: Acebutolol, Atenolol, Esmolol, Metoprolol^s
 - c) Betablockers with alpha1 antagonistic activity: Labetalol, Carvedilol

IV Cholinergic drugs and related agents

12 hours;15-16 marks

1. Cholinergic neurotransmitter: Biosynthesis, metabolism and functions of acetylcholine
2. Cholinergic receptors: Nicotinic, muscarinic and their subtypes

A. Cholinergic agonists:

1. Stereochemistry and SAR, Acetylcholine, Methacholine, Carbachol, Bethanechol, Pilocarpine
2. Cholinesterase inhibitors:
 - a) Reversible: Mode of action, Physostigmine, Neostigmine^s, Ambenonium, Demecarium, Edrophonium, Tacrine
 - b) Irreversible: Mode of action, Isoflurophate, Ecothiophate, Malathion, Parathion, Pralidoxime.

B. Cholinergic blockers: SAR

1. Postganglionic blockers: Structural considerations of solanaceous alkaloids and analogs, Atropine, Hyoscyamine, Scopolamine, Homatropine, Ipratropium
2. Synthetic agents: Clidinium, Dicyclomine^s, Glycopyrrolate, Methantheline, Propantheline, Benztropine, Procyclidine, Tropicamide^s
3. Ganglionic blockers: Mode of action, Trimethaphan, Mecamylamine
4. Neuromuscular blockers: Mode of action, Tubocurarine, Metocurine, Gallamine, Pancuronium, Vecuronium.

V Local anesthetics

4 hours;5-6 marks

A. Definition, classification, and mechanism of action

- B. SAR of lidocaine derivatives
- C. 1. Benzoic acid derivatives: Hexylcaine, Cyclomethicaine, Piperocaine
- 2. Aminobenzoic acid derivatives: Benzocaine, Procaine^s, Procainamide
- 3. Lidocaine derivatives (Anilides): Lidocaine^s, Prilocaine
- 4. Miscellaneous: Dimethisoquin, Dibucaine

VI Histamine and antihistaminic agents

6 hours;8-9 marks

- A. Histamine: receptors and its actions
- B. Antihistaminics: H1 antagonists
 - a) Aminoalkyl ethers: Diphenhydramine HCl, Bromodiphenhydramine, Doxylamine
 - b) Ethylene diamines: Tripelenamine, Pyrillamine
 - c) Propylamine derivatives: Pheniramine, Chlorpheniramine^s
 - d) Phenothiazine derivatives: Promethazine^s, Trimeprazine
 - e) Piperazine derivatives: Cyclizine, Meclizine, Cetrizine^s
 - f) Miscellaneous compounds: Phenindamine, Cyproheptadine
- C. H2 antagonists: Mechanism, Cimetidine, Ranitidine, Famotidine
- D. Gastric proton pump inhibitors: Mechanism of action, Omeprazole^s, Pantoprazole, Rabeprazole, Lansoprazole.

VII Analgesic agents

9 hours;11-12 marks

- A. 1. Narcotic analgesics: Opioid receptors, SAR, Morphine, Codeine, Diacetyl morphine, Levorphanol, Dextromethorphan^s, Pentazocine, Meperidine, Loperamide, Fentanyl, Methadone^s, Propoxyphene, Tramadol
- 2. Narcotic antagonists: Butorphanol, Nalorphine, Levalorphan, Naltrexone, Naloxone
- B. Non narcotic analgesics
 - 1. Steroidal anti-inflammatory agents: Cortisone, Hydrocortisone, Dexamethasone, Betamethasone, Triamcinolone, Fluocinolone
 - 2. Non steroidal anti-inflammatory agents: Mechanism of action
 - a) Salicylic acid derivatives: Aspirin
 - b) N-aryl anthranilic acid derivatives: Mefenamic acid^s, Diclofenac, Aceclofenac
 - c) Aryl acetic acid derivatives: Indomethacin, Ibuprofen^s, Piroxicam^s, Naproxen^s
 - d) Aniline and paraaminophenol derivatives: Phenacetin, Acetaminophen^s
 - e) Pyrazolone and pyrazolidine dione derivatives: Antipyrin, Oxyphenbutazone, Phenylbutazone
 - f) Diaryl sulphonamides: Nimesulide^s, Rofecoxib, Valdecoxib

VIII Structure and medicinal uses of important prostaglandins

1 hour;1-2 marks

IX Natural Products

6 hours;8-9 marks

- A. Alkaloids: Definition, Classification, Structural elucidation of ephedrine
- B. Purines: Definition, Structural elucidation of caffeine, Interrelation among caffeine, theophylline, theobromine.
- C. Terpenoids: Definition, classification, isoprene and special isoprene rule, Interrelationship among monocyclic monoterpenoids like limonene, dipentene, alpha terpenoid, alpha terpenion, terpenolene, terpin, terpene hydrate, carvone and cineone.

MEDICINAL CHEMISTRY I (PRACTICALS)

75 hours ; 3 hours/week

I. Identification test and test for purity of*

1. Benzocaine
2. Phenytoin sodium
3. Diclofenac sodium
4. Aminophylline
5. Aspirin
6. Caffeine
7. Paracetamol

II Assay of medicinally useful compounds (in solid dosage form)**

1. Ibuprofen by alkalimetry
2. Analgin by iodimetry
3. Ephedrine HCl/Phenobarbitone by non-aqueous titration
4. Procaine/Benzocaine by diazotisation
5. Chlorpromazine by cerimetry

III Preparation of medicinally useful compounds*

1. Phenytoin from benzoin
2. Paracetamol from p-nitrophenol
3. Benzocaine from p-aminobenzoic acid
4. 4-hydroxycoumarin from resorcinol
5. Mefenamic acid from anthranilic acid
6. Phenothiazine from diphenylamine

IV Degradation of Ephedrine to benzoic acid*

V Determination of partition coefficient and log P for any two drugs**

Note: ** Denotes major experiments * Denotes minor experiments

Scheme of Examination

1 Synopsis	10 Marks
2 Major (indicated by **)	25 Marks
3 Minor (indicated by *)	15 Marks
4 Minor (indicated by *)	10 Marks
5 Practical Viva-voce	10 Marks

Total

70 Marks

MEDICINAL CHEMISTRY I TEXT BOOKS (THEORY)

Latest editions and all volumes of

- 1 Wilson and Giswold's Text book of Organic Medicinal and Pharmaceutical Chemistry, Wolters Kluwer
- 2 William O Foye Principles of Medicinal Chemistry, Lea and Febiger, Philadelphia
- 3 Medicinal Chemistry Ashutosh Kar New age international publishers, New Delhi
- 4 Chemistry of Natural Products by Chatwal and Anand
- 5 Organic medicinal chemistry by Pandey

MEDICINAL CHEMISTRY I REFERENCE BOOKS (THEORY)

Latest editions and all volumes of

- 1 Burger's Medicinal Chemistry, ME Walffed Johnwilley and sons
- 2 Martindale the Extra Pharmacopoeia, JE Reynolds The pharmaceutical press, London
- 3 Beckett and Stenlake Practical Pharmaceutical Chemistry, the sthalone press, University of London
- 4 IP 2014 Govt. of India, Ministry of health
- 5 BS Furniss et al Vogel's TB of Practical Organic Chemistry including quantitative analysis, ELBS/Longman, London
- 6 Mann and Saunders Practical Organic Chemistry Longman Green and Co London
- 7 Organic Chemistry of Drug Synthesis Lednicer Mitzsher
- 8 Current Index of Medical Specialities (CIMS)
- 9 Essentials of Medicinal Chemistry Korolkovas
- 10 Natural Product Chemistry by Agarwal

MEDICINAL CHEMISTRY I REFERENCE BOOKS (PRACTICALS)

Latest editions and all volumes of

- 1 IP
- 2 IL Finar TB of organic chemistry
- 3 AI Vogel TB of Practical organic chemistry
- 4 The Organic chemistry of drug synthesis Lednicer Mitzsher
- 5 Mann and Saunders Practical organic chemistry
- 6 T Robinson Organic constituents of higher medicinal plants
- 7 CIMS

LIST OF MINIMUM EQUIPMENTS REQUIRED

1	Suction pump	01
2	Analytical balance	10
3	Water bath, reflux flask and condenser	10
4	Hot plate	01
5	Mechanical stirrer	02
6	Magnetic stirrer with thermostat	02
7	Distillation unit	01
8	Refrigerator	01
9	Fuming hood	01
10	Oven	01

3.2 PHARMACEUTICAL JURISPRUDENCE AND ETHICS (THEORY)

50 hours ; 2 hours/week

1. Introduction

- a) Pharmaceutical legislations - brief review. **1 hour;2-3 marks**

2. An elaborate (practical oriented) study of the following

- a) Code of pharmaceutical ethics. **1 hour;2-3 marks**
b) Pharmacy act 1948. **2 hours;3-5 marks**
c) Drugs and cosmetic act 1940 and rules 1945 (with special reference to schedules M,P,U,V, and Y). **20 hours;25-30 marks**
d) Medicinal and toilet preparations (Excise Duties) Act 1955. **3 hours;5-7 marks**
e) Medical Termination of pregnancy act **2 hours;3-5 marks**
f) Narcotic drugs and psychotropic substances act 1985 and rules. **3 hours;5-7 marks**
g) DPCO 2013. **2 hours;3-5 marks**
h) Pharmaceutical policy 2002. **2 hours;3-5 marks**
i) Right to information act. **2 hours;3-5 marks**
j) Hatch Waxman act 1984. **2 hours;3-5 marks**

3. A brief study of the following with special reference to be main provisions

- a) Drugs and magic remedies (Objectionable advertisements) act 1954 **2 hours;3-5 marks**
b) Prevention of cruelty to animals act 1960 including study of CPSCEA guidelines **2 hours;3-5 marks**
c) Indian Patents Act with special reference to pharmaceuticals along with amendment bills, process patent and product patent. a. General procedure for obtaining pharmaceutical patents, introduction to intellectual properties. Trademark, copyright, trade secrets. **4 hours;6-10 marks**

4. New Drug Application, Abbreviated new drug application (ANDA) 2 hours;3-5 marks

Note: The teaching of all the above acts should cover the latest amendments.

PHARMACEUTICAL JURISPRUDENCE AND ETHICS REFERENCE BOOKS

1. CPSCEA Guidelines.
2. Gennaro AL. Remington: The science and practice of pharmacy Vol I and II. 20th ed. Philadelphia:Lippincott Williams and Wilkins;2000.
3. Helsinki Guidelines.
4. ICMR Guidelines.
5. Jain NK. A textbook of forensic pharmacy. 6th ed. New Delhi:Vallabh Prakashan,2003.
6. Jani GK. Pharmaceutical jurisprudence vol I and II. Ahmedabad:Atul Prakashan.
7. Kuchekar BS. A textbook of pharmaceutical jurisprudence. Pune:Nirali Prakashan;1994.
8. Latest issues of CIMS, MIMS, PDR, DDR.
9. Latest issues of IDMA Bulletin.
10. Mithal BM. A textbook of forensic pharmacy. Delhi:Vallabh Prakashan. Year
11. Parikshit B. IPR handbook for pharma students & researchers.
12. Saikishore. Drug regulatory affairs.
13. Subramanyam CVS, Thimmasetty J. Pharmaceutical regulatory affairs. Delhi: Vallabh Prakashan;2012.
14. Sudhakar Y. Novel drug delivery systems & regulatory affairs.
15. Suresh B. A text book of forensic pharmacy.

3.3 PHARMACOGNOSY AND PHYTOCHEMISTRY (THEORY)

75 hours ; 3 hours/week

1. Isolation and purification of phytoconstituents: a) Different methods of extraction: maceration, percolation and supercritical fluid extraction. Choice of suitable solvents, processing and drying methods. b) Preliminary phytochemical screening of various secondary metabolites in plant extracts. c) Chromatographic methods applied for the isolation and purification of phytoconstituents. **10 hours; 10-12 marks**

2. Evaluation of crude drugs: Organoleptic, Microscopical, Physical, Chemical, Spectroscopic and Biological methods **4 hours; 5-10 marks**

3. Biogenesis of Phytopharmaceuticals: a) Techniques employed in the elucidation of biosynthetic pathways b) Detailed study of basic metabolic pathways, Shikimic acid pathway and Isoprenoid pathway c) Biosynthesis of - Tropane, Quinoline, Opium and Indole alkaloids, Anthraquinone glycosides and Steroids. **12 hours; 12-15 marks**

4. Glycosides: a) Definition, properties, chemical tests, classification and general method of extraction of glycosides **b) Definition, properties, chemical nature and uses of the following:** i) Cardiac glycosides ii) Anthracene glycosides iii) Saponins iv) Cyanogenetic glycosides v) Flavonoids vi) Lactones and bitter glycosides vii) Isothiocyanate glycosides viii) Steroidal glyco-alkaloids **c) Source, diagnostic characters, chemical constituents, uses and adulterants of** i) Digitalis ii) Squill iii) Senna iv) Aloes v) Cochineal vi) Ginseng vii) Liquorice viii) Wild Cherry bark ix) Bio-flavonoids (Lemon & Orange peel) x) Gingko xi) Milk-thistle xii) Chirata xiii) Dioscorea xiv) Mustard xv) Solanum nigrum. **15 hours; 15-20 marks**

5. Alkaloids: a) Definition, properties, chemical tests, classification and general method of extraction of alkaloids b) Source, diagnostic characters, chemical constituents, uses and adulterants of i) Lobelia ii) Tobacco iii) Datura iv) Atropa v) Cinchona vi) Ipecac vii) Opium viii) Rauwolfia ix) Ergot x) Aconite xi) Kurchi xii) Ephedra xiii) Colchicum xiv) Tea xv) Taxus. **15 hours; 15-20 marks**

6. Essential oils : a) Definition, properties, chemical nature, classification and general method of extraction of volatile oils b) Source, diagnostic characters, chemical constituents and uses of: i) Clove ii) Cinnamon iii) Fennel iv) Caraway v) Eucalyptus vi) Mentha vii) Nutmeg viii) Lemon grass oil c) Analysis of the following: Clove oil, Cinnamon oil, Eucalyptus oil, Mentha oil and lemon grass oil. **10 hours; 10-12 marks**

7. Tannins: a) Definition, properties, classification, general method of extraction and estimation of tannins. b) Source, chemical constituents, chemical tests, uses and adulterants of i) Pale and Black catechu ii) Nutgal iii) Arjuna iv) Myrobalan v) Bahera. **3 hours; 2-5 marks**

8. Carotenoids: a) Definition, properties and classification of carotenoids. b) Source, chemical nature and uses of α and β -Carotenes, Lycopene, Xanthophyll. **2 hours; 2-5 marks**

9. Marine Pharmacognosy: Novel medicinal agents from marine sources **2 hours; 2-5 marks**

10. Natural allergens, photosensitizing agents and fungal toxins **2 hours; 2-5 marks**

PHARMACOGNOSY AND PHYTOCHEMISTRY (PRACTICALS)

75 hours ; 3 hours/week

1) Study of Powder microscopy of the following crude drugs*

Digitalis, Squill, Senna, Liquorice, Wild Cherry bark, Cinchona, Ipecac, Rauwolfia, Kurchi, Ephedra, Clove, Cinnamon.

2) Qualitative general and specific chemical tests for the following phytoconstituents*

Alkaloids: Quinine, Atropine, Caffeine,

Glycosides: Sennosides, Aloin, Flavonoids, Saponins and Cardiac glycosides

Tannins: Tannic acid, Pale catechu and Black catechu.

3) Determination of proximate values *

i) Moisture content

ii) Ash values

iii) Extractive values

4) Quantitative microscopy**

i) Determination of Stomatal number and Stomatal index

ii) Determination of Starch grains dimensions and length of fibres using eye piece micrometer and camera lucida methods

iii) Determination of percentage purity of crude drugs by using Lycopodium spore method

5) Determination of total polyphenolic content by Folin-cu method**

6) Demonstration experiments

i) Soxhlet extraction

ii) Extraction of essential oils by Clevenger's apparatus

Note: ** Denotes major experiments

*** Denotes minor experiments**

SCHEME OF EXAMINATION

1. Synopsis	10 marks
2. Quantitative Microscopy	25 marks
3. Powder Microscopy	15 marks
4. Minor experiment	10 marks
5. Viva-Voce	10 marks
Total	70 marks

PHARMACOGNOSY AND PHYTOCHEMISTRY REFERENCE BOOKS

1. Evans WC. 2002. Trease and Evans Pharmacognosy, 15th ed. Elsevier Science Ltd, Philadelphia.
2. Kokate CK, Purohit AR, and Gokhale S.B., 2010. Pharmacognosy 45th ed. Nirali Prakashan, Pune.
3. Tyler V.E and Brady R., 1981. Text book of Pharmacognosy, 8th ed. Lea and Febiger, Philadelphia.
4. Wallis T.E., 1985. Textbook of Pharmacognosy, 5th ed. J.A., Churchill Limited, London.
5. Jean Bruneton, 1999. Pharmacognosy, Phytochemistry & Medicinal Plants, 2nd ed. Lavoisier Publishing House, UK.
6. Pridham J.B and Swain T., 2012. Biosynthetic pathways in higher plants, 1st ed. Academic Press, New Delhi.
7. Pulok Mukherjee, 2002. Quality control of herbal drugs, 1st ed. Business horizons, New Delhi.
8. Biren Shah N and Seth A.K., 2010. Text Book of Pharmacognosy and Phytochemistry, 1st ed. A Division of Reed Elsevier India Private Ltd, New Delhi.
9. Ashutosh Kar, 2013. Essentials of Pharmacognosy, 1st ed. Ahuja Book House Pvt Ltd, Delhi.
10. Khadabadi S.S., Deore S.L and Bavskar B.A., 2010. Pharmacognosy and Phytochemistry: A Comprehensive approach, 1st ed. Pharma Med Press, Hyderabad.
11. Bhakuns and Rawat, 2005. Bioactive Marine Natural Products, 1st ed. Anmaya Publishers, New Delhi.
12. Harborne J.B., 1998. Phytochemical methods, 3rd ed. Springer (India) Pvt Ltd, New Delhi.
13. Iyengar M.A 2001. Study of Crude Drugs, 14th ed. Manipal Power Press, Manipal.
14. Iyengar M.A and Nayak S.G.K., 2001. Anatomy of Crude Drugs, 8th ed. Manipal Power Press, Manipal.
15. Iyengar M.A 2001. Pharmacognosy of Powdered Crude Drugs, 6th ed. Manipal Power Press, Manipal.
16. Kokate C.K., 1994. Practical Pharmacognosy, 4th ed. Vallabh Prakashan, New Delhi.
17. Khandelwal K.R., 2006. Practical Pharmacognosy Techniques and Experiments, 16th ed. Nirali Prakashan, Pune.
18. Wallis T.E., 2011. Practical Pharmacognosy, 4th ed. Pharma Med Press, Hyderabad.
19. Indian Herbal Pharmacopoeia 1998 & 1999, Vol I & Vol II. Government of India, Ministry of Health. A Joint Publication of RRL, Jammu and IDMA, Mumbai.
20. National and International Journals- Pharmacognosy Reviews, Pharmacognosy Magazine, Journal of Natural Products, Phytotherapy Research, Phytochemistry.

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Camera lucida	20
2. Eye piece micrometer	20
3. Stage micrometer	20
4. Microscope	20
5. Clavengers apparatus	05
6. Balance (Digital)	02
7. Muffle furnace	01
8. Hot air oven	01
9. Spectrophotometer	01
10. Soxhlet apparatus	05
11. Heating mantle	10
12. Vacuum pump	02

3.4 PHARMACEUTICAL ENGINEERING (THEORY)

75 hours ; 3 hours/week

1. **Stoichiometry:** Unit processes, material and energy balances, units and their conversions, dimensional formulae, dimensionless equations. **2 hours; 2-3 marks**
2. **Heat transfer:** Concept of heat flow by conducting through single wall, applications of Fourier's law, forced and natural convections, surface co-efficients, study on single, multi pass heat exchangers and liquid-liquid heat interchangers, radiation, black body, Stefan-Boltzmann equation. **6 hours; 6-8 marks**
3. **Evaporation:** Theory of evaporation. Evaporators – steam jacketed kettle, horizontal tube evaporator, vertical tube evaporator, climbing film evaporator, falling film evaporator, forced circulation evaporator, multiple effect evaporator. **5 hours; 6-8 marks**
4. **Distillation:** Raoult's law, volatility, Rayleigh's equation, Study on principles and equipments of simple, flash, fractional, azeotropic, extractive, vacuum, steam, and molecular distillation methods. **6 hours; 6-8 marks**
5. **Drying:** Theory of drying, Classification and types of dryers – Principle, construction and working of tray dryer, fluidized bed dryer, drum dryer, vacuum dryer, freeze dryer, and spray dryer. **6 hours; 6-8 marks**
6. **Size reduction:** Definition, objectives, factors affecting size reduction, laws governing energy and power requirement of a mill, stress strain relationship of deformation in solids. Types of mills, construction and working of ball mill, hammer mill, fluid energy mill, edge runner mill, end runner mill, and cutter mill. **6 hours; 6-8 marks**
7. **Size separation:** Definition and objectives of size separation, standard sieves as per IP. Mechanical sieve shakers, sedimentation tanks, mechanical classifiers, cyclone separators, air separators, bag filter. **4 hours; 4-6 marks**
8. **Mixing:** Theory of mixing, solid-solid, solid-liquid and liquid-liquid mixing. Equipments- cylindrical, V-cone, double cone, ribbon, sigma blade, planetary, zig-zag and barrel mixers. Mixing devices, -propellers, turbines, paddles, and baffles. Vortex formation and prevention. Homogenization and study on Silverson emulsifier, Rapisonic homogenizer and colloid mill. **7 hours; 8-10 marks**
9. **Material Handling Systems:** Transportation of solids: Construction and working of belt conveyor, screw, chain, pneumatic, and bucket conveyors.

Transportation of fluids: Pumps - positive displacement pumps, centrifugal pump, peristaltic pump. Cycloidal blower. **7 hours; 8-10 marks**
10. **Filtration and centrifugation:** Study of Poiseuille's equation, Kozeny-Carman equation, Darcy's equation, filter aids and filter media. Construction and working of filter press, filter leaf, meta filter, drum filter, sintered glass filter, seitz filter, and

candle filter. Theory and principle of centrifugation, industrial centrifuges - basket, super, and conical disk centrifuges. **8 hours; 8-10 marks**

- 11. Crystallization:** Definition, characteristics, crystal forms, crystal habits, mechanism of crystallization, solubility curves, Mier's super-saturation theory, construction and working of agitated batch crystallizer, Swenson-Walker crystallizer, Krystal crystallizer and vacuum crystallizer. Caking of crystals and its prevention.

6 hours; 6-8 marks

- 12. Humidification:** Definition of humidity, humid heat, humid volume, study of psychrometric charts, wet bulb theory. Applications of humidity, control in various pharmaceutical departments like powders, capsules and tablets. **4 hours; 4-6 marks**

- 13. Materials of construction:** Applications and corrosion resistance properties of stainless steel, plastic and rubber, classification and mechanism of corrosion, factors, prevention and control. **4 hours; 4-6 marks**

- 14. Ion exchange:** Mechanisms, ion exchange resins, preparation and applications of ion exchange resins. Ion exchange equipment – Fixed bed ion exchange equipment, moving bed ion exchange equipment, fluidized bed ion exchange equipment.

4 hours; 4-6 marks

PHARMACEUTICAL ENGINEERING (PRACTICALS)
75 hours ; 3 hours/week

- 01 Drying of wet granules/calcium carbonate slurry and plotting drying rate curves.**
- 02 Size reduction of granular material using ball mill and calculation of Rittinger's, Kick's and Bond's coefficients.**
- 03 Determination of particle size weight distribution of a sample using sieve shaker and derivation of various statistical parameters.*
- 04 Study of the effect of materials related factors like concentration, viscosity, filter aids on the rate of filtration using calcium carbonate suspension.*
- 05 Study of the effect of process related factors like surface area, thickness, pressure on the rate of filtration using calcium carbonate suspension.*
- 06 Determination of the mixing index for the blending of calcium carbonate and talc (or salicylic acid and lactose)**
- 07 Determination of leaching of ampoules and vials in terms of powdered glass test and water attack test.**
- 08 Determination of mixing efficiency when the propeller blade is introduced in different positions during liquid-liquid mixing.**
- 09 Measurement of homogenizing capacity of Silverson Emulsifier for mixing of immiscible liquids (liquid paraffin-water)**
- 10 Preparation of crystals of potassium nitrate by shock cooling technique and study of its crystal habit.*
- 11 Study of the effect of surface area, viscosity, concentration on the rate of evaporation*
- 12 Study the influence of centrifugal effect in separating the oil phase of turpentine liniment.**
- 13 Separation of turpentine oil from oil mixture by steam distillation process.*
- 14 Determination of water vapour permeability across packing material*
- 15 Determination of equilibrium moisture content (EMC) of substances (starch or bentonite) at different humidities at room temperature.*
- 16 Analysis of pharmaceutical packing materials: Corrugated box.*

Note: ** Denotes major experiments * Denotes minor experiments

SCHEME OF EXAMINATION

1. Synopsis	-10 Marks
2. Major experiment (indicated by **)	-30 Marks
3. Minor experiment (indicated by *)	-20 Marks
4. Viva voce	-10 Marks

Total

= 70 Marks

PHARMACEUTICAL ENGINEERING REFERENCE BOOKS

1. Badger WL, Banchero JT. Introduction to chemical engineering. Singapore:McGraw-Hill Book Company;1955.
2. Carter SJ. Cooper and Gunn's Tutorial pharmacy. 6th ed. New Delhi:CBS Publishers;2000.
3. Coulson JM, Richardson JF, Backhurst JR, Harker JH. Chemical engineering Vol 1 and 2. 2nd ed. New Delhi:Asian Book Pvt Ltd;1998.
4. Don WG, James O. Perry's chemical engineer's handbook. Singapore: McGraw-Hill Book Company;1984.
5. Gennaro AL. Remington: The science and practice of pharmacy Vol I and II. 20th ed. Philadelphia:Lippincott Williams and Wilkins;2000.
6. McCabe WL, Smith JC, Harriott P. Unit operations of chemical engineering. 5th ed. Singapore: McGraw-Hill Book Company;1993.
7. Paradkar A. Introduction to pharmaceutical engineering. 11th ed. Pune:Nirali Prakashan;2009.
8. Rawlins EA. Bentley's textbook of pharmaceuticals. 8th ed. New Delhi:Reed Elsevier India Pvt Ltd;2010.
9. Sambamurthy K. Pharmaceutical engineering. New Delhi: New Age International Publishers;1998.
10. Subrahmanyam CVS, Thimmasetty J, Sarasija S, Kusumdevi V. Pharmaceutical engineering Unit operations I and II. 2nd ed. Delhi: Vallabh Prakashan;2012.

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Autoclave	01 no.
2. Automatic ball mill	01 no.
3. Buchner filtration apparatus	01 no.
4. Centrifuge	01 no.
5. Desiccators	05 nos.
6. Double cone Blender	01 no.
7. Permeability cups	05 nos.
8. Propeller type mechanical agitator	05 nos.
9. Refrigerator	01 no.
10. Sieve Shaker with set of sieves	01 no.
11. Silverson Homogeniser	03 nos.
12. Steam distillation still	01 no.
13. Tray dryer	01 no.
14. Vacuum Pump	01 no.
15. Water bath	01 no.

3.5 PHARMACOLOGY (THEORY)

75 hours ; 3 hours/week

1. General Pharmacology : Introduction and definitions—Health, Drug, Pharmacology, Pharmacokinetics and Pharmacodynamics, Sources of drugs. Routes of administration of drugs. Absorption of drug and the factors affecting them. Drug distribution, metabolism and excretion. Mechanism of drug action—Drug-Receptor interactions and molecular & biochemical basis of drug action, additive effect, synergism, potentiation. Factors modifying drug effects; Patient related factors & Drug related factors. Classification and mechanism of action of ADR. Dose response relationship, structure activity relationship. Definitions, Basic concepts and mechanisms of Drug-Drug, Drug-Food interactions, classification of Drug-Drug interaction.

15 hours;15-19 marks

2. Pharmacology of drugs acting on Autonomic Nervous System : Introduction — Neurohumoral Transmission. Adrenergic Drugs ; Adrenergic transmission, adrenergic receptors and drugs affecting adrenergic transmission, Classification of drugs and mechanism of action, Pharmacology of adrenaline (a proto type adrenergic drug) and salient features of other adrenergic drugs. Adrenergic Blockers; Classification, pharmacology of phenoxybenzamine (a proto type Alpha blocker), pharmacology of propranolol (a proto type beta blocker), salient features of alpha & beta blockers. Adrenergic neuronal blockers & mechanism of action. Cholinergic Drugs: Cholinergic transmission, cholinergic receptors and drugs affecting cholinergic transmission, Classification of drugs and mechanism of action, Pharmacology of Acetylcholine (a proto type cholinergic drug). Salient features of other cholinergic drugs, including cholinesterase inhibitors and enzyme reactivators. Anti cholinergic Drugs; Pharmacology of atropine (a proto type anti cholinergic drug) and salient features of other anti cholinergic drugs; Ganglionic blockers and stimulants, Neuromuscular blocking agents and drugs used in myasthenia gravis.

19 hours;16-20 marks

3. Pharmacology of Drugs acting on Cardiovascular System: Anti- hypertensives agents: Classification and mechanism of action, Pharmacology of centrally acting drugs (Clonidine and methyldopa), Classification of vasodilators including calcium channel blockers, Pharmacology of drugs affecting Renin Angiotensin system. Anti - anginal drugs; Classification and pharmacology of anti -anginal drugs. Anti-arrhythmic drugs; Classification and mechanism of action, Pharmacology of quinidine (A proto type sodium channel blocker), Salient features of other anti-arrhythmic drugs, Drugs used for therapy of congestive cardiac failure (CCF); Classification and mechanism of action of drugs used for CCF, pharmacology of digoxin, Salient features of other drugs used in CCF. Drugs used in treatment of hyperlipidaemias; Classification and mechanism of action of anti- hyperlipidaemics, Pharmacology of atorvastatin (A proto type of HMG CoA reductase inhibitor), Salient features of other anti- hyperlipidaemic agents.

14 hours; 12-14 marks

4. Pharmacology of Drugs Acting on Renal System (Diuretics) and antidiuretics; Classification and mechanism of action of diuretics, Pharmacology of furosemide, Salient features of other diuretics, Pharmacology of anti-diuretics, Uses and adverse effects of Urine acidifiers and alkalinizers.

3 hours;5-7 marks

5. Pharmacology of Drugs Acting on Blood and Blood forming Agents: Classification and mechanism of action & salient features of coagulants and anti-coagulants, haemopoietics, thrombolytics and antiplatelet agents.

4 hours;5-7 marks

6. Pharmacology of Autocoids & their antagonists: Histamine and antihistaminics, 5-Hydroxytryptamine and its antagonists, Lipid derived autocoids and platelet activating factor.
4 hours;5-7 marks

7. Pharmacology of Drug Acting on Respiratory Tract: Drugs used in asthma and COPD, mucolytics, expectorants, antitussives, nasal decongestants.
3 hours;2-4 marks

8. Pharmacology of Hormones and Hormones Antagonists: Thyroid and antithyroid drugs: Classification, mechanism of action and salient features of thyroid and antithyroid drugs, Anti-diabetic drugs, Insulin, Insulin preparations, Oral hypoglycemic agents: Classification, mechanism of action, salient features of oral anti-diabetics including newer agents, Pharmacology of corticosteroids, Pharmacology of sex hormones and oral contraceptives, Pharmacology of oxytocin, other uterine stimulants and relaxants.
13 hours;10-12 marks

PHARMACOLOGY (PRACTICALS)

75 hours ; 3 hours/week

1. Regulatory perspectives of animal experiments with special reference to CPCSEA guidelines.
2. Study of laboratory animals and their handling.
3. Study of physiological salt solutions used in experimental pharmacology.
4. Study of laboratory appliances used in experimental pharmacology.
5. Study of use of anesthetics in lab animals. *
6. Study of techniques of euthanasia in lab animals.*
7. To study the routes of administration of drugs.*
8. To study the absorption of glucose/drugs using everted gut sac from rat/chick.*
9. To study the *in vitro* protein binding and displacement of bound drug using egg albumin.*
10. To record the dose response curve of histamine using isolated guinea pig/chick/rat ileum preparation.*
11. Study of agonistic effects of histaminergic drugs using isolated guinea pig /chick/rat ileum preparation. **
12. Study of antihistaminic drugs using isolated guinea pig /chick/rat ileum preparation. **
13. To record the dose response curve of acetylcholine using isolated guinea pig/chick/rat ileum preparation.*
14. Study of potentiating effects of cholinergic drugs using isolated guinea pig /chick/rat ileum preparation. **
15. Study of anticholinergic drugs using isolated guinea pig /chick/rat ileum preparation. **
16. Simulated experiments on effects of drugs on isolated heart of frog.*
17. Simulated experiments on effects of drugs on hypodynamic heart of frog.*
18. Simulated experiments on effects on B.P, HR and RR of dog.*
19. Simulated experiments on effects of mydriatic and miotic drugs on rabbit's eye. *
20. Simulated experiments on effects of local anaesthetic drugs on rabbit's eye. *
21. Simulated experiments on effects of drugs on ciliary motility of frog's esophagus. *

Note: ** Denotes major experiments

*** Denotes minor experiments**

SCHEME OF EXAMINATION

1. Identification	-	10 Marks
2. Synopsis	-	10 Marks
3. Major Experiment	-	25 Marks
4. Minor Experiment	-	15 Marks
5. Viva	-	10 Marks
Total		= 70 Marks

PHARMACOLOGY TEXT BOOKS

1. Tripathi KD, Essentials of Medical Pharmacology, 7th Edition, Jaypee Brothers, 2010.
2. Satoskar R.S., Bhandarkar S.D. and Rege N.N., Pharmacology and Pharmacotherapeutics, 21st Edition, Popular Prakashan Pvt Ltd, 2010.
3. Chaudhary S.K., Quintessence of Medical Pharmacology, 3rd Revised Edition, Central Book Agency Pvt. Ltd., 2010.
4. Sharma H.L. and Sharma K.K., 2nd Edition, Principles of Pharmacology, Paras Medical, 2011.
5. Ghosh M.N., Fundamentals of Experimental Pharmacology, 5th Edition, Hilton & Company, 2011.
6. Kulkarni S.K., Hand book of Experimental Pharmacology, 3rd Edition, Vallabh Prakashan, 2005.
7. Medhi B. and Prakash A., Practical manual of experimental and clinical pharmacology, 1st Edition, Jaypee Brothers, Medical Publishers, 2010.

PHARMACOLOGY REFERENCE BOOKS

1. Brunton L.L., Chabner B.A., and Knollmann B.C., Goodman and Gilman's The Pharmacological Basis of Therapeutics, 12th Edition, McGraw-Hill Professional, 2010.
2. Katzung B.G., Masters S.B. and Trevor A.J., Basic and Clinical Pharmacology, 12th Edition, McGraw-Hill, 2011.
3. Rang H.P., M.M. Dale, J.M. Ritter., Flower R.J. and Henderson G., Pharmacology, 7th illustrated Edition, Elsevier Science Health Science Division, 2011.
4. Craig C.R. and Stitzel R.E., Modern Pharmacology with Clinical Applications, 6th Edition, Lippincott Williams and Wilkins, 2003.
5. Harvey R.A., Clark M.A., Finkel R, Jose A.R. and Whalen K, 5th Edition, Lippincott's Illustrated Reviews: Pharmacology, Lippincott Williams and Wilkins, 2011.
6. Barar F.S.K., Essentials of Pharmacotherapeutics, 6th Revised Edition, S.Chand & Co. Ltd, 2011.
7. DiPiro J, Talbert R.L., Yee G., Matzke G., Wells B. and Posey L.M., Pharmacotherapy: A Pathophysiologic Approach, 8th Edition, McGraw-Hill Medical, 2011.

LIST OF MINIMUM EQUIPMENT REQUIRED

(For a batch of 20 students)

1. Pharmacology appliances	Sufficient
2. Sherrington's Kymograph Machine	20
3. Sherrington's Drum	20
4. Perspex bath assembly (single unit)	20
5. Aerators	20
6. Dissection trays	20
7. Dissection boards	20
8. Haemostatic arterial forceps	20
9. Hypodermic syringes and needles of size 18, 24, 26G	20
10. Computers	10
11. LCD Projector	01
12. Software package for experiments	01
13. Standard graphs for various drugs	Sufficient
14. Levers	20
15. Cannulae	20

3.6 PHARMACEUTICAL MARKETING AND MANAGEMENT (THEORY)

50 hours; 2 hours/week

1. Marketing: a) The meaning and scope of marketing. b) The pharmaceutical market- quantitative and qualitative aspects, size and composition of the market, demographic descriptions and socio-psychological characteristics of the consumer, market segmentation. c) Analyzing the market- role of market research. d) Consumer profile- Motivation and prescribing habits of the physician, patients' choice of physician and retail pharmacist.

11 hours; 15-20 marks

2. The Organization: Manufacturer- company objectives, influence of internal controls such as company policy on the company's operation, effects of government regulations and controls on marketing practices.

2 hours; 2-5 marks

3. The Pharmaceutical Product: a) Market consideration in product development, marketing mix, product life cycle(PLC), effects of different elements of marketing mix at different stages of PLC, product classification, product planning, product differentiation, me-too products, modification of existing product. b) New product development- all stages from the new product idea to the stage of marketing in developed product (Bulk drugs and formulations). c) Branding- concept of brand, different types of brand, importance and reasons for branding, packaging.

6 hours; 10-15 marks

4. Competitive Practices in the Pharmaceutical Industries: a) Price competition-Pricing, objectives, basis and strategies. Rate contracts. b) Non-price competition: all types of non-price competition with special emphasis on competition through research and development, competition through quality.

3 hours; 5-7 marks

5. Promotions: a) Communication and its importance b) Different ways of promotion- Advertising, direct mail, professionals, journals, sampling, retailing, medical exhibition, public relations, Online Promotional Techniques for OTC Products. c) Professional sales representative- duties of PSR, purpose of detailing, selection and training, compensation and future prospects of the PSR.

5 hours; 8-10 marks

6. Distribution: a) The wholesale- his role in distribution of pharmaceutical services offered to the manufacturer and the retailer, advantages and disadvantages of distribution through wholesaler. b) The retailer- Classification of retail institution, advantages and disadvantages of retail institution, the hospital as retail outlet.

4 hours; 5-7 marks

7. Management: a) Concepts of management, Nature of management, principles of management. b) Primary functions of management- planning, organizing, staffing, directing and controlling, motivation, and entrepreneurship development. c) Secondary functions of management: Decision- making, Leadership, innovation, delegation of authority/ responsibility.

12 hours; 15-20 marks

8. Current Health Scenario in India

1 hour; 2 marks

9. Importance of Entrepreneurship

2 hours; 2-5 marks

10. Quality Management: Introduction to Statistical Methods, Statistical Quality Control Tools, Statistical Tools for Decision Making, Total Quality Management/Kaizen: Six Sigma, Quality Circle and CPM (Critical Path Method)

4 hours; 5-10 marks

PHARMACEUTICAL MARKETING AND MANAGEMENT REFERENCE BOOKS

1. Ashwathappa K. Production management. Mumbai:Himalaya Publishing House;2010.
2. Chary SN. Production and operation management. 2nd ed. Delhi:Tata McGraw Hill Publishing Co;2009.
3. Ghosh SK. Introduction to ISO 9000 & total quality management. Calcutta:Oxford Publishing House.
4. Harold TA, John AR, Oliver S. Manufacturing organization and management. 4th ed. New Delhi:Prentice Hall of India Pvt Ltd.
5. Heinz W, Harold K, Management: A global perspective. 10th ed. McGraw Hill International Edition;2007.
6. Mehra ML. GMP. 1st ed. Allahabad:University Book Agency.
7. Mickey CS. Pharmaceutical marketing in the 21st century. New Delhi;Viva Books Pvt Ltd;2001.
8. Mickey CS. Principles of pharmaceutical marketing. 3rd ed. New Delhi;CRS Publishers and Distributors;2004.
9. Patani A. Drug & Cosmetics Act 1940. Lucknow:Eastern Book Co.
10. Quality Assurance of Pharmaceuticals, Compendium of guidelines and related materials, vol. I, WHO Publications, Geneva.
11. Subbarao. Pharmaceutical marketing in India. Hyderabad;Asian Institute of Pharmaceutical Marketing;1998.
12. Tripathi PC, Reddy PN. Principles of management. 3rd ed. New Delhi:Tata McGraw Hill Publishing Co Ltd;2006.
13. Varma MM, Agarwal RK. Production management. Delhi:King Books Educational Publishers.
14. WHO Experts Committee on “Specifications for Pharmaceutical Preparation” 13th, 22nd, 23rd, 24th, 34th Reports.

Websites

1. www.ich.org
2. www.ifpma.org/ich 5
3. www.fda.gov
4. www.health.gov.au/tga/
5. www.mca.gov.uk

4.1 PHARMACEUTICAL TECHNOLOGY AND BIOPHARMACEUTICS (THEORY)

75 hours ; 3 hours/week

1. Preformulation:

- a. Study of physicochemical characteristics of drug substances. Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms. **6 hours;6-8marks**

Tablets:

- b. Classification of tablets. Processing of tablets: Formulation, granulation methods, compression and processing problems. Equipment's and tablet tooling. **5 hours; 5-7 marks**
- c. Tablet coating: Types of coating, coating materials, formulation of coating materials, method of coating, equipment employed and defects in coating. **4 hours; 4-6 marks**
- d. In process quality control, evaluation of tablets and packaging. **2 hours;2-5marks**

2. Capsules:

- a) Hard gelatin capsules: Extraction of gelatin and production of hard gelatin capsule shells. Filling, finishing and special techniques of formulation of hard gelatin capsules. Quality control tests for capsules. **5 hours; 5-7 marks**
- b) Soft gelatin capsules: Nature of shell and capsule content, importance of base adsorption and minimum/gram factors, production, in process and final product quality control tests. **3 hours; 3-5 marks**

3. **Parenteral Preparations:** Definition, types, advantages and limitations, general formulation, vehicles, production procedure, production facilities and controls. Formulation of injections, sterile powders, emulsions and suspensions. Containers and closures pertinent to sterile preparations and quality control tests.

14 hours;15-20 marks

4. **Ophthalmic formulations:** Requirements, formulation of eye drops, eye lotion and eye ointments, containers and evaluation. **5 hours; 5-7 marks**

5. **Liquid orals:** Formulation and manufacturing considerations. Filling and packaging methods. **5 hours; 5-7 marks**

6. **Pharmaceutical aerosols:** Definition, propellants, containers, valves, types of aerosol systems, manufacture of aerosols. Evaluation of aerosols: Quality control and stability studies. **6 hours; 5-10 marks**

7. **Cosmetics:** Formulation and preparation of the following cosmetic preparations. Lipsticks, Shampoos, Face and Talcum powders, Nail lacquers, cold cream and vanishing cream, tooth pastes, and hair dyes and sunscreens. **10 hours; 10-15 marks**

8. A) Biopharmaceutics:

- a. Definition and applications, Absorption of drugs through GIT: Mechanisms and factors affecting.
- b. Bioavailability and Bioequivalence. Measurement of Bioavailability (C_{max} , T_{max} , AUC).

- B) Pharmacokinetics-Basic concepts:** Blood level curves for I.V, Constant rate infusion, Oral, I.M, and Sustained release dosage forms. **11 hours; 10-15 marks**

PHARMACEUTICAL TECHNOLOGY & BIO PHARMACEUTICS (PRACTICALS)
75 hours ; 3 hours/week

- 1. Manufacture of tablets. ****
 - a) Tablets prepared by wet granulation.
 - b) Tablets prepared by direct compression.
 - c) Mouth dissolving tablet.
 - d) Chewable tablet.
- 2. Manufacture of sterile products. ****
 - a) Ampoules of ascorbic acid injection IP
 - b) Ampoules of calcium gluconate injection IP
 - c) Sodium chloride intravenous infusion IP
 - d) Vials of oxytetracycline injection IP
 - e) Eye drops
- 3. Evaluation of pharmaceutical formulations. (Q.C. tests)***
 - a) Tablets.
 - b) Capsules.
 - c) Sterile products.
- 4. Formulation of two liquid oral preparations* and evaluation by assay**.**
 - a) Preparation and evaluation of paracetamol syrup.
 - b) Preparation and evaluation of magnesium hydroxide mixture BP.
- 5. Cosmetic preparations.***
 - a) Lipsticks
 - b) Cold cream and vanishing cream
 - c) Clear liquid shampoo
 - d) Tooth paste and tooth powders
 - e) Sunscreens
- 6. Tablet coating. (demonstration)**
- 7. Demonstration of microencapsulation technique/ matrix tablets/ transdermal patches.**

Note: ** Denotes major experiments * Denotes minor experiments

SCHEME OF EXAMINATION

1. Synopsis	-10 Marks
2. Major experiment (indicated by **)	-30 Marks
3. Minor experiment (indicated by *)	-20 Marks
4. Viva voce	-10 Marks
Total	= 70 Marks

PHARMACEUTICAL TECHNOLOGY & BIO PHARMACEUTICS

REFERENCE BOOKS

1. Aulton ME. *Pharmaceutics, The science of dosage form design*. 2nd ed. Edinburgh:Churchill Livingstone;2002.
2. Banker GS, Rhodes CT. *Modern pharmaceutics*. 4th ed. New York: Marcel Dekker Inc; 2005.
3. Carter SJ. *Cooper and Gunn's Tutorial pharmacy*. 6th ed. New Delhi:CBS Publishers;2000.
4. Gennaro AL. *Remington: The science and practice of pharmacy, Vol I and II*. 20th ed. Philadelphia:Lippincott Williams and Wilkins;2000.
5. Lachman L, Lieberman HA, Kanig JL. *Theory and practice of industrial pharmacy*. 3rd ed. Bombay: Varghese Publishing House; 1987.
6. Lachman L, Lieberman HA, Kenneth EA. *Pharmaceutical dosage forms: Parenteral medications Vol I,II and III*. New York:Marcel Dekker Inc;1992.
7. Lachman L, Lieberman HA. *Pharmaceutical dosage forms: Tablets Vol I,II and III*. New York:Marcel Dekker Inc;1980.
8. Loyd VA, Nicholas GP, Howard CA. *Ansel's pharmaceutical dosage forms and drug delivery systems*. 8th ed. Noida: BI Publications Pvt Ltd;2005.
9. *Pharmacopoeias: I.P., B.P., U.S.P.*
10. Rawlins EA. *Bentley's textbook of pharmaceutics*. 8th ed. New Delhi:Reed Elsevier India Pvt Ltd;2010.
11. Shargel L, Andrew BC, Susanna WP. *Applied biopharmaceutics and pharmacokinetics*. 5th ed. New York: The McGraw Hill Companies Inc;2005.
12. Sharma PP. *Cosmetics – Formulation, manufacturing and quality control*. 2nd ed. Delhi: Vandana Publications; 2001.
13. Subrahmanyam CVS, Thimmasetty J, Vijayendraswamy SM, Shivanand K. *Laboratory manual of industrial pharmacy*. Delhi:Vallabh Prakashan;2009.
14. Venkateswarlu V. *Biopharmaceutics and pharmacokinetics*. Hyderabad:Pharma Book Syndicate;2004.
15. Wilkinson JB, Moore RJ. *Harry's cosmeticology*. 7th ed. London:Longman Scientific & Technical;1989.

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Ampoule filling sealing machine	01 no.
2. Ampoule washing machine	01 no.
3. Capsule filling machine	01 no.
4. Clarity test apparatus	02 nos.
5. Digital thermometers	02 nos.
6. Friability test apparatus	02 nos.
7. Lipstick moulds	10 nos.

8. Magnetic stirrers, 500 ml and 1 liter capacity	05 nos.
9. Mechanical stirrers	03 nos.
10. Monsanto's hardness testers	02 nos.
11. Ointment crimping machine	01 no.
12. Ointment filling machine	01 no.
13. Pfizer type hardness testers	02 nos.
14. Standard granulating sieves	2 sets
15. Tablet coating pan	01 no.
16. Tablet disintegration test apparatus IP	01 no.
17. Tablet dissolution test apparatus	01 no.
18. Tablet punching machine	01 no.
19. Tray dryer	01 no.
20. Vial crimping machine	01 no.

4.2 INSTRUMENTAL AND BIOMEDICAL ANALYSIS (THEORY)

75 hours ; 3 hours/week

The subject to be discussed with special reference to quality control and assurance of pharmaceuticals, its scope and its importance in the pharmaceutical industry. The following analytical techniques should be discussed with suitable examples.

1. Spectroscopy

Electromagnetic radiation, Electromagnetic spectra, Quantization of energy, criteria for absorption of EMR, wavelength, frequency, wave number, Chromophores, Auxochromes, Bathochromic shift, hypsochromic shift, Hyperchromic and hypochromic effects. Theory of electronic, atomic and molecular spectra, Beer and Lambert's law, Derivation and Deviations, Effect of solvent and pH on absorption spectra, Application of Beer's law to single component analysis and multicomponent systems. **6 hours; 8-9 marks**

Absorption Spectroscopy: UV/Visible spectroscopy, Instrumentation and working; Sources of radiation, Wavelength selectors; Filters-Prisms and Gratings, Sample cells, Detectors- Phototube, Photomultiplier tube, Barrier layer cell and Silicon photo diode. Measurement of equilibrium constant and rate constant by spectroscopy, spectrophotometric titrations **7 hours;9-10 marks**

IR Spectroscopy: Theory, Hook's law, vibration modes of in molecule, Instrumentation, Working and Sample handling methods, Sources of radiation, Monochromators, Sample cells and detectors- Bolometers, Thermocouples, Golay cells. IR Frequency - structure correlation, study of characteristic fundamental stretching vibrations of functional groups like Alcohol, Carboxyl, Amide, Amine, Aldehyde, and Ketone **6 hours;8-9 marks**

2. Fluorimetric analysis: Theory, concept of singlet and triplet electronic states, Internal and external conversions, intersystem crossing, factors affecting fluorescence, Quenching.

Instrumentation- Fluorimeter, Spectrofluorimeter and Applications Estimation of vitamin B₁₂ by fluorimetry **4 hours;5-6 marks**

3. Flame emission and atomic absorption spectrometry: Theory, Nebulization, flames and flame temperatures, interferences, Hallow cathode lamp, flame spectrometric techniques, applications. **4 hours;5-6 marks**

4. Nephelometry and Turbidimetric Analysis: Theory, General principles, Instrumentation and applications. **2 hours;3-4 marks**

5. Chromatography: Introduction and classification **2 hours;3-4 marks**

A) Paper Chromatography: Introduction, Principle, Technique, Development, methods and applications. **2 hours;3-4 marks**

B) Thin layer chromatography: Introduction, principle, technique, R_f, R_X and R_m values and applications. **2 hours;3-4 marks**

C) Column chromatography: Adsorption column chromatography, development Techniques – Frontalanalysis, Displacement analysis and elution analysis. Factors affecting column efficiency, Applications, Partition Chromatography **3 hours;4-5 marks**

D) HPTLC: Basic concept, difference between TLC and HPTLC **2 hours;3-4 marks**

E) Ion exchange chromatography: Ion exchange materials, synthetic ion exchange resins, Properties of ion exchangers, mechanism of ion exchange process, factors affecting ion exchange, applications. **3 hours;4-5 marks**

F) HPLC: Introduction, theory, instrumentation –Solvent treatment systems, Pumps- Reciprocating and displacement pumps, Columns, Guard column, Detectors- UV detectors, Fluorimetric detectors, Refractive index detectors and applications. **4 hours;5-6 marks**

G) Size exclusion chromatography: Theory, gels and applications **2 hours;3-4 marks**

H) Gas chromatography: Introduction, theory, instrumentation-carrier gas, types of columns, Stationary phases in gas liquid chromatography and gas solid chromatography, Detectors- Flame ionization detector, electron capture detector, thermal conductivity detector. Gas chromatogram, Derivatisation techniques like silylation, and esterification. Programmed temperature gas chromatography, Applications. **5 hours;6-7 marks**

I) Electrophoresis: Principles of separation, Factors affecting separation, equipment for paper and gel electrophoresis, Moving boundary electrophoresis, isoelectric focusing electrophoresis, Applications . **3 hours;4-5 marks**

6. Electrometric methods:

A) Potentiometry: Electrochemical cell, construction and working of reference electrode, Normal hydrogen electrode, calomel electrode, silver-silver chloride electrode, Indicator electrodes- Glass electrode, Antimony electrode, Quinhydrone electrode, Potentiometric titrations, methods of detecting end point, applications. **6 hours;8-9 marks**

B) Conductometry: Introduction, conductivity cell, cell constant, conductometric titrations, Applications **2 hours;3-4 marks**

7. NMR: Theory and instrumentation of ^1H NMR, applications. **2 hours;3-4 marks**

8. Mass Spectroscopy: Basic concept mass spectroscopy, applications. **2 hours;3-4 marks**

9. X-ray Diffraction: Theory of X-ray diffraction, applications. **2 hours;3-4 marks**

10. Quality assurance: Introduction, Sources of quality variation, control of quality variation, Validation methods. **4 hours;5-6 marks**

INSTRUMENTAL AND BIOMEDICAL ANALYSIS (PRACTICALS)
75 hours ; 3 hours/week

Note: At least 18-19 experiments to be covered from the following list

1. Calibration of UV-Visible spectrophotometer
2. Determination of absorption maxima for a given solution of the drug*
3. Determination of isobestic point*
4. Separation and identification of amino acids by paper chromatography*
5. Separation and identification of alkaloids by thin layer chromatography*
6. Separation and Identification of Dyes by radial paper chromatography*
7. U.V. Spectrometric determination of Ibuprofen tablets*
8. U.V. Spectrometric determination of Paracetamol tablets*
9. Colorimetric estimation of Ferrous ions using 1, 10 Phenanthroline**
10. Colorimetric estimation of Sulphanilamide using N-1-Naphthyl Ethylene Diaminedihydrochloride**
11. Colorimetric estimation of salicylic acid**
12. Assay of Dextrose injection by colorimetry**
13. Estimation of quinine sulphate by fluorimetry**
14. Estimation of Riboflavine by fluorimetry**
15. Quenching of Quinine fluorescence by iodide ions*
16. Conductometric titration of Benzoic acid with NaOH**
17. Potentiometric titration of HCl with NaOH**
18. Determination of chloride and sulphate in calcium gluconate by Nepheloturbidimetric analysis**
19. Infrared spectral peaks identification of samples with different functional groups such as -COOH, -COOR, CONHR, -NH₂, -NHR, -OH, -CHO, -C=O*
20. Determination of Sodium / Potassium by flame photometry**

Note: ** Denotes major experiments * Denotes minor experiments

SCHEME OF EXAMINATION

1. Synopsis	10 Marks
2. Major experiment (Experiment indicated by**)	30 Marks
3. Minor experiment (Experiment indicated by*)	20 Marks
4. Viva voce	10 Marks
Total	70 Marks

INSTRUMENTAL AND BIOMEDICAL ANALYSIS REFERENCE BOOKS (THEORY)

Latest editions and all volumes of

1. Hobarth Willard, Lynne L. Merritt, John A. Dean & Frank A. Settle Jr, Instrumental methods of analysis, 6 edition, CBS Publishers & Distributors, New Delhi
2. Skoog and West, Pharmaceutical Analysis
3. Kenneth A. Connors, A Text book of Pharmaceutical analysis, 3 Edition, John Wiley & Sons, New York (1982)
4. Instrumental approach to chemical analysis – AK Srivatsava, PC Jain, S Chand publishers
5. A.I. Vogel, Text book of Quantitative chemical analysis, ELBS/ Longman, London
6. Stahl.E , Thin layer chromatography-A Hand book, Springer verlag, Berlin
7. Leon Lachman, Lieberman, and J.L.Kanig, Theory and practice of industrial pharmacy
8. Y.R Sharma, Organic spectroscopy

INSTRUMENTAL AND BIOMEDICAL ANALYSIS REFERENCE BOOKS (PRACTICALS)

Latest editions and all volumes of

1. Garratt. D.C. Quantitative analysis of drugs, 3 edition, CBS Publishers & Distributors, New Delhi.(2001).
2. Melean. C.E., Kiser.R.W., Problems and experiments in instrumental analysis.
3. Beckett A.H., Stenlake J.B, Practical Pharmaceutical Chemistry, 4 edition, The Athlone Press, London.
4. Kenneth A.Connors, A Text book of Pharmaceutical analysis, 3 edition , John Wiley & Sons, New York (1982),.
5. Hobarth Willard, Lynne L. Merritt, John A. Dean , Frank A. Settle Jr,, Instrumental methods of analysis, 6 edition, CBS Publishers & Distributors, New Delhi.
6. Indian Pharmacopoeia, Vol I & II , , Ministry of Health & Family welfare, Govt. of India, Published by Controller of the Publications, New Delhi, 1996.
7. United States Pharmacopoeia.
8. British Pharmacopoeia.
9. Alfonso R. Gennaro, Remington's: The Science & Practice of Pharmacy, Vol I & II – Lippincotts Wiliams & Wilkins.
10. Higuchi T & Hanssen E.B., Text Book of Pharmaceutical Analysis, A Wiley Inter science Publications.
11. William Kemp, Spectroscopy methods, ELBS.
12. John R. Dyer, Applications of Absorption spectroscopy of organic compounds, Prentice Hall of India Pvt. Ltd., New Delhi.
13. R. M. Silverstein, G. Clayton, Terence C. Morill, Spectrometric identification of organic compounds, John Wiley & Sons, New York.

LIST OF MINIMUM EQUIPMENTS REQUIRED

Equipments

1. Colorimeter	01
2. UV Spectrophotometer	01
3. Fourier Transform Infra Red spectrometer	01
4. Fluorimeter	01
5. Nephelo turbidity meter	01
6. Flame photometer	01
7. Potentiometer	02
8. Conductivity meter	02
9. Analytical weighing Balance (1 mg sensitivity)	01
10. Oven	01

Apparatus

1. Volumetric flask 10 ml, 25 ml, 50 ml and 100ml
2. Weighing bottle
3. Pipette – Graduated 10 ml
4. Pipette – Bulb 1ml, 2ml, 5ml and 10 ml
5. Beaker – 100 ml, 250 ml and 500 ml
6. Separating funnel
7. TLC plate
8. Chromatographic paper
9. TLC and Paper chromatography – Development chamber
10. Water bath

4.3 PHARMACOLOGY & TOXICOLOGY (THEORY)

75 hours ; 3 hours/week

1. **Bio Assays:** Scope, General Principles and Methods **2 hours;5-10 marks**
2. **Drug discovery and development:** a. Preclinical evaluation (Regulatory Toxicity Studies) b. Clinical evaluation including pharmacovigilance **3 hours;4-5 marks**
3. **Pharmacology of Drugs Acting on Central Nervous System :** General consideration (Introduction), Alcohol, General anesthetics, Sedatives and hypnotics, Anti-Epileptics, Psychopharmacological agents, Classification and mechanism of action of drugs used in psychosis, Pharmacology of Chlorpromazine (a prototype drug), Salient features of Antipsychotics including atypical Antipsychotics. Drugs used in Parkinsonism and Alzheimer's disease. Antidepressants: Classification and mechanism of action of drugs used in Depression, Pharmacology of imipramine (a prototype TCA), Salient features of other Antidepressants, including SSRIs and atypical antidepressants, Pharmacology of Lithium and other agents used in bipolar disorder. Anxiolytics, Drug dependence and drug abuse **19 hours;17-20 marks**
4. **Analgesics and anti-inflammatory agents :** Pain pathway, classification and mechanism of action of centrally acting analgesics, Pharmacology of Morphine (a prototype Opioid), Salient features of other opioids including antagonists, Classification and mechanism of action of NSAIDs, Pharmacology of Aspirin (a prototype NSAID), Salient features of other NSAIDs including COX-2 inhibitors **8 hours; 9-10 marks**
5. **Pharmacology of Drugs Acting on Gastro Intestinal Tract:** Antiulcer drugs, Antacids, Laxatives and Purgatives, Emetics and Antiemetics, Appetizers, Digestants, Carminatives **4 hours; 8-10 marks**
6. **Chemotherapy:** Introduction and principles of chemotherapy including general mechanisms of antimicrobials, mechanism of resistance, super infections, antimicrobial combinations. Classification, mechanism of action, spectrum of activity, resistance development, adverse drug reactions and therapeutic use of the following: 1. Sulfonamides and Co-trimoxazole, 2. Penicillins and Cephalosporins, 3. Tetracyclines and Chloramphenicol, 4. Macrolides, 5. Aminoglycosides, 6. Polyene & Polypeptide antibiotics, 7. Quinolones and Fluoroquinolones, 8 Lincosamides, Glycopeptides, urinary antiseptics, 9. Antifungal agents, 10. Antiviral agents including anti-HIV, 11. Chemotherapy of Tuberculosis and Leprosy, 12. Chemotherapy of Malaria, 13. Chemotherapy of Protozoal infections (amoebiasis, Giardiasis), 14. Pharmacology of Anthelmintic drugs, 15. Chemotherapy of Cancer **31 hours; 17-20 marks**
7. **Immunopharmacology** Pharmacology of immunosuppressants and stimulants **2 hours; 4-5 marks**
8. **Principles of Toxicology:** General principles of treatment of acute toxicity and acute poisoning Signs, Symptoms and treatment of acute and chronic poisoning due to i) Barbiturates ii) Alcohols iii) Benzodiazapines iv) Antidepressants, v) Neuroleptics vi) Insecticides vii) Snake bite viii) Heavy metals (iron, lead, mercury, arsenic). **4 hours; 4-5 marks**
9. **Pharmacology of Local anesthetics** **2 hours; 2-5 marks**

PHARMACOLOGY & TOXICOLOGY (PRACTICALS)
75 hours ; 3 hours/week

1. To record the dose response curve of Histamine using isolated chick/rat/guinea pig ileum preparation.**
2. To carry out bioassay of Histamine using isolated chick/rat/guinea pig ileum preparation by matching method.**
3. To carry out bioassay of Histamine using isolated chick/rat/guinea pig ileum preparation by interpolation method.**
4. To carry out bioassay of Histamine using isolated chick/rat/guinea pig ileum preparation by three point method.**
5. To record the dose response curve of Acetylcholine using isolated ileum preparation.**
6. To carry out bioassay of Ach using isolated chick/rat/guinea pig ileum preparation by interpolation method.**
7. To carry out bioassay of Acetylcholine using isolated ileum preparation by matching method.**
8. To carry out bioassay of Acetylcholine using isolated ileum preparation by three-point method.**
9. To carry out MAO inhibitory activity using chick/rat liver homogenate.*
10. To carry out amylase/ α -glucosidase inhibitory activity using *in vitro* technique.*
11. Study of principle, procedure involved and interpretation of given results for analgesic property of drug using analgesiometer*
12. Study of principle, procedure involved and interpretation of given results for Anti inflammatory effect of drugs using rat-paw edema method.*
13. Study of principle, procedure involved and interpretation of given results for Anti convulsant activity of drugs using MES method.*
14. Study of principle, procedure involved and interpretation of given results for Anti convulsant activity of drugs using pentylenetetrazole method.*
15. Study of principle, procedure involved and interpretation of given results for antidepressant activity of drugs using pole climbing apparatus.*
16. Study of principle, procedure involved and interpretation of given results for hypnotic and sedative property using Pentobarbitone induced sleeping time method.*
17. Study of principle, procedure involved and interpretation of given results for locomotor activity evaluation of drugs using Actophotometer.*
18. Study of principle, procedure involved and interpretation of given results for evaluation of muscle grip strength/relaxant effect of drugs using rotarod.*
19. Study of principle, procedure involved and evaluation of anthelmintic activity of drugs using earthworm as a model.*

Note: ** Denotes major experiments

*** Denotes minor experiments**

SCHEME OF EXAMINATION

1. Identification	-	10 Marks
2. Synopsis	-	10 Marks
3. Major Experiment	-	25 Marks
4. Minor Experiment	-	15 Marks
5. Viva	-	<u>10 Marks</u>
Total	-	<u>70 Marks</u>

PHARMACOLOGY & TOXICOLOGY TEXT BOOKS

1. Tripathi KD, Essentials of Medical Pharmacology, 7th Edition, Jaypee Brothers, 2010.
2. Satoskar R.S., Bhandarkar S.D. and Rege N.N., Pharmacology and Pharmacotherapeutics, 21st Edition, Popular Prakashan Pvt Ltd, 2010.
3. Chaudhary S.K., Quintessence of Medical Pharmacology, 3rd Revised Edition, Central Book Agency Pvt. Ltd., 2010.
4. Sharma H.L. and Sharma K.K., 2nd Edition, Principles of Pharmacology, Paras Medical, 2011.
5. Ghosh M.N., Fundamentals of Experimental Pharmacology, 5th Edition, Hilton & Company, 2011.
6. Kulkarni S.K., Hand book of Experimental Pharmacology, 3rd Edition, Vallabh Prakashan, 2005.
7. Medhi B. and Prakash A., Practical manual of experimental and clinical pharmacology, 1st Edition, Jaypee Brothers, Medical Publishers, 2010.

PHARMACOLOGY & TOXICOLOGY REFERENCE BOOKS

1. Brunton L.L., Chabner B.A., and Knollmann B.C., Goodman and Gilman's The Pharmacological Basis of Therapeutics, 12th Edition, McGraw-Hill Professional, 2010.
2. Katzung B.G., Masters S.B. and Trevor A.J., Basic and Clinical Pharmacology, 12th Edition, McGraw-Hill, 2011.
3. Rang H.P., M.M. Dale, J.M. Ritter., Flower R.J. and Henderson G., Pharmacology, 7th illustrated Edition, Elsevier Science Health Science Division, 2011.
4. Craig C.R. and Stitzel R.E., Modern Pharmacology with Clinical Applications, 6th Edition, Lippincott Williams and Wilkins, 2003.
5. Harvey R.A., Clark M.A., Finkel R, Jose A.R. and Whalen K, 5th Edition, Lippincott's Illustrated Reviews: Pharmacology, Lippincott Williams and Wilkins, 2011.
6. Barar F.S.K., Essentials of Pharmacotherapeutics, 6th Revised Edition, S.Chand & Co. Ltd, 2011.
7. DiPiro J, Talbert R.L., Yee G., Matzke G., Wells B. and Posey L.M., Pharmacotherapy: A Pathophysiologic Approach, 8th Edition, McGraw-Hill Medical, 2011.

LIST OF MINIMUM EQUIPMENT REQUIRED

(For a batch of 20 students)

1. Pharmacology appliances	Sufficient
2. Sherrington's Kymograph Machine	20
3. Sherrington's Drum	20
4. Perspex bath assembly (single unit)	20
5. Aerators	20
6. Dissection trays	20
7. Dissection boards	20

8. Haemostatic arterial forceps	20
9. Hypodermic syringes and needles of size 18, 24, 26G	20
10. Computers	10
11. LCD Projector	01
12. Software package for experiments	01
13. Standard graphs for various drugs	Sufficient
14. Levers	20
15. Cannulae	20
16. Analgesiometer (Radiant heat)	01
17. Eddy's Hot Plate	01
18. Plethysmometer	01
19. Electro-Convulsiometer	01
20. Pole climbing apparatus	01
21. Actophotometer	01
22. Rotarod apparatus (03 / 05 compartments)	01

4.4 MEDICINAL CHEMISTRY II (THEORY)

75 hours ; 3 hours/week

- A. Introduction to QSAR:** Study of hydrophobic, Electronic & Steric parameters
2 hours;3-4 marks
- B. Prodrugs:** Definition and examples
1 hour;1-2 marks
- C. Introduction to drug discovery-** Definition of lead molecule and its identification methods viz, high throughput screening, wholesale screening, and fragment based lead generation, fast followers
2 hours;3-4 marks

D. History and development of chemotherapeutic agents: Structure, uses and synthesis of only those compounds that are underlined and superscripted by 's'.

1. Antifungal agents:
 - a) Antifungal antibiotics- Nystatin, Griseofulvin, Amphoterecin-B, Synthetic anti fungal agents:
 - b) Substituted imidazoles: Clotrimazole, Miconazole^s, Ketoconazole, oxyconazole, Intraconazole.
 - c) Miscellaneous–Zinc propionate, Sodium caprylate, Tolnaftate^s. 4 hours;5-6 marks
2. Urinary tract anti-infectives:
 - a) Quinalones: Nalidixic acid, Cinoxacin, Norfloxacin, Ciprofloxacin^s, Pefloxacin, Ofloxacin, Sparfloxacin
 - b) Miscellaneous: Nitrofurantoin^s. 3 hours;4-5 marks
3. Antitubercular drugs:
 - a) Synthetic antitubercular agents: p-Aminosalicylic acid, Isoniazid, Ethambutol, Pyrazinamide, Ethionamide, Clofazamine, Bedaquiline
 - b) Antitubercular Antibiotics: Cycloserine, Viomycin sulfate, Capreomycin sulfate, Rifampicin.
 - c) Combination therapy for TB 4 hours;5-6 marks
4. Antiviral Agents
 - a) Amantidine hydrochloride, Idoxuridine, Acyclovir, Zidovudine.
 - b) Anti-AIDS: Azidothymidine, Suramin 2 hours;3-4 marks
5. Antiprotozoal agents: Emetine hydrochloride, Metronidazole^s, tinidazole, ornidazole, secnidazole, Diloxanide furoate, 8-hydroxy quinoline derivatives (chloroquine, iodoquine) Carbarsone 2 hours;3-4 marks
6. Anthelmintics: Piperazine, Diethyl carbamazine, Pyrantel pamoate, Thiabendazole^s Albendazole^s, Mebendazole 2 hours;3-4 marks

E. Sulfonamides, Sulfones as antibacterial agents :

1. SAR and mode of Sulfonamides.
2. Classification of sulfonamides based on duration of action and site of action with examples. Sulfamethiazole, Sulfisoxazole^s, Sulfapyridine, Sulfamethoxazole^s, Sulfadiazine, Sulfacetamide, sulfasalazine, Phthalyl sulfathiazole.
3. Folate reductase inhibitors: Trimethoprim, Synergistic action of the combination of sulfamethoxazole and trimethoprim^s.
4. Sulfone: Dapsone^s 4 hours;5-6 marks

F. Antimalarials: Etiology of malaria, History, Mechanism and SAR

1. Quinolines and analogues: 7-chloro-4-amino quinolines :Chloroquine phosphate^s, Hydroxychloroquine sulphate, Amodiaquine, 8-amino quinolines: Pamaquine, Primaquine,

9-amino acridines: Quinacrine.

2. Artimicin and its derivatives: Artiether, Artimether, Artisunate

3. Biguanides and Dihydrothiazines: Chloroguanide, Cycloguanil.

4. Miscellaneous: Mefloquine, Pyrimethamine, Trimethoprim. **6 hours;8-9 marks**

G. Antibiotics: Classification and Mechanism of action

1. Beta lactam antibiotics: Pencillins – structures, chemical degradation, bacterial resistance. Penicillin G, Penicillin V, Cloxacillin sodium, Nafcillin sodium, Ampicillin, Amoxycillin.

2. Cephalosporins: Structure and uses of Cephalexin, Cephadrine, Cefadroxil, Cefixime, Cefaprydine, Cefuroxime

3. Monolactams: Sulfazecin, Aztreonam, Tigmonam.

4. Beta lactamase inhibitors: Clavulanic acid and its salts, Thienamycin.

5. Aminoglycosides: Structural features and Mechanism of action, Streptomycin, Amikacin, Neomycin, Kanamycin, Gentamycin, Netilmycin

6. Tetracyclines: Chemistry and SAR, tetracycline, Chlortetracycline, Methacycline, Demeclocycline, Oxytetracycline, Meclocycline, Doxycycline, Minocycline.

7. Macrolide: Structure and specific uses of Erythromycin, Azithrocin, leandomycin.

8. Lincomycins: Lincomycin, Clindamycin.

9. Polypeptides: Gramicidin, Bacitracin, Polymyxin B, Colistin.

10. Miscellaneous: Chlormphenicol^s, Vancomycin, Novobiocin. **12 hours;15-16 marks**

H. Antineoplastic agents: Introduction, mechanism of action and classification with examples.

1. Alkylating agents: Mechlorethamine, Cyclophosphamide, Melphalan, Chlorambucil^s, Busulfan, Lomustine,

2. Antimetabolites: Mercaptopurine, Thioguanine, 5-Fluorouracil, Methotrexate^s,

3. Antibiotics: Dactinomycin, Bleomycin, Mitomycin, Streptozocin.

4. Plant products: Etoposide, Taxol, Camphothecin, Vincristine, Vinblastin.

5. Hormones: Dromostanalone, Megestrol,

6. Kinase inhibitors: Imatinibmesylate

6. Miscellaneous: Asparaginase, Cisplatin, Hydroxy urea.

7. Immunotherapy: Interferon alpha 2a and 2b. **6 hours;8-9 marks**

I. Cardiovascular agents:

1. Antianginal agents and vasodilators: Chemical structure and specific uses of Amyl nitrite, Nitroglycerine, Isosorbide dinitrate.

2. Calcium antagonists: Brief introduction of calcium channels and their blockers. Chemical structures and uses of Verapamil, Diltiazem, Nifedipine, Nimodipine, Felodipine, Dipyridamole, Cyclandelate.

3. Antiarrhythmic drugs: Structure, chemical name, and classification of antiarrhythmics with examples

Class I- Membrane depressant drugs: Quinidine Procainamide, Phenytoin.

Class II-Beta adrenergic blocking agents. Tocainide, propranolol

Class III-Repolarization prolongators. Bretylium, Amiodarone

Class IV-Calcium channel blocker. Diltiazem, Verapamil

4. Antihypertensive agents:

Beta-blockers: Propranolol. Timolol

ACE Inhibitors: Captopril, Enalapril

Diuretics: Hydrochlorthiazide, Spiranolactone

Calcium channel blockers: Nifedipine, Felodipine, Amlodipine

α_1 -Antagonist: Prazocin

α_2 -agonist: Clonidine, Guanithedine

Angiotensin –II receptor antagonist: Losartan, Valsartan

Miscellaneous: Reserpine, Hydralazine, Minoxidil

5. Antihyperlipidemic agents: Structure and specific uses.

Clofibrate, Lovastatin, Cholesteramine, Colestipol, Atorvastatin

6. Anticoagulants: Dicumorol, Warfarin^s, Phenindione

14 hours;17-18 marks

J. Hypoglycemic agents: Insulin and its preparations.

Sulfonylureas–Chlorpropamide^s, Acetohexamide, Glipizide,

Biguanides-Phenformin, Metformin

Substituted benzoic acid derivatives – Meglitinides, Nateglinide

Thiazolidinediones –Glitazones, Pioglitazone, Ciglitazone, Rosiglitazone

Glipitines – Sitagliptin, Anagliptin

2 hours;3-4 marks

K. Thyroid hormones : L-thyroxine, L-tyronine,

1 hour;1-2 marks

L. Antithyroid drugs: Propylthiouracil, Methimazole.

1 hour;1-2 marks

M. Estrogens and progesterones- Skeletal structure and their uses

2 hour;3-4 marks

N. Diuretics: Introduction

1. Carbonic anhydrase inhibitors: Acetazolamide^s, Methazolamide.

2. Thiazide and Thiazide like diuretics: Chlorthiazides, Benzthiazide, Xipamide, Chlorthalidone.

3. High-ceiling or loop diuretics: Furosemide^s, Ethacrynic acid^s.

4. Potassium sparing diuretics: Spironolactone, Triamterene, Amiloride.

5. Miscellaneous: Mannitol.

5 hours;6-7 marks

MEDICINAL CHEMISTRY II (PRACTICALS)
75 hours ; 3 hours/week

Assay of

1. Sulphadiazine by diazotization
2. Chloroquine by nonaqueous titration
3. Ascorbic acid by Iodimetry
4. Isonicotinic acid by KBrO_3 (bromimetry)
5. Benzyl penicillin by Iodometry
6. Metronidazole/Mepacrine by nonaqueous titration
7. Furosemide by neutralization titration
8. Diethyl carbamazine by neutralization titration

Preparation of medicinally important compounds or intermediates required for synthesis of drugs

1. PAS from p-nitro salicylic acid
2. Dichloramine T from toluene p-sulphonamide
3. Chloramine T from Dichloramine T
4. Fluorescein from phthalic anhydride
5. Eosin from Fluorescein
6. Sulphacetamide from sulphanilamide
7. Sulphanilamide from Acetanilide
8. INH from γ Picoline
9. Chlorobutanol
10. Benzotriazole
11. 3-Diphenyl quinoline
12. 2,4,5-Triphenyl imidazole from Benzoin

Green Chemistry Synthesis

1. Microwave assisted synthesis of 1,4-dihydropyridine/pyrimidine
2. Synthesis of p-bromoacetanilide from aniline using KBr

Estimation of the functional groups in medicinally important compound

1. Hydroxyl group in cholesterol
2. Ketone in camphor
3. Hydroxyl group in menthol
4. Amide in nicotinamide

SCHEME OF EXAMINATION

1. Synopsis	- 10 Marks
2. Assay/Estimation (including standardization)	- 30 Marks
3. Preparation including re-crystallisation and Melting Point determination	- 20 Marks
4. Practical viva	- 10 Marks

Total

- 70 Marks

MEDICINAL CHEMISTRY II TEXT BOOKS (THEORY)

Latest editions and all volumes of

1. Foye's principles of Medicinal chemistry
2. Wilson and Griswold's Text book of Organic and Pharmaceutical chemistry
3. Rama Rao Nadendla, Medicinal Chemistry

MEDICINAL CHEMISTRY II REFERENCE BOOKS (THEORY)

Latest editions and all volumes of

1. Burger's medicinal chemistry
2. The Martindale's Extra Pharmacopoeia
3. A.I.Vogel, Text Book of practical organic chemistry including the qualitative analysis
4. A.H.Becket and J.B.Stanlake, Practical Pharmaceutical chemistry
5. M Raghuprasad, Advanced medicinal chemistry: A laboratory guide
6. J.G.Mann and Saunders, Practical organic chemistry, ELBS Longman, London
7. I.P.1985, Ministry of Health, Govt. of India
8. LedniserMitzsher, Organic drug synthesis, Vol.1 and 2
9. I.L. Finar, Text Book organic chemistry
10. T. Robinson, Organic constituents of higher plants
11. Feiser and Feiser Steroids
12. Drug design by Ariens
13. Smith and Williams, Introduction to principles of drug design
14. Purcell, Strategy of drug design
15. CIMS

MEDICINAL CHEMISTRY II REFERENCE BOOKS (PRACTICALS)

1. A.I.Vogel, Text Book of practical organic chemistry
2. A.H. Beckett and Stanlake, Practical pharmaceutical chemistry
3. J.G.Mann and Saunders, Practical organic chemistry
4. Jayaveera KN, Practical medicinal chemistry
5. Raghuprasad M, Advanced medicinal Chemistry
6. Feiser and Feiser, Steroids
7. IP 1985
8. I.L.Finar, Textbook of organic chemistry
9. CIMS

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Suction Pump	01
2. Analytical Balance	10
3. Physical Balance	Adequate
4. Triple beam balance	10
5. Water Baths Reflux Flask and condenser	10
6. Hot Plate	01
7. Mechanical Stirrer	01
8. Magnetic Stirrers with Thermostat	01
9. Distillation Unit	01
10. Refrigerator	01
11. Fuming Hood	01
12. Microwave Oven	01

4.5 INDUSTRIAL PHARMACOGNOSY (THEORY)

50 hours ; 2 hours/week

1. Introduction:

2 hours;2-5 marks

- a) Importance and status of herbal drugs in national and international market.
- b) A brief account of plant based industries and research institutions in India.

2. Phytopharmaceuticals:

10 hours;10-15 marks

Detail method of isolation, identification and estimation of the following: Quinine, Catechins, Diosgenin, Glycyrrhizin, Hesperidine, Andrographolides, Curcumin, Podophyllotoxin, Solasodine and Caffeine.

3. Quality control and Standardization of Herbal drugs:

10 hours;10-15 marks

- a) Definition of the terms: evaluation, quality control and standardization.
- b) Importance of standardization of raw materials, extracts and formulations with suitable examples.
- c) Quality control methods for Herbal drugs as per WHO guidelines.
- d) Applications of HPTLC and HPLC techniques for evaluation of crude drugs and extracts. Role of marker compounds in evaluation and chromatographic finger printing analysis.
- e) Monographic analysis of the following drugs for Standardization: i) Vasaka ii) Gokhru iii) Ashwagandha iv) Guduchi v) Guggulipid

4. Herbal Cosmetics and Nutraceuticals:

3 hours;2-5 marks

- a) Role of following herbs in cosmetics.
 - i) Skin Care: Aloe vera, Neem, Turmeric, Saffron, Sandalwood
 - ii) Hair Care: Soapnut, Amla, Henna, Hybiscus, Bringaraj
- b) Nutraceuticals: Source and importance of antioxidants, probiotics and polyunsaturated fatty acids. Study of nutritional value of Spirulina and Garlic

5. Natural sweeteners and bitters

2 hours; 2-5 marks

6. Patenting and Regulatory requirements of natural products:

3 hours; 2-5 marks

- a) Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy
- b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.
- c) WHO guidelines for regulation of herbal medicines in South-East Asian region.

7. Plant Biotechnology:

7 hours;5-10 marks

- a) Chemodemes, Polyploidy and Hybridization and their applications in improving the quality of medicinal plants.
- b) Tissue Culture:
 - i) Types, techniques and applications
 - ii) Methods for enhancing the production of secondary metabolites.
 - iii) Transgenic plants and their applications

8. Enzyme Biotechnology:

3 hours; 2-5 marks

- a) Immobilization of cells and enzymes
- b) Bio-transformation

c) Source, isolation and uses of plant enzymes: Papain, Bromelin

9. Complementary and Alternative Medicines:

5 hours;5-8 marks

a) General introduction to Ayurveda, Siddha, Unani, and Homeopathy systems of medicines.

b) Method of preparation of some Ayurvedic formulations: Aristas, Asavas, Ghutika, Taila, Churna, Leha, and Bhasma.

c) Determination of alcohol content in Aristas and Asavas.

10. Study of some Traditional drugs:

5 hours;5-8 marks

Common and vernacular names, source, active constituents and uses of

i) Acorus ii) Apamarg iii) Bael iv) Brahmi v) Chirata vi) Coleus vii) Gudmar
viii) Kantakari ix) Methi x) Pippali xi) Punarnava xii) Rasna xiii) Shatavari xiv)
Shankapushpi xv) Shilajit

INDUSTRIAL PHARMACOGNOSY PRACTICALS

75 hours ; 3 hours/week

1. Isolation of Phytopharmaceuticals**
 - i) Quinine
 - ii) Ammonium glycyrrhizinate
 - iii) Ca-sennosides
 - iv) Caffeine
 - v) Hesperidin
 - vi) Curcumin
2. Estimation of Phytopharmaceuticals**
 - i) Quinine
 - iv) Caffeine
 - v) Hesperidin
 - vi) Curcumin[By Fluorimetric, Spectrophotometric or Chromatographic methods]
 - ii) HPTLC and HPLC profiles of a few drugs
3. Thin layer chromatography of Alkaloids*
4. Estimation of bitters in Kalmegh**
5. Determination of swelling index in mucilage containing drugs*
6. Determination of microbial contamination in plant drugs
7. Initiation of callus culture
8. Immobilization of enzymes and determination of its activity*
9. Estimation of alcohol content in traditional preparations*
10. Study of morphology of traditional drugs mentioned in theory*

Note: ** Denotes major experiments

*** Denotes minor experiments**

SCHEME OF EXAMINATION

1. Synopsis	10 marks
2. Identification of traditional drugs	10 marks
3. Isolation/ Estimation of phytoconstituents	25 marks
4. Minor experiment*	15 marks
5. Viva-Voce	10 marks
Total	70 marks

INDUSTRIAL PHARMACOGNOSY REFERENCE BOOKS

1. Chaudhri RD. Herbal drug industry, 1st ed. New Delhi:Eastern publishers;1996.
2. Rajpal V. Standardisation of botanicals. 1st ed. New Delhi:Eastern publishers; 2002.
3. Vinod DR. Pharmacognosy and phytochemistry. 1st ed. Nashik:Career publications; 2003.
4. Harborne JB. Phytochemical methods, 3rd ed. New Delhi:Springer (India) Pvt Ltd; 1998.
5. Indian Pharmacopoeia. Delhi:The Controller of Publications, Ministry of Health and Family Welfare; 2007.
6. Indian Herbal Pharmacopoeia Vol I & Vol II. Mumbai:Government of India, Ministry of Health. A Joint Publication of RRL, Jammu and IDMA; 1998, 1999.

7. Agrawal SS, Paridhavi M. Herbal drug technology. 1st ed. Hyderabad:Universities Press (India);2007.
8. Pulok M. Quality control of herbal drugs. 1st ed. New Delhi:Business horizons;2002.
9. WHO-Quality control methods for Medicinal plant materials;2011.
10. Wealth of India, A Dictionary of Indian Raw Materials & Industrial Products (All Volumes). New Delhi:NISCAIR, CSIR: 2000.
11. Kokate CK, Purohit AP, Gokhale SB. Pharmacognosy. 45th ed. Pune:Nirali Prakashan; 2010.
12. Evans WC. Trease and Evans Pharmacognosy. 15th ed. Philadelphia:Elsevier Science Ltd;2002.
13. Ashutosh K. Pharmacognosy and pharmacobiotechnology. 2nd ed. New Delhi:New Age International Publishers;2006.
14. Veeresham C. Medicinal Plant Biotechnology 1st ed. New Delhi:CBS publishers and distributors;2004.
15. Vyas SP, Dixit. Pharmaceutical Biotechnology. 1st ed. New Delhi:CBS Publishers & distributors;1998.
16. Gaud RS, Gupta GD, Gokhale. Practical Biotechnology. 1st ed. Pune:Nirali Prakashan;2000.
17. Indian Medicinal Plants - A Compendium of 500 species. Kottakal:Arya Vaidya Sala; 1997.
18. The Ayurvedic Pharmacopoeia of India Vol I & II, 1999. Government of India, Ministry of Health and Family Welfare, Department of ISM & H.
19. The Ayurvedic Formulary of India, 2000. Government of India, Ministry of Health and Family Welfare, Department of ISM & H.
20. National and International Journals- Phytochemistry, Pharmacognosy Reviews, Fitoterapia, Journal of Natural Products, Journal of Ethnopharmacology, Planta Medica, Phytotherapy Research

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Heating mantle	10
2. Soxhlet apparatus	10
3. TLC chamber & sprayer	10
4. Hot air oven	01
5. Water bath	20
6. Autoclave	01
7. Laminar air flow	01
8. B.O.D. Incubator	01
9. Microscope	20
10. Balance (Digital)	02
11. Spectrophotometer	01
12. Flourimeter	01
13. Reflux flasks & condensers	20

14. Distillation units	05
15. Vacuum pump	02
16. HPTLC	Desirable
17. HPLC	Desirable

4.6 ADVANCED INDUSTRIAL PHARMACY (THEORY)

50 hours ; 2 hours/week

1. **Biopharmaceutical classification systems** and methods to improve the bioavailability of poorly soluble drugs - solid dispersion and complexation techniques.
4 hours; 5-10 marks
2. **Controlled drug delivery systems:** Principle, advantages, disadvantages, selection of drug candidates. Approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles.
5 hours; 8-10 marks
Microencapsulation: Definition, applications, air suspension, coacervation and phase separation techniques.
3 hours; 5-7 marks
3. a) **Novel drug delivery systems:** Concepts, advantages and disadvantages, types of drug delivery systems such as transdermal, nasal, ocular, buccal and implants with suitable examples.
6 hours; 10-12 marks
b) **Targeted drug delivery systems:** Concepts and approaches, advantages and disadvantages. Applications of microspheres, liposomes, niosomes, nanoparticles.
4 hours; 5-10 marks
4. **Pilot Plant scale up:** General considerations - including significance of personnel requirements, space requirements, raw materials and development of Master Formula Records and Batch Manufacturing Records. Pilot plant scale up considerations for tablets.
6 hours; 10-12 marks
5. **Pharmaceutical Packaging:** Materials used for packaging of pharmaceutical products, advantages, disadvantages and quality control tests.
4 hours; 5-10 marks
6. **Current Good Manufacturing Practices (cGMP):** as per D&C Act, USFDA, MHRA and TGA guidelines.
4 hours; 5-10 marks
7. **Validation:** Definition, types of validation, methods for process validation of pharmaceutical operations – Mixing and compression.
6 hours; 10-12 marks
8. **Biostatistics:** Introduction, Types of data distribution, Measures describing the central tendency distributions- average, median, mode. Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean.
5 hours; 8-10 marks
9. **ICH guidelines and QbD:** Introduction to ICH guidelines: Quality, efficacy and safety of drugs. Introduction to the concepts of Quality by Design (QbD).
3 hours; 5-10 marks

ADVANCED INDUSTRIAL PHARMACY REFERENCE BOOKS

1. Chien YW. Novel drug delivery systems. 2nd ed. New York:Marcel Dekker Inc;2007.
2. Jain NK. Controlled and novel drug delivery. New Delhi: CBS Publishers and Distributors;1997.
3. Nash RA, Berry IR. Pharmaceutical process validation. 2nd ed. New York: Marcel Dekker Inc;1993
4. Robinson JR, Vincent HLL. Controlled drug delivery. 2nd ed. New York: Marcel Dekker Inc;1987.
5. Sharma PP. Validation in pharmaceutical industry. Delhi:Vandana Publications.
6. Subrahmanyam CVS, Thimmasetty J. Pharmaceutical regulatory affairs. 1st ed. New Delhi: VallabhPrakashan;2012.
7. Vyas SP, Khar RK. Controlled drug delivery. Delhi: Vallabh Prakashan; 2002.
8. Yajaman S. Novel drug delivery systems and regulatory affairs. New Delhi:S Chand Publishing.

Websites:

www.ich.org, www.cdsco.nic.in

SECTION V

ETHICS IN PHARMACY

Introduction

With the advances in science and technology and the increasing needs of the patient, their families and community, there is a concern for the health of the community as a whole. There is a shift to greater accountability to the society. It is therefore absolutely necessary for each and every one involved in the health care delivery to prepare themselves to deal with these problems. Pharmacists like the other professionals are confronted with many ethical problems.

Standards of professional conduct for pharmacist are necessary in the public interest to ensure an efficient pharmaceutical service. Every pharmacist should not only be willing to play his part in giving such a service, but should also avoid any act or omission which would prejudice the giving of the services or impair confidence, in respect, for pharmacist as a body.

To accomplish this and develop human values, it is desired that the students undergo ethical sensitization by lectures or discussion on ethical issues.

Introduction to ethics

Ethics may be defined as “the code of moral principles” or as “the science of morals”. The conduct of individuals in any society is governed by the governmental controls on the one hand and the social customs and duties on the other. The former has the sanction of the law and the latter is left to the individual and the society. For this purpose, societies lay down a code of conduct to help the individuals to decide what is right and what is wrong. Such a code, when practiced by any society for a long time, results in the culture of a conscience in the individuals, which gives them a faculty to decipher for themselves, the right way of conducting their daily life, conducive to the well being of the society. This way of conducting life is said to be the ethical way and the culture of such conscience may well be termed as morality.

The candidate after completion of B. Pharm, while practicing shall follow ethics in all spheres as under

- Pharmacist in relation to his job
- Pharmacist in relation to his trade
- Pharmacist in relation to medical profession
- Pharmacist in relation to his profession

Professional Ethics

The candidate is required to

- Follow code of conduct
- Maintain confidentiality
- Follow fair trade practice

- Follow ethics in handling of prescriptions
- Maintain professional vigilance

Human values, ethical practice and communication abilities

- Adopt ethical principles in all aspects of the professional practice.
- Foster professional honesty and integrity
- Discharge the duties irrespective of social status, caste, creed or religion of the customer / client
- Develop oral and written communication skills
- Provide leadership and get the best out of his or her team in a congenial working atmosphere
- Apply high moral and ethical standards while carrying out human or animal research
- Be humble and accept the limitations in his or her knowledge and skill and to ask for help from colleagues when needed.

Pharmacist Oath

I swear by the code of ethics of Pharmacy Council of India in relation to the community and shall act as an integral part of health care team

I shall uphold the laws and standards governing my profession

I shall strive to perfect and enlarge my knowledge to contribute to the advancement of Pharmacy and Public health

I shall follow the system, which I consider best for Pharmaceutical care and counseling of patients

I shall endeavor to discover and manufacture drugs of quality to alleviate sufferings of humanity

I shall hold in confidence the knowledge gained about the patients in connection with my professional practice and never divulge unless compelled to do so by the law

I shall associate with organizations having their objectives for betterment of the profession of Pharmacy and make contribution to carry out the work of those organizations

While I continue to keep this oath unviolated may it be granted to me to enjoy life and the practice of pharmacy respected by all at all times!

Should I trespass and violate this oath, may the reverse be my lot!

SECTION VI

NORMS AND STANDARDS

1.0 STAFF NORMS

The knowledge, Skills, Attitudes and value of staff are assets which greatly contribute to their own individual effectiveness as well as to institutional performance. In addition, to the pattern and structure of staff, staff norms should therefore, emphasize on process of recruitment, deployment and development as well as appraisal.

The norms stipulated are primarily for Pharmacy College with an annual intake of 40, 60 and 100 students.

1.1 Weekly Worked Schedule

Student contact hours per week	:	40 hrs.
Student contact hours in formal learning	:	32 to 35 hrs.
Student centered activities (Library Studies)	:	5 to 8 hrs.
Guidance and counseling, seminars, etc.		

1.2 Annual Work Schedule

In an academic year there should be a minimum of 180 instructional days, excluding examination. These norms are deemed to be essential for completion of the year.

1.3 Student-Teacher Ratio

The student teacher ratio in a class will depend on

1. Teacher time required for formal instruction requiring student contact.
2. Student time devoted to formal learning requiring teacher contact and
3. Class sizes for different forms of instruction.

The desirable student to teacher ratio for Pharmacy degree programme may be 10:1. However it should not be allowed to rise beyond 15:1.

The teacher will engage in group/class sizes for formal teaching in the ratio as given below:

Theory lecture class	:	60:1
Lab. Practical	:	20:1

For an intake of 100 students, the class has to be divided in to two sections, section A with 60 and section B with 40 students. The theory and practical classes are to be conducted accordingly.

1.4 Staff Pattern-Categories

1. Principal/HOD/Director and teaching staff.
2. Technical supporting staff.
3. Library and computer center staff.
4. Administrative staff.
5. Miscellaneous staff including maintenance staff.

1.5 Teaching Staff Cadre

The cadre structure should be as follow:

1. Principal/Director/HOD.
2. Professor.
3. Associate Professor.
4. Assistant Professor.

1.6 Cadre Distribution-Flexibility

The distribution of faculty position in the Pharmacy institution will depend on the work loads of the different departments based on the curriculum structure Flexibility in the distribution of different faculty cadres is permitted so long as such flexibility is for meeting the specific needs of the institution in terms of job requirements and courses offered.

1.7 Leave Training Reserves

To enable institutions to sponsor teachers for staff development programmes and to allow teachers to avail leave to which they are entitled it is necessary that adequate reserve capacity of teachers is available. Each institution will have such reserve capacity in accordance with leave training reserves sanctioned by central/state governments from time to time.

1.8 Selection and Recruitment of the Teaching Staff

The positions of Professors, Associate Professor and Asst. Professors should be filled up through an open selection process. The selection agencies of the states and institution should adopt reliable and valid procedures for selecting candidates on the basis of competence knowledge, skills, attitudes and values required for the profession, adhering to the stipulation regarding qualification and experience.

1.9 Job Description and Qualifications of Staff

As prescribed by AICTE and PCI time to time.

1.10 Performance Appraisal System

A performance appraisal system for teachers should be setup, well integrated with institutional functioning, and this should lead to the identification of individual training and development needs. This should also enable the identification of faculty members whose performance is outstanding. Such performance and excellence should be well recognized and rewarded. All institutions should introduced system for performance appraisal conforming with guidelines formulated in this regard.

1.11 Training and Development

Teachers will be provided with opportunity to improve their qualifications through Quality Improvement Programmes (for Ph.D. in Pharmacy based areas). In addition to these, opportunities will be provided for pedagogy and professional industrial training.

Under the Quality Improvement Programme a variety of short term courses to meet training and retaining needs will be provided for all levels of Teachers in Pharmacy colleges

2.0 NORMS AND INFRASTRUCTURE

2.1 Norms for Space and Buildings

The norms for space and building have been arrived at, based on the functions, a Pharmacy institutions' offering diploma, degree, post graduate and Ph.D. programmes has to perform. In all cases, unit norms have been evolved taking the absolute minimum needs which are indicated as norms. As such the institutions, while envisaging their space and building requirements, must keep their perspectives for development in mind and formulate their planes accordingly.

Around the administrative buildings, class rooms and drawing halls, there is considerable movement of students and there must be adequate veranda space in this part of the college building so that classes do not disturbed. For this reason, the ratio of plinth to carpet area for the normal building may be taken as 1:4.

Classification of Building Area

The building area required for the Pharmacy institution can be classified as instructional area, administrative area, amenities area and residential area.

Instructional area will include class rooms, tutorial rooms, laboratories, computer center, library, instructional resource centre, seminar hall etc.

Administrative area comprises Principal's room, various lounge, staff rooms, administrative office, departmental offices, stores, conference room, confidential room etc.

Area for amenities consists of common rooms, recreation centre, hobby centre, offices for gymkhana, N.S.S. and Alumni Association, Co-operative stores, Dispensary, etc.

Residential area includes student hostels, staff quarters and guest house.

2.2 Building Space for Instructional Area

The course structure of any pharmacy institution offering degree programme will include lecturers, tutorials, laboratory work and seminars/colloquium. The institute must have adequate building area for all these instructional activities.

According to the model curriculum, during annual session, the total number of hours per week for which the students is to have contact with the teacher will vary between 27 to 34. In view of this, the instructional schedule is spread over a period of 34 hours a week.

The student strength in a theory class should not exceed 60, the class should be divided into smaller groups of 20 in case of junior (I & II year) classes and 15 students for the senior (III & IV year) and a teacher is assigned to each group. In case of tutorial work, these smaller groups must be accommodated in separate rooms.

The seminars/ colloquium of the senior students must be conducted with the entire class of particular discipline.

2.3 Number of rooms for Theory Classes

The number of rooms required for the theory class can be determined by applying the following relationship.

2.4 Number of Rooms for Tutorial work

The number of rooms required for the Tutorial work can be determined by applying the following relationship.

2.5 Rooms size for Theory Classes and Tutorial work

The carpet area requirement of the class rooms and tutorial rooms depends upon the number and type of seating arrangement for the students and provisions for a platform, a table and a chair for the teacher. In pharmaceutical science classes, very frequently students make use of a data book, a calculator and note book. As such he will require slightly more spacious desk as compared to the requirements of classes for students of general education. Further, as the space required for teacher will remain the same irrespective of the class strength, the per student requirement of carpet area will increase with the decrease in class strength.

Considering the above requirements and size of class room furniture and drawing tables normally used in the institution, the following carpet area norms per student are prescribed for class rooms of different size and drawing halls.

<i>Type of Rooms</i>	<i>Carpet Area</i>	<i>Requirements in Sqm</i>
Classification of Size	Minimum	Desirable
Class rooms for 40 students	48	56
Class rooms for 60 students	66	78

2.6 Laboratories

The requirements of the laboratories depend upon the programmes that are being offered by the institution and the curricula adopted for these programmes irrespective of the students population. The norms for the carpet area of the different laboratories are given in the table below. Care should be taken to provide laboratories in all allied subjects to the taught in the programme.

The size of the laboratories should be suitable for a minimum batch of 20 students. The floor area of each laboratory may be calculated at the rate of 3.0 sq.mtr. per student with the minimum of space as given:

Department	Laboratory (Lab. Code)	Minimum Sqm	Maximum Sqm
1. Pharm.Chemistry	Pharmaceutical Chemistry		
	Laboratory- (PC1) Medicinal Chemistry & Natural Products	80	100
	Pharmaceutical Chemistry Laboratory- (PC2) Organic and Inorganic Chemistry Balance Rooms	80	100
	(2) 2*20 sq.m	40	50
2. Pharmaceutics	Pharmaceutics Laboratory-I (PH1) Dispensing	80	100
	Pharmaceutics and Cosmeticology		
	Pharmaceutics Laboratory II (PH2) including Microbiology and Bio-Pharmaceutics	80	100
	Microbiology laboratory (PH3) (Desirable)	80	100
	Aseptic Room	25	35
	Physical Pharmacy (Phy. Pharm.)	80	100
	Industrial Pharmacy (Ind. Pharm.)	80	100
	Machine Room		
3. Pharmaceutical Analysis	Pharmaceutical Analysis (PHA) and Biogeochemistry Instrument Room (Inst. Room) (Partly air conditioned)	80	100
4. Pharmacognosy	1. Pharm. Biology Laboratory	80	100
	2. Pharmacognosy Laboratory	80	100
5. Pharmacology	1) Human Anatomy & Physiology	80	100
	2) Pharmacology laboratory including Anatomy, Physiology and health education smoke room	80	100
		10	10
	3) Animal Room (including feed store)	80	100
6. General	Computer room	30	40
	Water pumps room	10	10
	Gas plant (where LPG gas is not available)	10	10
	Stores-I (General)	100	
	Store-II (for inflammable materials)	20	

The above areas do not include the rooms of the teaching staff even though such staff rooms are attached to the laboratories. However, they do include the sitting

space for the technical supporting staff and storage of laboratory consumables and instruments.

2.7 Library

Purpose:

Acquiring, storing, catalogue, indexing, issuing and returning of books, periodicals and non-print instructional material and providing reader services. Development and production of print and non-print instructional resources such as class notes, handouts, illustration, slides, filmstrips, audio-visual materials, models, charts etc.

NORMS

Minimum	Desirable
150 sq.mtr.	200 sq.mtr

FACILITIES

Projection Room:	One of the class rooms to be equipped with Projection facilities.

2.8 Museum

Every institution shall maintain a museum of crude drugs herbarium sheets/charts of the drugs and plants mentioned in the course in addition, the following is recommended.

1. Colored slides and charts of medicinal plants;
 2. Display of popular patent medicines; and
 3. Containers of common usages in medicines.
- The following fittings will be required for the museum:
1. Showcase.
 2. Cupboards.
 3. Counters with lighting arrangements.
 4. Literature counter on specimens.
- Minimum area required for museum will be 100 sq.mtr.

2.9 Other Provision

1. Examination hall cum Auditorium with CCTV shooting and recording facility.
- Purpose:** Conducting examinations, conference, extension lectures and function.
Area requirement: 150 sqm.

2.10 Building Space for Administrative Offices

The space to be provided for administrative office in technical institution/college will as per norms given below:

Carpet Area	(Sq.m)
Principal/Office	30
Confidential/Strong room	20
Conference room	25
Administrative room	30
Maintenance room	20

2.11 Other Space in the Department

In addition to the technical space the norms for buildings requirement in a teaching department for other purposes are as below:

Carpet Area	(Sq.m)
Head of Department	20
Facility rooms	10 Per Teacher
seminar room	30 (Desirable)
Store	10

2.12 Buildings Space for Amenities

The minimum unavoidable requirements for such amenities for normal functioning of the institute are given below along with norms for the building space.

2.13 Students Activity Centre

This will consist of provisions for the indoor games, gymnasium, dramatics and alumni centre etc. (60 sq.m)

2.14 Toilet Blocks

The college building and the hostels will be provided with adequate number of toilet blocks with urinals, lavatories and wash basins. It will also be necessary to provide separately one toilet block for women in the college buildings. Toilet area requirement is as below:

Education Building for 240 students- 24 sq.m.

2.15 Cycle and Scooter Stand

This will be provided as open or covered area as per requirement.

2.16 Other Amenities

The norms of space (Carpet area) or other miscellaneous amenities are as given below:

Carpet Area	(Sq.m)
Canteen	100 (Desirable)
Cooperative room	100 (Desirable)
NSS Office cum Stores	100 (Desirable)
Girls Common room	60 (Essential)

2.17 Play Fields

The institution must be provided with play fields so that the students can have adequate participation in games and sports for healthy and constructive activities within campus.

2.18 Building Space for Residential Area (Desirable)

The hostel requirements depend upon on a variety of factors like the location of the institution, the region from which students are admitted, local availability of accommodation and that of transport. Though, the requirement of residence for teachers and other employees of the institution also depend upon these factors but the same time it is necessary to provide

an attraction to the new teacher from far off place by providing suitable accommodation at the campus.

2.19 Hostels (Desirable)

The Hostel accommodation will be provided with the norms as given below:

Location of College	Hostel Strength
Within 20km of large City	25% of Boys and 50% girls enrollment
Other Locations	50% of Boys and 100% girls enrollment

The boy's hostel will be made as a unit for 120 students while there is minimum for a girls-hostel unit. The first year students will be accommodated in triple seated rooms. The norms for the room areas will be as follow:

Carpet area	(Sq.m)
Single room	9
Triple seated room	20

The other building space needed in hostel unit will be as per norm given below:

Carpet Area	(Sq.m)
Kitchen and Dining Hall	200
Indoor game cum Common hall	150
Medical room	50 (for all hostel)
Canteen	15
Warden office	18*
Guest rooms (2 nos)	18*

(* Four additional rooms of 9 sq.m. each within the hostel blocks)

2.20 Staff Residences

The minimum residential accommodation that should exist in the campus should be for the principal, all Heads of the Departments, all Wardens and the essential staff including a care taker, an electrician, a driver, a water supply operator and chowkidars.

The building space for residence will be as per norms given below:

Carpet Area	(Sq.m)
Principal	140 Sqm
Professor	100 Sqm
Asso. Professor/Asst.Prof	80 Sqm
Class III Staff	30 Sqm
Class IV Staff	20 Sqm

2.21 Guest House (Desirable)

To meet the needs of the guests visiting the institution for official works and the parents visiting the students it will be necessary to have a guest house having four suits with attached toilets, a common dining hall and a kitchen.

2.22 Furniture

All laboratories, library, lecture and tutorial rooms, offices, hostels and guest house etc. should be adequately furnished. No norms for furniture are being laid; however, it is expected that the furniture should conform to the requirements of a dignified institution. The institutions may equip the building with the furniture as available indigenously.

2.23 Land

It will not be desirable to set the norms of land requirements for the pharmacy college because of existing high pressure on land availability and other similar factors. If enough land is not available near a large town, the double and triple storey construction may have to be resorted to. However, it will be desirable to have the total land area so as all requirements of the building space are fully met as envisaged in these norms.

In addition it will be necessary to have additional land available within the campus for future expansion.

2.24 Laboratory Equipments

The following factors are to be considered in identifying the equipment for the laboratories and workshops.

- I. Development of laboratory skills, i.e., verification, calibration, performance testing, investigation and problem solving.
- II. Development of practical skills i.e., manufacturing dispensing and communication skills etc.

Laboratory models of equipments are necessary for imparting skills in the laboratories. Equipment similar to the ones used in industry are necessary for developing practical skills. Small scale and less expensive models available in the market, if found adequate for training should be preferred to large-scale and expensive equipment.

Development activities, which the pharmacy institution has to undertake, have a bearing on the equipment list. In such cases, provision may have to be made for drug store management, training in hospital-pharmacy and community services.

The number of tools/equipments/apparatus to be provided depends on the size of students group, utilization factors, capital cost and operating cost. The number of students in laboratories in any batch should not be more than 20 with one teacher. Typical layout of the labs for pharmacy programme.

- a. Purpose: Demonstrating, guiding, evaluating by the teacher and investigation, discussing, measuring and testing by the students.

b. Terminology: The names of the laboratories are in accordance with the terminology used in the model curriculum.

1.25 Norms of construction & fitting

Typical laboratory for a pharmacy institution should follow following norms of construction:

1. All the laboratory should be spacious, well lit and well ventilated.
2. All laboratories should be provided with basic amenities and services like exhaust fans and fume chamber to reduce pollution wherever necessary.
3. The work branches should smooth and easily cleanable preferably made of nonabsorbent material.
4. The water taps should be non-leaking and directly installed on sinks. Drainage should be efficient and enclosed.
5. Fire extinguisher and first aid kit should be provided in each lab.
6. Preparation room (minimum 10 sq.m.) attached to the laboratories.
7. Balance room attached to concerned laboratories.

Each laboratory should have the following fittings:

1. Gas, Water and electric supply, gas plant or cylinders.
2. Shelves for keeping reagent.
3. Working surfaces.
4. Sinks.
5. Storage cabinets (lockers) for students to keep the apparatus issued to them for a year wherever required.
6. Exhaust fans and ceiling fans.
7. Fume chambers whatever necessary.
8. Black board with light.
9. Furniture (suitable arrangement for sitting of the teachers).
10. Artificial lighting wherever required for microscopic work.

1.26 Library Books and Periodicals

The teaching norms for the initial stock of books, yearly addition of the books and the number of journals to be subscribed are as given below:

Sl.No.	Item	Minimum
1	Number of Books	1500 adequate coverage of a large number of titles in all disciplines of pharmacy.
2	Annual additions of books	100 to 150 books.
3	Periodicals	15 to 20 national periodicals.

1.27 Teaching Aids

The degree in pharmacy being professional courses with sufficient practical application component will require presentation and discussion in the class room. This can be greatly facilitated by the use of overhead projector, LCDs, LEDs video and computers. Thus a

institute shall have the following teaching aids such as projectors for lecture class room, computers, VCR TV and cassettes for the courses.

Staff Pattern for B.Pharm/D.Pharm/M.Pharm Courses Branch Wise

Department of Pharmaceutics	Name Of Post	With intake of 40 students	With intake of 60 students	With intake Of 100 students
1. College with B.Pharm only	Professor Asso. Professor Asst.Prof.	1 1 2	1 1 2	1 2 4
2. College with B.Pharm and M.Pharm	Professor Asso. Professor Asst.Prof	2 2 2	2 2 2	2 4 4
3. College with B.Pharm, M.Pharm & D.Pharm	Professor Asso. Professor Asst.Prof.	2 3 3	2 3 4	2 5 8
4. College with B.Pharm, D.Pharm	Professor Asso. Professor Asst.Prof.	1 2 3	1 2 4	1 2 5

Department of Pharmaceutical Chemistry	Name Of Post	With intake of 40 students	With intake of 60 students	With intake of 100 students
1. College with B.Pharm only	Professor Asso. Professor Asst.prof	1 1 2	1 1 3	1 2 5
2. College with B.Pharm and M.Pharm	Professor Asso. Professor Asst.Prof	2 2 3	2 2 4	2 4 8
3. College with B.Pharm, M.Pharm & D.Pharm	Professor Asso. Professor Asst.Prof	2 2 4	2 2 5	2 4 9
4. College with B.Pharm, D.Pharm	Professor Asso. Professor Asst.Prof	1 2 3	1 2 4	1 2 5

Department of Pharmacology	Name Of Post	With intake of 40 students	With intake of 60 students	With intake of 100 students
1. College with B.Pharm only	Professor Asso. Professor Asst.Prof.	1 1 1	1 1 2	1 2 4
2. College with B.Pharm and M.Pharm	Professor Asso. Professor Asst.Prof.	1 2 2	1 2 2	1 4 4
3. College with B.Pharm, M.Pharm & D.Pharm	Professor Asso. Professor Asst.prof.	1 2 3	1 2 4	1 2 5
4. College with B.Pharm, D.Pharm	Professor Asso. Professor Asst.Prof.	1 1 2	1 1 3	1 2 5

Department of Pharmacognosy	Name Of Post	With intake of 40 students	with intake of 60 students	With intake of 100 students
1. College with B.Pharm only	Professor Asso. Professor Asst.Prof.	1 1 1	1 1 1	1 2 2
2. College with B.Pharm and M.Pharm	Professor Asso. Professor Asst.Prof.	1 1 2	1 1 2	1 2 4
3. College with B.Pharm, M.Pharm & D.Pharm	Professor Asso. Professor Asst.Prof.	1 1 2	1 1 3	1 2 5
4. College with B.Pharm, D.Pharm	Professor Asso. Professor Asst.prof.	1 1 1	1 1 2	1 2 4

Note: Part time teaching staff for Maths, Biology, Computer Science, Kannada, Indian Constitution, Environmental Science may be appointed as per the requirements.

The Emblem



The Emblem of the Rajiv Gandhi University of Health Sciences is a symbolic expression of the confluence of both Eastern and Western Health Sciences. A central wand with entwined snakes symbolises Greek and Roman Gods of Health called Hermis and Mercury is adapted as symbol of modern medical science. The pot above depicts Amrutha Kalasham of Dhanvanthri, the father of all Health Sciences. The wings above it depicts Human Soul called Hamsa (Swan) in Indian philosophy. The rising Sun at the top symbolises knowledge and enlightenment. The two twigs of leaves in western philosophy symbolises olive branches, which is an expression of Peace, Love and Harmony. In Hindu Philosophy it depicts the Vanaspathi (also called as Oushadi) held in the hands of Dhanvanthri, which are the source of all Medicines. The lamp at the bottom depicts human energy (kundalini). The script “Devahitham Yadayahu” inside the lamp is taken from Upanishath Shanthi Manthram (Bhadram Karnebhi Shrunuyanadev...), which says “**May we live the full span of our lives allotted by God in perfect health**” which is the motto of the Rajiv Gandhi University of Health Sciences.

Rajiv Gandhi University of Health Sciences, Karnataka, Bangalore

Vision Statement

Rajiv Gandhi University of Health Sciences, Karnataka aims at bringing about a confluence of both Eastern and Western Health Sciences to enable the humankind “Live the full span of our lives allotted by God in Perfect Health”.

It would strive for achievement of academic excellence by educating and Training Health Professionals who

- ❖ Shall recognize health needs of community,
- ❖ Carry out professional obligations Ethically and Equitably and in keeping with National Health Policy,

It would promote development of scientific temper and Health Sciences Research.

It would Encourage inculcation of Social Accountability amongst students, teachers and institutions.

It would Support Quality Assurance for all its educational programmes

MOTTO

Right for Rightful Health Sciences Education

PHARMACEUTICAL SCIENCES

Revised Ordinance Governing

B. PHARMA DEGREE COURSE AND CURRICULUM - 2004



RAJIV GANDHI UNIVERSITY OF
HEALTH SCIENCES, KARNATAKA



**Rajiv Gandhi University of Health Sciences,
Karnataka, Bangalore**

The Emblem



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RAJIV GANDHI UNIVERSITY
OF HEALTH SCIENCES

NIBHESH RAJ ADHIKARI

Revised Ordinance Governing
BACHELOR OF PHARMACY (B.Pharm)
Degree Course



**RAJIV GANDHI UNIVERSITY OF
HEALTH SCIENCES KARNATAKA**

4th T Block, Jayanagar, Bangalore 560041

Revised Ordinance Governing **Bachelor of
Pharmacy (B. Pharm)**
Degree Course

First Edition : 2004 Reprint: 2007 Reprint:
2009

Published by: Registrar
Rajiv Gandhi University of Health Sciences 4th T
Block, Jayanagar, Bangalore - 560041.

This book can be had from:

Compiled by: Director, Prasaraanga
Rajiv Gandhi University of Health Sciences 4th T
Block, Jayanagar, Bangalore - 560041. Website:
www.rguhs.ac.in

Price: Rs. 105/-

Printed at: Unity Printers
No.20, Nagappa Street, RG.Halli,
Bangalore - 560 003 Mobile: 9342237844

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Rajiv Gandhi University of Health Sciences, Karnataka
ರಾಜೀವ್ ಗಾಂಧಿ ಆರೋಗ್ಯ ವಿಜ್ಞಾನಗಳ ವಿಶ್ವವಿದ್ಯಾಲಯ, ಕರ್ನಾಟಕ

Ref. No. : UASYNORD / B. Pharm / 148 / 2003-04

Date : 13/07/2004

NOTIFICATION

Sub : Revised Ordinance pertaining to B.Pharm Degree course.

- Ref : i) Minutes of Academic Council Meeting held on 27 the 44th Syndicate meeting held on 27th and 28th November 2003.
ii) Minutes of the 44th Syndicate meeting held on 22.6.2007,

In exercise of the powers conferred under sec. 35(1) of the RGUHS Act, the Syndicate at its meeting held on 22.03.2004 has been pleased to approve the revised Ordinances pertaining to B.Pharm Degree course given in schedule here to annexed.

The Revised Ordinance as above shall come into effect from the academic year 2004-05 onwards.

By Order,

Sd/-
REGISTRAR

To

1. The Principals of all Pharmacy Colleges affiliated to RGUHS.
2. All the Members of the Syndicate / Senate / Academic Council.

Copy to :

1. Secretary to Governor, Raj Bhavan, Bangalore - 560 001.
2. Secretary to Government, Medical Education, Health & Family Welfare Department, 3rd Stage, M.S. Building, Dr. B.R. Ambedkar Veedhi, Bangalore - 560 001.
3. PA to Vice Chancellor / Registrar / Registrar (Eva) / Finance Officer / Consultant, Curriculum Development, Computer Centre / PRO, RGUHS.
4. All Officers in the University
5. Guard file, Office Copy.



Rajiv Gandhi University of Health Sciences, Karnataka

ರಾಜೀವ್ ಗಾಂಧಿ ಆರೋಗ್ಯ ವಿಜ್ಞಾನಗಳ ವಿಶ್ವವಿದ್ಯಾಲಯ, ಕರ್ನಾಟಕ

Ref. No. : AUTH / B. Pharm / LES-316 / 2008-09

Date : 01/08/2008

NOTIFICATION

Sub: Admission of lapsed seats of 1st year B.Pharm directly to 2nd year B.pharm under Lateral Entry system.

- Ref: 1) Minutes of meeting of Principals of Pharmacy college at RGUHS dated: 28/07/2008.
2) Letter of PCI No.14-11/2002-PCI-4255-5049, dated 22/05/2008.
3) Orders of Hon ble Vice Chancellor dated 31/07/2008.

In Exercise of the powers conferred under section 13(1) of the RGUHS Act 1994, Hon ble Vice-Chancellor is pleased to approve and notify the admission of lapsed seats of 1st year B.Pharm directly to 2nd year B.Pharm under Lateral Entry System in the affiliated colleges of RGUHS as shows below:

i) to approve 10% seats in B.Pharm second year and above the sanctioned intake of first year B.Pharm (vacancy due to unfilled seats, failure of candidates or any other reasons plus 10% of over and above the sanctioned intake) for persons holding D.Pharm qualification from an institution approved u/s 12 of the Pharmacy Act, 1948 irrespective of the fact as to whether the candidate has passed out D.Pharm under Education Regulations, 1991 or repealed Education Regulation 1953, 1972 and 1981.

ii) In addition persons holding D.Pharm qualification from an institution approved by the PCI u/s 12 of the Pharmacy Act irrespective of the fact as to whether the candidate has passed out D.Pharm course under Education Regulations, 1991 or repealed Education Regulations 1953, 1972 and 1981 shall be eligible for admission in the 2nd year B.Pharm against the vacant seats of 1st year B.Pharm.

The above Ordinance shall come into effect from the academic year 2008-09 and onwards.

By Order,


(Dr. Vasantha Kumar S)
REGISTRAR

To

The Principals of Pharmacy Colleges affiliated to RGUHS.

Copy to:

01. The Secretary to Governor, Governor's Secretariat, Raj Bhavan, Bangalore - 560 001.
02. Secretary to Government, Health & Family Welfare Department, (Medical Education), Vikasa Soudha, Bangalore - 560 001.
03. The Director, Department of Medical Education, Anand Rao Circle, Bangalore - 560 009.
04. PA to Vice-Chancellor / Registrar / Registrar (Eva.) / Finance Officer.
05. Director, Curriculum Development Cell.
06. Public Information Officer.
07. The Home Page of RGUHS Website.
08. Guard File / Office Copy.



Rajiv Gandhi University of Health Sciences, Karnataka

ರಾಜೀವ್ ಗಾಂಧಿ ಆರೋಗ್ಯ ವಿಜ್ಞಾನಗಳ ವಿಶ್ವವಿದ್ಯಾಲಯ, ಕರ್ನಾಟಕ

Ref. No. : AUTH/Amend/B.Pharm-401/2009-10

Date : 03/08/2009

NOTIFICATION

Sub : Amendment to the Ordinance pertaining to B. Pharm Degree Course.

- Ref : 1. RGUHS Notification No. UA/SYN/ORD/B.Pharm/148/2003-04, dated: 13-07-2008.
2. Recommendation BOS in Pharmacy dated 18-02-2009, Faculty of Pharmacy dated 09-04-2009, Academic Council dated 06-05-2009.
3. Minutes of meeting of Syndicate held on 05-06-2009.
4. RGUHS Notification No. AUTH/Amend/B.Pharm-401/2009-10, dated: 08-06-2009.
5. Minutes of Meeting of Syndicate dated : 30-07-2009.

In exercise of the powers conferred under section 35(1) of RGUHS Act 1994, the Syndicate in its meeting held on 30-07-2009, is pleased to notify the amendment to the Ordinance pertaining to B. Pharm Degree course notified by RGUHS Notification RGUHS Notification No. AUTH/Amend/B.Pharm-401/2009-10, dated: 08/06/2009 pertaining to Minimum qualification for admission to the course (I 1,2) as shown below:

I Minimum qualification for admission to the course.

EXISTING	AMENDED
1. Candidates who have passed two year P.U.C. examination of Karnataka P.U.C. Board or an equivalent examination of any other approved Board or university with not less than 40% marks in any combination comprising PC.M. or PC.B. (minimum eligibility should be based on the aggregate of PC.M. or PC.B.) or PC.M.B., PC. and Computer Sciences PC. and Electronics. Note : In respect of candidates who have taken PC.M.B. combination, the aggregate of PC.M. or PC.B. whichever is higher shall be considered for the purpose of admission. 2. In case of students belonging to SC/ST/ or Category-I, the minimum percentage of marks for admission to B. Pharm Course shall be not less than 35% in P.U.C. or its equivalent examination (PC.B. or PC.M. or PC.M.B.), PC. and Computer Science, PC. and Electronics and D. Pharma.	1. Candidates who have passed two year P.U.C. examination of Karnataka P.U.C. Board or an equivalent examination of any other approved Board or university with not less than 40% marks in any combination comprising PC.M. or PC.B. (minimum eligibility should be based on the aggregate of PC.M. or PC.B.) or PC.M.B., PC. and Computer Sciences, PC. and Electronics. Note: In respect of candidates who have taken PC.M.B. combination, the aggregate of PC.M. or PC.B. whichever is higher shall be considered for the purpose of admission. 2. In case of students belonging to SC/ST/Category-I /OBC, the minimum percentage of marks for admission to B. Pharm Course shall be not less than 35% in P.U.C. or its equivalent examination (PC.B. or PC.M. or PC.M.B.) PC and Computer Science, PC and Electronics and D. Pharma.



Rajiv Gandhi University of Health Sciences, Karnataka

ರಾಜೀವ್ ಗಾಂಧಿ ಆರೋಗ್ಯ ವಿಜ್ಞಾನಗಳ ವಿಶ್ವವಿದ್ಯಾಲಯ, ಕರ್ನಾಟಕ

Ref. No. : AUTH/Amend/B.Pharm-401/2009-10

Date : 03/08/2009

The above Amendment to Ordinance pertaining to B. Pharm Degree Course shall come into force with immediate effect.

By Order,

(Dr. Vasantha Kumar S)
REGISTRAR

To

The Principals of all Colleges affiliated to RGUHS conducting B. Pharm Degree Course.

Copy to :

1. The Secretary to Governor, Governor's Secretariat, Raj Bhavan, Bangalore - 560001.
2. Secretary to Government, Health & Family Welfare Department, (Medical Education), Vikasa Soudha, Bangalore - 560001.
3. The Director, Department of Medical Education, Anand Rao Circle, Bangalore - 560009.
4. PA to Vice-Chancellor / Registrar / Registrar (Eva.) Finance Officer.
5. Director, Curriculum Development Cell.
6. Public Information Officer.
7. The Home Page of RGUHS Website
<http://www.rguhs.ac.in/Authoritysection/Fellowship.html>.
8. Guard File / Office Copy.

SECTION /

SECTION

GOALS OF EDUCATION & TRAINING IN PHARMACEUTICAL SCIENCES OF RGUHS

The pharmacy curriculum shall be oriented towards educating students of B.Pharm course to:

1. Imbibe the concept of better patient health care at every face of Health related activities.
2. Should be capable of functioning independently in both rural and urban environment.
3. Appraise fellow professionals in Hospitals, Community and Industry of newer developments in Pharmacy.
4. Be a part of all National & International sponsored health education programmes.
5. Educate the community about disease prevention measures, community hygiene and better health.
6. Inculcate critical thinking, clarity of expression, independent thinking and scientific temperament.
7. Encourage active learning methods like Group discussions, Seminars, Peer interactions etc., which would enable students to develop discipline, personality, communicating skills, and other qualities, which are necessary.
8. Be able to produce and market dosage forms and be responsible in minimizing the pollution hazards, by using proper scientific and logical techniques.

Regular periodic assessment shall be done throughout the course. Examinations shall be designed with a view to assess not merely the knowledge but also practical skills, habits and values which are necessary for a pharmacy graduate to carry out the professional obligations competently.

Toward achieving these goals every Pharmacy College should:

- Evolve institutional objectives, which would be in consonance with the national goals and health policies.
- Shift the role of Pharmacy teachers from merely imparting knowledge to that of facilitator and motivator of student learning.
- Establish an institution for faculty development, preparation of learning resource materials and for improving evaluation methods.
- Encourage and facilitate for Industry-Academic interaction.

SECTION II

AIMS & OBJECTIVES OF B. PHARM COURSE

Aims:

Pharmacy graduates are required to learn and acquire adequate knowledge, necessary skills to practice the profession of pharmacy including thorough and exhaustive knowledge of synthesis and assay of Medicinal agents including mode of action, drug interactions and Patient counseling and professional information exchange with Physicians and other paramedicos. The graduates are required to acquire an in-depth knowledge of formulation, storage and analysis of various pharmaceutical dosage forms including herbal medicines required for both large scale commercial production & research. The graduates should understand the concept of Community Pharmacy and be able to participate in rural and urban health care projects of State and Central government. The graduate is also required to detail the physicians and community and market the medicinal agents for diagnosis, prevention and therapeutic purposes. The pharmacist should act as bridge between Physicians and Patients and strive for better health care.

Objectives:

The objectives are covered under three headings namely:

- (a) Knowledge and understanding
- (b) Skills and
- (c) Attitude

(a) KNOWLEDGE & UNDERSTANDING

The graduate should acquire the following during their four-year B.Pharm course.

1. Adequate knowledge and scientific information regarding basic principles of Pharmaceutical chemistry, Pharmaceutics including cosmetics, Pharmacology and Pharmacognosy including Herbal drugs.
2. Adequate knowledge of practical aspects of synthesis, formulation and analysis of various pharmaceutical and Herbal medicinal agents.
3. Adequate knowledge of practical aspects of delivering a quality assured product as per pharmacopoeia, WHO and ISO standards.
4. Adequate knowledge of practical aspects of Pharmacological screening, biological standardization and in-vivo drug interactions.

5. Adequate knowledge of clinical studies for patient counseling leading to physical and social well being of patients.
6. Adequate knowledge of practical aspects of product detailing and marketing of Pharmaceutical products.

(B) SKILLS

A graduate should be able to demonstrate the following skills necessary for practice of a pharmacy.

1. Able to synthesize, purify, identify and analyze medicinal agents.
2. Able to formulate, store, dispense, analyze the prescriptions and / or manufacture the medicinal agents at commercial level.
3. Able to learn and apply the quality assurance principles including legal and ethical aspects involving drugs.
4. Able to extract, purify, identify and know the therapeutic value of herbal / crude / natural products.
5. Able to screen various medicinal agents using animal models for pharmacological activity.

(C) ATTITUDES

The graduate should develop the following attitudes during their four-year B.Pharm course.

1. Willing to apply the current knowledge of Pharmacy in the best interest of patients and the community.
 2. Maintain a high standard of professional ethics in discharging professional obligations.
 3. Continuously upgrade professional information and be conversant with latest advances in Pharmacy field to serve the community better.
 4. Willing to participate in continuing education programmes of PCI and AICTE to upgrade knowledge and professional skills.
-
5. To help and to participate in the implementation of National Health Programmes.

SECTION III

REGULATIONS

- I. Minimum qualification for admission to the course
1. Candidates who have passed two year PU.C. examination of Karnataka PU.C. Board or an equivalent examination of any other approved Board or university with not less than 50% marks in any combination comprising PC.M. or PC.B. (minimum eligibility should be based on the aggregate of PC.M. or PC.B.) or PC.M.B, PC. and Computer Sciences, PC. and Electronics.

Note: In respect of candidates who have taken PC.M.B. Combination the aggregate of PC.M. or PC.B. whichever is higher shall be considered for the purpose of admission.

2. In case of students belonging to SC/ST/or Category-I, the minimum percentage of marks for admission to B.Pharm Course shall be not less than 40% in PU.C. or its equivalent examination (PC.B, or PC.M. or PC.M.B.), PC and Computer Science, PC and Electronics and D.Pharm.
3. Candidates who have scored less than 50% marks in (10+2) but who have completed B.Sc. Degree with Chemistry as one of the compulsory subjects in combination with any two of the following subjects, namely, Physics or Mathematics, or Microbiology, or Botany, or Zoology, or Bio-technology, or Computer Sciences or Electronics securing not less than 50% marks in aggregate are eligible for admission to first year B.Pharm course.
4. Candidates who have scored less than 50% marks in 10+2 but who have completed D.Pharm course securing more than 50% marks in aggregate in D.Pharm are eligible to be admitted to I B.Pharm course.
5. Candidates who have passed D.Pharm course with not less than 60% aggregate approved by Pharmacy Council of India shall also be eligible to this course and shall be admitted directly to II B.Pharm course 10% over and above the sanctioned intake and shall have to study Mathematics, Computer science & Statistics of I B.Pharm in addition to the II B.Pharm subjects.

*Vide Notification: U A/S YN/O R D/B. Pharm/148/2003-04 dated 31.08.2005

II Duration of the course

The course of study for B.Pharm shall extend over a period of four academic years and three academic years for those admitted to second B. Pharm directly. The curricula and syllabii for the course shall be prescribed from time to time.

III Medium of Instruction and Examinations

Medium of Instruction and Examination shall be English.

IV Attendance and Progress

A candidate is required to put in at least 80% attendance in theory and practical subjects separately in a recognized institution approved by and affiliated to Rajiv Gandhi University of Health Sciences, Karnataka. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

V Course of study

The course of study for B.Pharm I, II, III and IV year shall include the respective Theory & Practical subjects as given in Table-1, II, III and IV respectively. The number of hours to be devoted to each theory and practical subject in an academic year shall not be less than that shown in Table-1, II, III and IV.

VI Approval of institution conducting the course of study

The regular course for B.Pharm I, II, III & IV year under clause V shall be conducted by an institution approved by All India Council for Technical Education and affiliated to Rajiv Gandhi University of Health Sciences, Karnataka. The approval and affiliation will be granted only if adequate arrangements for teaching- infrastructural facilities, accommodation, equipments, chemicals, glassware, library, teaching and non-teaching staff are provided as required under the norms of Rajiv Gandhi University of Health Sciences, Karnataka (as prescribed in Section V1).

VII Academic Work

A regular record of attendance both in Theory and Practicals shall be maintained by the teaching staff of respective subjects.

Internal Assessment Marks:

A. Theory: Three sessional examinations evenly spread during the academic year shall be conducted by tire affiliated colleges. The average marks of the best two examinations shall be computed out of a maximum of 30 marks and shall constitute the sessional award in theory. Provided further the colleges may conduct one special theory sessional examination towards the end of the academic session for those who might have missed any one of the regular sessional examination on genuine grounds. For special theory sessional examination, the portion prescribed shall be the entire syllabus of the subject.

B. Practical: Students are expected to perform the number of experiments listed in the respective syllabus.

The number of experiments are also listed. Marks shall be awarded out of a maximum of 10 to each of the practical exercise and an average of those shall be computed out of maximum of 10 marks. In addition, three practical sessional examinations evenly spread during each academic year shall be conducted. The average marks of the best two practical examinations shall be computed out of a maximum of 20 marks. A total of 30 marks shall constitute the sessional award in practical. While awarding the sessional marks for practical experiments, the following considerations should be taken into account.

1. Preparation of the candidate.
2. Manipulative skills.
3. Results of the experiment.
4. Knowledge of the experiment
5. Viva voce pertaining to the experiments only.

The college shall maintain the sessional books of the students and the record of sessional award of the students.

A regular record of both theory and practical class work and sessional examinations conducted in an institution imparting the course shall be maintained for each student in the institution. Marks shall be awarded as per the schemes given in Table- V, VI, VII and VIII.

III Examinations

There shall be four examinations namely, First Year, Second Year, Third Year and Final Year B.Pharm examination. The details regarding the duration of papers, maximum marks for each paper including the sessional marks allotted to each subject is given in Table- V, VI, VII and VIII.

IV Criteria for Pass

- a) Candidates who have secured a minimum of 50% marks in the Theory (including sessionals) and Practical (including sessionals) separately in any subject or subjects shall be declared to have passed in that subject/s and exempted from appearing in that subject/s at subsequent examination.
- b) Theory and Practical of a particular subject are considered as individual subjects for the purpose of pass criteria.

V Conditions under which candidates are permitted to proceed to next higher class:

- a) Out of seven subjects to be studied at I.B.Pharm course, there shall be an examination conducted by the college in respect of the following three subjects.

- i. Mathematics-theory.
 - ii. Biology-theory and practical.
 - iii. Computer Science & Statistics for the candidates admitted on PUC / 12th Standard / Equivalent qualifications and for the candidates admitted to II.B.Pharm, admitted on the basis of D.Pharm.
- b) The candidates are required to score a minimum of 40% marks of the total marks prescribed for pass in all the above three subjects both in theory and practical separately including their sessional marks for a pass.
 - c) Candidates of I B.Pharm are permitted to carryover all the failed subjects to II B.Pharm and appear for II B.Pharm examination concurrently along with failed subjects of I B.Pharm. However, these candidates have to pass all the failed subjects of I B.Pharm to become eligible to proceed to III B.Pharm.
 - d) Similarly, candidates of II B.Pharm who have completely passed all the subjects of I B.Pharm but have failed in II B.Pharm are permitted to carryover all the failed subjects of II B.Pharm to III B.Pharm and appear for III B.Pharm concurrently along with failed subjects of II B.Pharm. However, these candidates have to pass all the failed subjects of II B.Pharm to become eligible to proceed to IV B.Pharm.
 - e) Candidates of III B.Pharm who have completely passed all the subjects of II B.Pharm but have failed in III B.Pharm are permitted to carryover all the failed subjects of III B.Pharm and appear for IV B.Pharm examination concurrently along with failed subjects of III B.Pharm.
- The carryover facility as above shall be applicable to B.Pharm students of 1998- 99 batch and onwards.
- f) The final B.Pharm candidates can appear for all the subjects of IV B.Pharm along with the failed subjects of III B.Pharm. However they have to pass all the subjects of III B.Pharm before the announcement of IV B.Pharm results.
 - g) However in case of In-service candidates (those who are Registered Pharmacists and have put in minimum of 5 years working experience in either Government or Private sector), they are permitted to take admission into Final year B.Pharm even if he/she is having a carryover of II year and III year B.Pharm subjects but he/she cannot appear for final B.Pharm examination till he/she passes all the subjects of II year B.Pharm.
 - h) A candidate who has passed in all the subjects of IV B.Pharm will be eligible for the award of
A. Pharm Degree, provided he/she has passed in all the III B.Pharm subjects also in the case of carryover and he/she has satisfactorily completed the practical training as mentioned under clause XIII.

XI Improvement of sessional marks

Candidates who wish to improve the sessional marks only in theory subjects can do so by appearing in the special resessional examinations conducted by the college. A minimum of two and maximum of three sessional examinations shall be conducted by the college out of which the average marks of the best two of the three special resessional examination shall be forwarded to the university at least 15 days prior to the commencement of the next university Examination. In case the marks scored by the students in the resessional examination are less than regular sessional examination, the Head of the Institution shall forward the marks whichever is higher (Resessional/Regular sessional). The resessional/regular sessional marks shall be sent to the university at least 15 days prior to the next university examination.

XII Declaration of Class

Class shall be awarded at the end of I, II, III and final year of B.Pharm examination as shown below:

1) Distinction	75% and above
2) FirstClass	60% and above and less than 75%
3) Second class	50% and above and less than 60%

Pass class shall be awarded to such of the candidates who would have passed the examination in more than one attempt. However, this shall not be applicable to candidates who are exempted in Introductory Biology and Introductory Mathematics by the RGUHS Karnataka, Bangalore.

XIII Every candidate shall undergo practical training in Pharmaceutical Manufacturing House / Approved Hospital / CSIR research labs for a period of not less than one hundred and fifty hours to be covered in not less than 45 days after completing III B.Pharm or IV B.Pharm course.

Candidate should submit two copies of the training report duly certified by the authorities of the training center in which he / she has undergone training duly accepted and certified by the Head of the Institution.

XIV Industrial Tour

Candidates studying in final year of the course shall visit several Pharmaceutical manufacturing houses as a supplement to their academic training and submit a report to the satisfaction of the Head of the institution where he/ she has studied.

XV Award of Ranks

Ranks and Medals shall be awarded on the basis of aggregate of all the four university examinations of Rajiv Gandhi University of Health Sciences, Karnataka, Bangalore. However, candidates who fail in one or more subjects during the B.Pharm courses shall not be eligible for award of ranks.

8. Lipids:
 - a) Definition, method of extraction, chemistry and method of analysis
 - b) Study of method of production, chemical constituents, tests, uses and adulterants of the following oils:

i) Castor oil	ii) Shark liver oil	iii) Chaulmoogra oil	iv) Woolfat	
v) Beeswax	vi) Spermaceti	vii) Cocoa butter	viii) Olive oil	3
9. Proteins:
 - a) Definition, Classification, Chemistry, method of analysis
 - b) Study of collagen, gelatin and its products.

3
10. Study of plant fibers used in surgical dressing and related products.

2
11. Different methods of adulteration of crude drugs and general methods for detection of adulterants.

2

PHARMACOGNOSY (Practicals)

75 hours

1. Study of cell wall constituents and cell inclusions*.
2. General morphological study of different parts of the plants including surgical fibers*.

a) Leaf	Datura, Senna
b) Bark	Cinnamon (Cassia), Cinchona
c) Stem	Ephedra
d) Wood	Quassia
e) Flower	Clove
f) Fruits	Fennel, Coriander
g) Seeds	Isapgol, Nuxvomica
h) Root	Rauwolfia, Liquorice
i) Rhizome :	Ginger, Podophyllum
3. Transverse sections of drugs mentioned in 2**
4. Test for identification of/adulterants in*:

a) Castor oil b) Shark Liver oil c) Woolfat d) Beeswax. e) Sesame oil
5. Chemical tests for identification of the following drugs and adulterants in them*.

a) Acacia b) Agar c) Tragacanth d) Starch e) Honey f) Gelatin.
6. Analysis of fats and oils - Iodine values, Saponification values, Acid values and Ester values* *

1.4: PHARMACEUTICAL ORGANIC CHEMISTRY I (Theory)

75 Hours

1. Structure and physical properties:
 - a) Polarity and dipole moment: Hydrogen bonding and its applications and Protic and aprotic solvents.
 - b) Tautomerism, Keto-enol tautomerism.
 - c) Reaction intermediates -carbocations, carbanions and free radicals
 - d) Attacking reagents-electrophiles, nucleophiles.
 - e) Acids and bases: Lowry Bronsted and Lewis theories.
 - f) An introduction to Isomerism. 3

2. Nomenclature of organic compounds belonging to the following classes: alkanes, alkenes, dienes, alkynes, alcohols, aldehydes, ketones, amides, amines, phenols, alkyl halides, carboxylic acids, esters, acid chlorides and cycloalkanes. Concept of aromaticity, Huckel's rule nomenclature of aromatic compounds. 8

3. Free radical chain reactions of alkanes-mechanism, relative reactivity and stability. 3

4. Alicyclic compounds: Preparation of cycloalkanes, Bayer's strain theory, theory of strain in ring, molecular orbital concept. 4

5. Nucleophilic aliphatic substitution mechanism: nucleophiles, and leaving groups, kinetics of second and first order reaction. Mechanism and Stereochemistry of S_N2 reaction, Mechanism and Stereochemistry of S_N1 reaction. Rearrangement of carbocation, S_N2 versus S_N1 reactions, Reactivity of alkyl halides in S_N1 and S_N2 , Factors Affecting S_N1 and S_N2 . 8

6. Dehydrohalogenation of alkyl halides: 1,2 elimination, kinetics, $E2$, $E1$, mechanisms, $E2$ versus $E1$, elimination versus substitution. Dehydration of alcohols and its mechanism, orientation and reactivity in $E2$, $E1$, Saytzeff's and Hoffman's elimination. 7

7. Electrophilic addition: Reactions at carbon-carbon double bond, hydrogenation, Markovnikov's rule, addition of hydrogen halides, Addition of hydrogen bromides-peroxide effect. Electrophilic addition mechanism. Mechanism of cycloaddition reactions with examples. Addition of carbenes to alkenes. Diels-Alder reaction. 5

8. Theory of resonance: allyl radical as a resonance hybrid, stability, and orbital picture. Resonance stabilization of allyl cations: hyper conjugation, stability of conjugated dienes, mechanisms of 1,2 and 1,4-additions with examples, effect of temperature on 1,2 and 1,4 addition. 7
9. Electrophilic aromatic substitution; Effect of substituent groups, determination of orientation, determination of relative reactivity, classification of substituent groups, mechanism of nitration, sulphonation, halogenation, Friedel craft alkylation and Friedel craft's acylation, Reactivity and orientation, activating and deactivating (o, m, p, directing) groups, orientation and synthesis, orientation in disubstituted benzenes, theory of reactivity, theory of orientation, effects of halogens. 10
10. Nucleophilic additions in aldehydes and ketones, mechanisms with examples. Action of grignard reagent. Aldol condensation, crossed Aldol condensation, claisen condensation, cannizaro, crossed cannizaro reaction, benzoin's, perkins, knoevenagels and reformatsky reaction. 6
11. Nucleophilic acyl substitution in carboxylic acid derivatives, comparison with nucleophilic addition reaction, ionization of carboxylic acids, acidity of acids, structure of carboxylate ion, effect of substituents on acidity. Conversion of acids to acid chloride, amide, ester, anhydrides. 7
12. Migration to electron deficient nitrogen - Hofmanns, Beckmanns, Curtius, Smith. Diazotisation and Diazonium salts and its applications, Sandmeyer's Diazocoupling reactions. Basicity of amines, effect of substituents on basicity. Acidity of phenols, effect of substituents on acidity. Kolbe's reaction, Reimer Tiemann reaction, Fries rearrangement, Williamson's synthesis. 7

PHARMACEUTICAL ORGANIC CHEMISTRY I (Practicals)

75 hours

1. Introduction to the various laboratory techniques through demonstrations involving synthesis of the following compounds (atleast 8 compounds to be synthesized). *
 1. Acetanilide/Aspirin (acetylation)
 2. Benzanilide/Phenylbenzoate(Benzoylation)
 3. p-Bromo acetanilide/2,4,6Tribromoaniline. (Bromination)
 - 4 Dibenzylidene acetone (condensation)
 5. 1 -Phenylazo-2-naphthol (Diazotisation)
 6. Benzoicacid/Salicylicacid (hydrolysis of ester)
 7. m-Dinitro benzene (nitration)
 8. 9,10- Anthraquinone (oxidation of anthracene) / preparation of benzoic acid from toluene or benzaldehyde.
 9. m-Phenylenediamine (reduction of m-dinitrobenzene)/aniline from nitrobenzene
 10. Benzophenone oxime (oxime formation)
 11. Nitration of salicylicacid
 12. Preparation of picric acid
 13. Preparation of o-chloro benzoic acid from o-chloro toluene
 14. Preparation of cyclohexanone from cyclohexanol.
2. Identification of organic compounds belonging to the following classes by systematic qualitative organic analysis including preparation of derivatives* *.
 1. Phenols
 2. Amides
 3. Carbohydrates
 4. Amines
 5. Carboxylicacids
 6. Aldehydes and ketones
 7. Alcohols
 8. Esters
 9. Hydrocarbons
 10. Anilides
 11. Nitrocompounds
3. Introduction to the use of stereo models
 1. Methane
 2. Ethane
 3. Ethylene
 4. Acetylene
 5. cis-Alkene
 6. trans-Alkene
 7. Inversion of configuration

4. Determination of melting point and boiling point for some important pharmaceutical Organic compounds.

SCHEME OF EXAMINATION: Practical and Viva Voce

1. Synopsis	-10 Marks
2. Major Experiment (Experiments indicated by**) (Systematic Qual itative Analysis)	-35 Marks
3. Minor Experiment-I (Experiments indicated by)* (Preparation of Simple Organic Compound)	-15 Marks
4. Practical viva	-10 Marks
Total	- 70 Marks

PHARMACEUTICAL ORGANIC CHEMISTRY I REFERENCE BOOKS (Theory)

1. T.R.Morrison and R.Boyd, Text of Organic Chemistry, 6th edition Prentice Hall of India Pvt. Ltd., New Delhi.
2. Bentley and Driver's textbook of Pharmaceutical Chemistry. L.M. Atherden, 8th edition
3. I.L. Finar Organic Chemistry, the Fundamentals of Chemistry. Lingman Publishers Vol-1, ^A edition.
4. T.W.Graham Solomons, Fundamentals of Organic Chemistry, John Wiley & Sons Inc., USA, 5th edition.
5. J.M.Catm and D.J.Carm Organic Chemistry. Saunders college of Publishing, 13th edition.
6. Brown, Organic Chemistry.
7. I.P, Govt, of India, Ministry of Health and Family welfare, 3rd Edition (1985), 4th Edition (1996).
8. Jerry and March, Advanced Organic Chemistry, Wiley Eastern Limited, New Delhi 4th Edition.
9. Cram and Hammer, Pine Hendrickson Organic Chemistry.
10. Alinger. Cava, Dejongh Organic Chemistry.
11. Neckers and Doyle Organic Chemistry.
12. Agronnonov et. al., Problems and exercises in Organic Chemistry.

PHARMACEUTICAL ORGANIC CHEMISTRY I REFERENCE BOOKS (Practical)

1. A.I. Vogel, Elementary Practical organic chemistry, ELBS and Longman group Ltd., London.
2. Mann and Sounders, Practical Organic Chemistry-, ELBS and Longman group Ltd.,
3. D.L.Pavia, G.Lampman and G.D.Kriz. Introduction to Organic Laboratory Techniques.
4. I.P. Govt, of India, Ministry of Health and Family welfare, 3rd Edition (1985), 4th Edition (1996).
5. A.I. Vogel, Text Book of practical organic chemistry, ELBS Longman, London, 4th edition.

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Melting Point Apparatus	10
2. Triple beam balances	10
3. Physical balances	05
4. Suction Pumps	01
5. Water Baths	10
6. Hot Plates	01
7. Oven	01
8. Refrigerator	01
9. Distillation Unit	01

SECTION IV

COURSE CONTENTS

I B.Pharm

1. 1: HUMAN ANATOMY AND PHYSIOLOGY (Theory)

75 hours

1. Scope of Anatomy and Physiology, basic terminologies used in this subject. 1
2. Structure of cell-Its components and their functions 1
3. Elementary tissues of the human body: epithelial, connective, muscular and Nervous tissues-their sub-types and characteristics 2
4. a) Osseous system—structure, Classification of Bones, composition of Bones, functions of the skeleton. 2
 - b) Classification of joints, types of movements of joints and
 - c) Disorders of joints (definitions only)
5. Haemopoietic system
 - a) Composition and functions of blood 1
 - b) Haemopoiesis and disorders of blood & its components (Definition of Disorders) 2
 - c) Blood groups 1
 - d) Clotting factors and mechanism 1
 - e) Platelets and disorders of coagulation 1
6. Lymph
 - a) Lymph and lymphatic system; composition, formation and circulation 1
 - b) Disorders of Lymph and lymphatic system (Definitions only) 1
 - c) Spleen: Physiology and function 1
7. Cardiovascular system
 - a) Anatomy of heart 1
 - b) Blood vessels and circulation 2
 - c) Pulmonary and systemic circulation 1
 - d) ECG 1
 - e) Cardiac cycle and Heart Sounds 1
 - f) Blood Pressure maintenance and regulation 1
 - Definitions of the following disorders 1
 - i) Hypertension
 - ii) Hypotension
 - iii) Arteriosclerosis
 - iv) Atherosclerosis
 - v) Angina
 - vi) Myocardial infarction
 - vii) Congestive Heart failure and
 - viii) Cardiac arrhythmias

c)	Spermatogenesis and Oogenesis	1
d)	Sex determination (genetic basis)	1
e)	Pregnancy and its maintenance and parturition	1
f)	Contraceptive devices	1
14.	Sense Organ-Structure and functioning of	
a)	Eye	2
b)	Ear	2
c)	Skin	1
d)	Taste and Smell	1
15.	Skeletal muscles	
a)	Histology	1
b)	Physiology of muscle contraction	
c)	Physiological properties of skeletal muscle performance (Definition of the disorders)	1
16.	Sports physiology	
a)	Muscles in Exercise	
b)	Effect of athletic training on muscles and muscle performance	
c)	Respiration in exercise	
d)	CVS in exercise	
e)	Body heat in exercise	
f)	Body fluids and salt in exercise	
g)	Drugs and athletics	2

HUMAN ANATOMY AND PHYSIOLOGY (Practicals)

75 hours

1. Determination of hemoglobin content of blood
2. Determination of R.B.C. content of blood
3. Determination of W.B.C. content of blood
4. Determination of differential count of blood
5. Determination of blood groups
6. Determination of blood pressure
7. Determination of Bleeding time & clotting time
8. Determination of vital capacity
9. Study of appliances used in experimental physiology
10. Muscle physiology
 - a) To study simple muscle curve
 - b) To study the effect of temperature on muscle contraction
 - c) To study the effect of load and after load on muscle contraction
 - d) To study the fatigue curve
 - e) To study the summation muscle curve

11. Study of various models, specimens and bones
12. Study of histology slides of different tissues/organs
13. Study of different family planning appliances
14. To perform pregnancy diagnosis tests

SCHEME OF EXAMINATION

1 Identification	-	10	Marks
2 Synopsis	-	10	Marks
3 Hematology (2 Expt.)	-	20+	10 Marks
4 Muscle Physiologytheoretical explanation	-	10	Marks
5 Viva	-	10	Marks
Total	-	70	Marks

HUMAN ANATOMY AND PHYSIOLOGY REFERENCE BOOKS

- 1) AB Me Naught and Callander R., " Illustrated Physiology", B.I. Churchill Living Stone, New Delhi, 1st edition, 1987.
- 2) Anne Waugh and Allison Grant, " Ross and Wilson Anatomy and Physiology in Health and Illness", Churchill Living Stone, Edinburgh, 9th edition, 2002.
- 3) Arthur C. Guyton and John E. Hall, "Text book of Medical Physiology" W.B. Saunders Company, 10th edition, 2000.
- 4) Bhise S.B. and Yadav " Human Anatomy and Physiology", Nirali Prakashan, Pune (India), 8th edition, 2000.
- 5) C.C. Chatterjee, " Human Physiology"(Vol. Vol. II) & I, Medical Allied Agency, Calcutta, 11th edition, 1985.
- 6) Chaudhry Sujit K., "Consise Medical Physiology", New Cenrtal Book Agency, Calcutta, 2nd Edition, 1993.
- 7) De Gruchy's Clinical Haematology, "Clinical Haematology in Medical Practice, Blackwell Science publishers, 5th Edition, 1989.
- 8) Douglas E., Kelly, Richard Wood and Allen C. Enders, " Bailey's TextBook of Microscopic Anatomy", Williams and Wilkins publishers, London, 18th Edition, 1984.
- 9) Elaine N. Marieb, "Human Anatomy and Physiology", Addison Wesley, New York, 4th edition, 1997.
- 10) Elaine N. Marieb, "Human Anatomy and Physiology", Benjamin / Cumings publishing company, 2nd edition, 1992.

- 11) Gerard J. Tortora, "Principles of Anatomy and Physiology", John-Wiley & sons New York, 10th edition, 2003.
- 12) Inderbir Singh, "Text Book of Human Histology with Colour Atlas, Jaypee Brothers, New Delhi, 4th edition, 2002.
- 13) Park J.E. and Park K., "Preventive and Social Medicine", Banarasidas Bhanot, India, 13th edition, 1991.
- 14) Thakare Bhai, P Gandhi and Harit R., Derasari, "Elements of Human Anatomy Physiology and Health Education" B.S. Shah Publishers, Ahmedabad, 4th Edition, 1991.
- 15) Anatomy and Physiology by Kimber - Grey - Stackpole's
- 16) Practical Physiology and Biochemistry by Goel, Shah and Patel

LIST OF MINIMUM EQUIPMENT REQUIRED		(For abatch of 20 students)
1. Microscopes		20
2. Glass Slides		80
3. Haemocytometer with Micropipettes		20
4. Sahli's haemocytometer		20
5. Hutchinson's spirometer		01
6. Sphygmomanometer		20
7. Stethoscope		20
8. Permanent Slides for various tissues, Organs and endocrine glands	One pair of each tissue One model of each organ System	
9. Models for various organs	One model for each organ System	
10. Specimen for various organs and systems	One model for each organ System	
11. Skeleton and Bones	One set of skeleton and one spare bones	
12. Different contraceptive devices and models.	One set of each device	
13. Sherrington's drum		
14. Student Kymigraph		
15. Muscle electrodes		
16. Lucas Moist chamber		
17. Myographic lever		
18. Stimulator		

Items 13-18 are not required as the frog experiments are obsolete as per CPCSEA regulations.

I B.Pharm

1.2: PHARMACEUTICS (Theory)

50 hours

1. Historical background and development of profession of pharmacy and Pharmaceutical Industry in brief. 1
2. Development of Indian pharmacopoeia and introduction to other Pharmacopoeias such as B.P, U.S.P.European pharmacopoeia, Extra Pharmacopoeia and Indian National Formulary. 3
- 2 a) Introduction to dosage forms: Classification and definitions.
a) Prescription: Definition, parts of prescription and handling
b) Posology: Definition, factors affecting dose selection, calculation of children and Infant doses. 4
1. Different types of weights and measures, calculations involving percentage of solutions, alligation, proof spirit, isotonic solutions. 4
2. Introduction to different types of processes: Fusion, desiccation, sublimation, exsiccation and ignition. Definition of evaporation, distillation and drying. Various types of Baths; Water bath, Steam bath, Oil bath and Solvent bath 4
3. Galenicals: Definition, equipment for different extraction processes: Expression infusion, decoction, maceration and percolation, method of preparation of spirits, tinctures, extracts, soxhlet extraction. 6
4. Surgical aids: Definition and types of surgical sutures and ligatures. Manufacture and standardization of surgical catgut. 3
5. Powders and granules: Classification, advantages and disadvantages, preparation of simple, compound powders, insufflations, dusting powders, Eutectic and explosive powders, tooth powders and effervescent granules. 5
- 9 Monophasic dosage forms: Theoretical aspects including commonly used vehicles, essential adjuvants like stabilizers, colorants, and flavors with examples. Study of following monophasic liquids like gargles, mouthwashes, throat paints, eardrops, nasal drops, liniments and lotions, enemas, colloidions, syrups, elixirs and solutions. 6
10. Biphasic dosage forms: Suspensions: Definition and classification, diffusible and indiffusible suspensions, advantages and disadvantages.

Emulsions: Definition, types of emulsions, identification tests emulsifying agents, creaming and cracking of emulsions 7

11. Suppositories and pessaries: Definition, advantages and disadvantages, types of bases, method of preparation, displacement value.	4
12. Incompatibilities: Introduction, Physical and Therapeutic incompatibility and methods of overcome to same.	3

PHARMACEUTICS (Practicals)

75 hours

1. Syrups	a) Simple syrup IP*
	b) Syrup of ephedrine hydrochloride NF*
	c) Orange syrup.
2. Elixir	a) Piperazine citrate elixir BP*
	by Paracetamol paediatric elixir BPC*
3. Linctuses:	a) Simple linctus BPC*
	b) Pediatric simple linctus BPC*
4. Solutions:	a) Solution of cresol with soap IP*
	b) Aqueous iodine solution IP*
	c) Strong solution of iodine IP*
	e) Weak iodine solution IP*
	f) Strong solution of ammonium acetate* *
5. Liniments	a) Liniment of turpentine IP**
	b) Liniment of Camphor BPC**
	c) Soap liniment*
6. Suspensions	a) Calamine lotion IP**
	b) Magnesium hydroxide mixture BP**
7. Emulsions	a) Liquid paraffin emulsion,**
	b) Castor oil emulsion,**
	c) Cod liver oil emulsion**
8. Powders	a) Eutectic powder*
	b) Effervescent powder*
	c) Dusting powder*
	d) Effervescent granules**
9. Suppositories	a) Boric acid suppository**
	b) Zinc oxide suppository**
10. Colloidion	a) Salicylic acid colloidion
11. Gargle	a) Potassium chlorate gargle*
12. Mouthwash	a) Antiseptic mouthwash.*
13. Enema	a) Anyone*.

SCHEME OF EXAMINATION

1. Synopsis	-	15 Marks
2. Major Experiment (Experiments indicated by **)	-	30 Marks
3. Minor experiment (Experiments indicated by *)	-	15 Marks
4. Viva voce	-	10 Marks
Total	-	70 Marks

PHARMACEUTICS REFERENCE BOOKS

1. H. C. Ansel et. al., Pharmaceutical Dosage Forms and Drug Delivery Systems, Lippincott Williams and Wilkins, New Delhi, 7th Edition, 2000.
2. Mitchell J. Stoklosa and Howard C. Ansel, Pharmaceutical Calculations, BI Waverley Pvt. Ltd., New Delhi, 10th Edition, 1996.
3. Alfonso R. Gennaro, Remington: The Science and Practice of Pharmacy, Vol: I and II Lippincott Williams 20th Edition, 2000.
4. Carter S.J, Cooper and Gunn's- Dispensing for Pharmaceutical Students, CBS Publishers, New Delhi, 12th Edition, 2000.
5. Carter S.J, Cooper and Gunn's-Tutorial pharmacy, CBS Publishers, New Delhi, 6th edition, 2000
6. M.E.Aulton, Pharmaceutics, The Science of Dosage Form Design, Churchill Livingstone, Edinburgh, 2nd Edition, 2002.
7. The Pharmaceutical Codex, Pharmaceutical Press, London, 11th Edition, 1979.
8. Indian Pharmacopoeia-1966,1985, Published by The Controller of Publications, Delhi.
9. Latest Editions of: Indian Pharmacopoeia, British Pharmacopoeia, United States Pharmacopoeia, Extra Pharmacopoeia, Merk Index and British Pharmaceutical Codex.
10. E.A.Rawlins, Bentley's textbook of Pharmaceutics, English language book Society, 8th edition, 1997.

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Mechanical stirrers	10
2. Homogeniser	02
3. pH meter	01
4. Suppository moulds	20
5. Electronic balance	02

I B.Pharm

1.3: PHARMACOGNOSY (Theory)

	50 hours
1. Definition, history and scope of Pharmacognosy.	2
2. Classification of drugs viz. alphabetical, morphological, chemical, pharmacological, taxonomical and chemotaxonomical methods. General aspects of chemotaxonomy.	5
3. Cultivation, collection, processing and storage of crude drugs. Conservation of medicinal plants.	5
4. Detailed methods of cultivation of the following drugs: a) Senna b) Cinchona c) Isapgol c) Cardamom e) Opium f) Ergot	4
5. Study of morphological, microscopical and cell wall constituents of crude drugs: a) Study of cell wall constituents and cell inclusions. b) Study of morphology and microscopy of different plant parts. i. Leaf: Datura, Senna ii. Bark: Cinnamon (Cassia), Cinchona iii. Wood: Quassia iv. Stem: Ephedra v. Root: Rauwolfia, Liquorice vi. Rhizome: Ginger, Podophyllum vii. Flower: Clove viii. Fruits: Coriander, Fennel ix. Seeds: Isapgol, Nux Vomica	10
6. Study of Natural Pesticides: Pyrethrum, Neem, Tobacco	2
7. Study of plant constituents: a) Brief study of various plant constituents. b) Detailed study of primary cell constituents: Carbohydrates and related products. c) Biological source, method of production, chemical constituents, tests, uses & adulterants of: I) Isapgol ii) Linseed iii) Honey iv) Acacia v) Agar vi) Sterculia vii) Tragacanth viii) Cellulose and its products ix) Pectin x) Guar gum xi) Sodium alginate.	10

8. Lipids:
 - a) Definition, method of extraction, chemistry and method of analysis
 - b) Study of method of production, chemical constituents, tests, uses and adulterants of the following oils:

i) Castor oil	ii) Shark liver oil	iii) Chaulmoogra oil	iv) Woolfat	
v) Beeswax	vi) Spermaceti	vii) Cocobutter	viii) Olive oil	3
9. Proteins:
 - a) Definition, Classification, Chemistry, method of analysis
 - b) Study of collagen, gelatin and its products.
10. Study of plant fibers used in surgical dressing and related products. 2
11. Different methods of adulteration of crude drugs and general methods for detection of adulterants. 2

PHARMACOGNOSY (Practicals)

75 hours

1. Study of cell wall constituents and cell inclusions*.
2. General morphological study of different parts of the plants including surgical fibers*.
 - a) Leaf Datura, Senna
 - b) Bark Cinnamon (Cassia), Cinchona
 - c) Stem Ephedra
 - d) Wood Quassia
 - e) Flower Clove
 - f) Fruits Fennel, Coriander
 - g) Seeds Isapgol, NuxVomica
 - h) Root Rauwolfia, Liquorice
 - i) Rhizome Ginger, Podophyllum
3. Transverse sections of drugs mentioned in 2* *
4. Test for identification of/adulterants in*:
 - a) Castor oil b) Shark Liver oil c) Woolfat d) Beeswax. e) Sesame oil
5. Chemical tests for identification of the following drugs and adulterants in them*.
 - a) Acacia b) Agar c) Tragacanth d) Starch e) Honey f) Gelatin.
6. Analysis of fats and oils - Iodine values, Saponification values, Acid values and Ester values* *

SCHEME OF EXAMINATION: Practical and Viva Voce

1. Synopsis	- 10 Marks
2. Major Experiment**.	- 20 Marks
3. Minor Experiment*	- 15 Marks
4. Minor Experiment*.	-15 Marks
5. Viva-Voce	-10 Marks
Total	- 70 Marks

PHARMACOGNOSY REFERENCE BOOKS

1. Trease G.E. and Evans, W.C., Pharmacognosy, 15th Ed, Bailliere Tindall, Eastbourne, U.K., 2002
2. Kokate C.K., Purohit A.Pand Gokhale S.B., Pharmacognosy 1st Ed., Nirali Prakasham, 2003
3. Tyler V.E., Brady R Textbook of Pharmacognosy, 8th Ed, Lea and Febiger Philadelphia, 1981.
4. Iyengar M. A. & Nayak S. G. K., Anatomy of Crude Drugs, 8th Ed, Manipal Power Press, Manipal., 2001.
5. Kokate C.K., Practical Pharmacognosy, 3rd Ed, Vallabh Prakashan, Delhi., 1991.
6. Medicinal plants of India, Indian Council of Medical Research, and New Delhi.
7. Nadkarni, A.K., Indian Materia Media, 1-2 Popular Prakashan Pvt., Ltd., Bombay.
8. Pharmacopoeia of India, Government of India, New Delhi.
9. Smith P.M., The chemotaxonomic of Plants, Edinburgh, 1975.
10. The Wealth of India, Raw Materials (All Volumes) council of Scientific and Industrial Research, New Delhi.
11. Brain, K.R. and Turner, T.D., The practical Evaluation of Phytopharmaceuticals, Wright- Sciotechnica, Bristol
12. Wallis T.E., Textbook of Pharmacognosy, 5th Ed, J.A., Churchill Limited, London., 1985.
13. Whistler R.L., Industrial Gums, Polysaccharides and their derivatives, 2nd Ed. Academic Press, New York
14. Harborne J.B., Phytochemical methods, Chapman and Hall, International Edition, London.

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Microscope with Stage	20
2. Balance	20
3. Reflux flask with condenser	20
4. Heating mantle	20

I B.Pharm

1.4: PHARMACEUTICAL ORGANIC CHEMISTRY I (Theory)

75 Hours

1. Structure and physical properties:
 - a) Polarity and dipolemoment: Hydrogen bonding and its applications and Protic and aprotic solvents.
 - b) Tautomerism, Keto enol tautomerism.
 - c) Reaction intermediates -carbocations, carbanions and free radicals
 - d) Attacking reagents-electrophiles, nucleophiles.
 - e) Acids and bases: Lowry Bronsted and Lewis theories.
 - f) An introduction to Isomerism. 3
2. Nomenclature of organic compounds belonging to the following classes: alkanes, alkenes, dienes, alkynes, alcohols, aldehydes, ketones, amides, amines, phenols, alkyl halides, carboxylic acids, esters, acid chlorides and cycloalkanes. Concept of aromaticity, Huckel's rule nomenclature of aromatic compounds. 8
3. Free radical chain reactions of alkanes-mechanism, relative reactivity and stability. 3
4. Alicyclic compounds: Preparation of cycloalkanes, Bayer's strain theory, theory of strain in ring, molecular orbital concept. 4
5. Nucleophilic aliphatic substitution mechanism: nucleophiles, and leaving groups, kinetics of second and first order reaction. Mechanism and Stereochemistry of SN^2 reaction, Mechanism and Stereochemistry of SN^1 reaction. Rearrangement of carbocation, SN^3 versus SN^1 reactions, Reactivity of alkyl halides in SN^1 and SN^2 , Factors Affecting SN^1 and SN^2 . 8
6. Dehydrohalogenation of alkyl halides: 1,2 elimination, kinetics, E_2 , E_1 , mechanisms, E_2 versus E_1 , elimination versus substitution. Dehydration of alcohols and its mechanism, orientation and reactivity in E_2 , E_1 . Saytzeff's and Hoffman's elimination. 7
7. Electrophilic addition: Reactions at carbon-carbon double bond, hydrogenation, Markovnikov's rule, addition of hydrogen halides, Addition of hydrogen bromides-peroxide effect. Electrophilic addition mechanism. Mechanism of cycloaddition reactions with examples. Addition of carbenes to alkenes, Diel's Alder reaction. 5

8. Theory of resonance: allyl radical as a resonance hybrid, stability, and orbital picture. Resonance stabilization of allyl cations: hyper conjugation, stability of conjugated dienes, mechanisms of 1,2 and 1,4-additions with examples, effect of temperature on 1,2 and 1,4 addition. 7
9. Electrophilic aromatic substitution; Effect of substituent groups, determination of orientation, determination of relative reactivity, classification of substituent groups, mechanism of nitration, sulphonation, halogenation, Friedel craft alkylation and Friedel craft's acylation, Reactivity and orientation, activating and deactivating (o, m, p, directing) groups, orientation and synthesis, orientation in disubstituted benzenes, theory of reactivity, theory of orientation, effects of halogens. 10
10. Nucleophilic additions in aldehydes and ketones, mechanisms with examples. Action of grignard reagent. Aldol condensation, crossed Aldol condensation, claisen condensation, cannizaro, crossed cannizaro reaction, benzoin's, perkins, knoevenagels and reformatsky reaction. 6
11. Nucleophilic acyl substitution in carboxylic acid derivatives, comparison with nucleophilic addition reaction, ionization of carboxylic acids, acidity of acids, structure of carboxylate ion, effect of substituents on acidity. Conversion of acids to acid chloride, amide, ester, anhydrides. 7
12. Migration to electron deficient nitrogen - Hofmanns, Beckmanns, Curtius, Smith. Diazotisation and Diazonium salts and its applications, Sandmeyer's Diazocoupling reactions. Basicity of amines, effect of substituents on basicity. Acidity of phenols, effect of substituents on acidity. Kolbe's reaction, Reimer-Tiemann reaction, Fries rearrangement, Williamson's synthesis. 7

PHARMACEUTICAL ORGANIC CHEMISTRY I (Practicals)

75 hours

1. Introduction to the various laboratory techniques through demonstrations involving synthesis of the following compounds (atleast 8 compounds to be synthesized). *
 1. Acetanilide/Aspirin (acetylation)
 2. Benzanilide/Phenyl benzoate(Benzoylation)
 3. p-Bromoacetanilide/2,4,6Tribromoaniline. (Bromination)
 4. Dibenzylidene acetone (condensation)
 5. 1 -Phenylazo-2-naphthol (Diazotisation)
 6. Benzoic acid / Salicylic acid (hydrolysis of ester)
 7. m-Dinitro benzene (nitration)
 8. 9,10- Anthraquinone (oxidation of anthracene) / preparation of benzoic acid from toluene or benzaldehyde.
 9. m-Phenylenediamine (reduction of m-dinitrobenzene)/aniline from nitrobenzene
 10. Benzophenone oxime (oxime formation)
 11. Nitration of salicylic acid
 12. Preparation of picric acid
 13. Preparation of o-chloro benzoic acid from o-chloro toluene
 14. Preparation of cyclohexanone from cyclohexanol.
2. Identification of organic compounds belonging to the following classes by systematic qualitative organic analysis including preparation of derivatives* *.
 1. Phenols
 2. Amides
 3. Carbohydrates
 4. Amines
 5. Carboxylicacids
 6. Aldehydes and ketones
 7. Alcohols
 8. Esters
 9. Hydrocarbons
 10. Anilides
 11. Nitrocompounds
3. Introduction to the use of stereo models
 1. Methane
 2. Ethane
 3. Ethylene
 4. Acetylene
 5. cis-Alkene
 6. trans-Alkene
 7. Inversion of configuration

4. Determination of melting point and boiling point for some important pharmaceutical Organic compounds.

SCHEME OF EXAMINATION: Practical and Viva Voce

1. Synopsis	-10 Marks
2. Major Experiment (Experiments indicated by**) (Systematic Qualitative Analysis)	-35 Marks
3. Minor Experiment-I (Experiments indicated by)* (Preparation of Simple Organic Compound)	-15 Marks
4. Practical viva	-10 Marks
Total	-70 Marks

PHARMACEUTICAL ORGANIC CHEMISTRY I REFERENCE BOOKS (Theory)

1. T.R.Morrison and R.Boyd, Text of Organic Chemistry, 6th edition Prentice Hall of India Pvt. Ltd., New Delhi.
2. Bentley and Driver's textbook of Pharmaceutical Chemistry. L.M. Atherden, 8th edition
3. I.L. Finar Organic Chemistry, the Fundamentals of Chemistry. Lingman Publishers Vol-1, 6th edition.
4. T.W.Graham Solomons, Fundamentals of Organic Chemistry, John Wiley & Sons Inc., USA, 5th edition.
5. J.M.Catm and D.J.Carm Organic Chemistry. Saunders college of Publishing, 13th edition.
6. Brown, Organic Chemistry.
7. ITP, Govt, of India, Ministry of Health and Family welfare, 7th Edition (1985), 4th Edition (1996).
8. Jerry and March, Advanced Organic Chemistry, Wiley Eastern Limited, New Delhi 4th Edition.
9. Cram and Hammer, Pine Hendrickson Organic Chemistry.
10. Alinger. Cava, Dejongh Organic Chemistry.
11. Neckers and Doyle Organic Chemistry.
12. Agronnonov et. al., Problems and exercises in Organic Chemistry.

PHARMACEUTICAL ORGANIC CHEMISTRY I REFERENCE BOOKS (Practical)

1. A.I. Vogel, Elementary Practical organic chemistry, ELBS and Longman group Ltd., London.
2. Mann and Saunders, Practical Organic Chemistry-, ELBS and Longman group Ltd.,
3. D.L.Pavia, G.Lampman and G.D.Kriz. Introduction to Organic Laboratory Techniques.
4. I.P, Govt, of India, Ministry of Health and Family welfare, 3rd Edition (1985), 4th Edition (1996).
5. A. I. Vogel, Text Book of practical organic chemistry, ELBS Longman, London, 4th edition.

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Melting Point Apparatus	10
2. Triple beam balances	10
3. Physical balances	05
4. Suction Pumps	01
5. Water Baths	10
6. Hot Plates	01
7. Oven	01
8. Refrigerator	01
9. Distillation Unit	01

I B. Pharm

1.5: PHARMACEUTICAL INORGANIC CHEMISTRY (Theory)

75 hours

1. Sources and effects of impurities in pharmacopoeial substances, importance of limit test, general principles and procedures for limit tests for chloride, sulphate, iron, arsenic, lead and heavy metals. Special procedures for limit tests. 10
2. General methods of preparation, assays, storage condition & medicinal uses of inorganic compounds belonging to the following classes. (Assays)
- 2.1 Medicinal Gases: Oxygen, Nitrous oxide, Carbon dioxide 2
- 2.2 Gastrointestinal agents
Acidifiers: dil HCl

Antacids: Aluminium hydroxide gel, Calcium carbonate, Sod. bicarbonate, Magnesium trisilicate, Magnesium carbonate (light and heavy), Magnesium hydroxide mixture and Zinc oxide.

Protective and adsorbents: Kaolin and Talc,

Cathartics: Magnesium sulphate, Sodium orthophosphate, Sodium sulphate. 7
- 2.3 Major intra and extra cellular electrolytes, major physiological ions and electrolytes used for the replacement therapy, physiological acid base balance, electrolyte combination therapy ORS, Sodium chloride injection, Dextrose and Sodium chloride injection, Calcium gluconate injection. 6
- 2.4 Topical agents and dermatological preparations:
Protective: Talc, Zinc oxide, Zinc stearate, Titanium dioxide.
Antimicrobials: Potassium Permanganate, chlorinated lime, Iodine preparations, Boric acid, Borax. 6
- 2.5 Dental products: Dentifrices, anticaries agents, desensitizing agents, calcium carbonate, sodium fluoride, Stannous fluoride, Zinc chloride, Zinc eugenol cement. 3

2.6 Miscellaneous agents:

Expectorants	Ammonium chloride (Formal method), Potassium iodide.	
Haematinics	Ferrous sulfate', Ferrous gluconate, Ferrous Fumarate, Iron dextran injection, Iron and Ammonium citrate.	
Emetics	Copper sulphate'.	
Poisons and antidotes:	Sodium thiosulphate, Charcoal, (activated)	
Pharmaceutical Aids	: Bentonite, Sodium metabisulphite, Barium sulphate'.	4

3. Sources of errors, types of errors, methods of minimizing errors, accuracy, precision. 5

4. Fundamentals of volumetric analysis, theory of indicators and methods of expressing concentration. Primary and secondary standards. Preparation, standardization and storage of various volumetric solutions like oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulfate, potassium permanganate and Iodine solution. 8

4.1 Principles of redox titrations: Concepts of oxidation and reduction. Redox reactions, strength and equivalent weights of oxidizing and reducing agents, theory of redox titrations, iodometry, iodometry, bromometry, titrations with potassium iodate, potassium bromate, titanous chloride, 2,6-dichlorophenol indophenol. 10

4.2 Theory of nonaqueous titrations, classification of solvents used in nonaqueous titrations, estimation of Sodium Benzoate by nonaqueous titrations. 4

4.3 Principles of precipitation titrations, different methods-Mohr's, Modified Mohr's, Volhard's, Modified Volhard's, Fajans with example. Estimation of sodium chloride. 5

4.4 Principles of complexometric titrations, different types of complexometric titrations, methods of detecting the endpoints in complexometric titrations with example and estimation of calcium Gluconate. 5



PHARMACEUTICAL INORGANIC CHEMISTRY (Practicals)

75 Hours

(Following experiments to be covered in 25 different practical classes)

1. Limit tests (7 exercises)
 1. Limit test for chlorides*
 2. Limit test for sulphate*
 3. Limit test for Iron*
 4. Limit test for heavy metals*
 5. Limit test for Arsenic
 6. Modifications in limit tests* for chloride and sulphates in potassium permanganate, sodium bicarbonate, sodium benzoate and sodium Salicylate.
2. Preparation and standardization of the following (4 exercises).
 1. 0.1 N Sodium hydroxide
 2. 0.1NKMnO₄
 3. 0.1 NCeric ammonium sulphate
 4. 0.1NHClO₄
 5. 0.05M Di sodium EDTA
3. Assay of the following compounds (8 exercises)**
 1. Ammonium chloride-acid base titration (Formal titration)
 2. Ferrous sulphate- (redox) Ceric ammonium sulphate titration
 3. Copper sulphate- (redox) Iodometry
 4. Calcium gluconate-complexometry
 5. Hydrogen peroxide- (redox -Permanganometry)
 6. Sodium benzoate-nonaqueous titration
 7. Sodium chloride-Modified Volhard's method
 8. Assay of KI-KIO₃ titration
 9. Assay of Zinc oxide (acid base back titration)
4. Test for identify for the following (3 exercises)
 1. Sodium bicarbonate
 2. Ferrous sulphate
 3. Potassium chloride
 4. Calcium chloride
5. Test for purity for the following (2 exercises) *
 1. Swelling power in Bentonite
 2. Ammonium salts in Potash alum.
 3. Presence of Iodates in KI
6. Preparation of inorganic pharmaceuticals (2 exercises)*
 1. Boric acid
 2. Potash alum
 3. Magnesium hydroxide.
 4. Magnesium sulphate

SCHEME OF EXAMINATION: Practical and Viva Voce

1. Synopsis	-10 Marks
2. Major Experiment (Experiments indicated by**)	-25 Marks
3. Minor Experiment-1	
Limit Test	-13 Marks
4. Minor Experiment-2	
Test for Purity or Preparation	-12 Marks
5. Practical viva	-10 Marks

Total - 70 Marks

Note: * Denotes major experiments * Denotes minor experiments

PHARMACEUTICAL INORGANIC CHEMISTRY REFERENCE BOOKS

1. M.L.Schroff, Inorganic pharmaceutical chemistry.
2. Bentley and Driver's Textbook of pharmaceutical chemistry by L.M.Atherden
3. J.D.Lee, Concise Inorganic chemistry. 4th edition.
4. C.A.Discher, Modern inorganic pharmaceutical chemistry.
5. J.H.Block, E.B.Roche, T.O.Soine and C.O.Wilson, Inorganic medicinal and pharmaceutical chemistry.
6. John H.Kennedy, Analytical chemistry-principles. Sanders college publication New York, 3rd edition.
7. I.P1985 and 1996, Govt, of India, Ministry of Health, 3rd Editin, 1985 4* Edition 1996.
8. Ayers, Quantitative chemical analysis.
9. A.H.Beckett & J.B. Stenlake's -Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London, 4^m edition.
10. Analytical chemistry-principles and techniques by Hargis. G.Larry
11. D. A. Skoog, D. M.West, Fundamental of Analytical chemistry, 6th edition.
12. Walton, Principles and methods of chemical analysis.

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Analytical Balances	10
2. Physical Balances	05
3. Suction Pumps	
4. Muffle Furnace	01
5. Oven	01
6. Hot Plates	
7. Water Baths	10
8. Distillation Unit	01

IB. Pharm 1.6: MATHEMATICS

75 hours

1. Matrices: Definition of matrices, Addition, Subtraction, multiplication of matrices, inverse of a square matrix, solution of linear simultaneous equations by matrix method, the characteristic equation of a matrix statement of Cayley-Hamilton Theorem (without proof) - examples pharmaceutical applications of determinations and matrices, Determinants of order two & order three. adjoint kramer's rule 15
2. Trigonometry:
Relations between the sides and angles of a triangle, Solution of triangle. 6
3. Analytical Geometry:
Point: Distance formula-Examples.
Straight line: General form of the equation to a straight line, slope of the line, slope point form.
Condition for two lines to be parallel and perpendicular, angle between two lines, Perpendicular distance from the point to the line, Distance between parallel lines Circle: General equation of a circle, finding center and radius of the circle.
Parabola: Derivation of standard equation in the form: $Y^2=4ax$. 10
4. Differential Calculus:
Limit of a function, derivative of a function, Differentiation of a sum, Product and quotient, Differentiation of composite functions, Implicit functions, parametric functions, Logarithmic differentiation, differentiation of exponentials, logarithmic, trigonometric, inverse trigonometric functions, successive differentiation, Leibnitz Theorem for nth order derivative of a product, partial differentiation, Euler's theorem on homogeneous functions of two variables. 15
5. Integral Calculus:
Indefinite integrals, integration by substitution and integration by parts important properties of definite integrals. 8
6. Differential Equations:
Definition formation of differential equations, differential equations of the first order and first degree, Methods of solving ordinary differential equations: variables separable, homogeneous, linear, exact. Differential equations and equations reducible to these forms, exact differential equations, linear differential equations with constant coefficients (higher order), homogeneous linear differential equations, simultaneous linear differential equations of the first order, pharmaceutical applications. 15

7. Laplace Transforms:

Definition, Laplace transforms of elementary functions, properties of linearity and shifting, applications of differential equations using laplace transforms.

6

MATHEMATICS REFERENCE BOOKS

1. Differential calculus	Shantinakaran
2. Integral calculus	Shantinakaran
3. Engineering mathematics	Grewaf
4. Trigonometry Part-I	S.L.Loncy
5. A Textbook of Mathematics for second year Pre-university	Prof.B.M.Sreenivasa Rao and S.Nagaraj

I B.Pharm 1.6:
BIOLOGY (Theory)

50 hours

Part A. BOTANY

1. General organization of the plant and plant cell and its inclusions.	2
2. The plant tissues (Meristematic and permanent).	2
3. The broad classification of the plant kingdom.	2
4. Morphology of the plant parts like root, stem and leaf and their modifications.	2
5. Inflorescence, flower and its pollination.	2
6. Morphology of fruits and seeds.	2
7. Plant taxonomy: Study of different families viz. Leguminosae, Umbelliferae, Solanaceae, Liliaceae, Zingiberaceae and Rubiaceae with special reference to medicinal plants.	6
8. Plant Physiology: Transpiration, Photosynthesis, Respiration and Growth.	4
9. The study of 1) Fungi: eg. Yeast, Penicillin., 2) Bacteria.	3

Part B. ZOOLOGY

1. The study of Animal Cell, Animal tissues, Differences between plant and animal cell.	4
2. The detailed study of frog.	6
3. The study of representatives of Pices, Reptiles and Aves with special reference to the medicinal values.	5
4. General organization of a mammal.	5
5. The study of poisonous animals.	5

BIOLOGY (Practicals)

50 hrs

Part A. Botany

1. The general organization of typical plant and morphological study of plant parts studies in theory(Roots, Stem, Leaves and their modifications).*
2. Inflorescence and flower.*
3. Fruits and seeds(Identifications).*
4. Plant tissues through permanent slides* and Histological preparations of roots, stems, and Leaves by Eosin or Saphranin stain.**
5. Simple experiments on plant physiology.*
6. Identification of cell inclusion.*

Part-B: Zoology

1. The study of Animal tissues through permanent slides.*
2. The study of various systems of Frog using charts & models. **
3. Identification of poisonous Animals.*
4. Demonstration of the dissections in Rats.*
5. Identification of representatives of Animals Phyla like fish, frog, reptile and Mammal.*

SCHEME OF EXAMINATION

1. Synopsis	-10 Marks
2. Study of any one system of frog	-15 Marks
3. Transverse Section	-15 Marks
4. Minor Experiment 1	-10 Marks
5. Minor Experiment 2	-10 Marks
6. Viva-Voce	-10Marks

Total - 70 Marks

BIOLOGY REFERENCE BOOKS

1. A class book of Botany	- A.C.Dutta.
2. Outlines of Zoology	- Ekkambarnath Iyer
3. Functional Anatomy of a mammal	- Tayler and Weber
4. Comparative anatomy	- Atwood
5. Baleys Histology	
6. A Test Book of Vertebrate zoology	- S.N.Prasad
7. Vertebrate Zoology Vol.11	- Ekkambernath Iyer

I B. Pharm
1.7: COMPUTER SCIENCE AND STATISTICS (Theory)

75 hours

PART A: STATISTICS

1. Definition, data frequency, distribution, Classification of data. General graphical representation of the data: histogram, Frequency curve and frequency polygon and Ogive. Semilog line graph. Use of semilog scale-examples. 8
2. Measures of central tendency: Arithmetic mean, geometric mean and harmonic mean. Median, Mode, Calculation of quartiles and percentiles deciles. 6
3. Measures of dispersion: Range, quartile deviation, Mean deviation, Standard deviation, variance, coefficient of variation, skewness and kurtosis. 9
4. Correlation, Regression: Linear correlation, coefficient of correlation: Karl Pearson's formula, Spearman's rank method, curve fitting by the method of least squares: Fitting a straight line $y = a + bx$, Fitting a power curve $y = ax^n$, Fitting an exponential curve $y = ab^x$, $y = ae^{ax}$, Regression analysis for lines. 12
5. Definition of probability: Random experiment, sample space, Addition and multiplication laws of probability (without proof), probability distribution: binomial, Poisson's, normal and chi-square, Student test and Pharmaceutical examples. 10

PART B: COMPUTER SCIENCE

1. Introduction to computers:
 - a. History and evolution of computers, digital and analogue computers, major components of digital computers, word length of a computer, microprocessor, single chip micro computers (micro controllers), large and small computers, user interface, hardware, software and firmware. Operating systems. DOS, windows. Introduction to Linux, batch processing, multi programming and multi user system. Computer network: LAN, WAN, Parallel processing, Flynn's classification of computers. 7

2. Introduction to Programming:
 - a. Definition of a programme, types of programming language: machine language, decimal number system, binary number or base 2 system, conversion of a binary number to decimal number, conversion of a decimal number to a binary number. Binary addition and subtraction, high level language, types of high level language. 4
3. Language: Basics of programming: Algorithm, flow chart:
 - a. Introduction to C language: Development of C, Features, constants and variables, data types, operators and expressions, library functions. I/O statements: Formatted and unformatted I/O, scan (), print f (), getchar () and put char () function
 - b. Control structures: conditional and unconditional, if, for, while, switch, break and continue, goto statement. Arrays: one and multidimensional arrays, strings and string functions, bubble sort, linear and binary search. Functions: definition, different types, calling a function, passing parameters, call by reference, and call by value, local and global variables, recursive function 17
4. Computer graphics, computer application and clinical studies 2

COMPUTER SCIENCE (Practicals)

50 hours

1. Ms.Dos commands, Unix, MS-office
2. Study of software package: MS-OFFICE
3. Study of simple C programmes as follows:
 - Get a character and display the same using getchar () and putchar ()
 - Printing the reverse of an integer
 - Printing the odd and even series of N numbers
 - Get a string and convert the lowercase to uppercase and vice-versa using getchar () and Putchar()
 - Finding the occurrence of a particular character in a string
 - Accept N words and make it as a sentence by inserting blank spaces and a full stop at the end
 - Finding the first N terms of Fibonacci sequence
 - Printing and Multiplication tables of 2 matrices
 - Printing and subtraction of two matrices
 - Converting a hexadecimal number into its binary equivalent

COMPUTER SCIENCE REFERENCE BOOKS

1. Kapoor and Saxena, Mathematical statistics.
2. SC Gupta, Fundamental of statistics.
3. D.N.Elhance and Veen Elhance, Practical problems in statistics.
4. V.Rajaraman and H.V.Sahasraboudhe, Computer programming in Cobol.
5. Thomas Worth, Cobols for beginners.

STATISTICS REFERENCE BOOKS

1. PM. Steven, and K. Andreas, Applied stastics in the Pharmaceutical Industry, 310/STE, 2001.
2. B. H. Munrao, Statistical methods for health care research, Lippinocott company publication, 4^m edition 2000.
3. M. Pagano, Kimberlee, Gauvreau. Principles of Biostastics, Lib of American Publication, 10th edition 2000.
4. B.K. Gotteti and K.S. Patricia, Stastics, Jones and Bartlet Publication London, 1994.

**I B.PHARM 2.1: PHYSICAL
PHARMACEUTICS (Theory)**

75 hours

1. Physical properties of drug molecules: Refractive index, optical rotation, dielectric constant, dipole moment, dissociation constant, determination and applications. 5
2. pH, buffers and isotonic solutions: Sorensen's pH determinations (electrometric and calorimetric), applications, buffer equation, buffer capacity, buffers in pharmaceutical and biological systems, applications, buffered isotonic solutions. 7
3. Solubility phenomena: Solvent -solute interactions, solubility of gas in liquids, solubility of liquids in liquids (binary solutions, ideal solutions, Raoult's law, real solutions, distillation of binary mixtures, azeotropic mixtures and fractional distillation. Partially miscible liquids (conjugate mixtures), critical solution temperatures, applications, phenol-water system, triethylamine-water system, nicotine-water system. Solubility of solids in liquids: Definitions, determinations, factors influencing the solubility. 8
4. Distribution law: explanation, limitations and applications, effect of molecular association, dissociation and complexation. 5
5. Kinetics: Rates and molecularity of a reaction, determination of order, factors influencing rate of reactions, stabilization of drugs, applications of chemical kinetics to the stability testing of pharmaceuticals. Simple numerical problems. 8
6. Interfacial phenomenon: Liquid interfaces, adsorption at liquid/solid interfaces, adsorption isotherms, concept of contact angle, hydrophile lipophile balance, spreading coefficient, Gibb's adsorption equation, electrical properties of interfaces. 7
7. Diffusion and dissolution: Steady state diffusion, types of diffusion, diffusion equation, diffusion cells, Dissolution of tablets and capsules, Hixon-crowell cube root law. Dissolution apparatus; factors affecting dissolution. 6
8. Rheology: Newtonian and Non-newtonian systems, thixotropy, determinations of rheological properties (Single and multipoint instruments). Applications to pharmacy. 6
9. Micromeritics: Particle size distribution, methods for determining particle size, shape and surface area. Derived properties of powders. Simple numerical problems. 6

10. Coarse dispersions: Suspensions: Settling in Suspension, wetting, Controlled flocculation - flocculation in structured vehicles, Rheological consideration, preparation, physical stability and evaluation of suspensions.

Emulsions: Definition, mechanism of action of emulsifying agents, theories of emulsification. Formulation of emulsions-instability of emulsions, evaluation of emulsion stability. Rheology of emulsions, microemulsions, multiple emulsions 6
11. Colloids: Definition types, preparation, purification, stabilization of colloids, properties, optical properties, kinetic properties, electrical properties. Donnan membrane phenomenon. 6
12. Complexation: Types of complexes, metal complexes, organic molecular complexes, inclusion compounds, methods of analysis of complexes. 5

PHYSICAL PHARMACEUTICS (Practicals)

75 hours

1. Determination of viscosity of liquids using Ostwald's viscometer.*
2. Determination of surface tension of liquid by drop weight method.*
3. Preparation of buffers and measurement of pH using pH meter. *
4. Determination of dissociation constant and pKa values.*
5. Determination of solubility of solids in liquid.*
6. Study of flow properties of granules viz., rate of flow, angle of repose, bulk density.*
7. Preparation of deflocculated and flocculated suspension and their evaluation. *
8. Preparation, stabilization and evaluation of hydrophobic colloids.* *
9. Determination of partition coefficient of Iodine between water and carbon tetrachloride. * *
10. Determination of partition coefficient of Benzoic acid between Benzene and water.* *
11. Determination of % composition of sodium chloride and water using CST method.* *
12. Determination of HLB number of surfactants by Griffins method. * *
13. Determination of rate constant for first order and second order reactions. * *
14. Study of particle size distribution by optical microscopy.*
15. Determination of required HLB number for the oil phase to be presented as an emulsion. Formulation and evaluation of emulsion.* *
16. Determination of constants of Freundlich and Langmuir adsorption for adsorption of acetic acid on activated charcoal.**
17. Determination of stability constant of Glycine-Copper complex by pH titration method.**
18. Determination of CMC of a surfactant by surface tension measurements by stalagmometer method.**

19. Construction of rheograms and study of rheological behaviour of biphasic systems employing multipoint viscometers. (For demonstration)

SCHEME OF EXAMINATION: Practical and Viva Voce

1. Synopsis	-10 Marks
2. Major experiment(Experiments indicated by**)	-30 Marks
3. Minor experiment (Experiments indicated by*)	- 20 Marks
4. Viva voce	-10 Marks

Total - 70 Marks

PHYSICAL PHARMACEUTICS REFERENCE BOOKS

1. Alfred. Martin, P Bustamante, A.H.C.Chun, Physical Pharmacy, B.I.Waverly, Pvt.Ltd., New Delhi, 4th edition, 1995.
2. E.A.Rawlins, Bentley's textbook of Pharmaceutics, English language book Society, 8th edition, 1997.
3. Cooper and Gunn, Tutorial pharmacy, Carter S.J, CBS Publishers, New Delhi, 6th edition, 2000
4. Alfonso R Gennaro, Remington: The Science and Practice of Pharmacy, Lippincott Williams and Wilkins, Philadelphia, USA, Vol I, II, 20th edition, 2000.
5. C. V. S. Subrahmanium, Physical Pharmaceutics, Vallabh Prakash, 2nd edition, 2000.

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Ostwald's viscometer	15
2. Stalagmometer	15
3. Digital pH meter	01
4. Microscopes	05
5. Stage and eye piece micrometers	05
6. Brookfield's viscometer	01
7. Digital Electronic Balance	03

II B.Pharm

2.2: PHARMACEUTICAL MICROBIOLOGY AND BIOTECHNOLOGY (Theory)

75 hours

1. Introduction to the science of microbiology. Major divisions of microbial world, and relationship among them. 2
2. Classification of microbes and study of bacteria, fungi, yeasts, actinomycetes, virus, rickettsia and spirochaetes. Study of mode of transmission and treatment of microbial diseases like, Cholera, Typhoid, Tuberculosis, Diphtheria, Tetanus, Syphilis and AIDS. 10
3. Nutritional requirements, growth and cultivation of bacteria and virus. Study of different important media required for the growth of aerobic and anaerobic bacteria and fungi. Differential media, enriched media and selective media, maintenance of laboratory cultures. 6
4. Different methods used in isolation and identification of bacteria with emphasis on different staining techniques and biochemical reactions. Counting of bacteria. Total and viable count. Bacteriological analysis of drinking water. 5
5. Detailed study of different methods of sterilization including their merits and demerits. Sterilization of equipments, validation of sterilization. Sterilization methods for all pharmaceutical products. Detailed study of sterility testing of different pharmaceutical preparations. 11
6. Disinfectants: study of disinfectants, antiseptics, fungicidal and virucidal agents. Factors affecting their activities and mechanism of action. Evaluation of bactericidal, bacteriostatic, virucidal activities, evaluation of preservatives in pharmaceutical preparations. 6
7. Introduction to genetics, Phenotypic and genotypic changes in bacteria, Mutations, genetic exchange in bacteria-transformation, transduction and conjugation. 4
8. Genetic Engineering: Study of vector, plasmids, transposons, cosmids, Restriction endonucleases and DNA ligases. Steps involved in recombinant DNA technology and its applications in the production of recombinant products like Insulin, Hepatitis B vaccine, Growth hormone and Interferon. Application of gel electrophoresis and southern blot techniques. Legislation and risks involved in the use of recombinant DNA products. 11

9. Immunology: Antigen, structure and formation of antibodies, antigen-antibody reactions. Diagnostic tests such as Shick's test, Elisa test (HIV), Widal, Mantoux and VDRL. Methods involved in production of Vaccines- Polio myelitis, BCG, Typhoid, Diphtheria and Tetanus toxoid and production of Sera- Diphtheria antitoxin. 8
10. Fermentation: Introduction to fermentation technology. Methods of production of Penicillin, Streptomycin, Riboflavin and Cyanocobalamin. 4
11. Principles and methods of different microbiological assays including sensitivity testing, microbiological assay of Cephelexin, Streptomycin and Vitamin B₁₂. Standardisation of vaccines and sera. 4
12. Animal tissue culture- techniques, nutritional requirements and characters of animal cell cultures. Hybridoma technology. Production and application of monoclonal antibodies. 4

PHARMACEUTICAL MICROBIOLOGY AND BIOTECHNOLOGY (Practicals)

75 hours

1. Study of apparatus used in experimental microbiology.
2. Sterilisation of glasswares, Preparation and Sterilisation of media.
3. Staining techniques-Simple staining*, Gram's staining. **
4. Motility testing*
5. Total and viable count*.
6. Isolation and maintenance of pure culture*.
7. Biochemical tests. (IMViC reactions, Carbohydrate fermentation)*.
8. Sensitivity testing.*
9. Determination of MIC*
10. Microbiological assay of antibiotics by cup plate method*.
11. Sterility testing by direct transfer and membrane filtration technique*.
12. Bacteriological analysis of water by MPN technique*.
13. Estimation of DNA by spectroscopic method. * *
14. Estimation of RNA on spectroscopic method. **

SCHEME OF EXAMINATION

1. Synopsis	-10 Marks
2. Major Experiment**	-20 Marks
3. Major Experiment**	-20 Marks
4. Minor Experiment*	-10 Marks
5. Viva-Voce	-10 Marks

Total -70 Marks

Pharmaceutical Microbiology And Biotechnology Reference Books

1. W.B Hugo and Russel .Pharmaceutical Microbiology, eth Ed, Blackwell Scientific Publications, London.,1998.
2. Bergey's Manual of Determinative Microbiology 9th Ed, Williams and Wilkinson, 1994.
3. Collins C.H. Microbiological Methods. 6th Ed, Butterworth, London. 1989.
4. Cooper & Gunn's-Tutorial Pharmacy, 9th Ed, CBS Publisher and Distribution, 1986.
5. Frobishers, Fundamentals of Microbiologyth Ed, Toppan Company Ltd. Tokyo. Japan.
6. Pelczar Reid, Microbiology, 5th Ed, Tata MC Graw- Hill Publishers company, 1993.
7. Pharmacopoeia of India Govt, of India 1966 & 1996 editions
8. Prescott, Harley and Klein's Microbiology 2nd Ed, W. C Brown Publishers, 1993.
9. Roitt, Immunology, 4th Ed, Harwood academic publishers, Mosby, London.1997.
10. S.P Vyas.and Dixit Pharmaceutical Biotechnology, 1st Ed, CBS Publishers & distributors, New Delhi, 1998.
11. S.S Kori Pharmaceutical Biotechnology, .Fundamentals and Applications, 1st Ed Vallabh Prakashan, New Delhi
12. Stanier, Ingraham, General Microbiology 5th Ed., Wheeliesand Painter. 1987.
13. Bentley's Text Bookof Pharmaceutics by Rawlins 8th Ed, ELBS publication, 1984.
14. WatsonJ.D. Recombinant DNA Technology, 2nd Ed, Scientific American Books Limited, 1992
15. Ananth Narayan and Pannicker, Text Book of Microbiology, Sth Ed, Orient-longman, Chennai, 1995-

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Autoclave	02
2. Hotairoven	01
3. B.O.D. Incubator	01
4. Refrigerator	01
5. Laminar air flow	01
6. Colony counter	02
7. Zone reader	01
8. Spectrophotometer	01
9. Microscope with stage and oil immersion objective	20
10. Balances	20
11. Sterility testing unit	01

II B.Pharm 2.3: PATHOPHYSIOLOGY (Theory)

75 hours

1. Basic principles of cell injury and adaptation:
 - i) Causes, pathogenesis and morphology of cell injury 3
 - ii) Abnormalities in lipoproteinaemia, glycogen infiltration and glycogen storage disease 3
2. Inflammation:
 - A)
 - i) Pathogenesis of acute inflammation
 - ii) Chemical mediators in inflammation.
 - iii) Pathogenesis of chronic inflammation 5
 - B) Repairs of wounds in the skin, Factors influencing healing of wounds. 2
3. Diseases of Immunity:
 - i) Introduction to T and B cells
 - ii) MHC proteins or transplantation antigens.
 - iii) Immune Tolerance 3
 - A) Hypersensitivity:
 - i) Hypersensitivity type I, II, III, IV
 - ii) Biological significance of hypersensitivity.
 - iii) Allergy due to food, chemicals and drugs. 4
 - B) Auto-immunity:
 - i) Mechanism of Autoimmunity.
 - ii) Classification of autoimmune diseases in man.
 - iii) Transplantation and allograft reactions, mechanism of rejection of allograft. 5
 - C) Acquired Immune Deficiency Syndrome (AIDS) 2
 - D) Amyloidosis 1

4. Cancer:	
Disturbances of growth of cells,	
General biology of tumors,	
Differences between benign and malignant tumors	
Classification of tumors Histological diagnosis of	
malignancy Etiology and pathogenesis of cancer	
Invasions, metastasis, patterns of spread of cancer.	10
5. Shock: Types, mechanism, stages and Management	2
6. Biological effects of radiation:	1
7. Environment and Nutritional diseases:	
i) Air pollution and smoking - SO ₂ , NO, NO ₂ , CO	
ii) Protein calorie malnutrition, vitamins, obesity, starvation.	5
8. Pathophysiology of common diseases:	
i) Parkinsonism	1
ii) Schizophrenia	1
iii) Depression and Mania	1
iv) Stroke (Ischemic and Hemorrhage)	1
v) Hypertension	2
vi) Angina	1
vii) Myocardial Infarction	1
viii)	CC
F	1
ix) Atherosclerosis	1
x) Diabetes Mellitus	2
xi) Peptic ulcer and inflammatory bowel disease	2
xii) Cirrhosis and Alcoholic liver diseases	2
xiii) Acute and chronic renal failure	1
xiv) Asthma and chronic obstructive airway diseases	2
9. Infectious diseases Hepatitis -	
infective hepatitis,	
Sexually transmitted diseases (Syphilis, Gonorrhea, HIV)	
Pneumonia, Typhoid, Urinary tract infections, Tuberculosis, Leprosy, Malaria, Dysentery (Bacterial and amoebic)	10

PATHOPHYSIOLOGY REFERENCE BOOKS

1. General Pathology-Y.M. Bhende, S.G. Deodhare, S.S. Kelkar (Popular Prakashan).
2. Essential Pathology-Emanuel Rubin, John L., Farber J.B. Lippincott company.
3. Text book of Robbins Pathology Basis of Disease - Robbins, Cotran, Kumar, Prism Indian Edition.
4. Pocket comparison to Robbins Pathologic Basis of Disease, 5th Edition - Robbins, Cotran, Kumar, Prism Indian Edition.

II B.Pharm 2.4: APPLIED BIOCHEMISTRY (Theory)

75 hours

1.	Bio chemical organization of the cell and transport processes across cell membranes.	3
2.	Bio energetics	3
	a) Concept of free energy and its determination; redox potential;	1
	b) Energy rich compounds; ATP; Cyclic AMP; their biological significance	2
3.	Biological Oxidation	5
	a) Electron transport chain (its mechanism and role)	2
	b) Inhibitors and Uncouplers of ETC	1
	c) Oxidative phosphorylation	1
	d) Substrate level phosphorylation and oxidative phosphorylation	1
4.	Enzymes and Coenzymes	14
	a) Definition; Nomenclature; IUB Classification	1
	b) Properties of enzymes;	1
	c) Factors effecting enzyme activity;	2
	d) Enzyme kinetics (Michaelis plot; Line Weaver Burke plot)	2
	e) Enzyme Inhibition (with examples)	1
	f) Iso-enzymes	1
	g) Enzyme Induction; repression	1
	h) Applications of enzymes	1
	i) Coenzymes, categories of reactions requiring coenzymes;	4
	a. Structure of, its coenzyme, and biochemical role of	
	b. Vitamins- water soluble, fat soluble	
5.	Carbohydrate metabolism	12
	a) Introduction	1
	b) Glycolysis,	2
	c) Glycogenesis glycogenolysis,	1
	d) TCA cycle; (Amphibolic nature of TCA cycle)	2
	e) Gluconeogenesis	1
	f) Various shuttle systems (glycerol phosphate; Malate aspartate)	1
	g) HMP Shunt Pathway;	2
	h) Uronic acid pathway and galactose metabolism	1
	i) Glucose tolerance test and blood glucose regulation.	1
6.	Lipid metabolism *	10
	a) Introduction	1
	b) -Oxidation of saturated (palmitic acid) fatty acids	2
	c) -Oxidation of unsaturated fatty acids (-linolenic acid)	1

d)	Formation and fate of ketone bodies	1
e)	Cholesterol metabolism,	2
f)	Biosynthesis of fatty acids (de novo)	2
g)	Phospholipids and sphingolipids.	1
7.	Amino acid metabolism	11
a)	Amino acids definition, classification and significance	1
b)	General reactions of amino acids: Transamination, Deamination and decarboxylations of amino acids	2
c)	Urea cycle	1
d)	Metabolism of sulphur containing amino acids	1
e)	Catabolism of tyrosine, tryptophan, phenylalanine	2
f)	Synthesis & significance of biologically important substances: creatine, histamine, 5-HT, dopamine, noradrenaline, adrenaline.	2
g)	Porphyrins, Bile Pigments: Hyperbilirubinemia	2
8.	Nucleotides and Nucleic acids	12
a)	Introduction	1
b)	Purine nucleotides biosynthesis	1
c)	Pyrimidine nucleotides biosynthesis	1
d)	Catabolism of purines and pyrimidines	1
e)	DNA structure, significance as genetic material	1
f)	RNA types, structure and significance	1
g)	DNA replication	1
h)	Mutation and repair of DNA	1
i)	Transcription or RNA synthesis	1
j)	Genetic code	1
k)	Translation or protein synthesis and its Inhibition	2
9.	Principles and significance for following Biochemical tests	5
a)	Kidney function tests	2
b)	Liver function tests	2
c)	Lipid profile	1

APPLIED BIOCHEMISTRY (Practical)

75 hours

1. Identification of carbohydrates (Scheme and identification)
(glucose, fructose, lactose, maltose, sucrose)
- 2 Identification of proteins (Scheme and identification)
(casein, albumin, gelatin, peptone)
3. Quantitative estimation of carbohydrates (any one method)
DNS reagent
Anthrone Reagent
4. Quantitative estimation of proteins (any one method): Biuret Reagent, Lowry's Reagent
5. Qualitative analysis of Urine
 - a) For Normal constituents
 - b) Abnormal constituents
6. Quantitative Urine analysis
 - a. Titrable acidity and ammonia
 - b. Estimation of reducing sugars in Urine (benedicts method)
 - c. Estimation of chlorides in Urine
 - d. Estimation of Creatinine in Urine
 - e. Estimation of calcium in Urine
7. Quantitative analysis of blood
 - a. Estimation of glucose in blood (Folin-Wu method)
 - b. Estimation of creatinine in blood
 - c. Estimation of cholesterol in blood
 - d. Estimation of urea in serum
 - e. Estimation of SGOT in serum
 - f. Estimation of SGPT in serum
8. Enzyme
 - a. Salivary amylase activity
 - b. Effect of temperature on enzyme (amylase) activity
 - c. Effect of pH on enzyme (amylase) activity
9. Preparation of Std. Buffer solutions (Acetate; Borate; Carbonate; Citrate and Phosphate) and measurement of pH (any two)

SCHEME OF EXAMINATION : Practical and Viva Voce

1. Synopsis	-10 Marks
2. Urine Analysis	-15 Marks
3. Titrimetric Experiment	-20 Marks
4. Colorimetric Experiment	-15 Marks
5. Viva	-10 Marks
Total	-70 Marks

APPLIED BIOCHEMISTRY REFERENCE BOOKS

- 1) Harpers Review of Biochemistry- Martin
- 2) Text book of Biochemistry - Lehninger
- 3) Outlines of Biochemistry - Conn and Stump
- 4) Text Book of Biochemistry - Harron and Mazur
- 5) Hawk's Physiological Chemistry- Oser
- 6) Text Book of Biochemistry-Varun Kumar Malhotra
- 7) Hand Book of Basic Pharmacokinetics- Pitachel

LIST OF MINIMUM EQUIPMENTS REQUIRED

1) Colorimeter	01
2) Centrifuge	01
3) Electronic Balance	01
4) Physical/Chemical Balance	01
5) pH meter	01
6) Water bath	
a) Temperature controlled	01
b) Ordinary	01
7) Volumetric flasks	60
8) Pipettes	
a) Graduated	
b) Bulb	
9) Burettes	20
10) Conical flasks	20
11) China dish	20
12) Burners	20
13) Glass wares such as measuring cylinders, reagent bottles, glass rods, tubes etc.	
14) Folin-Wu tubes	120

II B.Pharm
2.5: PHARMACEUTICAL ORGANIC CHEMISTRY-II (Theory)

75 hours

The subject is to be treated in the light of modern perspective giving stress wherever possible on the following aspects-structure, nomenclature, preparation, properties, energy of activation, transition state, resonance, stereochemistry, optical isomerism, Geometric isomerism and mechanism of reaction.

I. Stereochemistry:

1. Stereo isomerism, tetrahedral optical activity, enantiomerism, diastereoisomerism, meso structures, elements of symmetry, chirality, chiral centers, reaction of chiral molecules, configuration, specification of D and L configuration. Nature of E and Z forms. Racemic modification and resolution of racemic mixture, conformational isomers, asymmetric synthesis. 12
2. Stereo selective and stereospecific reactions. Stereochemical mechanisms for the following reaction such as addition of halogen to alkenes, E^1 and E^2 reactions, syn and anti reactions, and nucleophilic substitution reactions. 4
3. Geometrical isomerism, its nature of formation, rotation about bonds: nomenclature of isomers, determination of configuration. 4
4. Stereochemistry of alicyclic compounds and biphenyls, stereochemistry of oximes. 3

II. Heterocyclic Chemistry:

1. General classification of heterocyclic compounds, nature and nomenclature, reactions, synthesis and properties of the following heterocyclic systems and their derivatives.
 - a) Pyrrole, Furan and Thiophene 7
 - b) Fused ring systems involving Pyrrole, Furan, Thiophene, Indole and Benzofuran 4
 - c) Pyridine 4
 - d) Quinoline, Isoquinoline, acridine 3
 - e) Pyrazole, Imidazole, Oxazole, Isoxazole 4
 - f) Pyrimidine, Pyrazine, Pyridazine, Purine, benzodiazepines

1. Study of basic structures, compounds having pharmacological activity/medicinal compounds of tricyclic hetero ring systems-phenothiazines, and benzodiazepines. 3
2. Structure and medicinal uses of the following official compounds
 1. Phenazone 2.Nicotinicacid 3.Nikethamide 4.Isoniazid 5.Mepyramine 6.Benzhexol 1. Chloro
 - quine 8.Histamine 9.Carbimazole.10.Pyreimethamine 11. Piperazine. 12.Diazepam Diethyl
 9. carbamazine citrate 14.Sulphadiazine 15. Metronidazole. 3
- II Poly Nuclear Hydrocarbons; Synthesis (Haworth's and Diel's Alder)

properties and reactions of Naphthalene, Phenanthrene and Anthracene. Structure and medicinal uses of Propranolol, Tolnaftate, Menadione, Naphzoline,, Phenindione, Morphine and Codeine. 4
- III Chemistry of bio molecules of pharmaceutical importance:
 1. **Carbohydrates:**

Introduction, Definition, Classification, Nomenclature, Structural determination of Glucose and Fructose. Stereoisomers of monosaccharides, reactions, conversions, configuration, cyclic structures of glucose, determination of ring size in Glucose. Fischer projection formulae, and conformations. Disaccharides and polysaccharides. Chemical nature of maltose, lactose, sucrose, starch and cellulose, derivatives used in pharmacy. 9
 2. **Fats and Oils:**

Chemistry of fats oils and waxes. Occurrence and composition. Hydrolysis of fats, esterification. Fats as sources of pure acids and alcohols. Analytical constants of fats and oils. Methods of their determination and significance. Unsaturated fats, hardening of oils, hydrogenation of oils, drying, semidrying and nondrying oils. 3
 3. **Proteins and Amino acids:**

Introduction, definition, classification of proteins and amino acids and their properties, reactions, synthesis of amino acids (Gabriel's Pthalimide, synthesis, Strecker's synthesis, Koop's and Erlenmeyer's azalactone synthesis). Peptide linkages, structures of proteins, C-terminal and N-terminal analysis. Isoelectric points and its significance. 6

PHARMACEUTICAL ORGANIC CHEMISTRY-II (Practicals)

75 hours

(Following experiments to be in 25 different classes)

I. Quantitative determination of organic compounds via functional groups * *

1. Phenolic group by bromination method.
2. Alcoholic group by acetylation method.
3. Carbonyl group by hydroxylamine hydrochloride-pyridine method.
4. Aldehyde group by sodium sulphite-sulphuric acid procedure.
5. Carboxyl group by acid-base method.
6. Determination of acetone by sodium hypoiodide method
7. Amino group by bromination method.
8. Amino acid Formal titration method.

II. Analysis of oils and fats: (I.P. Method).

1. Acid value.
2. Saponification value.
3. Iodine value.

III. Synthesis/preparation involving more than one step*

1. p-bromoaniline from acetanilide.
2. p-Nitroaniline from acetanilide.
3. p-Nitrophenyldrazine from p-nitroaniline.
4. 3-methyl-1-phenyl-5-pyrazole from ethyl acetoacetate.
5. Benzoic acid from benzene.
6. Phthalimide from benzophenone.
7. Phthalimide from phthalic acid.
8. Benzyl benzoate from benzaldehyde. (Cannizzaro's reaction)
9. Synthesis of 2,3-Diphenyl quinoxaline.
10. Preparation of 2,5, -Dimethyl thiophene.
11. Preparation of 2,5, -Dimethyl pyrrole.
12. Preparation of 2,5, -Dimethyl furan.

PHARMACEUTICAL ORGANIC CHEMISTRY-II REFERENCE BOOKS (Theory)

75 hours

1. E. L. Eliel, John Wiley and Son, Stereochemistry of Organic Compounds. New York, 1993.
2. I. L. Finar. Organic Chemistry Vol. I and II, Sixth Edition, 2003, ELBS.
3. R.O.C Norman and J. M. Conon, Principals of Organic Synthesis, Third Edition, 1995, ELBS,
4. Raj K. Bansal, Heterocyclic Chemistry, New age international Ltd., New Delhi, Third Edition, 2001.
5. B. S. Bhal and Arun Bhal, S. Chand, Advanced Organic Chemistry and Company, New Delhi, 2001.
6. R. J. Morrison and R. N. Boyd Organic Chemistry, Fifth Edition, Prentice Hall of India Pvt. Ltd., New Delhi.
7. J. A. Joule and L. K. Milis, Heterocyclic Chemistry Fourth edition, Blackwell Science Publisher, 2000.
8. S. M. Mukherji and S. P Singh, Reaction Mechanisms in Organic Chemistry, Third Edition Macmillan publishers, 2001.
9. T. W. G. Solomans, Organic Chemistry, Sixth Edition,, John Wiley and Son, New York, 1996.
10. I. P 1996, Govt, of India, Ministry of Health and Family Welfare, Controller of Publications, Delhi. 2000.
11. A. I. Vogel, Elementary Organic Chemistry, Part-3, Quantitative Organic Analysis, second edition, CBS Publishers and Distributors, New Delhi, 2000.
12. B. S. Furniss, A. J. Hannaford, P.W.G. Smith and A. R. Tatchell, Vogel's Text Book of Practical Organic Chemistry, Edited, Fifth Edition, Addison Wesley Longman, England, 1998.

PHARMACEUTICAL ORGANIC CHEMISTRY-II REFERENCE BOOKS (Practical)

1. A.I. Vogel, Elementary Practical organic chemistry, ELBS and Longman group Ltd., London.
2. Mann and Sounders, Practical Organic Chemistry-ELBS and Longman group Ltd.,
3. D.L. Pavia, G. Lampman and G.D. Kriz. Introduction to Organic Laboratory Techniques.
4. I.P, Govt, of India, Ministry of Health and Family welfare, 3rd Edition (1985), 4th Edition (1996).
5. A. I. Vogel, Text Book of practical organic chemistry, ELBS Longman, London, 4th edition.

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Suction Pumps	01
2. Analytical Balances	01
3. Physical Balances	05
4. Triple Beam Balances	
5. Water Baths, Reflux flask and condenser	10
6. Hot Plates	
7. Mechanical Stirrers	
8. Magnetic Stirrers with Thermostat	
9. Distillation Unit	01
10. Refrigerator	01
11. Oven	01

SCHEME OF EXAMINATION

1 Synopsis	-10 Marks
2 Major Experiment (**)	-30 Marks
3 Minor Experiment (*or oil analysis)	-20 Marks
4 Viva	-10 Marks

Total -70 Marks

III B. Pharm 3.1: MEDICINAL CHEMISTRY I (Theory)

75 hours

I. Basic Principles of Medicinal Chemistry

- A. A brief introduction to the subject, history and development of medicinal Chemistry, definition and fundamental principles of drug therapy. 2
- B. Effects of the following physicochemical properties of drug molecules on biological activity: Solubility, partition coefficient, hydrogen bonding, protein binding, chelation, Geometrical and optical isomers, redox potential, ionization and surface activity. 6
- C. Principles of drug design (theoretical aspects): General principles of drug action and drug receptor interactions. 2
- D. Drug metabolism: General pathways of drug metabolism, sites of drug biotransformation, role of cytochrome P-450 and monoaminoxygenase in oxidative biotransformations. Oxidative, reductive, hydrolytic and conjugation reactions. Factors affecting drug metabolism. 6

A study of the development of the following classes of drugs including structure activity relationships (SAR), mechanisms of action, synthesis of compounds underlined and superscribed by 's', chemical nomenclature, generic names, brand names (a few important marketed products and side effects).

II. Central nervous system depressants

- A. General anaesthetics:
1. Inhalation anaesthetics: Halothanes, Methoxy flurane, Nitrous oxide.
 2. Ultra short acting barbiturates: Methohexital sodiums, Thiopentalsodium,
 3. Dissociative anaesthetics: Ketamine hydrochloride. 2
- B. Anxiolytic, sedative and hypnotic agents:
1. SAR of Benzodiazepine Chlordiazepoxides, Diazepam, Oxazepam, Chlorazepam, Lorazepam, Flurazepam, Alprazolam. 1
 2. SAR of Barbiturates:
 - a) Barbitals, methabarbitol, Phenobarbitals,
 - b) Amobarbitals, Butabarbitol,
 - c) Pentobarbitals, Secobarbitol 1

3. Miscellaneous sedative hypnotics:

- a) Amides and Imides: Glutethimide⁵, Methypylon, Methaqualone.
- b) carbamate derivatives: Ethchlorvynol, Ethinamate,
- c) Aldehydes and their derivatives: Chloral hydrate⁵, Paraldehyde.

Alcohols and their
Meprobamate⁵.

C. Skeletal muscle relaxants: Chlorphenisn⁵, Methocarbamol.

6

D. Drugs used in spasticity: Baclofen, Buspirone.

E. Anticonvulsants:

- 1. Mechanism of anticonvulsant action.
- 2. Barbiturates: Phenobarbitone.
- 3. Hydantoin: Phenyton sodium. Ethtoin, Mephyntoin
- 4. Oxazolidine diones: Triemethadione⁵, Paramethadione
- 5. Succinimides: Phensuximides, Methsuximide⁵, Ethosuximide.
- 6. Urea and monoacylureas: Phenacetamide⁵, Carbamazepine⁵.
- 7. Miscellaneous: Primidone⁵, Valproic acid.

8. Benzodiazepines: Clonazepam⁵, Diazepam, Chlorazepam.

3

III. Adrenergic agents:

A. Adrenergic neuro transmitters: function, structure and physicochemical Properties, biosynthesis and metabolism of noradrenaline. 1

B. Adrenergic receptors: alpha and beta-adrenergic receptors, their distribution in the human body. 1

C. Sympathomimetic agents:

- 1. Direct acting agents: Definition and examples: Phenylethylamine, Noradrenaline
- 2. Indirect acting agents: Definition and examples: Isoproterenol⁵, Terbutalin.
- 3. Agents with mixed mechanism: Examples: Clonidine⁵,
- 4. Alpha adrenergic receptor agonists: Examples: Ergotamine.
- 5. Beta adrenergic receptor agonists: examples: Pseudoephedrine.
- 6. Aliphatic amines: Triaminoheptane, Cyclopentamine⁵,
- 7. Imidazoline derivatives: Naphazoline⁵, Tetrahydrozoline, Oxymetazoline, Xylometazoline. 4

}. Adrenergic blocking agents

- 1. Neuronal blocking agents: Alpha-adrenergic blocking agents-ergot alkaloids.
- 2. Beta halo alkyl amines: Dibenzamine, Phenoxybenzamine⁵
- 3. Imidazolines: Tolazoline, Phentolamine⁵, Prazocin.

4. Beta adrenergic blocking agents: Propranolol⁵,
4-hydroxy propranolol, practolol, Metoprolol. 3

IV. Cholinergic drugs and related agents.

A. Cholinergic agents;

1. Cholinergic neurotransmitter: function, structure, physiochemical properties, biosynthesis and metabolism of Acetylcholine.
Cholinergic receptors: muscarinic and nicotinic receptor, their distribution in the human body
2. Indirectly acting cholinergic agonists:
 - a) Cholinesterase inhibitors: Physostigmine⁵, Neostigmine. Pyridostigmine⁵.
 - b) Irreversible inhibitors: Malathion, Parathion. 7
- B. Cholinergic blocking agents: Parasympathetic postganglionic blocking Agents:
Atropine, Hyoscyamine, Scopolamine, Homatropine, Methscopolamine.
- C. Synthetic Cholinergic blocking agents: Clidinium bromide, Dicyclomine³, Propantheline, Benzotropine Chlorphenoxamine,
- D. Ganglionic blocking agents: Trimethaphan camsylate, Mecamylamine.
- E. Neuromuscular blocking agents: d-Tubocurarine chloride, Metocurine iodide. Synthetic compounds with curare form activity—Decamethonium bromide. 8

V. Local anaesthetics

- A. Historical development, mechanism of action of local anaesthetics.
- B. SAR of - Benzoic acid derivatives, Lidocaine derivatives.
- C.
 1. Benzoic acid derivatives: Hexylcaine, cyclomethycaine, Piperocaine⁵.
 2. Amino benzoic acid derivatives: Benzocaine⁵, Procaine⁵, Procainamide.
 3. Lidocaine derivatives (Anilides): Lidocaine⁵, Prilocaine,
 4. Miscellaneous: Dimethisoquin, Dibucaine⁵. 3

VI. Histamines and anti histaminic agents

- A. Histamine, receptors and their distribution in the human body
- B. Antihistaminic agents: H₁ antagonists.
 1. Amino alkyl ethers: Diphenhydramine hydrochloride⁵, Bromodiphenhydramine, Doxylamine.
 2. Ethylene diamines: Tripeleminamine⁵, Pyrilamine.
 3. Propylamine derivatives: Pheniramine⁵, Chlorpheniramine.
 4. Phenothiazine derivatives: Promethazine⁵, Trimeprazine.
 5. Piperazine derivatives: Cyclizine, Meclizine⁵.
 6. Miscellaneous compounds: Phenindamine, Cyproheptidine.

A.	H ₂ - Antagonists: Mechanism of H ₂ -Antagonists Cimetidine ⁵ , Ranitidine. Gastric proton pump inhibitor- an introduction Omeprazole.	6
I.	Analgesic Agents	
A)	Structure and uses of morphine, codeine and diacetyl morphine.	
B)	Narcotic Antagonists: Structure and uses of Nalorphine, Levalorphan.	
C)	Antitussive agents: Structure and uses of Noscapine, Dextromethorphan	2
D)	Peripheral and Nuclear modification of Morphine.	2
E)	Anti-Inflammatory agents	
1.	Salicylic derivatives: Sodium Salicylate	
2.	N-aryl anthranilic acid derivatives: Mefenamic acid ⁵ Diclofenac sodium.	
3.	Aryl Acetic acid derivatives: Indomethacin, Ibuprofen ⁵ , Piroxicam ⁵ .	
4.	Aniline and P-aminophenol derivatives: Phenacetin ⁵ Acetaminophen ⁵ .	
5.	Pyrazolone and Pyrazolidinedione derivatives: Antipyrin, Aminopyrin, Oxyphenbutazone ⁵ , Phenylbutazone.	4
II.	Prostaglandins and other Eicosanoids	
A.	History and discovery	
B.	Eicosanoid biosynthesis	
C.	Drug action mediated by Eicosanoids.	
D.	Design of Eicosanoid drugs.	
E.	Eicosanoid approved for human clinical use.	
F.	Prostaglandins F ₂ , Prostaglandin E ₂ , 15-(s)-methyl-PG F ₂ Prostaglandin E ₁ , 16-(R, S) methyl—16—hydroxy—methyl ester.	5

MEDICINAL CHEMISTRY I REFERENCE BOOKS (Theory)

1. Burger's medicinal chemistry M.E. Welly Medicinal Chemistry M.E. Walffed Johnwiley and sons, Vo 1,2 and 3.
2. Wilson and Giswold's Text Book of Organic and Medicinal Chemistry.
3. William. O.Foye, Principles of Medicinal chemistry, Lea and Febiger, Philadelphia.
4. Martindale, the extra pharmacopoeia, J.E.Reynolds. The Pharmaceutical Press, London.
5. A.M. Beckett and J.B. Stanlake and Garrel, Practical Pharmaceutical Chemistry, the Sthalone Press, University of London, London.
6. I.P85 and 96, Govt, of India, Ministry of Health.
7. B.S.'Furniss', A.J. Hannaford, V.Regers, PW.G. Smith and A.R.Tachell, Vogel's practical organic chemistry, including quantitative analysis. ELBS/Longman, London. textbook of

8. J.G.Mann and S.C.Saunders, Practical Organic Chemistry, Longmann Green and Co. Ltd., London.
9. Organic drug synthesis-Ledniser MitzsherVol. 1 and 2.
10. Current index of medical specialties (CIMS)

MEDICINAL CHEMISTRY I (Practicals)

75 hours

I. Monograph analysis of the following compounds *

1. Acetazolamide
2. Aminophylline
3. Ascorbic acid
4. Aspirin
5. Atropine sulphate
6. Caffeine
7. INH
8. Paracetamol
9. Sulphanilamide.

11. Assay of medically useful compounds (in solid dosage forms)**

1. Ibuprofen by alkalimetry
2. Diclofenac by alkalimetry
3. Analgin by iodimetry
4. Ephedrine hydrochloride by non-aqueous titration.
5. Phenobarbitone sodium by non-aqueous titration.
6. Procaine/Benzocaine by diazotisation.
7. Chlorpromazine by Cerrimetry.

I. Preparation of medically useful compounds*

1. Phenytoin from Benzoin.
2. Paracetamol from p-nitro phenol.
3. Benzocaine from p-amino benzoic acid.
4. 4-hydroxy coumarin from resorcinol.
2. Mefenamic acid from anthranilic acid.

- IV**
1. Degradation of Ephedrine to Benzoic acid.
 1. Degradation of Caffeine to Demethyl alloxan and methyl urea.

SCHEME OF EXAMINATION

1. Synopsis	-10 Marks
2. Assay or Estimation (Major Experiment)	
(Major experiments indicated by **)	-25 Marks
3. Preparation	-15 Marks
(Minor experiments indicated by *)	

4. Test for Identity/purity -10 Marks

5. Practical viva-voce -10 Marks

Total -70 Marks

MEDICINAL CHEMISTRY I REFERENCE BOOKS (Practicals)

1. I.P1985.
2. I.L.Finar, Textbook of Organic Chemistry.
3. Lednicer Mitzsher, The Organic Chemistry of drug synthesis, Vol. 1 and 2. '
4. A.I.Vogel, A Text Book of Practical Organic Chemistry.
5. J.G. Mann and S.C. Saunders, Practical Organic Chemistry.
6. T.Robinson, Organic constituents of higher medicinal plants.
7. CIMS.

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Suction Pumps	01
2. Analytical Balances	10
3. Physical Balances	
4. Triple beam balances	
5. Water Baths, Reflux flask and condenser	10
6. Hot Plates	01
7. Mechanical Stirrers	02
8. Magnetic Stirrers with Thermostat	02
9. Distillation Unit	01
10. Refrigerator	01
11. Fuming Hood	01
12. Oven	01

III B. Pharm

3.2: PHARMACEUTICAL JURISPRUDENCE AND ETHICS (Theory)

50 hours

1. Introduction
 - a. Pharmaceutical legislations-brief review. 1
 - b. Drugs and pharmaceutical industry-a brief review. 2
2. An elaborate (practical oriented) study of the following
 - a. Pharmaceutical ethics 2
 - b. Pharmacy Act 1948 3
 - c. Drugs and Cosmetics Act 1940 and rules 1945 (with special reference to schedule M, P, U, V and Y) 23
 - d. Medicinal and Toilet Preparations (Excise Duties) Act 1955 3
 - e. Narcotic Drugs and Psychotropic Substances Act 1985 and rules
 - f. Drugs Price Control Order, Pharmaceutical Policy 2002 3
3. A brief study of the following with special reference to the main provisions
 - a. Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 2
 - b. Prevention of Cruelty to Animals Act 1960 including study of CPSCEA guidelines, INSA & ICMR guidelines 4
 - c. Indian Patents Act with special reference to pharmaceuticals along with amendment bills, process patent and product patent 2
4. A brief study of the various prescription/non-prescription products, Medical/surgical accessories, diagnostic aids, appliances available in the market. 2

Note: The teaching of all the above acts should cover the latest amendments

PHARMACEUTICAL JURISPRUDENCE REFERENCE BOOKS

1. N.K.Jain, A text book of Forensic Pharmacy, Vallabh Prakashan New Delhi, 2002
2. Latest issues of CIMS, MIMS, PDR, DDR.
3. Remington's Practice of Pharmacy.
4. Latest issues of IDMA Bulletin
5. ICMR Guidelines
6. CPSCEA Guidelines
7. Helsinki Guidelines

III B.Pharm
3.3: PHARMACOGNOSY AND PHYTOCHEMISTRY (Theory)

75 hours

1. Isolation, purification and estimation of phytoconstituents:
 - a) General methods used for the isolation and purification of natural products including superfluid critical extraction.
 - b) General methods of identification & estimation of phytoconstituents.
 - c) Detailed study of chromatographic techniques for separation, isolation & identification of phytoconstituents.
 - d) Evaluation of natural products - Morphological, Physical, Microscopical, Chemical, Spectroscopical and Biological methods.

15
2. Biogenesis of phytopharmaceuticals:
 - a) Techniques employed in the elucidation of biosynthetic pathways.
 - b) Brief study of basic metabolic pathways
 - c) Biosynthesis of - Tropane, Quinoline, Opium and Indole alkaloids, Steroids and Anthraquinone glycosides.

10
3. Glycosides:
 - a) Definition, general characters and classification.
 - b) Definition, general properties, chemical nature, general methods of isolation, estimation and uses of the followings:
 - i) Cardiac glycosides ii) Anthracene glycosides iii) Saponins
 - iv) Cyanogenetic glycosides v) Flavonoids vi) Lactones and bitter glycosides
 - vii) Isothiocyanate glycosides.
 - c) Sources, diagnostic characters, constituents, uses and adulterants of (i) Digitalis (ii) Strophanthus (iii) Squill (iv) Senna (v) Rhubarb (vi) Cascara (vii) Aloes (viii) Ginseng (ix) Liquorice (x) Solanum species (xi) Wild Cherry (xii) Bitter almond (xiii) Quassia (xiv) Dioscorea (xv) Citrus bioflavanoids (Lemon and Orange peel) (xvi) Mustard.

16
4. Alkaloids:
 - a) Definition, general properties, chemical tests, general methods of isolation and estimation of alkaloids.
 - b) Sources, diagnostic characters, constituents, uses and adulterants of:
 - (i) Lobelia (ii) Solanaceous drugs (iii) Cinchona (iv) Ipecac
 - (v) Opium (vi) Rauwolfia (vii) Ergot (viii) Nux-vomica (ix) Vinca
 - (x) Taxus species (xi) Aconite (xii) Kurchi (xiii) Ephedra (xiv) Colchicum

14
5. Essential Oils:
 - a) Introduction, definition, general properties, chemical nature, and classification.
 - b) Source, diagnostic characters, chemical constituents and uses of:
 - (i) Clove (ii) Cinnamon (iii) Coriander (iv) Fennel (v) Eucalyptus
 - (vi) Mentha piperita (vii) Sandal wood.

c) Methods of production and analysis of -Clove, Cinnamon, Eucalyptus, Mentha and Sandal wood oils. 10

6. Resins:

- a) Study of properties, classification and method of production
- b) Sources, diagnostic characters, active constituents, uses and adulterants of:
 - (ii) Cannabis (ii) Podophyllum (iii) Ginger (iv) Capsicum (v) Benzoin (vi) Asafoetida (vii) Colophony.

6

7. Tannins:

- a) Definition, properties, classification, general method of isolation, estimation and uses of tannins.
- b) Source, chemical constituents, tests and adulterants of
 - (i) Catechu (ii) Tannic Acid (iii) Nutgall

4

PHARMACOGNOSY AND PHYTOCHEMISTRY (Practicals)

75 hours

1. Quantitative Microscopy**.

- i. Ratio Values: Stomatal number and Stomatal Index.
- ii. Determination of dimension of starch grains and lengths of fibre using eye piece micrometer and camera lucida methods.
- iii. Determination of starch grains using lycopodium spore method.

2. Chemical tests for Asafoetida, Benzoin, Tannic acid, Pale catechu, Black catechu, Aloes *

3. Determination of Proximate Values :*

- (i) Moisture Content (ii) Ash Value (iii) Extractive Values

4. Study of Morphology of drugs:*

Strophanthus, Squill, Rhubarb, Cascara, Ginseng, Liquorice, Senna, Wild cherry bark, Bitter almonds, Cinchona, Ipecac, Rauwolfia, Ergot, Nux-Vomica, Vinca, Aconite, Kurchi, Ephedra, Colchicum, Fennel, Clove, Cinnamon, Coriander, Eucalyptus, Ginger.

5. Study of Powder Microscopy (including analysis of mixture) **

Digitalis, Squill, Senna, Rhubarb, Cascara, Liquorice, Wild Cherry Bark, Lobelia, Cinchona, Ipecac, Rauwolfia, Kurchi, Ephedra, Clove, Cinnamon, Coriander, Fennel, Ginger.

5. Production of volatile oils, resins, tannins.*

SCHEME OF EXAMINATION

1. Synopsis	-10 Marks
2. Quantitative Microscopy**	-20 Marks
3. Powder Microscopy**	-20 Marks
4. Minor Experiment*	-10 Marks
5. Viva-Voce	-10 Marks/

Total -70 Marks !

PHARMACOGNOSY AND PHYTOCHEMISTRY REFERENCE BOOKS

1. Kokate C.K. Purohit A.Pand Gokhale S.B., Text book of Pharmacognosy, 14th Ed, Nirali Prakashan, Pune, 1996.
2. Kokate C.K., Purohit A.P and Gokhale S.B., Pharmacognosy, 22nd Ed, Nirali Prakashan, Pune, 2003.
3. Trease G.E. and Evans, W.C., Pharmacognosy, 15th Ed, Bailliere Tindall, Eastbourne, U.K., 2002
4. Tyler V.E., Brady R, Textbook of Pharmacognosy, 8th Ed, Leaand Febiger, Philadelphia, 1981.
5. Eghon Stahl, Thin Layer Chromatography, 2TM Ed, Springer - Verlag, Berlin, Heidelberg, New York., 1969.
6. Wagner H and Bladt S, Plant Drug Analysis, TLC Atlas, 2nd Ed, Springer- verlag 1984.
7. WallisT.E., Textbookof Pharmacognosy, 5^h Ed, J.A., Churchill Limited, London., 1985.
8. Betty P Jackson and Derek W. Snowdon. Powdered Vegetable Drugs, J & A Churchill Ltd., 1968.
9. Brain, K.R. and Turner T.D., The Practical Evaluation of Phytopharmaceuticals, Wright-Scientechnica, Bristol
10. Manske R.H.F., The Alkaloids- Academic Press, New York.
11. Manitto P, the Biosynthesis of Natural Products, Ellis Horwood, Chichester.
12. Denston T.C., A textbook of Pharmacognosy, 5ⁿ Ed., Pitman Medical Publishing Co. Ltd., 1958.
13. Iyengar M.A., Study of Crude Drugs, Manipal Power Press Manipal., 14^m Ed, 2001.
14. Iyengar M.A. and Nayak S.G.K., Anatomy of Crude Drugs, 8th Ed, Manipal Power Press, Manipal., 2001.
15. Iyengar M.A., Pharmacognosy of Powered Crude Drugs, 6th Ed., Manipal Power Press Manipal., 2001.

16. Jean Bruneton, Pharmacognosy, Phytochemistry, Medicinal Plants 2nd Ed, Lavoisier Publishing House, 1995.
17. Herbal Pharmacopoeia of India, Government of India, Ministry of Health, Vol I & Vol (1998 & 2001)

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Camera lucida	20
2. Eye piece micrometer	20
3. Stage micrometer	20
4. Microscope with stage	20
5. Clavengersapparatus	20
6. Heating mantle	01
7. Incinerator	01
8. Moisture balance.	01
9. Vaccumpump	02
10. Balances	20

III B.Pharm

3.4: PHARMACEUTICAL ENGINEERING (Theory)

75 Hours

1. Stoichiometry: Unit Processes, material and energy balances, units and their conversions
Dimensional formulae, dimensionless numbers. 2
2. Fluid flow:
 - a) Fluid statics: hydrostatic pressure, definition of heads, manometers,
 - b) Fluid dynamics: mechanism of fluid flow, Reynolds's experiment, Bernoulli's theorem and its applications, Flow meters-, orifice meter, venturimeter, pitot tube and rotameter 6
3. Heat transfer: Concept of heat flow by conduction through single wall, applications of Fourier's law, Forced and natural convection, surface coefficients, Boiling liquids, Condensing vapors, Temperature gradients in parallel and counter current heat exchangers. Heat interchangers, Radiation, black body, Stefan-Boltzmann equation, Kirchoff's law. 6
4. Evaporation: Basic concept of phase equilibria, factors affecting evaporation. Evaporators, - film evaporators, single effect and multiple effect evaporators, theory and economy. 5
5. Distillation: Raoult's law, Volatility, simple, steam and flash distillations. Principles of rectification, azeotropic, molecular and extractive distillation. 6
6. Drying: Moisture content and mechanism of drying, factors affecting drying. Classification and types of dryers, dryers used in pharmaceutical industries. Construction and working of tray dryer, fluidized bed dryer, drum dryer, vacuum Dryer, Freeze dryer and Spray dryer. 5
7. Size reduction: Definition, objectives of size reduction, factors affecting size reduction, laws governing energy and power requirements of a mill, types of mills, construction and working of ball mill, hammer mill, fluid energy mill, Edge runner and end runner mill. 3
8. Size separation: Different techniques of size separation- sieves, sieve shakers, sedimentation tanks, Mechanical classifiers, Cyclone separators, Air separators, Bag Filter. 3

1. Mixing: Theory of mixing, solid-solid, solid-liquid and liquid - liquid mixing. Equipments- tumbler, V-cone, double cone, ribbon blenders, Sigma blade and planetary, zig-zag mixers. Mixing devices, - Propellers, turbines, paddles, and baffles. Vortex formation and prevention. Homogenisation, and homogenisers 6
2. Material handling system: Construction and working of a belt conveyor screw conveyor, pneumatic conveyor, cycloidal blowers and chain conveyers. 5
3. Filtration and Centrifugation: Theory of filtration and Kozeny's equation, classification of industrial filters, Construction and working of filter press, filter leaf, meta filter, candle filter. Filter aids. Theory and principle of centrifugation, classification of industrial centrifuges. Centrifuges, - basket, tubular bowl, conical disc, semi continuous, and continuous horizontal centrifuges. 5
4. Crystallization: Crystal habits, solubility curves, Mier's theory, construction and working of agitated batch crystalliser, Swenson-walker, Krystal and Vacuum crystallisers. Caking of crystals. 6
5. Humidification, Airconditioning and Refrigeration: Definition of humidity, humid heat, humid volume, study of psychrometric charts, wet bulb theory, theory of air conditioning and air conditioner. Refrigerator-, single stage refrigeration, Molliers diagram, coefficient of performance, and their application to pharmacy. 6
6. Materials of construction: Iron, Steel, lead, glass, aluminum, rubber and plastic as construction materials. 5
7. Corrosion: Classification and mechanism of corrosion, Factors, Prevention and control. 3
8. Plant location: Layout, utilities and services. Industrial hazards and safety measures. 3

PHARMACEUTICAL ENGINEERING (Practicals)

100 hours

1. Drying of wet granules and to plot the rate of drying curves. * *
2. Operation of Ball mill and to calculate Rittinger's and Kick's coefficient**.
3. Operation of sieve shaker and sieve analysis and deriving various statistical parameters. * *
4. Particle size measurement by Stoke's law. * *
5. Determination of mixing index of blenders for solid mixture using salicylic acid.*
6. Rate of filtration studies, Calculation of specific cake and filter medium resistance. * *
7. Determination of water vapor permeability across the packaging material.*
8. Experiment to determine the leaching of contents from packaging material: Ampoules and Vials.**
9. Analysis of pharmaceutical packaging materials- Corrugated box.*
10. Mixing: Determination of mixing efficiency when propeller blade is introduced in different positions.**
11. Homogenising: measurement of efficiency of Homogenization.**
12. Methods of crystallization, study of crystal habit.*
13. Steam distillation: collection of volatile oil (Demonstration)
14. Evaporation: factors affecting the rate of evaporation.* *

SCHEME OF EXAMINATION

1. Synopsis	-15 Marks
2. Experiment (One only) Two	
i) Major** :25M	
ii) Minor* :20M	-45Marks
3. Viva voce	-10 Marks
Total	-70 Marks

PHARMACEUTICAL ENGINEERING REFERENCE BOOKS

1. Cooper and Gunn, Tutorial pharmacy, CBS Publishers and Distributors, 6th edition, 1986.
2. Walter. L. Badger and Julius T. Banchero, Introduction to Chemical Engineering, Me Graw Hill Series.
3. Max Peters, Elementary Chemical Engineering, 2nd edition Me Graw Hill International Book Company, 1984.
4. Don. W. Green and James. O. Maloney. Perry's Chemical Engineer's Handbook, edition, Me Graw Hill Book Company, 1984.

5. E. A. Rawlins, Bentley's Text Book of Pharmaceutics, 8th edition, ELBS Publishers, 1984.
6. J. M. Coulson and J. F. Richardson, Chemical Engineering, Vol I, 3^d edition, Pergemon Press, 1977.
7. A.R. Paradkar, Introduction to Pharmaceutical Engineering.
8. Sambamurthy, Text Book of Engineering.
9. Subramanyam and Kusumdevi Pharmaceutical Engineering- Principles and Practices, Vallabh Prakashan, 2002.

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Tray dryer	01
2. Ball mill	01
3. Sieve shaker with set of sieves	01
4. Double cone blender	01
5. Propeller type mechanical agitator	05
6. Homogeniser	03
7. Buchner filtration apparatus	01
8. Vaccumpump	01
9. Desiccators	05
10. Energy meter	01
11. Permeability cups	05
12. Andreason's Pipette	03
13. Autoclave	01
14. Steam distillation still	01

III B.Pharm 3.5:
PHARMACOLOGY I (Theory)

75 hours

1. General Pharmacology
 - a) Introduction and definitions- Sources and active ingredients of drugs. 1
 - b) Routes of administration of drugs. 1
 - c) Absorption of drug and the factors affecting them. 2
 - d) Drug Distribution, Bio-transformation and Excretion 4
 - e) Mechanism of drug action - Drug-Receptor interactions and molecular & biochemical basis of drug action. Additive effect, synergism, potentiation. 4
 - f) Factors modifying drug effects. 1
 - g) Drug toxicity 2
 - h) Dose response relationship, structure activity relationship 2
 - i) Drug interactions: Basic concepts of Drug interactions (Both in vitro & in vivo) 1
 - j) Pre-clinical & clinical evaluations. 3

- Note : The term Pharmacology used here refers to the classification, mechanism of action, Pharmacokinetics, pharmacodynamics, adverse effects, contraindications, therapeutic uses and dosage.

2. Pharmacology of drugs acting on Autonomic Nervous System
 - a) Introduction-Neurohumoral Transmission 2
 - b) Adrenergic and Cholinergic receptors 1
 - c) Adrenergic drugs. 2
 - d) Adrenergic receptor blockers, adrenergic neuron blockers. 2
 - e) Cholinomimetics, Anticholinesterases. 3
 - f) Antimuscarinic agents 1
 - g) Ganglionic blockers and stimulants 1
 - h) Neuromuscular blocking agents 1
 - i) Drugs used in parkinsonism and myasthenia gravis. 2

Definition: Health, Drug, Pharmacology, Pharmacokinetics and Pharmacodynamics.

3. Pharmacology of Drug acting on Cardiovascular System
 - a) Anti-hypertensives. 2
 - b) Anti-anginal drugs 2
 - c) Anti-arrhythmic drugs. 2
 - d) Drugs used for therapy of congestive cardiac failure 2
 - e) Drugs used in hyperlipidaemias 1

4. Pharmacology of Drugs Acting on Central Nervous System	
a) General consideration (Introduction)	1
b) Alcohol	1
c) General anaesthetics	2
d) Sedatives and hypnotics	3
e) Anti-convulsants	2
f) Narcotic analgesics	
g) Non-steroidal anti inflammatory agents and Analgesics	4
h) Psychopharmacological agents: Antipsychotics, Antidepressants, Anxiolytics	5
i) Drug dependence and drug abuse	1
2. Pharmacology of Local anaesthetics	2
3. Pharmacology of Drugs Acting on Blood and Blood forming Agents	
a) Coagulants and anti-coagulants.	2
b) Haemopoietics.	2
c) Thrombolytics and antiplatelet agents.	2
4. Pharmacology of Drugs Acting on Renal System (Diuretics) and antidiuretics.	3

PHARMACOLOGY I REFERENCE BOOKS

1. Goodman and Gilman's the Pharmacological basis of Therapeutics. Editors: A Goodman Gilman, T.W.Rall, AIS, Nies, PTaylor, Pergamon Press, 2000.
2. Katzung, B.G.: Basic and Clinical Pharmacology, Prentice Hall, International.
3. M.PRang, M.M.Dale, J.M.Riter., Pharmacology, 4th Edition, Churchill, Livingstone, 1995.
4. Modern Pharmacology, C.R.Craig and R.E.Stitzel, Little Brown and Company, 1994.
5. Paul, L. Principles of Pharmacology, Chapman and Hall, 1995.
6. Mycek MJ, Harvey RA and Champe PC, Lipponcott's Illustrated Reviews: Pharmacology. T Edition. Lipponcott Williams & Wilkins, 1997.
7. Lawrence, D.R. and Bennet PN. Clinical Pharmacology, Scientific Book agency, Calcutta.
8. Barar F.S.K., Test book of Pharmacology, Interprint, New Delhi.
9. PS.R.K. Haranath, Synopsis of Pharmacology, 1995, Bombay.
10. Clinical Pharmacy and Therapeutics, Herfindal E.T., and Hirschman J.L. Williamsand Wilkins.
11. Applied therapeutics: The clinical use of drugs, applied therapeutics, Inc.
12. Pharmacotherapy: A Pathophysiological approach, Dipiro, J.L. Elsevier.3
13. Tripathi KD: Essentials of Medical Pharmacology. 2001, 4^m Edition, Jaypee Brothers, New Delhi.
14. Ghosh M.N., Fundamentals of Experimental Pharmacology, Scientific Bookagency, Calcutta.
15. Hand book of Experimental Pharmacology, 2nd Ed., S.K.Kulkarni., Vallabh Prakashan, Delhi.

IV B.Pharm

4.1: PHARMACEUTICAL TECHNOLOGY AND BIOPHARMACEUTICS (Theory)

75 hours

1. Tablets:
 - a. Formulation of different types of tablets, granulation technique, equipment employed. In process, evaluation of tablets and packaging. 5
 - b. Tablet coating: Types of coating, coating materials, formulation of coating solution, methods of coating and equipment employed, quality control tests of coated tablets. 5
2. Capsules:
 - a. Hard gelatin capsules: Extraction of gelatin, production and filling of hard gelatin capsules, finishing and special techniques, quality control tests for capsule.
 - b. Soft gelatin capsules: Nature of shell and capsule content, importance of base adsorption and minim/gram factors, production, in process and final product quality control tests. 8
3. Parenteral Preparation: Definition, types, advantages and limitation, general formulation, vehicles, production procedure, production facilities and controls. Formulation of injections, sterile powders, implants and long acting parenterals, emulsions and suspensions. Containers and closures pertinent to sterile preparations and Pharmacopoeial quality control tests. 14
4. Ophthalmic formulations: Requirements, formulation of eye drops, eye lotions and eye ointments, containers and evaluation. 4
5. Liquid orals: Formulation of solutions, manufacturing, filling and packaging. 5
6. Semisolid dosage forms: Definition, types, semisolid bases, their selection. Formulation of semisolidssuch as ointments, gels, jellies, suppositories, packaging, and their evaluation. 4

7. Pharmaceutical aerosols: Definition, propellants, containers, valves, types of aerosol systems, manufacture of aerosols, quality control and stability studies. 6
8. Radiopharmaceutical: Uses in diagnosis and treatment, methods of preparation handling and safety precaution. 3
9. Cosmetics: Formulation and preparation of the following cosmetic preparations. Lipsticks, Shampoos, Face and talcum powders, Nail lacquers, cold cream and vanishing cream and toothpastes, hair dyes. 13
10. Biopharmaceutics: Definition and applications, passage of drugs across the biological barriers (passive diffusion, active transport, facilitated, pinocytosis) factors influencing absorption- Physiological, physicochemical, and pharmaceutical, blood level curves for I.V, constant rate infusion, oral, I.M., and sustained release dosage forms. Bioavailability, measurement of Bioavailability (C_{max} , T_{max} , AUC). Definition of Bio equivalence 8

PHARMACEUTICAL TECHNOLOGY AND BIOPHARMACEUTICS (Practicals)

75 hours

1. Manufacture of tablets**
 - a. Ordinary compressed tablet-wet granulation
 - b. Tablets prepared by direct compression
 - c. Soluble tablet
 - d. Chewable tablet
2. Formulation and filling of hard gelatin capsules*
3. Manufacture of parenterals. * *
 - a. Ascorbic acid injection
 - b. Calcium gluconate injection
 - c. Sodium chloride infusion
 - d. Dextrose and Sodium chloride injection/infusion
4. Evaluation of pharmaceutical formulations (Q.C. tests)*
 - a. Tablets
 - b. Capsules
 - c. Injections

1. Formulation of two liquid oral preparations* and evaluation by assay* *
 - a. Solution: Paracetamol syrup
 - b. Antacid suspensions - aluminum hydroxide gel
2. Formulation of semisolids* and evaluation by assay* *
 - a. Salicylic acid and benzoic acid ointment
 - b. Gel Formulation Diclofenac gel
3. Cosmetic preparations*
 - a. Lipsticks.
 - b. Cold cream and vanishing cream
 - c. Clear liquid shampoo
 - d. Tooth paste and tooth powders.
4. Tablet coating (demonstration)

SCHEME OF EXAMINATION

1. Synopsis	-10 Marks
2. Major experiment (Experiments indicated by**)	-30 Marks
3. Minor experiment (Experiments indicated by *)	-20 Marks
4. Viva voce	-10 Marks
Total	-70 Marks

PHARMACEUTICAL TECHNOLOGY AND BIOPHARMACEUTICS

REFERENCE BOOKS

1. Leon Lachman, Lieberman, and J.L. Kanig, Theory and Practice of Industrial Pharmacy, Varghese Publishing House, Bombay, 3rd Edition, 1987.
2. M.E. Aulton, Pharmaceutics - The Science of Dosage Form Design, Churchill Livingstone, 2nd edition, 2002.
3. Banker and Rhodes, Modern Pharmaceutics, Marcel Dekker Inc., New York, 2nd Edition, 1990.
4. H.C. Ansel, Introduction to Pharmaceutical Dosage Forms, Lea and Febiger, Philadelphia, 4th edition, 1985.
5. Lachmann and Liebermann, Pharmaceutical Dosage Form- Tablets, Marcel Dekker Inc., New York, 2nd Edition, 1989.
6. Remington, Remington: The Science and Practice of Pharmacy, Lippincott Williams, 20th edition, 2000.
7. Cartensen, Drug Stability, Marcel Dekker.
8. Lachmann and Liebermann, Pharmaceutical Dosage Form- Parenteral Medication, Marcel Dekker Inc., New York, 2nd Edition, 1989.

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Standard Granulating sieves, 2 sets, Sieve No, 10,12,22,24	10
2. Tray dryer	01
3. Tablet punching machine	01
4. Capsule tilling machine	01
5. Ampoule washing machine	01
6. Ampoule filling and sealing machine	01
7. Tablet Disintegration test apparatus IP	01
8. Tablet dissolution test apparatus IP	01
9. Monsanto's hardness tester	02
10. Pfizer type hardness tester	02
11. Friability test apparatus	02
12. Clarity test apparatus	02
13. Digital thermometer	02
14. Mechanical stirrer	03
15. Ointment filling machine	01
16. Ointment crimping machine	01
17. Lipstick moulds	10
18. Tablet coating pan	01
19. Magnetic Stirrer, 500ml and 1 litre capacity	05

IV B.Pharm

4.2: INSTRUMENTAL AND BIOMEDICAL ANALYSIS (Theory)

50 hours

The subject to be discussed with special reference to quality control and assurance of pharmaceuticals, its scope and its importance in the pharmaceutical industry. The following analytical techniques should be discussed with suitable examples.

1. Absorption spectroscopy: Theory of electronic, atomic and molecular spectra, Beer and Lambert's law, Derivation and Deviations, Application of Beer's law to single component analysis and multicomponent systems, Chromophores, Auxochromes, Bathochromic shift, hypsochromic shift, Hyperchromic and hypochromic effects, Effect of solvent on absorption spectra. 5

UV/Visible spectroscopy: Instrumentation and working; Sources of radiation, Wavelength selectors; Filters-Prisms and Gratings, Sample cells, Detectors- Phototube, Photomultiplier tube, Barrier layer cell and Silicon photo diode. 4

IR Spectroscopy: Instrumentation, Working and Sample handling methods, Sources of radiation, Monochromators, Sample cells and detectors- Bolometers, Thermocouples, Golay cells. 3

Applications: Measurement of equilibrium constant and rate constant by spectroscopy, spectrophotometric titrations, IR Frequency - structure correlation, study of characteristic fundamental stretching vibrations of functional groups like Alcohol, Carboxyl, Amide esters, Amine, Aldehyde, Ketone and Phenol. 5

2. Fluorimetric analysis: Theory, concept of singlet and triplet electronic states, Internal and external conversions, intersystem crossing, factors affecting fluorescence, Quenching. Instrumentation- Study of Fluorimeter, Spectrofluorimeter and Applications 3
3. Flame emission and atomic absorption spectrometry: Theory, Nebulization, flames and flame temperatures, interferences, flame spectrometric techniques. 3

4. Nephelometry and Turbidimetric Analysis: Theory, General principles, Instrumentation and applications.	1
5. Chromatography: Introduction and classification,	1
A) Column chromatography: Adsorption column chromatography, development Techniques - Frontal analysis, Displacement analysis and elution analysis. Factors affecting column efficiency. Applications, Partition Chromatography.	2
B) Thin layer chromatography: Introduction, principle, technique, R _f values and applications.	1
C) Paper Chromatography: Introduction, Principle, Technique, Development, methods and applications.	1
D) Ion exchange chromatography: Ion exchange materials, synthetic ion exchange resins, Properties of ion exchangers, mechanism of ion exchange process, factors affecting ion exchange, applications.	3
E) Gas chromatography: Introduction, theory, instrumentation-carrier gas, types of columns, stationary phases in gas liquid chromatography and gas solid chromatography. Detectors- Flame ionization detector, electron capture detector, thermal conductivity detector. Gas chromatogram, Derivatisation techniques like silylation, and esterification, Programmed temperature gas chromatography, Applications.	4
F) HPLC: Introduction, theory, instrumentation -Solvent treatment systems, Pumps- Reciprocating and displacement pumps, Columns, Detectors- UV detectors, Fluorimetric detectors, Refractive index detectors and applications.	2
G) Electrophoresis: Principles of separation, equipment for paper and gel electrophoresis, Moving boundary electrophoresis, Applications.	2
6. Electrometric methods:	
A) Potentiometry: Electrochemical cell, construction and working of reference electrode, Normal hydrogen electrode, calomel electrode, silver-silver chloride electrode, Indicator electrodes- Glass electrode, Antimony electrode, Quinhydrone electrode, Potentiometric titrations, methods of detecting end point.	5

B) Conductometry: Introduction, conductivity cell, conductometric titrations, Applications. 2

4. Quality assurance: Introduction, Sources of quality variation, control of quality variation, Validation methods. 3

INSTRUMENTAL AND BIOMEDICAL ANALYSIS (Practicals)
75 hours

At least 15 experiments to be covered from the following list:

1. Separation and identification of amino acids by paper chromatography*
2. Separation and identification of alkaloids by thin layer chromatography.*
3. Separation and Identification of Dyes by radial paper chromatography*
4. Conductometric titration of Benzoic acid with NaOH* *
5. Potentiometric titration of HCl with NaOH.**
6. Estimation of quinine sulphate by fluorimetry. * *
7. Estimation of Riboflavine by fluorimetry. * *
8. Study of quenching effect in fluorimetry: ex Quenching of Quinine fluorescence by iodide ions*.
9. Determination of absorption maxima for a given solution of the drug.*
10. Colorimetric estimation of Ferrous ions using 1,10 Phenanthroline.**
11. Colorimetric estimation of Sulphanilamide using N-1 -Naphthyl Ethylene Diamine dihydrochloride.**
12. Assay of Dextrose injection by colorimetry. * *
13. U.V.spectrometric determination of Ibuprofen tablets.*
14. Determination of chloride and sulphate in calcium gluconate by Nepheloturbidimetric analysis. **
15. Infrared spectral graphs/ peaks identification of samples with different functional groups (-COOH, -COOR, CONHR, -NH₂, -NHR, -OH, -CHO, -C=O)...
16. Determination of Sodium/ Potassium by flame photometry.
17. Kinetics of Aspirin hydrolysis.
18. Determination of water content by Karl Fischer electrometric titration method. * *

SCHEME OF EXAMINATION

1. Synopsis	-10 Marks
2. Major experiment (Experiment indicated by**)	-30 Marks
3. Minor experiment (Experiment indicated by*)	-20 Marks
4. Viva voce	-10 Marks

Total -70 Marks

INSTRUMENTAL AND BIOMEDICAL ANALYSIS REFERENCE BOOKS
(Theory)

1. Hobarth Willard, Lynne L. Merritt, John A. Dean & Frank A. Settle Jr, Instrumental methods of analysis, 6th edition, CBS Publishers & Distributors, New Delhi.
2. Skoog and West, Pharmaceutical Analysis,
3. A.I. Vogel, Text book of Quantitative chemical analysis, ELBS/Longman, London.
4. Kenneth A. Connors, A Text book of Pharmaceutical analysis, 3rd Edition, John Wiley & Sons, New York (1982).
5. Stahl.E, Thin layer chromatography-a Handbook, Springer-Verlag, Berlin
6. Leon Lachman, Lieberman, and J.L. Kanig, Theory and practice of industrial pharmacy

(Practicals)

1. Garratt. D.C. Quantitative analysis of drugs, 3rd edition, CBS Publishers & Distributors, New Delhi. (2001).
2. Melean. C.E., Kiser.R.W., Problems and experiments in instrumental analysis.
3. Beckett A.H., Stenlake J.B, Practical Pharmaceutical Chemistry, 4th edition, The Athlone Press, London.
4. Kenneth A. Connors, A Text book of Pharmaceutical analysis, 3rd edition, John Wiley & Sons, New York (1982),.
5. Hobarth Willard, Lynne L. Merritt, John A. Dean, Frank A. Settle Jr., Instrumental methods of analysis, 6th edition, CBS Publishers & Distributors, New Delhi.
6. Indian Pharmacopoeia, Vol I & II, , Ministry of Health & Family welfare, Govt, of India, Published by Controller of the Publications, New Delhi, 1996.
7. United States Pharmacopoeia.
8. British Pharmacopoeia.
9. Alfonso R. Gennaro, Remington's: The Science & Practice of Pharmacy, Vol I & II - Lippincott Williams & Wilkins.
10. Higuchi T & Hanssen E.B., Text Book of Pharmaceutical Analysis, A Wiley Interscience Publications.
11. William Kemp, Spectroscopy methods, ELBS.
12. John R. Dyer, Applications of Absorption spectroscopy of organic compounds, Prentice Hall of India Pvt. Ltd., New Delhi.
13. R. M. Silverstein, G. Clayton, Terence C. Morill, Spectrometric identification of organic compounds, John Wiley & Sons, New York.

LIST OF MINIMUM EQUIPMENTS REQUIRED

Equipments

1. Colorimeter	01
2. UV Spectrophotometer	01
3. Fourier Transform Infra Red spectrometer	01
4. Fluorimeter	01
5. Nephelo turbidity meter	01
6. Flame photometer	01
7. Potentiometer	02
8. Conductivity meter	02
9. Analytical weighing Balance (1 mg sensitivity)	01
10. Oven	01

Apparatus

1. Volumetric flasks 10 ml, 25 ml, 50 ml and 100ml.
2. Weighing bottles
3. Pipettes-Graduated 10 ml
4. Pipettes-Bulb 1 ml, 2ml, 5ml and 10ml
5. Beakers-100 ml, 250 ml and 500 ml
6. Separating funnels
7. TLC plates
8. Chromatographic papers
9. TLC and Paper chromatography- Development chambers.
10. Water bath

IV B.Pharm
4.3: PHARMACOLOGY & TOXICOLOGY II (Theory)

50 hours

1.	Pharmacology of Autacoids and their Antagonists	
	Histamine and antihistaminics	1
	5-Hydroxytryptamine and its antagonists	1
	Lipid derived autacoids and platelet activating factor	1
2.	Pharmacology of Drugs Acting on Respiratory Tract	3
	Bronchodilators, Mucolytics, Expectorants, Antitussives, Nasal decongestants.	
3.	Pharmacology of Drugs Acting on Gastro Intestinal Tract	
	Antiulcer drugs, Antacids	1
	Laxatives and Purgatives	1
	Emetics and Antiemetics	1
	Appetizers, Digestants, Carminatives	1
4.	Pharmacology of Hormones and Hormone Antagonists	
	Thyroid and antithyroid drugs.	2
	Insulin, Insulin analogues and oral hypoglycemic agents	2
	Sex hormones and oral contraceptives	2
	Oxytocin and other uterine stimulants and relaxants	1
5.	Chemotherapy	
	a) Introduction	1
	b) Sulfonamides and Co-trimoxazole	1
	c) Penicillins and Cephalosporins	2
	d) Tetracyclins and Chloramphenicol	1
	e) Macrolides Aminoglycosides, Polyene & Polypeptide antibiotics.	2
	f) Quinolones and Fluoroquinolones	1
	g) Antifungal antibiotics	1
	h) Antiviral agents	2
	i) Chemotherapy of Tuberculosis and Leprosy	3
	j) Chemotherapy of Malaria	3
	k) Chemotherapy of Protozoal infections (amoebiasis, Giardiasis)	2
	l) Pharmacology of Anthelmintic drugs	1
	m) Chemotherapy of Cancer (Neoplasms)	2
6.	Bio Assays	
	Scope, Principles involved and General methods.	2
7.	Immunopharmacology	
	Pharmacology of immunosuppressants and stimulants	2

1. Principles of Toxicology
 - a) Acute, Subacute & Chronic toxicity
 - b) General principles of treatment of acute toxicity and acute poisoning. 1
 - c) Signs, Symptoms and treatment of acute and chronic poisoning due to. 3
 - i) Barbiturates ii) Alcohols iii) Benzodiazepines iv) Antidepressants
 - v) Neuroleptics vi) Insecticides vii) Snake bite viii) Heavy metals (iron, lead, mercury, arsenic).
2. Definitions of Drug-Drug, Drug-food interactions classification of Drug-Drug interaction. Basic concepts of mechanisms of drug - drug interactions. 2

PHARMACOLOGY & TOXICOLOGY II (Practicals)

100 hours

1. Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea pigs and e. Rabbits)
2. Study of physiological salt solutions used in experimental pharmacology
3. Study of laboratory appliances used in experimental pharmacology
4. Study of use of anesthetics in lab animals.
5. To record the dose response curve of histamine using isolated guinea pig ileum preparation.
6. Study of agonistic and antagonistic effects of drugs using isolated guinea pig ileum preparation.
7. To carry out bioassay of Histamine using isolated guinea pig ileum preparation by interpolation method.
8. To carry out bioassay of Histamine using isolated guinea pig ileum preparation by three point method.
9. To record the dose response curve of Acetylcholine using isolated ileum/rectus abdominis muscle preparation.
10. To carry out bioassay of Acetylcholine using isolated ileum/rectus abdominis muscle preparation by interpolation method.
11. To carry out bioassay of Acetylcholine using isolated ileum/rectus abdominis muscle preparation by three-point method.
12. To study the routes of administration of drugs in animals (Rats, Mice, Rabbits)
13. Study of theory, principle, procedure involved and interpretation of given results for the following experiments:
 - a) Analgesic property of drug using analgesimeter
 - b) Anti inflammatory effect of drugs using rat-paw edema method

- c) Anti convulsant activity of drugs using MES and pentylene tetrazole methods.
 - d) Antidepressant activity of drugs using pole climbing apparatus and Pentobarbitone induced sleeping time methods.
 - e) Locomotor activity evaluation of drugs using Actophotometer and rotarod.
 - f) Cardiotoxic activity of drugs using isolated frog heart and mammalian heart preparations.
1. Simulated Experiments:
 - a) Effects of drugs on isolated heart of frog.
 - b) Effects on B.P, HR and RR of dog.
 - c) Effects of drugs on locomotor activity of rat
 - d) Effects of drugs on rabbit's eye
 - e) Effects of drugs on ciliary motility of frog's esophagus
 - f) Ileum - Dose response curve and matching assay
 - g) Mouse-Evaluation of analgesic activity by hot plate method.

Note: CPCSEA approval to be obtained for experiments on animals

SCHEME OF EXAMINATION

1. Synopsis	-10marks
2. Identifications	-10marks
3. Experiments	
a) Interpretation of given graph/simulated experiment	-10 marks
b) Bioassay	- 30 marks
4. Viva voce	-10 marks

Total - 70 Marks

PHARMACOLOGY & TOXICOLOGY II REFERENCE BOOKS

1. Goodman and Gilman's the Pharmacological basis of Therapeutics. Editors: A Goodman Gilman, T.W.Rall, A.L.S. Nies, P.Taylor, Pergamon Press, 2000.
2. Katzung, B.G.: Basic and Clinical Pharmacology, Prentice Hall, International.
3. M.P.Rang, M.M.Dale, J.M.Riter., Pharmacology, 4th Edition, Churchill, Livingstone, 1995.
4. Modern Pharmacology, C.R.Craig and R.E.Stitzel, Little Brown and Company, 1994.
5. Paul, L. Principles of Pharmacology, Chapman and Hall, 1995.
6. Mycek MJ, Harvey RA and Champe PC, Lipponcott's Illustrated Reviews: Pharmacology. 2nd Edition. Lipponcott Williams & Wilkins, 1997.

7. Lawrence, D.R. and Bennet PN. Clinical Pharmacology, Scientific Book agency, Calcutta.
8. Barar F.S.K., Test book of Pharmacology, Interprint, New Delhi.
9. PS.R.K. Haranath, Synopsis of Pharmacology, 1995, Bombay.
10. Clinical Pharmacy and Therapeutics, Herfindal E.T., and Hirschman J.L. Williams and Wilkings.
11. Applied therapeutics: The clinical use of drugs, applied therapeutics, Inc.
12. Pharmacotherapy: A Pathophysiological approach, Dipiro, J.L. Elsevier.3
13. Tripathi KD: Essentials of Medical Pharmacology. 2001 ,th4 Edition, Jaypee Brothers, New Delhi.
14. Ghosh M.N., Fundamentals of Experimental Pharmacology, Scientific Book agency, Calcutta.
15. Hand book of Experimental Pharmacology, 2nd Ed., S.K.Kulkarni., Vallabh Prakashan, Delhi **LIST OF**

MINIMUM EQUIPMENTS REQUIRED

1. Sherrington's Kymograph Machine	20
2. Sherrington Drum	20
3. Perspex bath assembly (single unit)	20
4. Aerators	20
5. Dissection Tray and Boards	20
6. Haemostatic artery forceps	20
7. Hypodermic syringes and needles of size 18,24,26G	20
8. Computer with LCD	20
9. Software packages for experiment.	01
10. Standard graphs of various drugs.	Sufficient
11. Actophotometer	01
12. Rotarod	01
13. Pole climbing apparatus	01
14. Analgesiometer(Eddy's hot plate and radiant heat methods)	01
15. Convulsiometer	01
16. Plethysmograph	01
17. Levers, Cannulae	40
18. Website: expfarm.virtulave.net	

IV B.Pharm 4.4: MEDICINAL CHEMISTRY II (Theory)

75 hours

- A. Modern concepts of rational drug design: A brief introduction to quantitative structure activity relationship (QSAR), Prodrug, combinatorial chemistry and computer aided drug design. (CADD) 4
- B. History and development of chemotherapeutic agents: Structure, uses and synthesis of only those compounds that are underlined and superscribed by 's'.
- C. Anti-infective agents:
1. Local anti-infective agents:
 - a) Alcohols and related compounds: Alcohol, isopropyl alcohol, formaldehyde solution.
 - b) Phenols and their derivatives: p-Chloro phenol, hexachlorophene, Resorcinol, hexyl resorcinol.
 - c) Oxidizing agents: Hydrogen peroxide solution, hydrous benzoyl peroxide.
 - d) Halogen containing compounds: Iodine Tincture, Chlorine containing compounds halozone.
 - e) Cationic surfactants: Benzalkonium chloride, cetylpyridinium chloride.
 - f) Dyes-Gentian Violet, Methylene blue.
 - g) Nitrogen compounds: Nitrofurazone, Furazolidone⁵. 3
 2. Preservatives:
 - a) Para hydroxy benzoic acid derivatives: Methylparaben, Propyl paraben, Ethyl paraben.
 - b) Miscellaneous: Chlorobutanol, Benzyl alcohol, Phenylethyl alcohol, Sodium benzoate, Phenyl mercuric nitrate, Phenyl mercuric acetate. 1
 3. Antifungal agents:
 - a) Antifungal antibiotics- Nystatin, Candicidin, Hamycin, Griseofulvin, Amphotericin-B
Synthetic anti fungal agents: 3
 - b) Substituted imidazoles: Clotrimazole, Miconazole, Ketoconazole.
 - c) Miscellaneous-Zinc propionate, Sodium caprylate, Tolnaftate⁵.
 4. Urinary tract anti-infectives:
 - a) Quinalones: Nalidixic acid, Cinoxacin, Norfloxacin, Ciprofloxacin⁵, Pefloxacin, Ofloxacin, Sparfloxacin
 - b) Miscellaneous: Nitrofurantoin⁵. 2

1. Antitubercular drugs: SAR of antitubercular drugs,
 - a) Synthetic antitubercular agents: p-Aminosalicylic acid³, Isoniazid⁵, Ethambutol^P, Pyrazinamide, Ethionamide, Clofazimine.
 - b) Antitubercular Antibiotics: Cycloserine, Viomycin sulfate, Capreomycin sulfate, Rifampicin. 4
 2. Anti Viral Agents.
 - a) Amantidine hydrochloride, Idoxuridine, Acyclovir, Zidovudine. 2
 - b) Anti-AIDS: Zalcitabine, Suramin
 3. Antiprotozoal agents: Emetine hydrochloride, Metronidazole⁵, Diloxanide furoate⁵, 8-hydroxy quinoline derivatives (chloroquine⁵, iodoquine). Carbarsone. 2
 4. Anthelmintics: Piperazine, Diethyl carbamazine⁵, Pyrantel pamoate, Thiabendazole⁵, Mebendazole, 2
- A. Sulfonamides, Sulfones as antibacterial agents:**
1. SAR of Sulfonamides.
 2. Classification of sulfonamides based on duration of action and site of action with examples. Sulfamethiazole, Sulfisoxazole⁵, Sulfapyridine, Sulfamethoxazole⁵, Sulfadiazine, Sulfacetamide, sulfasalazine, Phthalyl sulfathiazole.
 3. Folate reductase inhibitors: Trimethoprim⁵, Synergistic action of the combination of sulfamethoxazole and trimethoprim.
 4. Sulfone: Dapsone⁵. 4
- B. Antimalarials: Etiology of malaria, History, Mechanism and SAR**
1. Quinolines and analogues
7-chloro-4-amino quinolines : Chloroquine phosphate⁵, Hydroxy Chloroquine sulphate, Amodiaquine. 8-amino quinolines: Pamaquine Primaquine⁵, 9-amino acridines: Quinacrine⁵
 2. Miscellaneous: Mefloquine, Pyrimethamine⁵, Trimethoprim.
 3. Biguanides and Dihydrothiazines: Chloroguanide, Cycloguanil. 6
- C. Antibiotics: Historical background, Mechanism of action, classification-**
1. Beta lactam antibiotics: Penicillins - structures, chemical degradation, bacterial resistance. Penicillin G, Penicillin V, Cloxacillin sodium, Nafcillin sodium, Ampicillin, Amoxycillin.
 2. Beta lactamase inhibitors: Clavulanic acid and its salts, Tienamycin.
 3. Cephalosporins: Structure and uses of Cephalexin, Cephadrine, Cefadroxil, Cefixime, Cefaprydine, Cefuroxime

4. Monolactams: Sulfazecin, Aztreonam, Tigmonam.
 5. Aminoglycosides: Structural features and Mechanism of action, Streptomycin, Amikacin Neomycin. Kanamycin, Gentamycin, Netilmycin
 6. Teracyclines: Chemistry and SAR, tetracycline, Chlortetracycline, Methacycline, Demeclocycline, Oxytetracycline, Meclocycline, Doxycycline, Minocycline.
 7. Macrolide: Structure and specific uses of Erythromycin, Azithrocin, Oleandomycin.
 8. Lincomycins: Lincomycin, Clindamycin.
 9. Polypeptides: Gramicidin, Bacitracin, Polymyxin B, Colistin.
 10. Miscellaneous: Chlormphenicol*, Vancomycin. Novobiocin. 12
- G. Antineoplastic agents: Introduction, mechanism of action and classification with examples. 5
1. Alkylating agents: Mechlorethamine, Cyclophosphamide*, Melphalan, Chlorambucil⁵, Busulfan, Lomustine⁵,
 2. Antimetabolites: Mercaptopurine, Thioguanine, 5-Fluorouracil, Methotrexate,
 3. Antibiotics: Dactinomycin, Bleomycin, Mitomycin, Streptozocin.
 4. Plant products: Etoposide Jaxol, Camphothecin, Vincristine, Vinorelbine.
 5. Hormones: Dromostanalone, Megestrol,
 6. Miscellaneous: Asparaginase, Cisplatin, Hydroxy urea.
 7. Immunotherapy: interferon alpha 2a and 2b.
- H. **Cardiovascular agents:**
- I. Antianginal agents and vasodilators: Chemical structure and specific uses of Amyl nitrite, Nitroglycerine, Isosorbide dinitrate.
 2. Calcium antagonists: Brief introduction of calcium channels and their blockers. Chemical structures and uses of Verapamil, Diltiazem, Nifedipine, Nimodipine, Felodipine Dipyridamole, Cyclandelate. 3
 3. Antiarrhythmic drugs: Structure, chemical name, and classification of antiarrhythmics with examples
- Class I- Membrane depressant drugs: Quinidine Procainamide, Phenytoin.
- Class II-Beta adrenergic blocking agents. Tocainide, propranolol
- Class III-Repolarization prolongators. Bretylium, Amiodarone
- Class IV-Calcium channel blocker. Diltiazem, Verapamil 3

1. Antihypertensive agents:	4
Beta-blockers: Propranolol, Timolol	
ACE Inhibitors: Captopril, Enalapril	
Diuretics: Hydrochlorothiazide, Spiranolactone	
Calcium channel blockers: Nifedipine, Felodipine, Amlodipine	
α_1 -Antagonist: Prazosin	
α_2 -agonist: Clonidine, Guanethidine	
Miscellaneous: Reserpine, Hydralazine, Minoxidil	
2. Antihyperlipidemic agents: Structure and specific uses.	
Clofibrate, Lovastatin, Cholestyramine, Colestipol.	2
3. Anticoagulants: Dicumarol, Warfarin ⁵ , Phenindione.	1
4. Hypoglycemic agents: Sulfonyl ureas—Chlorpropamide ⁵ ,	
Acetohexamide, Glipizide,	2
5. Thyroid hormones: L-thyroxine, L-thyronine,	0.5
6. Antithyroid drugs: Propylthiouracil, Methimazole.	0.5
I. Diuretics: Introduction	5
1. Carbonic anhydrase inhibitors: Acetazolamide, Methazolamide.	
2. Thiazide and Thiazide like diuretics: Chlorthiazides, Benzthiazide ⁵ , Xipamide, Chlorthalidone.	
3. High-ceiling or loop diuretics: Furosemide ⁵ , Ethacrynic acid ⁵ .	
4. Potassium sparing diuretics: Spironolactone, Triamterene, Amiloride.	
5. Miscellaneous: Mannitol	

MEDICINAL CHEMISTRY II REFERENCE BOOKS (Theory)

1. Foye's principles of Medicinal chemistry.
2. Wilson and Griswold's, Text book of Organic and Pharmaceutical chemistry.
3. Burger's medicinal chemistry.
4. The Martindale's Extra Pharmacopoeia.
5. A.I.Vogel, Text Book of practical organic chemistry including the qualitative analysis.
6. A.H.Becket and J.B.Stanlake, Practical Pharmaceutical chemistry.
7. J.G.Mann and Saunders, Practical organic chemistry, ELBS Longman, London.
8. I.P1985, Ministry of Health, Govt.of. India.
9. Ledniser Mitzsher, Organic drug synthesis, Vol.1 and 2.
10. I.L. Finar, Text Book organic chemistry.
11. T.Robbinson, Organic constituents of higher plants
12. Feiserand Feiser Steroids.
13. Drug design by Ariens.
14. Smith and Williams, Introduction to principles of drug design.
15. Purcell, Strategy of drug design
16. CIMS.

MEDICINAL CHEMISTRY II (Practicals)

75 hours

Assay of

1. Sulphadiazinebydiazotization.
2. Chloroquine by nonaqueous titratio
3. Ascorbic acid by Iodimetry.
4. Isonicotinic acid by KBrO_3 (bromimetry)
5. Benzyl penicillin by Iodometry.
6. Metronidazole/Mepacrine by nonaqueous titration.
7. Dapsorie by diazotization.

Preparation of medicinally important compounds or intermediates required for synthesis of drugs.

1. Benzimidazole from o-phenylene diamine.
2. PAS from p-nitro salicylic acid.
3. DichloramineT fromtoluence p-sulphonamide.
4. ChloramineTfrom DichloramineT.
5. Fluorescein from pthalic anhydride.
6. Eosin from Fluorescin.
7. Sulphacetamide from sulphanilamide.
8. Phenothiazinefrom Diphenylamine.
9. Sulphanilamide from Acetanilide.
10. Cinnamic acid from Perkin's reaction.
11. Benzyl alcohol by Cannizoro's reaction.
12. INH from Isonicotinic acid.

13. Chlorobutanol.
14. Napthoquinone.
15. Quinoxaline.
16. Benzotriazole.
17. 3-Diphenyl quinoline.
18. 2,4,5 Triphenyl imidazole from Benzoin

Estimation of the functional groups in medically important compound.

1. Hydroxyl group in cholesterol.
2. Ketone in camphor.
3. Hydroxyl group in menthol.
4. Amide in nicotinamide.

SCHEME OF EXAMINATION

1. Synopsis	-10 Marks
2. Assay/Estimation (including standardization)	-30 Marks
3. Preparation including re-crystallisation and Melting Point determination	-20 Marks
4. Practical viva	-10 Marks

Total -70 Marks

MEDICINAL CHEMISTRY II REFERENCE BOOKS (Practicals)

1. A.I.Vogel, Text Book of practical organic chemistry.
2. A.H.Beckett and Stanlake, Practical pharmaceutical chemistry.
3. J.G.Mann and Saunders, Practical organic chemistry.
4. Feiser and Feiser, Steroids.
5. IP 1985.
6. I.L.Finar, Text Book of organic chemistry.
7. CIMS.

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Suction Pumps	01
2. Analytical Balances	10
3. Physical Balances	
4. Triple beam balances	10
5. Water Baths Reflux Flask and condensers	10
6. Hot Plates	01
7. Mechanical Stirrers	01
8. Magnetic Stirrers with Thermostat	01
9. Distillation Unit	01
10. Refrigerator	01
Fuming Hood	01

IV B.Pharm
4.5: INDUSTRIAL PHARMACOGNOSY (Theory)

50 hours

1. **Introduction:**
 - a) Importance and status of herbal medicines and cosmetics.
 - b) Brief account of herbal drug Industry. 3

2. **Phytopharmaceuticals:**

Detailed methods of isolation, identification and estimation of the following: Quinine, Ephedrine, Digitoxin, Ca-sennosides, Diosgenin, Glycyrrhizin, Rutin, Andrographolides, Phyllanthin, Guggulusterone, Gymnemic acid, Asiaticoside, 10

3. **Herbal Formulations:**
 - a) General introduction to alternative systems of medicine like Ayurveda, Siddha, Unani and Homeopathy.
 - b) Methods of preparation of formulations in Ayurveda like Aristas, Asava, Ghutika, Taila, Churna, Leha and Bhasma.
 - c) Role of herbs in cosmetics. Study of the following herbs.
Shampoos: Soapnut
Conditioners: Amla, Henna,
Hair colorants: Amla, Henna
Skin Care: Aloe vera, Turmeric, Sandalwood
 - d) Nutraceuticals: Spirulina, Garlic
 - e) Different methods of processing extract 8

4. **Standardization:**
 - a) Importance of standardization of raw materials, extracts and formulations with suitable examples.
 - b) WHO guidelines for the assessment of crude drugs and extracts.
 - c) Role of markers in the evaluation of Herbal drugs. Applications of HPLC and HPTLC for the evaluation of drugs and extracts.
 - d) Standardization of the following drugs:
 - i) Gokhru ii) Aswagandha iii) Kalmegh iv) Brahmi v) Phyllanthus vi) Tinospora vii) Vasaka viii) Gymnema ix) Curcuma x) Glycyrrhiza
 - e) Determination of alcohol content in Aristas and Asavas. 8

5. **Patenting of Natural Products** 2

6. Plant Biotechnology and applications:
 - a) Polyploidy. Mutation and Chemodemes and their applications in improving the quality of medicinal plants.
 - b) Tissue Culture:
 - i) Types, techniques and applications
 - ii) Callus and Suspension cultures.
 - iii) Production of secondary metabolites.
 - iv) Protoplast isolation and fusion
 - v) Bio transformation, immobilisation of cells and enzymes.
 - c) Transgenic plants and their applications: Gene transfer in plants using vectors and physical delivery methods
7. Enzyme Biotechnology:
 - a) Introduction, general methods of isolation and purification of enzymes, enzyme reactors, applications of immobilized enzymes in drug manufacture and drug analysis.
 - b) Sources, method of preparations, chemical natures and uses of Papain and Bromelain.
 - c) Study of Streptokinase and Urokinase.
8. Study of Traditional Drugs:

Common and vernacular names, source, active constituents and uses of

 - i) Kantakari ii) Malkangani iii) Shatavari iv) Tylophorav) Bilvavi) Kalijeera
 - vii) Karvera viii) Rasna ix) Apamarg x) Gokhru xi) Shankapushpi xii) Gaduchi
 - xiii) Arjunaxiv) Shelajitxv) Chirata

INDUSTRIAL PHARMACOGNOSY (Practicals)

75 hours

1. Isolation of Phytopharmaceuticals**
 - i) Aloin ii) Andrographolide
 - iii) Quinine iv) Ammonium glycyrrhizinate
 - v) Ca sennosides vi) Caffeine
2. Estimation of Curcumin, Aloin, Quinine, Caffeine **
3. General and specific chemical tests for
 - a) Alkaloids-Atropine, quinine
 - b) Caffeine
 - c) Cardiac glycosides- Digitoxin, Digoxin
 - d) Saponins-Glycyrrhizin
 - e) Anthraquinone glycosides - Sennosides, Aloin
 - f) Flavone glycosides
 - g) Cyanogenetic glycosides

4. Chromatographic techniques*
 - a) Paper chromatography of sugars
 - b) Thin layer chromatography of alkaloids
 - c) Identification of markers in glycyrrhiza, Aloe, Berberis, Cinchona.
5. Evaluation of crude drugs by powder microscopy*
 - i) Punarnava ii) Ashwagandha iii) Kalmegh iv) Vasaka v) Ashoka vi) Tinospora
6. Estimation of alcohol content in various preparation*
7. Estimation of bitters in Kalmegh
8. Initiation of callus culture*
9. Immobilization of enzymes and determination of its activity.*
10. Study of morphology of traditional drugs. *
11. HPTLC and HPLC profiles of few drugs.

SCHEME OF EXAMINATION

1. Synopsis	-10 Marks
2. Isolation and identification/estimation of Phytopharmaceuticals* *	- 20 Marks
3. Chromatography of Phytopharmaceuticals**	-20 Marks
4. Minor experiment*	-10 Marks
5. Viva-Voce	-10 Marks
Total	-70 Marks

INDUSTRIAL PHARMACOGNOSY REFERENCE BOOKS

1. Chopra.R.N., Nayar S.L. and chopra.I.C., Glossary of Indian Medicinal Plants, C.S.I.R., New Delhi.
2. Grieve M., A Modern Herbal, Tiger Books international, London, 1992.
3. Guenther.E., The essential oils-Vol I-4, D.Van Nostrand Co. Inc. New York.
4. Indian Medicinal Plants, A Compendium of 500 species By Arya Vaidya Sala, Kottakal, Orient Longman, 1997.
5. Kokate C.K., Purohit A.Pand Gokhale S.B., Pharmacognosy (Degree) Nirali Prakashan, Pune.
6. Manske R.H.F., The Alkaloids-Academic Press, New York.
7. Satyavati, Medicinal Plants of India, 1. Indian Council of Medical Research, New Delhi.
8. Nadkarni.A.K., Indian Material Medica, 1 -2, Popular Prakashan Pvt.Ltd., Bombay
9. Herbal Pharmacopoeia of India, Government of India, Ministry of Health, Vol I & Vol (1998 & 2001)
10. Pulkot Mukherjee, Quality control of herbal drugs, Business horizons. Pharmaceutical press, 1st Ed,2001.
11. Vinod Ranagari, Pharmacognosy and Phytochemistry, Career publications, 1st Ed, 2003.

1. Chaudary R.D., Herbal drug industry, Eastern publishers, 1st Ed, 1996.
2. Rajpal. V., Standardisation of botanicals, Eastern publishers, Vol 1, 2002.
3. S.P.Vyas, and Dixit Pharmaceutical Biotechnology, 1st Ed, CBS Publishers & distributors, New Delhi, 1998.
4. Vyas S.P and D.V.Kohli. Methods in biotechnology and bioengineering, CBS publishers & Distributors, New Delhi. 1st Ed, 2002.
5. Narayanswamy, Plant cell and tissue culture. Tata Me Graw Hill, publishing company, New Delhi, 1994.
6. Pareek, L.K., Trends in plant tissue culture and biotechnology, Agro botanical publishers, 1st Ed, 1999.
7. Gupta.PK., Elements of biotechnology, Rastogi publications, 1st Ed, 1997.
8. Singh, B.D., Biotechnology, Kalyani Publishers, 1st Ed, 2002.
9. www.ars.grin.gov/hpgs/tax/index/html
10. www.botanical.com
11. National and International Journals- Phytochemistry, Fitoterapia, Journal of Natural Products, Indian Journal of Natural Remedies, Journal of Ethnopharmacology, Phytotherapy Research.

LIST OF MINIMUM EQUIPMENTS REQUIRED

1. Heating mantle	20
2. Soxhlet apparatus	10
3. TLC chamber and sprayer	10
4. Hot air oven	01
5. Water bath	20
6. Autoclave	01
7. Laminar airflow	01
8. B.O.D. Incubator	01
9. Microscope	20
10. Balance (Digital)	02
11. Spectrophotometer	01
12. Flourimeter	01
13. Reflux flasks and condensers	20
14. Distillation units	05
15. Vacuum pump	02
16. HPTLC	01
17. HPLC	01

IV B.Pharm 4.6.1: INDUSTRIAL PHARMACY 4.6.1 (a): ADVANCED INDUSTRIAL PHARMACY

50 hours

1. Controlled delivery systems: Principle, advantages, disadvantages, selection of drug candidates, approaches to design of controlled release formulations- methods such as ion exchange resins, microencapsulation (definition, applications, air suspension, coacervation and phase separation), matrix tablets, invitro evaluation. 8
2. Novel drug delivery systems: Concepts, advantages and disadvantages, types of drug delivery systems such as transdermal, nasal ocular, buccal with suitable examples. Drug carriers and drug targeting-Explanation and applications of liposomes, niosomes, microspheres, nanoparticles, advantages and disadvantages. 8
3. Methods to improve bioavailability of drugs: Solid dispersion and complexation 4
4. Pilot Plant and scale up: General considerations including significance of personnel requirements, space requirements, raw materials and preparation of Master procedure (SOP). Product consideration: Solid dosage forms in brief. Protocol preparation of multi- vitamin preparations 8
5. Herbal Formulations Antibacterial preparations, toothpaste, antitussive preparations - Definitions, formula and preparation. 6
6. Validation: Design, development of process validation, methods for pharmaceutical operations involved in the production of pharmaceutical products. 6
7. Formulation of Veterinary products: Antibacterials, Anthelmintics, Antiamoebic in the form of bolus, powder and liquid. 6
8. Allergenic extracts: Allergy: Definition & manifestations, allergenic extracts, pollen, dust & fungal extracts. 4

ADVANCED INDUSTRIAL PHARMACY REFERENCE BOOKS

1. Leon Lachman, Lieberman, and J.L.Kanig, Theory and Practice of Industrial Pharmacy, Varghese Publishing House, Bombay, 3rd Edition, 1987.
2. Banker and Rhodes, Modern Pharmaceutics, Marcel Decker Inc., New York, 2nd Edition, 1990.
3. H. C. Ansel, Introduction to Pharmaceutical Dosage Forms and Drug Delivery Systems, Lippincott Williams and Wilkins, New York, 7th Edition, 2000.
4. Milo Gibaldi, Biopharmaceutics and Pharmacokinetics, Lea and Febiger, Philadelphia, 3rd Edition, 1984.
5. Gibaldi and Perrier, Pharmacokinetics, Marcel Decker Inc., New York, 2nd Edition, 1982.
6. J.G. Wagner, Fundamentals of Clinical Pharmacokinetics.
7. R.L.Juliano, Drug Delivery Systems, Oxford University Press.
8. Robert E. Notari, Biopharmaceutics and Pharmacokinetics.
9. Rowland and Tozer, Clinical Pharmacokinetics, Lea and Febiger, Philadelphia, 2nd Edition, 1989..
10. J.R. Robinson and Vincent Lee, Controlled Drug Delivery-Fundamentals and Applications, Marcel Decker Inc., New York, 2nd Edition, 1987.
11. Dr.N.Udupa, Drug Delivery Systems-Manipal experience.
12. Remington, Remington: The Science and Practice of Pharmacy, Lippincott Williams, 20th Edition, 2000.
13. Y.W.Chien, Novel Drug Delivery Systems, Marcel Decker Inc., New York, 2nd Edition, 1992.

IV B.Pharm 4.6.1: INDUSTRIAL PHARMACY
4.6.1 (b): PHARMACEUTICAL MARKETING AND MANAGEMENT

50 hours

- 1. Marketing:**
 - a. The meaning and scope of marketing.
 - b. The Pharmaceutical market: Quantitative and qualitative aspects, size and composition of the market, demographic descriptions and socio psychological characteristics of the consumer, market segmentation.
 - c. Analysing the market-Role of market research
 - d. Consumer profile-Motivation and prescribing habits of the physician, patients' choice of physician and retail pharmacist.

11

- 2. The Pharmaceutical product:**
 - a. Market consideration in product development, marketing mix, product life cycle (PLC), effects of different elements of marketing mix at different stages of PLC, product classification, product planning, product differentiation, me-too products, modification of existing product.
 - b. New product development-All stages from the new product idea to the stage of marketing the developed product (bulk drugs and formulations)
 - c. Branding- Concept of brand, Different types of brand, importance and reasons for branding, packaging.

6

- 3. The organization:**

Manufacturer-Company objectives, influence of internal controls such as company policy on the company's operation, effects of Government regulations and controls on marketing practices.

2

- 4. Distribution:**
 - a. The wholesaler-His role in distribution of Pharmaceutical services offered to the manufacturer and the retailer, advantages and disadvantages of distribution through wholesaler.
 - b. The retailer-Classification of retail institutions, advantages and disadvantages of retail institutions, the hospital as retail outlet.

4

- 5. Competitive practices in the Pharmaceutical Industry:**
 - a. Patent laws, trade marks laws.
 - b. Price competition-Pricing, rate contracts.

- c. Non-price competition-All types of non-price competition with special emphasis on competition through research and development, competition through quality 4
6. **Promotions:**
 - a. Communication and its importance
 - b. Different ways of promotion- Advertising, direct mail, professionals, journals, sampling, retailing, medical exhibition, public relations.
 - c. Professional sales representative-duties of PSR, purpose of detailing, selection and training, compensation and future prospects of the PSR. 5
7. **Management:**
 - a. Concepts of management, Principles of management
 - b. Primary functions of management - planning, organizing, staffing, directing controlling, motivation, entrepreneurship development.
 - c. Secondary functions of management: decision-making, leadership, innovation, delegation of authority/responsibility. 12
8. **Good manufacturing practices (GMP):**
GMP as per schedule M, WHO guidelines, USFDA guidelines, MCA guidelines and TGA guidelines. 4
9. **ICH guidelines:**
Quality, efficacy and safety of drugs, impurity profiles. 2

PHARMACEUTICAL MARKETING AND MANAGEMENT REFERENCE BOOKS

1. Harold T Amrine, John A Ritchey, Oliver S. Hulley, Manufacturing organization and management, Prentice Hall of India Pvt Ltd, New Delhi, Fourth Edition
2. Heinz Wehrich, Harold Koontz, Management: A global perspective, McGraw Hill International Edition Tenth edition
3. Dr Varma, R.K.Agarwal, Production management, King Books, Educational publishers, Delhi
4. K.Aswathappa, Production management: Himalaya publishing House
5. PC.Tripathi, PN Reddy, Principles of management, Tata McGraw Hill publishing Co. Ltd.
6. SN Chary, Production and operations management, Tata McGraw Hill publishing Co. Second Edition 2000.

7. Subba Rao, Pharmaceutical marketing in India, Asian Institute of Pharmaceutical Marketing, Hyderabad 1998 Edition
8. Mickey C Smith, Principles of Pharmaceutical marketing CRS Publishers and Distributors, New Delhi, 3rd Edition
9. Mickey C Smith, Pharmaceutical marketing in the 21st century, Viva Books Pvt Ltd, 2001 10 ML

Mehra, GMP, University Book Agency, Allahabad, I Edition.

5. Dr.A.Patani, Drug & Cosmetics Act 1940, Eastern Book Co., Lucknow
6. Quality Assurance of Pharmaceuticals, Compendium of Guidelines and related materials, Vol I, WHO Publications, Geneva
7. WHO Expert Committee on "Specifications for Pharmaceutical preparations" 13th, 22nd, 23rd, 24th, 34th Reports.
8. www.ich.org
9. www.ifpma.org/ich5.html
10. www.fda.gov
11. www.health.gov.au/tga/
12. www.mca.gov.uk ■

IV B.Pharm 4.6.11: PHARMACY PRACTICE

4.6.11 (a): PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING

50 hours

- 1 a) Introduction to Pharmacokinetics, Types of pharmacokinetic models, Their advantages and limitations. 2
- b) Model-Independent calculations (from equations as well as graphs) for pharmacokinetic parameters - Area under the curve, k_a , k_e , Biological half-life, Apparent volume of distribution and Clearance. 10
2. Compartment models:
 - a) One compartment open model - monoexponential decline - IV bolus (blood & urine analysis), IV infusion and oral (Blood analysis). 6
 - b) Two compartment model-biexponential disposition-IVbolus. 2
 - c) Three compartment model - triexponential disposition -The concept. 1
 - d) Multiple dosing - consequences, equations to calculate C_{min} , and C_{ss} , accumulation index, concept of loading dose and maintenance dose. 3
3. Drug distribution:
 - a) Factors affecting (perfusion & permeability)
 - b) Protein binding - Kinetics of protein binding & Clinical significance. 6
4. Therapeutic Drug Monitoring:
Introduction, Necessity of TDM, Criteria for valid TDM, Essentials for effective TDM, Organization of a TDM service, Effectiveness of TDM. 5
5. Analytical aspects of TDM, Uses of HPLC and Immunoassays in TDM for measurement of serum drug concentrations. 3
6. Dosage regimen design, Dosing of drug in special population - Pregnancy & lactation, Paediatrics & Geriatrics, Dosage adjustment in renal and hepatic impairment, Patient compliance. 6

7. TDM. of selected individual drugs-Aminoglycosides, Carbamazepine, Cyclosporine, Digoxin and Methotrexate. 6

PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING REFERENCE BOOKS

1. Leon Shargel and Andrew B.C, Applied Biopharmaceutics and Pharmacokinetics, Appleton-Century-Crofts, 1985.
2. Alfonso. R. Gennaro, Remington: The Science and Practice of Pharmacy, Lippincott Williams & Wilkins, 2001.
3. Abdou, Dissolution, Bio-availability and Bio-equivalence, Mack Publishing Company, 1989.
4. Shobha Rani. R. Hiremath, Textbook of Biopharmaceutics and Pharmacokinetics, Prism, 2000.
1. Mike Hallworth and Nigel Caps, Therapeutic Drug Monitoring and Clinical Biochemistry.
2. Robert E. Notari, Biopharmaceutics and Pharmacokinetics.
3. Leon Shargel, Pharmacy Review.
4. James Swarbrick, Current Concepts in Pharmaceutical Sciences.
5. Milo Gibaldi & Donald Perrier, Pharmacokinetics.

IV B.Pharm 4.6.11: PHARMACY PRACTICE 4.6.11 (b): CLINICAL AND HOSPITAL PHARMACY

50 hours

I. Clinical pharmacy and Therapeutics

1. Introduction to Clinical Pharmacy:

Definition, History and Development of Clinical Pharmacy, Study of daily activities of a clinical pharmacist like Drug therapy monitoring (Medication chart review, Clinical review, TDM, Pharmacist interventions), Ward round participation, Adverse drug reaction management, Medication history interview and patient counseling. 3

2. Drug and Poison information:

Requirements for setting up a Drug Information Center, Types of resources and Answering a Drug Information query. 2

3. Patient data analysis:

Clinical laboratory tests used in the evaluation of common disease states, and interpretation of test results of Liver function tests, Pulmonary function tests, Haemogram and Renal function tests.3

4. Adverse drug reactions:

Epidemiology, Classification, Risk factors, Monitoring and detecting adverse drug Reaction Assessing Casualty using WHO scale and Reporting adverse drug reactions. 2

5. Definition, Symptoms, Classification of the diseases, treatment and parameters to monitor the therapy of following systems/diseases:

5.1 Cardiovascular system	
Hypertension, Congestive cardiac failure and Ischaemic heart disease,	3
5.2 Respiratory system	
Asthma.	1
5.3 Renal system	
Acute and chronic renal failure.	3

5.4	Heamatological disease Iron, B ₁₂ and Folic acid deficiency anaemias.	2
5.5	Endocrine System Diabetes Mellitus.	1
5.6	Nervous System Epilepsy.	1
5.7	Gastrointestinal System Ulcer disease and Hepatitis.	2
5.8	Infectious disease Gastro-enteritis, Pneumonia, Typhoid, Tuberculosis, Malaria and Amebiasis.	6
6.	Concept of Essential Drugs and Rational Drug use.	3
li. Hospital and Community Pharmacy		
1.	The role of the hospital pharmacy, department and itsrelationship to other hospital departments and staff.	1
2. Hospital Drug Policy:		
1.	Pharmacy and Therapeutics committee.	
2.	Formulary and guidelines.	3
3. Organisation of Hospital Pharmacy Services:		
1.	Purchasing and Inventory control, Storage and drug recallprocedure.	
2.	Drug distribution methods	
3.	Central sterile supply division	4
4. Research:		
1.	Practice-based research	
2	Clinical trials.	3

1. The role of the community pharmacy and its relationship to other local health care providers. 1
2. Prescribed medication order and interpretation. 1
3. Patient counseling in community pharmacy including OTC products 1
4. **Social Pharmacy:**
 1. General concepts of health and disease, disease causing agents and prevention of disease.
 2. Classification of food requirements, balanced diet, nutritional deficiency disorders, their treatment and prevention.
 3. Demography and family planning. 3
5. **Code of Ethics for community pharmacists.** 1

CLINICAL AND HOSPITAL PHARMACY REFERENCE BOOKS

1. Roger and Walker, Clinical Pharmacy and Therapeutics, Churchill Livingstone Publication, 1999.
2. Joseph T. Dipiro, et al., Pharmacotherapy: A Pathophysiologic approach, Appleton and Lange Publication, 1996.
3. Eric T. Herfindal, Clinical Pharmacy and Therapeutics, Lippincott Williams & Wilkins, 2000.
4. Scott L.T, Basic skills in interpreting laboratory data, American Society of Health System Pharmacists Inc, 1996.
5. Alfonso. R. Gennaro, Remington: The Science & Practice of Pharmacy, Lippincott Williams & Wilkins, 2001.
6. William Hassan, Hospital Pharmacy, Lea and Febiger, 1981.
7. Russel. T.G, Pathology and Therapeutics for Pharmacists: A basis for Clinical Pharmacy Practice, Chapman and Hall Publication.
8. Koda-Kimble. M.A., et al., Applied Therapeutics: The Clinical Uses of Drugs.
9. Me Allwood and J.T. Fell, Textbook of Hospital Pharmacy.
10. Relevant review articles from recent medical and pharmaceutical literature.

SECTION V

ETHICS IN PHARMACY

Introduction

With the advances in science and technology and the increasing needs of the patient, their families and community, there is a concern for the health of the community as a whole. There is a shift to greater accountability to the society. It is therefore absolutely necessary for each and every one involved in the health care delivery to prepare themselves to deal with these problems. Pharmacists like the other professionals are confronted with many ethical problems.

Standards of professional conduct for pharmacist are necessary in the public interest to ensure an efficient pharmaceutical service. Every pharmacist should not only be willing to play his part in giving such a service, but should also avoid any act or omission which would prejudice the giving of the services or impair confidence, in respect, for pharmacist as a body.

To accomplish this and develop human values, it is desired that all the students undergo ethical sensitization by lectures or discussion on ethical issues.

Introduction to ethics

Ethics may be defined as “the code of moral principles” or as “the science of morals”. The conduct of individuals in any society is governed by the governmental controls on the one hand and the social customs and duties on the other. The former has the sanction of the law and the latter is left to the individual and the society. For this purpose, societies lay down a code of conduct to help the individuals to decide what is right and what is wrong. Such a code, when practiced by any society for a long time, results in the culture of a conscience in the individuals, which gives them a faculty to decipher for themselves, the right way of conducting their daily life, conducive to the well being of the society. This way of conducting life is said to be the ethical way and the culture of such conscience may well be termed as morality.

The candidate after completion of B.Pharm, while practicing shall follow ethics in all spheres asunder

- Pharmacist in relation to his job
- Pharmacist in relation to his trade
- Pharmacist in relation to medical profession
- Pharmacist in relation to his profession

Professional Ethics

The candidate is required to

- Follow Code of conduct
- Maintain confidentiality
- Follow Fairtrade practice
- Follow ethics in handling of prescriptions
- Maintain professional vigilance

Human values, ethical practice and communication abilities

- Adopt ethical principles in all aspects of the professional practice
- Foster professional honesty and integrity
- Discharge the duties irrespective of social status, caste, creed or religion of the customer / client
- Develop oral and written communication skills
- Provide leadership and get the best out of his or her team in a congenial working atmosphere
- Apply high moral and ethical standards while carrying out human or animal research
- Be humble and accept the limitations in his or her knowledge and skill and to ask for help from colleagues when needed.

Pharmacist Oath

I swear by the code of ethics of Pharmacy Council of India in relation to the community and shall act as an integral part of health care team

I shall uphold the laws and standards governing my profession

I shall strive to perfect and enlarge my knowledge to contribute to the advancement of Pharmacy and Public health

I shall follow the system, which I consider best for Pharmaceutical care and counseling of patients

I shall endeavor to discover and manufacture drugs of quality to alleviate sufferings of humanity

I shall hold in confidence the knowledge gained about the patients in connection with my professional practice and never divulge unless compelled to do so by the law

I shall associate with organizations having their objectives for betterment of the profession of Pharmacy and make contribution to carry out the work of those organizations

While I continue to keep this oath unviolated may it be granted to me to enjoy life and the practice of pharmacy respected by all at all times!

Should I trespass and violate this oath, may the reverse be my lot!

SECTION VI

NORMS AND STANDARDS

1.0 STAFF NORMS

The knowledge, skills, attitudes and values of staff are assets which greatly contribute to their own individual effectiveness as well as to institutional performance. In addition, to the pattern and structure of staff, staff norms should therefore, emphasize on processes of recruitment, deployment and development as well as appraisal.

The norms stipulated are primarily for a Pharmacy college with an annual intake of 40 & 60 students.

1.1 Weekly work schedule

Student contact hours per week	:	40 hrs.
Student contact hours in formal learning	:	32 to 35 hrs.
Student centered activities (Library studies) guidance & counseling, Seminars, etc.	:	5 to 8 hrs.

1.2 Annual Work Schedule

In a semester there should be a minimum of 72 (desirable 90 days) instructional days, excluding examination. These norms are deemed to be essential for completion of the semester.

1.3 Student-Teacher Ratio

The student teacher ratio in a class will depend on (i) teacher time required for formal instruction requiring student contact (ii) student time devoted to formal learning requiring teacher contact and (iii) class sizes for different forms of instruction.

The desirable student to teacher ratio for pharmacy degree programme may be 10:1. However, it should not be allowed to rise beyond 15:1.

The teacher will engage in group/class sizes for formal teaching in the ratio as given below:

Theory lecture class	:	60:1
Lab practical	:	20:1

1.1 Staff Pattern - Categories

- i) Principal/HOD/Director and Teaching Staff
- ii) Technical supporting staff
- iii) Library & computer centre staff
- iv) Administrative staff
- v) Miscellaneous staff including maintenance staff

1.2 Teaching Staff cadre

The cadre structure should be as follows:

- i) Principal/Director/Chairman/HOD
- ii) Professor
- iii) Reader/Assistant Professor
- iv) Lecturer-Selection Grade
- v) Lecturer-Senior Scale
- vi) Lecturer

1.3 Cadre distribution - flexibility

The distribution of faculty position in the Pharmacy institution, will depend on the work loads of the different departments based on the curriculum structure. Flexibility in the distribution of different faculty cadres is permitted so long as such flexibility is for meeting the specific needs of the institution in terms of job requirements and courses offered.

1.4 Leave training reserves

To enable institutions to sponsor teachers for staff development programmes and to allow teachers to avail leave to which they are entitled it is necessary that adequate reserve capacity of teachers is available. Each institution will have such reserve capacity in accordance with leave training reserves sanctioned by Central/State Governments from time to time.

1.5 Selection and Recruitment of the teaching staff

The positions of Professors, Assistant Professors/Readers and Lecturers should be filled up through an open selection process. The posts of Senior Lecturers and Lecturers (Selection grade) shall be filled by promotion from the cadre of Lecturers. The selection agencies of states and institutions should adopt reliable and valid procedures for selecting candidates on the basis of competence knowledge, skills, attitudes and values required for the profession, adhering to the stipulations regarding qualification and experience.

1.6 Job description and qualifications of staff

As prescribed by AICTE from time to time.

1.10 Performance Appraisal system

A performance appraisal system for teachers should be set up, well integrated with institutional functioning, and this should lead to the identification of individual training and development needs. This should also enable the identification of faculty members whose performance is outstanding. Such performance and excellence should be well recognized and rewarded. All institutions should introduce a system for performance appraisal conforming with the guidelines formulated in this regard.

1.11 Training and Development

Teachers will be provided with opportunity to improve their qualifications through Quality Improvement Programmes (for Ph.D. in Pharmacy based areas). In addition to these, opportunities will be provided for pedagogy and professional industrial training.

Under the Quality Improvement Programme a variety of short term courses to meet training and retraining needs will be provided for all levels of teachers in Pharmacy Colleges. In addition, Managerial skills Development Programmes for Principals and senior teachers would be made available.

Selected institutions would be offering short-term and long-term training programmes. States and institutions would have to plan training requirements and deployments of trained teachers on an annual basis, making use of these programmes for development of their staff.

Training of teachers is expected to contribute both towards their professional development and improvement in career prospects.

Similarly, summer schools and winter schools will be organized by institutions having expertise in selected areas of interest with the help of ISTE, State Govt, or other funding agencies for the benefit of the teachers in Pharmacy institutions.

2.0 NORMS FOR INFRASTRUCTURE

2.1 Norms for Space and Buildings

The norms for space and buildings have been arrived at, based on the functions, a pharmacy institutions offering degree or diploma programmes, has to perform. In all cases, unit norms have been evolved taking the absolute minimum needs which are indicated as norms. As such the institutions, while envisaging their space and building requirements, must keep their perspectives for development in mind and formulate their plans accordingly.

Around the administrative buildings, class rooms and drawing halls, there is considerable movement of students and there must be adequate veranda space in this part of the college building so that the classes do not disturbed. For this reason, the ratio of plinth to carpet area for the normal building may be taken as 1:4.

Classification of Building Area

The building area required for the pharmacy institution can be classified as instructional area, administrative area, amenities area and residential area.

Instructional area will include class rooms, tutorial rooms, laboratories, computer centre, library, instructional resource centre, seminar hall etc.

Administrative area comprises Principal's room, visitors lounge, staff rooms, administrative office, departmental offices, stores, conference room, confidential room etc.

Area for amenities consists of common rooms, recreation centre, hobby centre, offices for Gymkhana, N.S.S. and Alumni Association, Co-operative Stores, Dispensary, etc.

Residential area includes student hostels, staff quarters and guest house.

2.2 Building Space for Instructional Area

The course structure of any pharmacy institution offering degree programme will include lecturers, tutorials, laboratory work and seminars/colloquium. The institute must have adequate building area for all these instructional activities.

According to the model curriculum, during annual session, the total number of hours per week for which the student is to have contact with the teacher will vary between 27 to 34. In view of this, the instructional schedule is spread over a period of 34 hours a week.

The student strength in a theory class should not exceed 60. the class should be divided into smaller groups of 20 in case of junior (I & II year) classes and 15 students for the senior (III & IV year) and a teacher is assigned to each group. In case of tutorial work, these smaller groups must be accommodated in separate rooms.

The seminars/colloquium of the senior students must be conducted with the entire class of particular discipline.

2.3 Number of Rooms for Theory Classes

The number of rooms required for the theory class can be determined by applying the following relationship.

1.1 Number of Rooms for Tutorial Work

The number of rooms required for the Tutorial work can be determined by applying the following relationship.

1.2 Rooms size for Theory Classes and Tutorial Work

The carpet area requirement of the class rooms and tutorial rooms depends upon the number and type of seating arrangement for the students and provisions for a platform, a table and a chair for the teacher. In pharmaceutical science classes, very frequently students make use of a data book, a calculator and note book. As such he will require slightly more spacious desk as compared to the requirements of classes for students of general education. Further, as the space required for teacher will remain the same irrespective of the class strength, the per student requirement of carpet area will increase with the decrease in class strength.

Considering the above requirements and size of class room furniture and drawing tables normally used in the institution, the following carpet area norms per student are prescribed for class rooms of different size and drawing halls.

Type of Rooms	Carpet Area Requirements in Sqm	
	Minimum	Desirable
Classification of Size		
Class rooms for 40 students	48	56
Class rooms for 60 students	66	78

1.1 Laboratories

The requirements of the laboratories depend upon the programmes that are being offered by the institution and the curricula adopted for these programmes irrespective of the students population. The norms for the carpet area of the different laboratories are given in the Table below. Care should be taken to provide laboratories in all allied subjects to be taught in a programme.

The size of the laboratories should be suitable for a minimum batch of 20 students. The floor area of each laboratory may be calculated at the rate of 3.0 sq.mtr. per student with the minimum of space as given:

Department	Laboratory (Lab.code)	Minimum	Desirable
1. Pharm. Chemistry	Pharmaceutical Chemistry	80	100
	Laboratory-(PCI) Medicinal Chemistry & Natural Products Pharmaceutical Chemistry Laboratory-II (PC2) Organic and Inorganic Chemistry Balance Rooms (2)	80	100
	2*20 sq.m.	40	50
2. Pharmaceutics	Pharmaceutics Laboratory-1 (PH1)	80	100

	Dispensing Pharmacy and Cosmeticology Pharmaceutics Laboratory-II (PH2) including Microbiology and Bio-pharmaceutics	80	100
	Microbiology Laboratory (PH3) (Desirable)	80	100
	Aseptic room	25	35
	Physical Pharmacy (Phy. Pharm.)	80	100
	Industrial Pharmacy (Ind. Pharm.)	80	100
	Machine Room	80	100
3. Pharmaceutical Analysis	Pharmaceutical Analysis (PHA) and Biochemistry	80	100
	Instrument Room (Inst. room) (partly air conditioned)	80	100
4. Pharmacognosy	1) Pharm. Biology Laboratory	80	100
	2) Pharmacognosy Laboratory	80	100
5. Pharmacology	1) Human Anatomy & Physiology	80	100
	2) Pharmacology Laboratory including Anatomy, Physiology and health education smoke room	80 10	100 10
6. General	Animal House (including feed store)	80	100
	Computer room	30	40
	Water pumps room	10	10
	Gas Plant (where LPG gas is not available)	10	10
	Stores-I (General)	100	
	Stores-II (for inflammable materials)	20	

The above areas do not include the rooms of the teaching staff even though such staff rooms are attached to the laboratories. However, they do include the sitting space for the technical supporting staff and storage of laboratory consumables and instruments.

2.7 Library

Purpose: Acquiring, storing, cataloguing, indexing, issuing and returning of books, periodicals and non-print instructional material and providing reader services. Development and production of print and non-print instructional resources such as class notes, handouts, illustrations, slides, filmstrips, audio-visual materials, models charts etc.

NORMS

Minimum	Desirable
150sq.m.	200sq.m.

FACILITIES

Projection Room: One of the class rooms to be equipped with Projection facilities.

2.8 Museum

Every institution shall maintain a museum of crude drugs herbarium sheets/charts of the drugs and plants mentioned in the course in addition, the following is recommended.

1. Colored slides and charts of medicinal plants;
2. Display of popular patent medicines; and
3. Containers of common usage in medicines

The following fittings will be required for the museum:

1. Showcases
2. Cupboards
3. Counters with lighting arrangement
4. Literature counter on specimens.

Minimum area required for museum will be 100 sq.m.

2.9 Other Provisions

(1) Examination Hall cum Auditorium

Purpose: Conducting examinations, conference, extension lectures and functions.
Area requirement: 150 sq.m.

2.10 Building Space for Administrative Offices

The space to be provided for administrative office in technical institution/college will be as per norms given below:

	Carpet area (Sq.m.)
Principal/Office	30
Confidential/Strongroom	20
Conference room	25
Administrative office	30
Maintenance office	20

2.11 Other Space in the Department

In addition to the teaching space the norms for building requirement in a teaching department for other purposes are as below:

	Carpet area (Sq.m.)
Head of	20
Department	10 per
Faculty rooms	teacher 30
Seminar room	(Desirable)

2.12 Building Space for Amenities

The minimum unavoidable requirements for such amenities for normal functioning of the institute are given below along with the norms for the building space

2.13 Students Activity Centre

This will consist of provisions for the indoor games, gymnasium, dramatics and alumni centre etc. (60 sq.m.)

2.14 Toilet Blocks

The college building and the hostels will be provided with adequate number of toilet blocks with urinals, lavatories and wash basins. It will also be necessary to provide separately one toilet block for women in the college building.

Toilet area requirement is as below:

Education Building for 240 students - 24 sq.m.

2.15 Cycle and Scooter Stand

This will be provided as open or covered area as per requirement.

2.16 Other Amenities

The norms of space (Carpet area) or other miscellaneous amenities are as given below:

	Sq.m.
Canteen	100 (Desirable)
Cooperative Stores	100 (Desirable)
NSS Office cum	100 (Desirable)
Stores Girls common	60 (Essential)

2.17 Play Fields

The institution must be provided with play fields so that the students can have adequate participation in games and sports for healthy and constructive activities within the campus.

2.18 Building Space for Residential Area (Desirable)

The hostel requirements depend on a variety of factors like the location of the institution, the region from which students are admitted, local availability of accommodation and that of transport. Though, the requirement of residence for teachers and other employees of the institution also depend upon these factors but at the same time it is necessary to provide an attraction to the new teacher from far off places by providing suitable accommodation at the campus.

2.19 Hostels (Desirable)

The hostel accommodation will be provided with the norms as given below:

Location of College	Hostel Strength
Within 20km of large city	25% of boys and 50% of girls enrollment
Other locations	50% of boys and 100% of girls enrollment

The boys' hostel will be made as a unit for 120 students while there is no minimum for a girls-hostel unit. The first year students will be accommodated in triple seated rooms while others will be given single seated rooms. The norms for the room areas will be as below:

	Carpet area (Sq.m.)
Single room	9
Triple seated	20

The other building space needed in a hostel unit will be as per norm given below:

	Carpet area (Sq.m.)
Kitchen and Dining Hall	20
Indoor game cum Common Hall	0
Medical room	15
Canteen	50 (for all hostels)
Warden office	15
Guest rooms (2 nos)	18
	*

(* Four additional rooms of 9 sq.m. each within the hostel blocks)

2.20 Staff Residences

The minimum residential accommodation that should exist in the campus should be for the Principal all Heads of the Departments all Wardens and the essential staff including a care taker, an electrician, a driver, a water supply operator and chowkidars.

The building space for residence will be as per norms given below:

Principal	140
Professor	Sqm.
Asst.	100
Professor/Lecturer	Sqm.
Class III Staff Class IV	80

2.21 Guest House (Desirable)

To meet the needs of the guests visiting the institution for official work and the parents visiting the students it will be necessary to have a guest house having four suits with attached toilets, a common dining hall and a kitchen.

2.22 Furniture

All laboratories, library, lecture and tutorial rooms, offices, hostels and guest house etc. should be adequately furnished. No norms for furniture are being laid, however, it is expected that the furniture should conform to the requirements of a dignified institution. The institutions may equip the buildings with the furniture as available indigenously.

2.24 Land

It will not be desirable to set the norms of land requirements for the pharmacy college because of existing high pressure on land availability and other similar factors. If enough land is not available near a large town, the double and triple storey construction may have to be resorted to. However, it will be desirable to have the total land area so as all requirements of the building space are fully met as envisaged in these norms.

In addition it will be necessary to have additional land available within the campus for future expansion.

2.23 Laboratory Equipments

The following factors are to be considered in identifying the equipment for the laboratories and workshops:

- i) Development of laboratory skills, i.e., verification calibration, performance testing, investigation and problem solving.
- ii) Development of practical skills, i.e., manufacturing dispensing and communication skills etc.

Laboratory models of equipment are necessary for imparting skills in the laboratories. Equipment similar to the ones used in industry are necessary for developing practical skills. Small scale and less expensive models available in the market, if found adequate for training, should be preferred to large-scale and expensive equipment.

Development activities, which the pharmacy institution has to undertake, have a bearing on the equipment list. In such cases, provision may have to be made for drug store management, training in hospital - pharmacy and community services.

The number of tools/equipments/apparatus to be provided depends on the size of students group, utilization factor, capital cost and operating cost. The number of students in laboratories in any batch should not be, more than 20 with one teacher. Typical layout of the labs for pharmacy programme.

- a. Purpose: Demonstrating, guiding, evaluating by the teacher and investigation, discussing, measuring and testing by the students.
- b. Terminology: The names of the laboratories are in accordance with the terminology used in the model curriculum.

2.25 Norms of construction & fitting

Typical laboratory for a pharmacy institution should follow following norms of construction:

1. All the laboratories should be spacious, well lit and well ventilated.
2. All laboratories should be provided with basic amenities and services like exhaust fans and fume chamber to reduce the pollution wherever necessary.
3. The work benches should be smooth and easily cleanable preferably made of nonabsorbent material.
4. The water taps should be non-leaking and directly installed on sinks. Drainage should be efficient and enclosed.
5. Fire extinguisher and first Aid Kit should be provided in each lab.
6. Preparation room (minimum 10 sq.m.) attached to the laboratories.
7. Balance room attached to concerned laboratories.

Each laboratory should have the following fittings:

1. Gas, Water and electric supply, gas plant or cylinders.

2. Shelves for keeping reagents
3. Working surfaces
4. Sinks
5. Storage cabinets (lockers) for students to keep .the apparatus issued to them for a year wherever required.
6. Exhaust fans and ceiling fans
7. Fume chambers whatever necessary
8. Black board with light
9. Furniture (suitable arrangement for sitting of the teachers)
10. Artificial lighting wherever required for microscopic work.

2.26 Library Books and Periodicals

The minimum norms for the initial stock of books, yearly addition of the books and the number of journals to be subscribed are as given below:

Sl, No.	Item	Minimum
1	Number of books	1500 adequate coverage of a large number of titles in all disciplines of pharmacy
2	Annual addition of books	100 to 150 books
3	Periodicals	15 to 20 national periodicals

2.27 Teaching Aids

The degree in pharmacy being professional courses with sufficient practical application component, will require presentation and discussion in the class room. This can be greatly facilitated by the use of overhead projector, video and computers. Thus a institute shall have the following teaching aids such as overhead projectors for lecture class room, computers, VCR TV and cassettes for the courses.

**Staff Pattern for B.Pharm/D.Pharm/Nl.Pharm
Courses Branch Wise**

Department of Pharmaceutics	Name of Post	With intake of 40 students	Branch wise intake 60 students
1. College with B.Pharm only	Professor	1	1
	Asst. Professor	1	1
	Lecturers	2	2
2. College with B.Pharm and M.Pharm	Professor	2	2
	Asst. Professor	2	2
	Lecturers	2	2
3. College with B.Pharm, M.Pharm & D.Pharm	Professor	2	2
	Asst. Professor	3	3
	Lecturers	3	4
4. College with B.Pharm and D.Pharm	Professor	1	1
	Asst. Professor	2	2
	Lecturers	3	4

Department of Pharmaceutical Chemistry	Name of Post	With intake of 40 students	Branch wise intake 60 students
1. College with B.Pharm only	Professor	1	1
	Asst. Professor	1	1
	Lecturers	2	3
2. College with B.Pharm and M. Pharm	Professor	2	2
	Asst. Professor	2	2
	Lecturers	3	4
3. College with B.Pharm, M.Pharm & D.Pharm	Professor	2	2
	Asst. Professor	2	2
	Lecturers	4	5
4. College with B.Pharm and D.Pharm	Professor	1	1
	Asst. Professor	2	2
	Lecturers	3	4

Department of Pharmacology	Name of Post	With intake of 40 students	Branch wise intake 60 students
1. College with B.Pharm only	Professor Asst. Professor Lecturers	1 1 1	1 1 2
2. College with B.Pharm and M.Pharm	Professor Asst. Professor Lecturers	1 2 2	1 2 2
3. College with B.Pharm, M.Pharm & D.Pharm	Professor Asst. Professor Lecturers	1 2 3	1 2 4
4. College with B.Pharm and D.Pharm	Professor Asst. Professor Lecturers	1 1 2	1 1 3

f

Department of Pharmacognosy	Name of Post	With intake of 40 students	Branch wise intake 60 students
1. College with B.Pharm only	Professor Asst. Professor Lecturers	1 1 1	1 1 1
2. College with B.Pharm and M.Pharm	Professor Asst. Professor Lecturers	1 1 1	1 1 1
3. College with B.Pharm, M.Pharm & D.Pharm	Professor Asst. Professor Lecturers	1 1 1	1 1 1
4. College with B.Pharm and D.Pharm	Professor Asst. Professor Lecturers	1 1 1	1 1 2

Note: Part time teaching staff for Maths, Biology & Computer Science may be appointed

RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES



VISION STATEMENT

The Rajiv Gandhi University of Health Sciences, Karnataka, aims at bringing about a confluence of both Eastern and Western Health Sciences to enable the humankind "Live the full span of our lives allotted by God in Perfect Health"

It would strive for achievement of academic excellence by Educating and Training

Health Professionals who

- > Shall recognize health needs of community,
- > Carry out professional obligations Ethically and Equitably and in keeping with National Health Policy, It would promote development of scientific temper and Health Sciences Research.

It would encourage inculcation of Social Accountability amongst students, teachers and Institutions.

It would Support Quality Assurance for all its educational programmes.

MOTTO

Right for Rightful Health Sciences Education



Rajiv Gandhi University of Health Sciences, Karnataka

4th 'T' Block, Jayanagar, Bangalore 560041.



**RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES, KARNATAKA
(RGUHS), BANGALORE – 560 041**

Pharm D Revised Regulations 2008

(Effective from 2012-2013)

1. ELIGIBILITY

1.1 Qualifying Examination

i) Candidates who have passed two year P.U.C. examination of Karnataka P.U.C. Board or an equivalent examination of any other approved Board or University established by law in India with English as one of the subject and Physics, Chemistry as compulsory subjects along with one of the following subject – Mathematics or Biology or P.C.M.B. Minimum eligibility should be based on the aggregate of P.C.M. or P.C.B. The candidates shall have passed subjects of English, Physics, Chemistry and Biology / Mathematics individually also.

ii) Candidates who have passed D.Pharm course from institutions approved by Pharmacy Council of India U/S 12 of Pharmacy Act, 1948, are only eligible to be admitted to first year Pharm. D course.

1.2 Age

The candidate should have completed 17 years of age on or before 31st day of December of the year of admission to the course.

2. Duration of the course

Pharm.D: The duration of the course shall be six academic years (five years of study and one year of internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of six years duration is divided into two phases –

Phase I – consisting of First, Second, Third, Fourth and Fifth academic year.

Phase II – consisting of internship or residency training during sixth year involving posting in speciality units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services and acquires skill under supervision so that he or she may become capable of functioning independently.

3. Medium of Instruction

Medium of Instruction and Examination Shall be English.

4. Attendance and Progress

A candidate is required to put in at least 80% attendance in theory and practical subjects separately in a recognized institution approved by Pharmacy council of India and affiliated to Rajiv Gandhi University of Health Sciences, Karnataka. The candidate shall complete prescribed course satisfactorily to be eligible to appear for the respective examination.

5. Course of study

- a) The course of study for Pharm.D. Shall include the subjects as given in the Tables below. The number of hours in a week, devoted to each subject for its teaching in theory, practical and tutorial shall not be less than that noted against it in columns (3), (4) and (5) below.

T A B L E S

First Year :

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
1.1	Human Anatomy and Physiology	3	3	1
1.2	Pharmaceutics	2	3	1
1.3	Medicinal Biochemistry	3	3	1
1.4	Pharmaceutical Organic Chemistry	3	3	1
1.5	Pharmaceutical Inorganic Chemistry	2	3	1
1.6	Remedial Mathematics/ Biology**	3	3*	1
	Total hours	16	18	6 = (40)

* For Biology

** For candidates who have studied PCMB in 10+2 course are exempted.

** Colleges to conduct the Examination.

Second Year:

S.No	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
2.1	Pathophysiology	3	-	1
2.2	Pharmaceutical Microbiology	3	3	1
2.3	Pharmacognosy & Phytopharmaceuticals	3	3	1
2.4	Pharmacology-I	3	-	1
2.5	Community Pharmacy	2	-	1
2.6	Pharmacotherapeutics-I	3	3	1
	Total Hours	17	9	6 = 32

Third Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
3.1	Pharmacology-II	3	3	1
3.2	Pharmaceutical Analysis	3	3	1
3.3	Pharmacotherapeutics-II	3	3	1
3.4	Pharmaceutical Jurisprudence	2	-	-
3.5	Medicinal Chemistry	3	3	1
3.6	Pharmaceutical Formulations	2	3	1
	Total hours	16	15	5 = 36

Fourth Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical/ Hospital Posting	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
4.1	Pharmacotherapeutics-III	3	3	1
4.2	Hospital Pharmacy	2	3	1
4.3	Clinical Pharmacy	3	3	1
4.4	Biostatistics & Research Methodology	2	-	1
4.5	Biopharmaceutics & Pharmacokinetics	3	3	1
4.6	Clinical Toxicology	2	-	1
	Total hours	15	12	6 = 33

Fifth Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Hospital posting*	No. of hours of Seminar
(1)	(2)	(3)	(4)	(5)
5.1	Clinical Research	3	-	1
5.2	Pharmacoepidemiology and Pharmacoeconomics	3	-	1
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	2	-	1
5.4	Clerkship *	-	-	1
5.5	Project work (Six Months)	-	20	-
	Total hours	8	20	4 = 32

* Attending ward rounds on daily basis.

Sixth Year:

Internship or residency training including postings in speciality units. Student should independently provide the clinical pharmacy services to the allotted wards.

- (i) Six months in General Medicine department, and
- (ii) Two months each in three other speciality departments

6. Approval of institution conducting the course of study

The regular course for Pharm.D. I, II, III, IV, V and VI year shall be conducted by an institution approved by Pharmacy Council of India and affiliated to Rajiv Gandhi University of Health Sciences, Karnataka. Institution running Pharm D regular courses only shall be permitted to start Pharm D (Post Baccalaureate) course. The approval and affiliation will be granted only if adequate arrangements for teaching-infrastructural facilities, accommodation, equipments, chemicals, glassware, library, teaching and non- teaching staff are provided as prescribed by Pharmacy Council of India and as required under the norms of Rajiv Gandhi University of Health Science, Karnataka(as prescribed in Appendix B).

7. Academic Work

The teaching staff of respective subjects shall maintain a regular record of attendance in both Theory and Practical.

Internal Assessment Marks

A. Theory: Three sessional examinations evenly spread during the academic year shall be conducted by the affiliated colleges. The average marks of the best two examinations shall be computed out of a maximum 30 marks and shall constitute the sessional marks in theory. Provided further the colleges may conduct one special theory sessional examination towards the end of the academic session for those who might have missed any one of the regular sessional examination on genuine grounds.

B. Practical: Students are expected to perform the number of experiments listed in the respective syllabus. Marks shall be awarded out of a maximum of 10 to each of the practical exercise and an average of those shall be computed out of maximum of 10 each marks. In addition, three practical sessional examinations evenly spread during academic year shall be conducted. The average marks of the best two practical examinations shall be computed out of a maximum of 20 marks. A total of 30 marks shall constitute the sessional award in practical. While awarding the sessional marks of practical experiments, the following considerations should be taken into account.

1. Preparation of the candidate.
2. Manipulative skills.
3. Results of the experiment.
4. Knowledge of the experiment
5. Viva voce pertaining to the experiments only.

The College shall maintain the sessional books of the students and the record of sessional marks of the students.

A regular record of both theory and practical class work and sessional examinations conducted in an institution imparting the course shall be maintained for each student in the institution.

8. Examination for Pharm D

- (1) Every year there shall be an examination to examine the students.
- (2) Each examination may be held twice every year. The first examination in a year shall be the annual examination and the second examination shall be supplementary examination.
- (3) The examinations shall be of written and practical (including oral nature) carrying maximum marks for each part of a subject as indicated in Tables below :

T A B L E S

First Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
1.1	Human Anatomy and Physiology	70	30	100	70	30	100
1.2	Pharmaceutics	70	30	100	70	30	100
1.3	Medicinal Biochemistry	70	30	100	70	30	100
1.4	Pharmaceutical Organic Chemistry	70	30	100	70	30	100
1.5	Pharmaceutical Inorganic Chemistry	70	30	100	70	30	100
1.6	Remedial Mathematics/Biology	70	30	100	70*	30*	100*
				600			600 = 1200

* for Biology.

Second Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
2.1	Pathophysiology	70	30	100	-	-	-
2.2	Pharmaceutical Microbiology	70	30	100	70	30	100
2.3	Pharmacognosy & Phytopharmaceuticals	70	30	100	70	30	100
2.4	Pharmacology-I	70	30	100	-	-	-
2.5	Community Pharmacy	70	30	100	-	-	-
2.6	Pharmacotherapeutics-I	70	30	100	70	30	100
				600			300 = 900

Third Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
3.1	Pharmacology-II	70	30	100	70	30	100
3.2	Pharmaceutical Analysis	70	30	100	70	30	100
3.3	Pharmacotherapeutics-II	70	30	100	70	30	100
3.4	Pharmaceutical Jurisprudence	70	30	100	-	-	-
3.5	Medicinal Chemistry	70	30	100	70	30	100
3.6	Pharmaceutical Formulations	70	30	100	70	30	100
				600			500 = 1100

Fourth Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
4.1	Pharmacotherapeutics-III	70	30	100	70	30	100
4.2	Hospital Pharmacy	70	30	100	70	30	100
4.3	Clinical Pharmacy	70	30	100	70	30	100
4.4	Biostatistics & Research Methodology	70	30	100	-	-	-
4.5	Biopharmaceutics & Pharmacokinetics	70	30	100	70	30	100
4.6	Clinical Toxicology	70	30	100	-	-	-
				600			400 = 1000

Fifth Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
5.1	Clinical Research	70	30	100	-	-	-
5.2	Pharmacoepidemiology and Pharmacoeconomics	70	30	100	-	-	-
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	70	30	100	-	-	-
5.4	Clerkship *	-	-	-	70	30	100
5.5	Project work (Six Months)	-	-	-	100**	-	100
				300			200 = 500

* Attending ward rounds on daily basis.

** 30 marks – viva-voce (oral)

70 marks

– Thesis
work

9. Mode of examinations

(1) Theory examination shall be of three hours and practical examination shall be of four hours duration.

(2) Practical examination shall also consist of a viva –voce (Oral) examination.

(3) Clerkship examination – Oral examination shall be conducted after the completion of clerkship of students. An external and an internal examiner will evaluate the student. Students may be asked to present the allotted medical cases followed by discussion. Students' capabilities in delivering clinical pharmacy services, pharmaceutical care planning and knowledge of therapeutics shall be assessed.

10. Criteria for Pass

a) Candidates who have secured a minimum of 50% marks in the Theory (including sessional) and Practical (including sessional) separately in any subject or subjects shall be declared to have passed in that subject/ and exempted from appearing in that subject/s at subsequent examination.

b) Theory and Practical of a particular subject are considered as individual subjects for the purpose of pass criteria.

11. Eligibility for promotion to next year

All students who have appeared for all the subjects and passed the first year annual examination are eligible for promotion to the second year and, so on. However, failure in more than three subjects shall debar him or her from promotion to the next year classes.

12. Declaration of Class

Class shall be awarded at the end of I, II, III, IV, V and final year of Pharm. D examination as shown below:

1) Distinction	75%
2) First class	60% and above and less than 75%
3) Second Class	50% and above and less than 60%

Pass class shall be awarded to such of the candidates who would have passed the examination in more than one attempt. However, this shall not be applicable to candidates who are exempted in Remedial Biology and Remedial Mathematics by the RGUHS Karnataka, Bangalore.

13. Internship

- (1) Internship is a phase of training wherein a student is expected to conduct actual practice of pharmacy and health care and acquires skills under the supervision so that he or she may become capable of functioning independently.
- (2) A student shall be permitted to start the internship only after having passed in theory and practical of all subjects of all the previous years.
- (3) Every student has to undergo one-year internship as per Appendix-C to these regulations.

14. Award of Degree

- a) A candidate who has passed in all the subjects of Pharm.D course has successfully completed the Internship (as described in appendix C) will be eligible for the award of Pharm. D degree.

15. Practical training

1. **Hospital posting** — Every student shall be posted in constituent hospital for a period of not less than seventy five hours to be covered in not less than 200 working days in each of second, third & fourth year course. Each student shall submit report duly certified by the preceptor and duly attested by the Head of the Department or Institution as prescribed. In the fifth year, every student shall spend half a day in the morning hours attending ward rounds on daily basis as a part of clerkship. Theory teaching may be scheduled in the afternoon.
2. **Project work** — (1) To allow the student to develop data collection and reporting skills in the area of community, hospital and clinical pharmacy, a project work shall be carried out under the supervision of a teacher. The project topic must be approved by the Head of the Department or Head of the Institution. The same shall be announced to students within one month of commencement of the fifth year classes. Project work shall be presented in a written report and as a seminar at the end of the year. External and the internal examiners shall do the assessment of the project work.

- (2) Project work shall comprise of objectives of the work, methodology, results, discussions and conclusions.
3. **Objectives of project work** — The main objectives of the project work is to—
- show the evidence of having made accurate description of published work of others and of having recorded the findings in an impartial manner; and
 - develop the students in data collection, analysis and reporting and interpretation skills.
4. **Methodology** — To complete the project work following methodology shall be adopted, namely:—
- students shall work in groups of not less than *two* and not more than *four* under an authorised teacher;
 - project topic shall be approved by the Head of the Department or Head of the Institution;
 - project work chosen shall be related to the pharmacy practice in community, hospital and clinical setup. It shall be patient and treatment (Medicine) oriented, like drug utilization reviews, Pharmacoepidemiology, pharmacovigilance or pharmacoconomics;
 - project work shall be approved by the institutional ethics committee;
 - student shall present at least three seminars, one in the beginning, one at middle and one at the end of the project work; and
 - two-page write-up of the project indicating title, objectives, methodology anticipated benefits and references shall be submitted to the Head of the Department or Head of the Institution.
5. **Reporting** — (1) Student working on the project shall submit jointly to the Head of the Department or Head of the Institution a project report of about 40-50 pages. Project report should include a certificate issued by the RGUHS recognized teacher, Head of the Department as well as by the Head of the Institution
- (2) Project report shall be computer typed in double space using Times Roman font on A4 paper. The title shall be in bold with font size 18, subtitles in bold with font size 14 and the text with font size 12. The cover page of the project report shall contain details about the name of the student and the name of the authorized teacher with font size 14.
- (3) Submission of the project report shall be done at least one month prior to the commencement of annual or supplementary examination.
6. **Evaluation**— The following methodology shall be adopted for evaluating the project work—
- Project work shall be evaluated by internal and external examiners.
 - Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of four students).
 - Three seminars presented by students shall be evaluated for twenty marks each and the average of best two shall be forwarded to the university with marks of other subjects.
 - Evaluation shall be done on the following items:
- | | |
|-------------------------------|-------------------|
| a) Write up of the seminar | (7.5) |
| b) Presentation of work | (7.5) |
| c) Communication skills | (7.5) |
| d) Question and answer skills | (7.5) |
| Total | (30 marks) |

(v) Final evaluation of project work shall be done on the following items: **Marks**

a) Write up of the seminar	(17.5)
b) Presentation of work	(17.5)
c) Communication skills	(17.5)
d) Question and answer skills	(17.5)
Total	(70 marks)

Explanation.— For the purposes of differentiation in the evaluation in case of topic being the same for the group of students, the same shall be done based on item numbers b, c and d mentioned above.

16. No. of Admissions

Pharm. D: 30 students

12
PHARM.D. SYLLABUS

First Year

1.1 HUMAN ANATOMY & PHYSIOLOGY (THEORY)

Theory : 3 Hrs. /Week

- 1. Scope and Objectives:** This course is designed to impart a fundamental knowledge on the structure and functions of the human body. It also helps in understanding both homeostasis mechanisms and homeostatic imbalances of various body systems. Since a medicament, which is produced by pharmacist, is used to correct the deviations in human body, it enhances the understanding of how the drugs act on the various body systems in correcting the disease state of the organs.
- 2. Upon completion of the course the student shall be able to:**
 - a. describe the structure (gross and histology) and functions of various organs of the human body;
 - b. describe the various homeostatic mechanisms and their imbalances of various systems;
 - c. identify the various tissues and organs of the different systems of the human body;
 - d. perform the hematological tests and also record blood pressure, heart rate, pulse and Respiratory volumes;
 - e. appreciate coordinated working pattern of different organs of each system; and
 - f. appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body
- 3. Course materials:**

Text books

 - a. Tortora Gerard J. and Nicholas, P. Principles of anatomy and physiology Publisher Harpercollins college New York.
 - b. Wilson, K.J.W. Ross and Wilson's foundations of anatomy and physiology. Publisher: Churchill Livingstone, Edinburg.

Reference books

 - a. Guyton arthur, C. *Physiology of human body*. Publisher: Holtsaunders.
 - b. Chatterjee,C.C. *Human physiology*. Volume 1&11. Publisher: medical allied agency, Calcutta.
 - c. Peter L. Williams, Roger Warwick, Mary Dyson and Lawrence, H.
 - d. *Gray's anatomy*. Publisher:Churchill Livingstone, London.

4. Lecture wise program : Topics

- 1 Scope of anatomy and physiology, basic terminologies used in this subject
(Description of the body as such planes and terminologies)
- 2 Structure of cell – its components and their functions.
- 3 Elementary tissues of the human body: epithelial, connective, Muscular and nervous tissues-their sub-types and characteristics
- 4 a) Osseous system - structure, composition and functions of the Skeleton. (done in practical classes - 6hrs)
b) Classification of joints, Types of movements of joints and disorders of joints
(Definitions only)
- 5 Haemopoetic System
a) Composition and functions of blood
b) Haemopoiesis and disorders of blood components (definition of disorder)
c) Blood groups
d) Clotting factors and mechanism
e) Platelets and disorders of coagulation
- 6 Lymph
a) Lymph and lymphatic system, composition, formation and circulation.
b) Spleen: structure and functions, Disorders
c) Disorders of lymphatic system (definition only)
- 7 Cardiovascular system
a) Anatomy and functions of heart
b) Blood vessels and circulation (Pulmonary, coronary and systemic circulation)
c) Electrocardiogram (ECG)
d) Cardiac cycle and heart sounds
e) Blood pressure – its maintenance and regulation
f) Definition of the following disorders
Hypertension, Hypotension, Arteriosclerosis, Atherosclerosis, Angina, Myocardial infarction, Congestive heart failure, Cardiac arrhythmias
- 8 Respiratory system
a) Anatomy of respiratory organs and functions
b) Mechanism / physiology of respiration and regulation of respiration
c) Transport of respiratory gases
d) Respiratory volumes and capacities, and Definition of: Hypoxia, Asphyxia, Dybarism, Oxygen therapy and resuscitation.
- 9 Digestive system
a) Anatomy and physiology of GIT
b) Anatomy and functions of accessory glands of GIT
c) Digestion and absorption
d) Disorders of GIT (definitions only)

- 10 Nervous system
 - a) Definition and classification of nervous system
 - b) Anatomy, physiology and functional areas of cerebrum
 - c) Anatomy and physiology of cerebellum
 - d) Anatomy and physiology of mid brain
 - e) Thalamus, hypothalamus and Basal Ganglia
 - f) Spinal cord: Structure & reflexes – mono-poly-planter
 - g) Cranial nerves – names and functions
 - h) ANS – Anatomy & functions of sympathetic & parasympathetic N.S.
- 11 Urinary system
 - a) Anatomy and physiology of urinary system
 - b) Formation of urine
 - c) Renin Angiotensin system – Juxtaglomerular apparatus - acid base Balance
 - d) Clearance tests and micturition
- 12 Endocrine system
 - a) Pituitary gland
 - b) Adrenal gland
 - c) Thyroid and Parathyroid glands
 - d) Pancreas and gonads
- 13 Reproductive system
 - a) Male and female reproductive system
 - b) Their hormones – Physiology of menstruation
 - c) Spermatogenesis & Oogenesis
 - d) Sex determination (genetic basis)
 - e) Pregnancy and maintenance and parturition
 - f) Contraceptive devices
- 14 Sense organs
 - a) Eye
 - b) Ear
 - c) Skin
 - d) Tongue & Nose
- 15 Skeletal muscles
 - a) Histology
 - b) Physiology of Muscle contraction
 - c) Physiological properties of skeletal muscle and their disorders (definitions)
- 16 Sports physiology
 - a) Muscles in exercise, Effect of athletic training on muscles and muscle performance,
 - b) Respiration in exercise, CVS in exercise, Body heat in exercise, Body fluids and salts in exercise,
 - c) Drugs and athletics

1.1 HUMAN ANATOMY & PHYSIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

General Requirements: Dissection box, Laboratory Napkin, muslin cloth, record, Observation book(100pages), Stationary items, Blood lancet.

Course materials:

Text books

Goyal, R. K, Natvar M.P, and Shah S.A, Practical anatomy, physiology and biochemistry, latest edition, Publisher: B.S Shah Prakashan, Ahmedabad.

Reference books

Ranade VG, Text book of practical physiology, Latest edition, Publisher: PVG, Pune
Anderson Experimental Physiology, Latest edition, Publisher: NA

List of Experiments:

1. Study of tissues of human body
 - (a) Epithelial tissue.
 - (b) Muscular tissue.
2. Study of tissues of human body
 - (a) Connective tissue.
 - (b) Nervous tissue.
3. Study of appliances used in hematological experiments.
4. Determination of W.B.C. count of blood.
5. Determination of R.B.C. count of blood.
6. Determination of differential count of blood.
7. Determination of
 - (a) Erythrocyte Sedimentation Rate.
 - (b) Hemoglobin content of Blood.
 - (c) Bleeding time & Clotting time.
8. Determination of
 - (a) Blood Pressure.
 - (b) Blood group.
9. Study of various systems with the help of charts, models & specimens
 - (a) Skeleton system part I-axial skeleton.
 - (b) Skeleton system part II- appendicular skeleton.
 - (c) Cardiovascular system.
 - (d) Respiratory system.

- (e) Digestive system. (f) Urinary system. (g) Nervous system. (h) Special senses.
(i) Reproductive system.

10. Study of different family planning appliances.
11. To perform pregnancy diagnosis test.
12. Study of appliances used in experimental physiology.
13. To record simple muscle curve using gastrocnemius sciatic nerve preparation.
14. To record simple summation curve using gastrocnemius sciatic nerve preparation.
15. To record simple effect of temperature using gastrocnemius sciatic nerve preparation.
16. To record simple effect of load & after load using gastrocnemius sciatic nerve preparation.
17. To record simple fatigue curve using gastrocnemius sciatic nerve preparation.

Scheme of Practical Examination:

	Sessionals	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.2 PHARMACEUTICS (THEORY)

Theory : 2 Hrs. /Week

1. **Scope and objectives:** This course is designed to impart a fundamental knowledge on the art and science of formulating different dosage forms. It prepares the students for most basics of the applied field of pharmacy.
2. **Upon the completion of the course the student should be able to:**
 - a. know the formulation aspects of different dosage forms;
 - b. do different pharmaceutical calculation involved in formulation;
 - c. formulate different types of dosage forms; and
 - d. appreciate the importance of good formulation for effectiveness.

3. Course materials:

Text books

- a. Cooper and Gunns Dispensing for pharmacy students.
- b. A text book Professional Pharmacy by N.K.Jain and S.N.Sharma.

Reference books

- a. Introduction to Pharmaceutical dosage forms by Howard C. Ansel.
- b. Remington's Pharmaceutical Sciences.
- c. Register of General Pharmacy by Cooper and Gunn.
- d. General Pharmacy by M.L.Schroff.

4. Lecture wise programme:

Topics

- 1
 - a. Introduction to dosage forms - classification and definitions
 - b. Prescription: definition, parts and handling
 - c. Posology: Definition, Factors affecting dose selection. Calculation of children and infant doses.
- 2 Historical back ground and development of profession of pharmacy and pharmaceutical industry in brief.
- 3 Development of Indian Pharmacopoeia and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.
- 4 Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc.
- 5 Powders and Granules: Classification advantages and disadvantages, Preparation of simple, compound powders, Insufflations, Dusting powders, Eutectic and Explosive powders, Tooth powder and effervescent powders and granules.
- 6 Monophasic Dosage forms: Theoretical aspects of formulation including adjuvant like stabilizers, colorants, flavours with examples. Study of Monophasic liquids like gargles, mouth washes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions.

- 7 Biphasic dosage forms: Suspensions and emulsions, Definition, advantages and disadvantages, classification, test for the type of emulsion, formulation, stability and evaluation.
- 8 Suppositories and pessaries: Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation.
- 9 Galenicals: Definition, equipment for different extraction processes like infusion, Decoction, Maceration and Percolation, methods of preparation of spirits, tinctures and extracts.
- 10 Pharmaceutical calculations.
- 11 Surgical aids: Surgical dressings, absorbable gelatin sponge, sutures, ligatures and medicated bandages.
- 12 Incompatibilities: Introduction, classification and methods to overcome the incompatibilities.

1.2 PHARMACEUTICS (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments:

- 1. Syrups**
 - a. Simple Syrup I.P
 - b. Syrup of Ephedrine Hcl NF
 - c. Syrup Vasaka IP
 - d. Syrup of ferrous Phosphate IP
 - e. Orange Syrup
- 2. Elixir**
 - a. Piperizine citrate elixir BP
 - b. Cascara elixir BPC
 - c. Paracetamol elixir BPC
- 3. Linctus**
 - a. Simple Linctus BPC
 - b. Pediatric simple Linctus BPC
- 4. Solutions**
 - a. Solution of cresol with soap IP
 - b. Strong solution of ferric chloride BPC
 - c. Aqueous Iodine Solution IP
 - d. Strong solution of Iodine IP
 - e. Strong solution of ammonium acetate IP

5. **Liniments**
 - a. Liniment of turpentine IP*
 - b. Liniment of camphor IP
6. **Suspensions***
 - a. Calamine lotion
 - b. Magnesium Hydroxide mixture BP
7. **Emulsions***
 - a. Cod liver oil emulsion
 - b. Liquid paraffin emulsion
8. **Powders** [□]
 - a. Eutectic powder
 - b. Explosive powder
 - c. Dusting powder
 - d. Insufflations
9. **Suppositories** [□]
 - a. Boric acid suppositories
 - b. Chloral suppositories
10. **Incompatibilities**
 - a. Mixtures with Physical
 - b. Chemical & Therapeutic incompatibilities

* colourless bottles required for dispensing [□] Paper envelope (white), butter paper and white paper required for dispensing.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.3 MEDICINAL BIOCHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

1. Scope of the Subject: Applied biochemistry deals with complete understanding of the molecular level of the chemical process associated with living cells. Clinical chemistry deals with the study of chemical aspects of human life in health and illness and the application of chemical laboratory methods to diagnosis, control of treatment, and prevention of diseases.

2. Objectives of the Subject (Know, do, appreciate) :

The objective of the present course is providing biochemical facts and the principles to the students of pharmacy. Upon completion of the subject student shall be able to –

- understand the catalytic activity of enzymes and importance of isoenzymes in diagnosis of diseases;
- know the metabolic process of biomolecules in health and illness (metabolic disorders);
- understand the genetic organization of mammalian genome; protein synthesis; replication; mutation and repair mechanism;
- know the biochemical principles of organ function tests of kidney, liver and endocrine gland; and
- do the qualitative analysis and determination of biomolecules in the body fluids.

Text books (Theory)

- Harpers review of biochemistry - Martin
- Text book of biochemistry – D.Satyanarayana
- Text book of clinical chemistry- Alex kaplan &Laverve L.Szabo

Reference books (Theory)

- Principles of biochemistry -- Lehninger
- Text book of biochemistry -- Ramarao
- Practical Biochemistry-David T.Plummer.
- Practical Biochemistry-Pattabhiraman.

3. Lecture wise programme:

Topics

- Introduction to biochemistry:** Cell and its biochemical organization, transport process across the cell membranes. Energy rich compounds; ATP, Cyclic AMP and their biological significance.
- Enzymes:** Definition; Nomenclature; IUB classification; Factor affecting enzyme activity; Enzyme action; enzyme inhibition. Isoenzymes and their therapeutic and diagnostic applications; Coenzymes and their biochemical role and deficiency diseases.
- Carbohydrate metabolism:** Glycolysis, Citric acid cycle (TCA cycle), HMP shunt, Glycogenolysis, gluconeogenesis, glycogenesis. Metabolic disorders of carbohydrate metabolism (diabetes mellitus and glycogen storage diseases); Glucose, Galactose tolerance test and their significance; hormonal regulation of carbohydrate metabolism.

- 4 **Lipid metabolism:** Oxidation of saturated (β -oxidation); Ketogenesis and ketolysis; biosynthesis of fatty acids, lipids; metabolism of cholesterol; Hormonal regulation of lipid metabolism. Defective metabolism of lipids (Atherosclerosis, fatty liver, hypercholesterolemia).
- 5 **Biological oxidation:** Coenzyme system involved in Biological oxidation. Electron transport chain (its mechanism in energy capture; regulation and inhibition); Uncouplers of ETC; Oxidative phosphorylation;
- 6 **Protein and amino acid metabolism:** protein turn over; nitrogen balance; Catabolism of Amino acids (Transamination, deamination & decarboxylation). Urea cycle and its metabolic disorders; production of bile pigments; hyperbilirubinemia, porphoria, jaundice. Metabolic disorder of Amino acids.
- 7 **Nucleic acid metabolism:** Metabolism of purine and pyrimidine nucleotides; Protein synthesis; Genetic code; inhibition of protein synthesis; mutation and repair mechanism; DNA replication (semiconservative /onion peel models) and DNA repair mechanism.
- 8 **Introduction to clinical chemistry: Cell;** composition; malfunction; Roll of the clinical chemistry laboratory.
- 9 **The kidney function tests:** Role of kidney; Laboratory tests for normal function includes-
 - a) Urine analysis (macroscopic and physical examination, quantitative and semiquantitative tests.)
 - b) Test for NPN constituents. (Creatinine /urea clearance, determination of blood and urine creatinine, urea and uric acid)
 - c) Urine concentration test
 - d) Urinary tract calculi. (stones)
- 10 **Liver function tests:** Physiological role of liver, metabolic, storage, excretory, protective, circulatory functions and function in blood coagulation.
 - a) Test for hepatic dysfunction-Bile pigments metabolism.
 - b) Test for hepatic function test- Serum bilirubin, urine bilirubin, and urine urobilinogen.
 - c) Dye tests of excretory function.
 - d) Tests based upon abnormalities of serum proteins.
 Selected enzyme tests.
- 11 **Lipid profile tests:** Lipoproteins, composition, functions. Determination of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides.
- 12 **Immunochemical techniques** for determination of hormone levels and protein levels in serum for endocrine diseases and infectious diseases.
Radio immuno assay (RIA) and Enzyme Linked Immuno Sorbent Assay (ELISA)
- 13 **Electrolytes:** Body water, compartments, water balance, and electrolyte distribution. Determination of sodium, calcium potassium, chlorides, bicarbonates in the body fluids.

1.3 MEDICINAL BIOCHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

Title of the Experiment:

- 1 Qualitative analysis of normal constituents of urine.*
 - 2 Qualitative analysis of abnormal constituents of urine.*
 - 3 Quantitative estimation of urine sugar by Benedict's reagent method.**
 - 4 Quantitative estimation of urine chlorides by Volhard's method.**
 - 5 Quantitative estimation of urine creatinine by Jaffe's method.**
 - 6 Quantitative estimation of urine calcium by precipitation method.**
 - 7 Quantitative estimation of serum cholesterol by Libermann Burchard's method.**
 - 8 Preparation of Folin Wu filtrate from blood.*
 - 9 Quantitative estimation of blood creatinine.**
 - 10 Quantitative estimation of blood sugar Folin-Wu tube method.**
 - 11 Estimation of SGOT in serum.**
 - 12 Estimation of SGPT in serum.**
 - 13 Estimation of Urea in Serum.**
 - 14 Estimation of Proteins in Serum.**
 - 15 Determination of serum bilirubin**
 - 16 Determination of Glucose by means of Glucoseoxidase.**
 - 17 Enzymatic hydrolysis of Glycogen/Starch by Amylases.**
 - 18 Study of factors affecting Enzyme activity. (pH & Temp.)**
 - 19 Preparation of standard buffer solutions and its pH measurements (any two)*
 - 20 Experiment on lipid profile tests**
 - 21 Determination of sodium, calcium and potassium in serum.**
- ** indicate major experiments & * indicate minor experiments

Assignments:

Format of the assignment

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.4 PHARMACEUTICAL ORGANIC CHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

- 1. Scope and objectives:** This course is designed to impart a very good knowledge about
 - a. IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds;
 - b. Some important physical properties of organic compounds;
 - c. Free radical/ nucleophilic [alkyl/ acyl/ aryl] /electrophilic substitution, free radical/ nucleophilic / electrophilic addition, elimination, oxidation and reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability of compounds;
 - d. Some named organic reactions with mechanisms; and
 - e. Methods of preparation, test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.

2. Course materials:

Text books

- a. T.R.Morrison and R. Boyd - Organic chemistry,
- b. Bentley and Driver-Text book of Pharmaceutical chemistry
- c. I.L.Finer- Organic chemistry, the fundamentals of chemistry

Reference books

- a. Organic chemistry – J.M.Cram and D.J.Cram
- b. Organic chemistry- Brown
- c. Advanced organic chemistry- Jerry March, Wiley
- d. Organic chemistry- Cram and Hammered, Pine Hendrickson

3. Lecture wise programme :

Topics

- 1 Structures and Physical properties:
 - a. Polarity of bonds, polarity of molecules, M.P, Inter molecular forces, B.P, Solubility, non ionic solutes and ionic solutes, protic and aprotic Solvents, ion pairs,
 - b. Acids and bases, Lowry bronsted and Lewis theories
 - c. Isomerism
- 2 Nomenclature of organic compound belonging to the following classes Alkanes, Alkenes, Dienes, Alkynes, Alcohols, Aldehydes, Ketones, Amides, Amines, Phenols, Alkyl Halides, Carboxylic Acid, Esters, Acid Chlorides And Cycloalkanes.
- 3 Free radicals chain reactions of alkane : Mechanism, relative reactivity and stability
- 4 Alicyclic compounds : Preparations of cyclo alkanes, Bayer strain theory and orbital picture of angle strain.
- 5 Nucleophilic aliphatic substitution mechanism: Nucleophiles and leaving groups, kinetics of second and first order reaction, mechanism and kinetics of SN_2 reactions. Stereochemistry and steric hindrance, role of solvents, phase transfer catalysis, mechanism and kinetics of SN_1 reactions, stereochemistry, carbocation and their stability, rearrangement of carbocation, role of solvents in SN_1 reaction, Ion dipole bonds, SN_2 versus SN_1 solvolyses, nucleophilic assistance by the solvents.

- 6 Dehydro halogenation of alkyl halides: 1,2 elimination, kinetics, E2 and E1 mechanism, elimination via carbocation, evidence for E2 mechanism, absence of rearrangement isotope effect, absence hydrogen exchange, the element effect, orientation and reactivity, E2 versus E1, elimination versus substitution, dehydration of alcohol, ease of dehydration, acid catalysis, reversibility, orientation.
- 7 Electrophilic and free radicals addition: Reactions at carbon-carbon, double bond, electrophile, hydrogenation, heat of hydrogenation and stability of alkenes, markownikoff rule, addition of hydrogen halides, addition of hydrogen bromides, peroxide effect, electrophilic addition, mechanism, rearrangement, absence of hydrogen exchange, orientation and reactivity, addition of halogen, mechanism, halohydrin formation, mechanism of free radicals addition, mechanism of peroxide initiated addition of hydrogen bromide, orientation of free addition, additions of carbene to alkene, cyclo addition reactions.
- 8 Carbon-carbon double bond as substituents: Free radical halogenations of alkenes, comparison of free radical substitution with free radical addition, free radical substitution in alkenes, orientation and reactivity, allylic rearrangements.
- 9 Theory of resonance: Allyl radical as a resonance hybrid, stability, orbital picture, resonance stabilisation of allyl radicals, hyper conjugation, allyl cation as a resonance hybrid, nucleophilic substitution in allylic substrate, SN1 reactivity, allylic rearrangement, resonance stabilisation of allyl cation, hyper conjugation, nucleophilic substitution in allylic substrate, SN2 nucleophilic substitution in vinylic substrate, vinylic cation, stability of conjugated dienes, resonance in alkenes, hyper conjugation, ease of formation of conjugated dienes, orientation of elimination, electrophilic addition to conjugated dienes, 1,4- addition, 1,2-versus 1,4-addition, rate versus equilibrium, orientation and reactivity of free radical addition to conjugated dienes.
- 10 Electrophilic aromatic substitution: Effect of substituent groups, determination of orientation, determination of relative reactivity, classification of substituent group, mechanism of nitration, sulphonation, halogenation, friedel craft alkylation, friedel craft acylation, reactivity and orientation, activating and deactivating O,P,M directing groups, electron release via resonance, effect of halogen on electrophilic aromatic substitution in alkyl benzene, side chain halogenation of alkyl benzene, resonance stabilization of benzyl radical.
- 11 Nucleophilic addition reaction: Mechanism, ionisation of carboxylic acids, acidity constants, acidity of acids, structure of carboxylate ions, effect of substituent on acidity, nucleophilic acyl substitution reaction, conversion of acid to acid chloride, esters, amide and anhydride. Role of carboxyl group, comparison of alkyl nucleophilic substitution with acyl nucleophilic substitution.

- 12 Mechanism of aldol condensation, claisen condensation, cannizzaro reaction, crossed aldol condensation, crossed cannizzaro reaction, benzoin condensation, perkin condensation. Knoevenagel, Reformatsky reaction, Wittig reaction, Michael addition.
- 13 Hoffman rearrangement: Migration to electron deficient nitrogen, Sandmeyer's reaction, basicity of amines, diazotisation and coupling, acidity of phenols, Williamson synthesis, Fries rearrangement, Kolbe reaction, Reimer tieman's reactions.
- 14 Nucleophilic aromatic substitution: Bimolecular displacement mechanisms, orientation, comparison of aliphatic nucleophilic substitution with that of aromatic.
- 15 Oxidation reduction reaction.
- 16 Study of the following official compounds- preparation, test for purity, assay and medicinal uses of Chlorbutol, Dimercaprol, Glyceryl trinitrate, Urea, Ethylene diamine dihydrate, Vanillin, Paraldehyde, Ethylene chloride, Lactic acid, Tartaric acid, citric acid, salicylic acid, aspirin, methyl salicylate, ethyl benzoate, benzyl benzoate, dimethyl phthalate, sodium lauryl sulphate, saccharin sodium, mephensin.

1.4 PHARMACEUTICAL ORGANIC CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

I. Introduction to the various laboratory techniques through demonstration involving synthesis of the following compounds (at least 8 compounds to be synthesised):

1. Acetanilide / aspirin (Acetylation)
2. Benzanilide / Phenyl benzoate (Benzoylation)
3. P-bromo acetanilide / 2,4,6 – tribromo aniline (Bromination)
4. Dibenzylidene acetone (Condensation)
5. 1-Phenylazo-2-naphthol (Diazotisation and coupling)
6. Benzoic acid / salicylic acid (Hydrolysis of ester)
7. M-dinitro benzene (Nitration)
8. 9, 10 – Anthraquinone (Oxidation of anthracene) / preparation of benzoic acid from toluene or benzaldehyde
9. M-phenylene diamine (Reduction of M-dinitrobenzene) / Aniline from nitrobenzene
10. Benzophenone oxime
11. Nitration of salicylic acid
12. Preparation of picric acid
13. Preparation of O-chlorobenzoic acid from O-chlorotoluene
14. Preparation of cyclohexanone from cyclohexanol

II. Identification of organic compounds belonging to the following classes by :

Systematic qualitative organic analysis including preparation of derivatives
 Phenols, amides, carbohydrates, amines, carboxylic acids, aldehyde and ketones,
 Alcohols, esters, hydrocarbons, anilides, nitrocompounds.

III. Introduction to the use of stereo models:

Methane, Ethane, Ethylene, Acetylene, Cis alkene, Trans alkene, inversion of configuration.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.5 PHARMACEUTICAL INORGANIC CHEMISTRY (THEORY)

**Theory : 2 Hrs.
/Week**

1. **Scope and objectives:** This course mainly deals with fundamentals of Analytical chemistry and also the study of inorganic pharmaceuticals regarding their monographs and also the course deals with basic knowledge of analysis of various pharmaceuticals.
2. **Upon completion of the course student shall be able to:**
 - a. under stand the principles and procedures of analysis of drugs and also regarding the application of inorganic pharmaceuticals;
 - b. know the analysis of the inorganic pharmaceuticals their applications; and
 - c. appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.

3. Course

materials:

Text books

- a. A text book Inorganic medicinal chemistry by Surendra N. Pandeya
- b. A. H. Beckett and J. B. Stanlake's Practical Pharmaceutical chemistry Vol-I & Vol-II
- c. Inorganic Pharmaceutical Chemistry III-Edition P.Gundu Rao

Reference books

- a. Inorganic Pharmaceutical Chemistry by Anand & Chetwal
- b. Pharmaceutical Inorganic chemistry by Dr.B.G.Nagavi
- c. Analytical chemistry principles by John H. Kennedy
d. I.P.1985 and 1996, Govt. of India, Ministry of health

4. Lecture wise

programme: Topics

- 1 Errors: Errors in quantitative analysis, classification of errors, concept of accuracy and precision, treatment of analytical
- 2 Volumetric analysis: Principle of volumetric analysis, different methods of analysis, different methods of expressing concentrations of solutions, Primary and secondary standards.
- 3 Acid-base titrations: Acid-base concepts, relative strength of acids and bases, law of mass action, common ion effect, ionic product of water, Henderson-Hasselbalch equation, buffer solutions, theory of indicators, neutralization curves, choice of indicators, mixed and universal indicators.
- 4 Redox titrations: Concepts of oxidation and reduction reactions. Redox reactions, theory of redox titrations, redox indicators, iodometry, iodimetry, titrations involving ceric sulphate, potassium iodate, potassium bromate, titanous chloride, Potassium permanganate.
- 5 Non aqueous titrations: Theoretical basis, types of solvents, preparations and standardization of titrant solutions, titration of weak acid, weak bases and indicators. Standardization of perchloric acid, lithium and sodium methoxide, tetra butyl ammonium hydroxide.

- 6 Precipitation titrations: Introduction, types of precipitation titrations, end point detection.
- 7 Complexometric titrations: Introduction, principle, types of titrations, end point detection.
- 8 Theory of indicators
- 9 Gravimetry: Basic concepts, precipitation techniques, co-precipitations, post precipitation, various steps involved in gravimetric analysis, pharmaceutical applications.
- 10 Limit tests: Definition, importance, general procedure for limit test for chlorides, sulphates, iron, arsenic, lead and heavy metals.
- 11 Medicinal gases: Preparation and uses of the following oxygen, carbon dioxide, Helium, Nitrogen and Nitrous oxide.
Method of preparation, assay, storage conditions and uses of Inorganic compounds listed in IP belonging to the following categories.
- 12 Acidifiers: Dilute HCl, Sodium Phosphate, Ammonium chloride.
- 13 Antacids: Classification, qualities of an ideal antacid, side effects, advantages, combination therapy, acid neutralizing capacity, sodium bicarbonate, Potassium citrate, Aluminium hydroxide gel, Dried Aluminium hydroxide gel, magnesium hydroxide, Light and Heavy magnesium trisilicate, Light and Heavy magnesium carbonate, Calcium carbonate, Magaldrate and Bismuth carbonate.
- 14 Cathartics: Magnesium hydroxide, Magnesium sulphate, Magnesium carbonate, Sodium phosphate.
- 15 Electrolyte replenishers: Electrolytes used for replacement therapy: sodium chloride, potassium chloride, calcium chloride, calcium gluconate.
Electrolytes used in acid-base therapy: Sodium acetate, potassium acetate, sodium bicarbonate, potassium bicarbonate, sodium citrate, sodium lactate, ammonium chloride, Electrolyte combination therapy, compound sodium chloride solution, sodium chloride injection and oral rehydration salt.
- 16 Essential Trace elements: Definition, physiological role of Iron, Copper, Zinc, Chromium, Manganese, Molybdenum, Selenium, Sulphur and Iodine.
- 17 Antimicrobials: Hydrogen peroxide, Potassium permanganate, Chlorinated Lime, Iodine, Boric acid, Silver nitrate, Selenium Sulphide.
- 18 Pharmaceutical Aids: Sodium bisulphate, sodium metabisulphite, bentonite, magnesium stearate, zinc stearate, aluminium sulphate, sodium carboxy methylcellulose, purified water, water for injection and sterile water for injection.
- 19 Dental Products:
Anti-caries agents: Role of Fluorides as anti-caries agents, Sodium Fluoride.
Dentifrices: Calcium carbonate, dibasic calcium phosphate, Zinc chloride.
- 20 Miscellaneous compounds
Sclerosing agents: Hypertonic saline, Sodium tetradecyl sulphate.
Expectorants: Potassium citrate and Potassium iodide.
Sedative: Potassium bromide.
Antidotes: Sodium nitrite, Sodium thiosulphate and Charcoal
Respiratory stimulant: Ammonium carbonate.
- 21 Radio Pharmaceuticals: Introduction, measurement of radioactivity, clinical applications and dosage, hazards and precautions.

1.5 PHARMACEUTICAL INORGANIC CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

1. Limit test (6 exercises)

- a. Limit test for chlorides
- b. Limit test for sulphates
- c. Limit test for iron
- d. Limit test for heavy metals
- e. Limit test for arsenic
- f. Modified limit tests for chlorides and sulphates

2. Assays (10 exercises)

- a. Ammonium chloride- Acid-base titration
- b. Ferrous sulphate- Cerimetry
- c. Copper sulphate- Iodometry
- d. Calcilugluconate- Complexometry
- e. Hydrogen peroxide – Permanganometry
- f. Sodium benzoate – Nonaqueous titration
- g. Sodium chloride – Modified volhard's method
- h. Assay of KI – KIO_3 titration
- i. Gravimetric estimation of barium as barium sulphate
- j. Sodium antimony gluconate or antimony potassium tartarate

3. Estimation of mixture (Any two exercises)

- a. Sodium hydroxide and sodium carbonate
- b. Boric acid and Borax
- c. Oxalic acid and sodium oxalate

4. Test for identity (Any three exercises)

- a. Sodium bicarbonate
- b. Barium sulphate
- c. Ferrous sulphate
- d. Potassium chloride

5. Test for purity (Any two exercises)

- a. Swelling power in Bentonite
- b. Acid neutralising capacity in aluminium hydroxide gel
- c. Ammonium salts in potash alum
- d. Adsorption power heavy Kaolin
- e. Presence of Iodates in KI

6. Preparations (Any two exercises)

- a. Boric acids
- b. Potash alum
- c. Calcium lactate
- d. Magnesium sulphate

Scheme of Practical Examination :

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment 1&2	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.6 REMEDIAL MATHEMATICS/BIOLOGY (THEORY)

Theory : 3 Hrs. /Week

REMEDIAL MATHEMATICS :

1. **Scope and objectives:** This is an introductory course in mathematics. This subjects deals with the introduction to matrices, determinants, trigonometry, analytical geometry, differential calculus, integral calculus, differential equations, laplace transform.
2. **Upon completion of the course the student shall be able to : –**
 - a. Know Trigonometry, Analytical geometry, Matrices, Determinant, Integration, Differential equation, Laplace transform and their applications;
 - b. solve the problems of different types by applying theory; and
 - c. appreciate the important applications of mathematics in pharmacy.

3. Course materials:

Text books

- a. Differential calculus By Shantinakaran
- b. Text book of Mathematics for second year pre-university by Prof.B.M.Sreenivas

Reference books

- a. Integral calculus By Shanthinarayan
- b. Engineering mathematics By B.S.Grewal
- c. Trigonometry Part-I By S.L.Loney

4. Lecture wise programme :

Topics

- 1 **Algebra** : Determinants, Matrices
- 2 **Trigonometry** : Sides and angles of a triangle, solution of triangles
- 3 **Analytical Geometry** :Points, Straight line, circle, parabola
- 4 **Differential calculus**: Limit of a function, Differential calculus, Differentiation of a sum, Product, Quotient Composite, Parametric, exponential, trigonometric and Logarithmic function. Successive differentiation, Leibnitz's theorem, Partial differentiation, Euler's theorem on homogeneous functions of two variables
- 5 **Integral Calculus**: Definite integrals, integration by substitution and by parts, Properties of definite integrals.
- 6 **Differential equations**: Definition, order, degree, variable separable, homogeneous, Linear, heterogeneous, linear, differential equation with constant coefficient, simultaneous linear equation of second order.
- 7 **Laplace transform**: Definition, Laplace transform of elementary functions, Properties of linearity and shifting.

BIOLOGY :

1. **Scope and objectives:** This is an introductory course in Biology, which gives detailed study of natural sources such as plant and animal origin. This subject has been introduced to the pharmacy course in order to make the student aware of various naturally occurring drugs and its history, sources, classification, distribution and the characters of the plants and animals. This subject gives basic foundation to Pharmacognosy.

2. **Course materials:**

Text books

- a. Text book of Biology by S.B.Gokhale
- b. A Text book of Biology by Dr.Thulajappa and Dr. Seetaram.

Reference books

- a. A Text book of Biology by B.V.Sreenivasa Naidu
- b. A Text book of Biology by Naidu and Murthy
- c. Botany for Degree students By A.C.Dutta.
- d. Outlines of Zoology by M.Ekambaranatha ayyer and T.N.Ananthakrishnan.
- e. A manual for pharmaceutical biology practical by S.B.Gokhale and C.K.Kokate.

3. **Lecture wise programme :**

Topic

PART – A

- 01 Introduction
- 02 General organization of plants and its inclusions
- 03 Plant tissues
- 04 Plant kingdom and its classification
- 05 Morphology of plants
- 06 Root, Stem, Leaf and Its modifications
- 07 Inflorescence and Pollination of flowers
- 08 Morphology of fruits and seeds
- 09 Plant physiology
- 10 Taxonomy of Leguminosae, umbelliferae, Solanaceae, Lilliaceae, Zinziberaceae, Rubiaceae
- 11 Study of Fungi, Yeast, Penicillin and Bacteria

PART-B

- 01 Study of Animal cell
- 02 Study animal tissues
- 03 Detailed study of frog
- 04 Study of Pisces, Raptiles, Aves
- 05 Geneareal organization of mammals
- 06 Study of poisonous animals

1.6 BIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

Title:

1. Introduction of biology experiments
2. Study of cell wall constituents and cell inclusions
3. Study of Stem modifications
4. Study of Root modifications
5. Study of Leaf modifications
6. Identification of Fruits and seeds
7. Preparation of Permanent slides
8. T.S. of Senna, Cassia, Ephedra, Podophyllum.
9. Simple plant physiological experiments
10. Identification of animals
11. Detailed study of Frog
12. Computer based tutorials

Scheme of Practical Examination :

	Sessionals	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Second year

2.1 PATHOPHYSIOLOGY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic Pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge of its application in other subject of pharmacy.
2. **Objectives of the Subject :** Upon completion of the subject student shall be able to –
 - a. describe the etiology and pathogenesis of the selected disease states;
 - b. name the signs and symptoms of the diseases; and
 - c. mention the complications of the diseases.

Text books (Theory)

- a. Pathologic basis of disease by- Cotran, Kumar, Robbins
- b. Text book of Pathology- Harsh Mohan
- c. Text book of Pathology- Y.M. Bhide

Reference books (Theory)

- a. Clinical Pharmacy and Therapeutics; Second edition; Roger Walker; Churchill Livingstone publication

3. Detailed syllabus and lecture wise schedule :

Chapter

- 1 **Basic principles of cell injury and Adaptation**
 - a) Causes, Pathogenesis and morphology of cell injury
 - b) Abnormalities in lipoproteinaemia, glycogen infiltration and glycogen infiltration and glycogen infiltration and glycogen storage diseases
- 2 **Inflammation**
 - a) Pathogenesis of acute inflammation, Chemical mediators in inflammation, Types of chronic inflammation
 - b) Repairs of wounds in the skin, factors influencing healing of wounds
- 3 **Diseases of Immunity**
 - a) Introduction to T and B cells
 - b) MHC proteins or transplantation antigens
 - c) Immune tolerance
 - Hypersensitivity
Hypersensitivity type I, II, III, IV, Biological significance, Allergy due to food, chemicals and drugs
 - Autoimmunity
Criteria for autoimmunity, Classifications of autoimmune diseases in man, mechanism of autoimmunity, Transplantation and immunologic tolerance, allograft rejections, transplantation antigens, mechanism of rejection of allograft.
 - Acquired immune deficiency syndrome (AIDS)

- Amylodosis

- 4 **Cancer:** differences between benign and malignant tumors, Histological diagnosis of malignancy, invasions and metastasis, patterns of spread, disturbances of growth of cells, classification of tumors, general biology of tumors, spread of malignant tumors, etiology and pathogenesis of cancer.
- 5 Types of shock, mechanisms, stages and management
- 6 Biological effects of radiation
- 7 Environmental and nutritional diseases
 - i) Air pollution and smoking- SO₂, NO, NO₂, and CO
 - ii) Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation.
- 8 Pathophysiology of common diseases
 - a. Parkinsonism
 - b. Schizophrenia
 - c. Depression and mania
 - d. Hypertension,
 - e. Stroke (ischaemic and hemorrhage)
 - f. Angina, CCF, Atherosclerosis, Myocardial infarction
 - g. Diabetes Mellitus
 - h. Peptic ulcer and inflammatory bowel diseases
 - i. Cirrhosis and Alcoholic liver diseases
 - j. Acute and chronic renal failure
 - k. Asthma and chronic obstructive airway diseases
- 9 Infectious diseases :
Sexually transmitted diseases (HIV, Syphilis, Gonorrhea), Urinary tract infections, Pneumonia, Typhoid, Tuberculosis, Leprosy, Malaria Dysentery (bacterial and amoebic), Hepatitis- infective hepatitis.

4. Assignments :

Title of the Experiment

- 1 Chemical Mediators of inflammation
- 2 Drug Hypersensitivity
- 3 Cigarette smoking & its ill effects
- 4 Biological Effects of Radiation
- 5 Etiology and hazards of obesity
- 6 Complications of diabetes
- 7 Diagnosis of cancer
- 8 Disorders of vitamins
- 9 Methods in Pathology-Laboratory values of clinical significance
- 10 Pathophysiology of Dengue Hemorrhagic Fever (DHF)

Format of the assignment

- 1 Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy.
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

2.2 PHARMACEUTICAL MICROBIOLOGY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** Microbiology has always been an essential component of pharmacy curriculum. This is because of the relevance of microbiology to pharmaceutical sciences and more specifically to pharmaceutical industry. Pharmaceutical biotechnology is the logical extension of pharmaceutical microbiology, which is expected to change the complete drug product scenario in the future.

This course deals with the various aspects of microorganisms, its classification, morphology, laboratory cultivation identification and maintenance. It also discusses with sterilization of pharmaceutical products, equipment, media etc. The course further discusses the immunological preparations, diseases its transmission, diagnosis, control and immunological tests.

2. **Objectives of the Subject :**

Upon completion of the subject student shall be able to –

- a. know the anatomy, identification, growth factors and sterilization of microorganisms;
- b. know the mode of transmission of disease causing microorganism, symptoms of disease, and treatment aspect;
- c. do estimation of RNA and DNA and there by identifying the source;
- d. do cultivation and identification of the microorganisms in the laboratory ;
- e. do identification of diseases by performing the diagnostic tests; and
- f. appreciate the behavior of motility and behavioral characteristics of microorganisms.

Text books (Theory)

- a. Vanitha Kale and Kishor Bhusari – Applied Microbiology □ Himalaya Publishing house Mumbai.
- b. Mary Louis Turgeon – Immunology and Serology in Laboratory Medicines □ 2nd edition, 1996 Mosby- Year book inc St. Louis Missouri 63146.
- c. Harsh Mohan, – Text book of Pathology □ 3rd edition, 1998, B-3 Ansari road Darya ganj N. Delhi.

Reference books (Theory)

- a. Prescott L.M., Jarley G.P Klein D.A –Microbiology □ 2nd- edition Mc Graw Hill Company Inc
- b. Rawlins E.A. □ Bentley's Text Book of Pharmaceutics □ B ailliere Tindals 24 -28 London 1988
- c. Forbisher – Fundamentals of Microbiology □ Philadelphia W.B. Saunders.
- d. Prescott L.M. Jarley G.P., Klein.D.A. – Microbiology. □ 2nd edition WMC Brown Publishers, Oxford. 1993
- e. War Roitt, Jonathan Brostoff, David male, – Immunology □ 3rd edition 1996, Mosby- year book Europe Ltd, London.
- f. Pharmacopoeia of India, Govt of India, 1996.

3. Detailed syllabus and lecture wise schedule :

Title of the topic

- 1 Introduction to the science of microbiology. Major divisions of microbial world and Relationship among them.
- 2 Different methods of classification of microbes and study of Bacteria, Fungi, virus, Rickettsiae, Spirochetes.
- 3 Nutritional requirements, growth and cultivation of bacteria and virus. Study of different important media required for the growth of aerobic and anaerobic bacteria & fungi. Differential media, enriched media and selective media, maintenance of lab cultures.
- 4 Different methods used in isolation and identification of bacteria with emphasis to different staining techniques and biochemical reactions. Counting of bacteria -Total and Viable counting techniques.
- 5 Detailed study of different methods of sterilization including their merits and demerits. Sterilization methods for all pharmaceutical products. Detailed study of sterility testing of different pharmaceutical preparations . Brief information on Validation.
- 6 Disinfectants- Study of disinfectants, antiseptics, fungicidal and virucidal agents factors affecting their activation and mechanism of action. Evaluation of bactericidal, bacteristatic, , virucidal activities, evaluation of preservatives in pharmaceutical preparations.
- 7 Immunology- Immunity, Definition, Classification, General principles of natural immunity, Phagocytosis, acquired immunity(active and passive) . Antigens, chemical nature of antigens structure and formation of Antibodies, Antigen-Antibody reactions. Bacterial exotoxins and endotoxins. Significance of toxoids in active immunity, Immunization programme, and importance of booster dose.
- 8 Diagnostic tests : Schick's Test, Elisa test, Western Blot test, Southern Blot PCR Widal, QBC, Mantoux Peripheral smear. Study of malarial parasite.
- 9 Microbial culture sensitivity Testing: Interpretation of results Principles and methods of different microbiological assays, microbiological assay of Penicillin, Streptomycin and vitamin B₂ and B₁₂. Standardisation of vaccines and sera.
- 10 Study of infectious diseases: Typhoid, Tuberculosis, Malaria, Cholera, Hepatitis, Meningitis, Syphilis & Gonorrhea and HIV.

2.2 PHARMACEUTICAL MICROBIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

Title of the Experiment:

- 1 Study of apparatus used in experimental microbiology*.
- 2 Sterilisation of glass ware's. Preparation of media and sterilisation.*
- 3 Staining techniques – Simple staining ; Gram's staining ; Negative staining**
- 4 Study of motility characters*.
- 5 Enumeration of micro-organisms (Total and Viable)*
- 6 Study of the methods of isolation of pure culture.*
- 7 Bio chemical testing for the identification of micro*-organisms.

- 8 Cultural sensitivity testing for some micro-organisms.*
- 9 Sterility testing for powders and liquids.*
- 10 Determination of minimum inhibitory concentration.*
- 11 Microbiological assay of antibiotics by cup plate method.*
- 12 Microbiological assay of vitamins by Turbidometric method**
- 13 Determination of RWC.**
- 14 Diagnostic tests for some common diseases, Widal, malarial parasite.**

* Indicate minor experiment & ** indicate major experiment

Assignments:

- 1 Visit to some pathological laboratories & study the activities and equipment/instruments used and reporting the same.
2. Visit to milk dairies (Pasturization) and microbial laboratories (other sterilization methods) & study the activities and equipment/instruments used and reporting the same.
3. Library assignments
 - a. Report of recent microbial techniques developed in diagnosing some common diseases.
 - b. Latest advancement developed in identifying, cultivating & handling of microorganisms.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

2.3 PHARMACOGNOSY & PHYTOPHARMACEUTICALS (THEORY)

Theory : 3 Hrs. /Week

1. **Scope and objectives:** This subject has been introduced for the pharmacy course in order to make the student aware of medicinal uses of various naturally occurring drugs its history, sources, distribution, method of cultivation, active constituents, medicinal uses, identification tests, preservation methods, substitutes and adulterants.
2. **Upon completion of the course student shall be able to:**
 - a. under stand the basic principles of cultivation, collection and storage of crude drugs;
 - b. know the source, active constituents and uses of crude drugs; and
 - c. appreciate the applications of primary and secondary metabolites of the plant.

3. Course materials:

Text books

- a. Pharmacognosy by G.E. Trease & W.C.Evans.
- b. Pharmacognosy by C.K.Kokate,Gokhale & A.C.Purohit.

Reference books

- a. Pharmacognosy by Brady &Tyler.E.
- b. Pharmacognosy by T.E.Wallis.
- c. Pharmacognosy by C.S. Shah & Qadery.
- d. Pharmacognosy by M.A. Iyengar.

4. Lecture wise programme:

Topics

- 1 Introduction.
- 2 Definition, history and scope of Pharmacognosy.
- 3 Classification of crude drugs.
- 4 Cultivation, collection, processing and storage of crude drugs.
- 5 Detailed method of cultivation of crude drugs.
- 6 Study of cell wall constituents and cell inclusions.
- 7 Microscopical and powder Microscopical study of crude drugs.
- 8 Study of natural pesticides.
- 9 Detailed study of various cell constituents.
- 10 Carbohydrates and related products.
- 11 Detailed study carbohydrates containing drugs.(11 drugs)
- 12 Definition sources, method extraction, chemistry and method of analysis of lipids.
- 13 Detailed study of oils.
- 14 Definition, classification, chemistry and method of analysis of protein.
- 15 Study of plants fibers used in surgical dressings and related products.
- 16 Different methods of adulteration of crude drugs.

2.3 PHARMACOGNOSY & PHYTOPHARMACEUTICALS (PRACTICAL)

Practical : 3 Hrs./Week

General Requirements: Laboratory Napkin, Observation Book 150 pages Zero brush, Needle, Blade, Match box.

List of experiments:

- 1 Introduction of Pharmacognosy laboratory and experiments.
- 2 Study of cell wall constituents and cell inclusions.
- 3 Macro, powder and microscopic study of Datura.
- 4 Macro, powder and microscopic study of Senna.
- 5 Macro, powder and microscopic study of Cassia.cinnamon.
- 6 Macro, powder and microscopic study of Cinchona.
- 7 Macro, powder and microscopic study of Ephedra.
- 8 Macro, powder and microscopic study of Quassia.
- 9 Macro, powder and microscopic study of Clove
- 10 Macro, powder and microscopic study of Fennel.
- 11 Macro, powder and microscopic study of Coriander.
- 12 Macro, powder and microscopic study of Isapgol.
- 13 Macro, powder and microscopic study of Nux vomica.
- 14 Macro, powder and microscopic study of Rauwolfia.
- 15 Macro, powder and microscopic study of Liquorice.
- 16 Macro, powder and microscopic study of Ginger.
- 17 Macro, powder and microscopic study of Podophyllum.
- 18 Determination of Iodine value.
- 19 Determination of Saponification value and unsaponifiable matter.
- 20 Determination of ester value.
- 21 Determination of Acid value.
- 22 Chemical tests for Acacia.
- 23 Chemical tests for Tragacanth.
- 24 Chemical tests for Agar.
- 25 Chemical tests for Starch.
- 26 Chemical tests for Lipids.(castor oil,sesame oil, shark liver oil,bees wax)
- 27 Chemical tests for Gelatin.

Scheme of Practical Examination:

	Sessionals	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance.

2.4 PHARMACOLOGY – I (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, apart from general pharmacology, drugs acting on autonomic nervous system, cardiovascular system, central nervous system, blood and blood forming agents and renal system will be taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.
2. **Objectives of the Subject :** Upon completion of the subject student shall be able to (Know, do, appreciate) –
 - a. understand the pharmacological aspects of drugs falling under the above mentioned chapters;
 - b. handle and carry out the animal experiments;
 - c. appreciate the importance of pharmacology subject as a basis of therapeutics; and
 - d. correlate and apply the knowledge therapeutically.

Text books (Theory) (Author, Title, Edition, Publication Place, Publisher, Year of Publication)

- a. Tripathi, K. D. Essentials of medical pharmacology. 4th Ed, 1999. Publisher: Jaypee, Delhi.
- b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
- c. Rang, H.P. & Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory)(Author, Title, Edition, Publication Place, Publisher, Publication Year)

- a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th Ed, 1996. Publisher Mc Graw Hill, Pergamon press.
- b. Craig, C.R.&Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown.Co
- c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, Int.
- d. Shargel and Leon. Applied Biopharmaceutics and pharmacokinetics. Latest edition. Publisher: Prentice Hall, London.

Text books (Practical) :

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

Reference books (Practical)

- a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.

- b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
- c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
- d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

3. Detailed syllabus and lecture wise schedule :

Title of the topic

1. General Pharmacology

- a) Introduction, definitions and scope of pharmacology
- b) Routes of administration of drugs
- c) Pharmacokinetics (absorption, distribution, metabolism and excretion)
- d) Pharmacodynamics
- e) Factors modifying drug effects
- f) Drug toxicity - Acute, sub- acute and chronic toxicity.
- g) Pre-clinical evaluations
- h) Drug interactions

Note: The term Pharmacology used here refers to the classification, mechanism of action, pharmacokinetics, pharmacodynamics, adverse effects, contraindications, Therapeutic uses, interactions and dose and route of administration.

2. Pharmacology of drugs acting on ANS

- a) Adrenergic and antiadrenergic drugs
- b) Cholinergic and anticholinergic drugs
- c) Neuromuscular blockers
- d) Mydriatics and miotics
- e) Drugs used in myasthenia gravis
- f) Drugs used in Parkinsonism

3. Pharmacology of drugs acting on cardiovascular system

- a) Antihypertensives
- b) Anti-anginal drugs
- c) Anti-arrhythmic drugs
- d) Drugs used for therapy of Congestive Heart Failure
- e) Drugs used for hyperlipidaemias

4. **Pharmacology of drugs acting on Central Nervous System**
 - a) General anesthetics
 - b) Sedatives and hypnotics
 - c) Anticonvulsants
 - d) Analgesic and anti-inflammatory agents
 - e) *Psychotropic drugs*
 - f) Alcohol and methyl alcohol
 - g) CNS stimulants and cognition enhancers
 - h) Pharmacology of local anaesthetics
5. **Pharmacology of Drugs acting on Respiratory tract**
 - a) Bronchodilators
 - b) Mucolytics
 - c) Expectorants
 - d) Antitussives
 - e) NasalDecongestants
6. **Pharmacology of Hormones and Hormone antagonists**
 - a) Thyroid and Antithyroid drugs
 - b) Insulin, Insulin analogues and oral hypoglycemic agents
 - c) Sex hormones and oral contraceptives
 - d) Oxytocin and other stimulants and relaxants
7. **Pharmacology of autocoids and their antagonists**
 - a) Histamines and Antihistaminics
 - b) 5-Hydroxytryptamine and its antagonists
 - c) Lipid derived autocoids and platelet activating factor

2.5 COMMUNITY PHARMACY (THEORY)

Theory : 2 Hrs. /Week

1. **Scope:** In the changing scenario of pharmacy practice in India, Community Pharmacists are expected to offer various pharmaceutical care services. In order to meet this demand, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling, health screening services for improved patient care in the community set up.
2. **Objectives:** Upon completion of the course, the student shall be able to –
 - a. know pharmaceutical care services;
 - b. know the business and professional practice management skills in community pharmacies;
 - c. do patient counselling & provide health screening services to public in community pharmacy;
 - d. respond to minor ailments and provide appropriate medication;
 - e. show empathy and sympathy to patients; and
 - f. appreciate the concept of Rational drug therapy.

Text Books:

- a. Health Education and Community Pharmacy by N.S.Parmar.
- b. WHO consultative group report.
- c. Drug store & Business management by Mohammed Ali & Jyoti.

Reference books:

- a. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.
- b. Comprehensive Pharmacy Review – Edt. Leon Shargel. Lippincott Williams & Wilkins.

Special requirements:

1. Either the college is having model community pharmacy (meeting the schedule N requirement) or sign MoU with at least 4-5 community pharmacies nearby to the college for training the students on dispensing and counselling activities.
2. Special equipments like B.P apparatus, Glucometer, Peak flow meter, and apparatus for cholesterol estimation.

3. Scheme of evaluation (80 Marks)

1. Synopsis	10
2. Major Experiment	30
(Counselling of patients with specific diseases – emphasis should be given on Counselling introduction, content, process and conclusion)	
3. Minor Experiment(Ability to measure B.P/ CBG / Lung function)	15
4. Prescription Analysis (Analyzing the prescriptions for probable drug interaction and ability to tell the management)	15
5. Viva – Voce	10

4. Lecture wise programme :

Topics

- 1 Definition, scope, of community pharmacy
Roles and responsibilities of Community pharmacist**
- 2 Community Pharmacy Management**
 - a) Selection of site, Space layout, and design
 - b) Staff, Materials- coding, stocking
 - c) Legal requirements
 - d) Maintenance of various registers
 - e) Use of Computers: Business and health care soft wares
- 3 Prescriptions** – parts of prescription, legality & identification of medication related problems like drug interactions.
- 4 Inventory control in community pharmacy**
Definition, various methods of Inventory Control
ABC, VED, EOQ, Lead time, safety stock
- 5 Pharmaceutical care**
Definition and Principles of Pharmaceutical care.
- 6 Patient counselling**
Definition, outcomes, various stages, barriers, Strategies to overcome barriers
Patient information leaflets- content, design, & layouts, advisory labels
- 7 Patient medication adherence**
Definition, Factors affecting medication adherence, role of pharmacist in improving the adherence.
- 8 Health screening services**
Definition, importance, methods for screening
Blood pressure/ blood sugar/ lung function
and Cholesterol testing
- 9 OTC Medication- Definition, OTC medication list & Counselling**
- 10 Health Education**
WHO Definition of health, and health promotion, care for children, pregnant & breast feeding women, and geriatric patients.
Commonly occurring Communicable Diseases, causative agents,
Clinical presentations and prevention of communicable diseases – Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy, Syphilis, Gonorrhea and AIDS
Balance diet, and treatment & prevention of deficiency disorders
Family planning – role of pharmacist
- 11 Responding to symptoms of minor ailments**
Relevant pathophysiology, common drug therapy to,
Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Pyrexia, Ophthalmic symptoms, worms infestations.
- 12 Essential Drugs concept and Rational Drug Therapy**
Role of community pharmacist
- 13 Code of ethics for community pharmacists**

2.6 PHARMACOTHERAPEUTICS - I (THEORY)

Theory : 3 Hrs. /Week

- 1. Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
- 2. Objectives:** At completion of this subject it is expected that students will be able to understand –
 - a. the pathophysiology of selected disease states and the rationale for drug therapy;
 - b. the therapeutic approach to management of these diseases;
 - c. the controversies in drug therapy;
 - d. the importance of preparation of individualised therapeutic plans based on diagnosis ;
 - e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
 - f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
 - g. summarise the therapeutic approach to management of these diseases including reference to the latest available evidence;
 - h. discuss the controversies in drug therapy;
 - i. discuss the preparation of individualised therapeutic plans based on diagnosis; and
 - j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

- a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.
- b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange.

Reference Books

- a. Pathologic basis of disease - Robins SL, W.B.Saunders publication.
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication.
- c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication.
- d. Applied Therapeutics:The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
- e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature.

3. Detailed syllabus and lecture wise schedule :

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

Title of the topic

- 1 **Cardiovascular system:** Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, , Hyperlipidaemias , Electrophysiology of heart and Arrhythmias
- 2 **Respiratory system :** Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases
Endocrine system : Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis
- 3 **General prescribing guidelines for**
 - a. Paediatric patients
 - b. Geriatric patients
 - c. Pregnancy and breast feeding
- 4 **Ophthalmology:** Glaucoma, Conjunctivitis- viral & bacterial
- 5 **Introduction to rational drug use**
Definition, Role of pharmacist Essential drug concept Rational drug formulations

2.6 PHARMACOTHERAPEUTICS - I (PRACTICAL)

Practical : 3 Hrs./Week

Practicals :

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Third Year

3.1 PHARMACOLOGY – II (THEORY)

Theory : 3 Hrs. /Week

- 1. Scope of the Subject:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, drugs acting on autacoids, respiratory system, GIT, immune system and hormones, and pharmacology of autacoids and hormones will be concentrated. In addition, pharmacology of chemotherapeutic agents, vitamins, essential minerals and principles of toxicology are also taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.
- 2. Objectives of the Subject Upon completion of the subject student shall be able to:**
 - a. understand the pharmacological aspects of drugs falling under the above mentioned chapters,
 - b. carry out the animal experiments confidently,
 - c. appreciate the importance of pharmacology subject as a basis of therapeutics, and
 - d. correlate and apply the knowledge therapeutically.

Text books (Theory)

- a. Tripathi, K. D. Essentials of medical pharmacology. 4th edition, 1999. Publisher: Jaypee, Delhi.
- b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
- c. Rang, H.P. and Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory)

- a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th edition, 1996. Publisher: Mc Graw Hill, Pergamon press.
- b. Craig, C.R. and Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown and company.
- c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, International.
- d. Gupta, P.K. and Salunkhe, D.K. Modern Toxicology. Volume I, II and III. Latest edition. Publisher: B.V. Gupta, Metropolitan Book Co. (p) Ltd, New Delhi.

Text books (Practical)

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

Reference books (Practical) :

- a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.
- b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
- c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
- d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

3. Detailed syllabus and lecture wise schedule:**Title of the topic**

1. **Pharmacology of Drugs acting on Blood and blood forming agents**
 - a) Anticoagulants
 - b) Thrombolytics and antiplatelet agents
 - c) Haemopoietics and plasma expanders
2. **Pharmacology of drugs acting on Renal System**
 - a) Diuretics
 - b) Antidiuretics
3. **Chemotherapy**
 - a) Introduction
 - b) Sulfonamides and co-trimoxazole
 - c) Penicillins and Cephalosporins
 - d) Tetracyclins and Chloramphenicol
 - e) Macrolides, Aminoglycosides, Polyene & Polypeptide antibiotics
 - f) Quinolines and Fluroquinolines
 - g) Antifungal antibiotics
 - h) Antiviral agents
 - i) Chemotherapy of tuberculosis and leprosy
 - j) Chemotherapy of Malaria
 - k) Chemotherapy of protozoal infections (amoebiasis, Giardiasis)
 - l) Pharmacology of Anthelmintic drugs
 - m) Chemotherapy of cancer (Neoplasms)
4. **Immunopharmacology**
Pharmacology of immunosuppressants and stimulants
5. **Principles of Animal toxicology**
Acute, sub acute and chronic toxicity

6. **The dynamic cell: The structures and functions of the components of the cell**

- a) Cell and macromolecules: Cellular classification, subcellular organelles, macromolecules, large macromolecular assemblies
- b) Chromosome structure: Pro and eukaryotic chromosome structures, chromatin structure, genome complexity, the flow of genetic information.
- c) DNA replication: General, bacterial and eukaryotic DNA replication.
- d) The cell cycle: Restriction point, cell cycle regulators and modifiers.
- e) Cell signaling: Communication between cells and their environment, ion-channels, signal transduction pathways (MAP kinase, P38 kinase, JNK, Ras and PI3-kinase pathways, biosensors).

The Gene: Genome structure and function:

- a) Gene structure: Organization and elucidation of genetic code.
- b) Gene expression: Expression systems (pro and eukaryotic), genetic elements that control gene expression (nucleosomes, histones, acetylation, HDACS, DNA binding protein families.
- c) Transcription and Transcription factors: Basic principles of transcription in pro and eukaryotes. Transcription factors that regulate transcription in pro and eukaryotes.

RNA processing: rRNA, tRNA and mRNA processing.

Protein synthesis: Mechanisms of protein synthesis, initiation in eukaryotes, translation control and post-translation events

Altered gene functions: Mutations, deletions, amplifications, LOH, traslocations, trinucleotide repeats and other genetic abnormalities.

Oncogenes and tumor suppressor genes.

The gene sequencing, mapping and cloning of human disease genes.

Introduction to gene therapy and targeting.

Recombinant DNA technology: principles. Processes (gene transfer technology) and applications

Books:

- 1 Molecular Biology of the Cell by Alberts B., Bray, D., Lewis, J., Raff M., Roberts, K and Watson, JD, 3rd edition.
- 2 Molecular Cell Biology By Lodish, H., Baltimore, D., Berk, A et al., 5th edition.
- 3 Molecular Biology by Turner, PC., McLennan, AG., Bates, AD and White MRH 2nd edition.
- 4 Genes VIII by Lewin, B., (2004)
- 5 Pharmaceutical Biotechnology, by Crommelin, DJA and Sindelar RD (1997)
- 6 Recombinant DNA by Watson, JD., Gilman, M., et al., (1996)
- 7 Biopharmaceutical: Biochemistry and Biotechnology by Walsh, G., (1998)

3.1 PHARMACOLOGY – II (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments:

1. Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea pigs, e. Rabbits).
2. Study of physiological salt solutions used in experimental pharmacology.
3. Study of laboratory appliances used in experimental pharmacology.
4. Study of use of anesthetics in laboratory animals.
5. To record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.
6. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.
7. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three point method.
8. To record the dose response curve of Histamine using isolated guinea-pig ileum preparation.
9. Study of agonistic and antagonistic effects of drugs using isolated guinea-pig ileum preparation.
10. To carry out bioassay of Histamine using isolated guinea-pig ileum preparation by interpolation method.
11. To carry out bioassay of Histamine using guinea-pig ileum preparation by three point method.
12. To study the routes of administration of drugs in animals (Rats, Mice, Rabbits).
13. Study of theory, principle, procedure involved and interpretation of given results for the following experiments:
 - a) Analgesic property of drug using analgesiometer.
 - b) Antiinflammatory effect of drugs using rat-paw edema method.
 - c) Anticonvulsant activity of drugs using maximal electroshock and pentylene tetrazole methods.
 - d) Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods.
 - e) Locomotor activity evaluation of drugs using actophotometer and rotorod.
 - f) Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.

Scheme of Practical Examination:

	Sessionals	Annual
Identification	02	10
Synopsis	04	10
Major Experiment (Bioassay)	08	30
Minor Experiment (Interpretation of given Graph or simulated experiment)	04	10
Viva	02	10
Max Marks	20	70
Duration	3hrs	4hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.2 PHARMACEUTICAL ANALYSIS (THEORY)

Theory : 3 Hrs. /Week

1. Quality Assurance:

- a. Introduction, sources of quality variation, control of quality variation.
- b. Concept of statistical quality control.
- c. Validation methods- quality of equipment, validation of equipment and validation of analytical instruments and calibration.
- d. GLP, ISO 9000.
- e. Total quality management, quality review and documentation.
- f. ICH- international conference for harmonization-guidelines.
- g. Regulatory control.

2. Chromatography:

Introduction, history, classification, separation techniques, choice of methods. The following techniques be discussed with relevant examples of pharmaceutical products involving principles and techniques of separation of drugs from excipients.

- a. **Column Chromatography:** Adsorption column chromatography, Operational technique, frontal analysis and elution analysis. Factors affecting column efficiency, applications and partition chromatography.
- b. **TLC:** Introduction, principle, techniques, R_f value and applications.
- c. **PC:** Introduction, principle, types of paper chromatography, preparation techniques, development techniques, applications.
- d. **Ion-exchange chromatography:** Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications.
- e. **HPLC:** Introduction, theory, instrumentation, and applications.
- f. **HPTLC:** Introduction, theory, instrumentation, and applications.
- g. **Gas Chromatography:** Introduction, theory, instrumentation-carrier gases, types of columns, stationary phases in GLC & GSC. Detectors - Flame ionization detectors, electron capture detector, thermal conductivity detector. Typical gas chromatogram, derivatisation techniques, programmed temperature gas chromatography, applications.
- h. **Electrophoresis:** Principles of separation, equipment for paper and gel electrophoresis, and application.
- i. **Gel filtration and affinity chromatography:** Introduction, technique, applications.

3. **Electrometric Methods:**

Theoretical aspects, instrumentation, interpretation of data/spectra and analytical applications be discussed on the following topics.

- a. **Potentiometry:** Electrical potential, electrochemical cell, reference electrodes, indicator electrodes, measurement of potential and pH, construction and working of electrodes, Potentiometric titrations, methods of detecting end point, Karl Fischer titration.
- b. **Conductometry:** Introduction, conductivity cell, conductometric titrations and applications.
- c. **Polarography:** Instrumentation, DME, residual current, diffusion current and limiting current, polarographic wave, Ilkovic's equation, Effect of oxygen on polarographic wave, Polarographic maxima and suppressors and applications.
- d. **Amperometric Titrations:** Introduction, types of electrodes used, reference and indicator electrode, instrumentation, titration procedure, advantages and disadvantages of Amperometry over potentiometry. Pharma applications.

4. **Spectroscopy:**

Theoretical aspects, instrumentation, elements of interpretation of data/spectra and application of analytical techniques be discussed on:

a. **Absorption Spectroscopy:**

- Theory of electronic, atomic and molecular spectra. Fundamental laws of photometry, Beer-Lambert's Law, application and its deviation, limitation of Beer law, application of the law to single and multiple component analysis, measurement of equilibrium constant and rate constant by spectroscopy. Spectra of isolated chromophores, auxochromes, batho-chromic shift, hypsochromic shift, hyperchromic and hypochromic effect, effect of solvent on absorption spectra, molecular structure and infrared spectra.

Instrumentation – Photometer, U.V.-Visible spectrophotometer – sources of U.V.-Visible radiations, collimating systems, monochromators, samples cells and following detectors-Photocell, Barrier layer cell, Phototube, Diode array, applications of U.V.-Visible spectroscopy in pharmacy and spectrophotometric titrations.

- **Infrared Spectroscopy:** Vibrational transitions, frequency – structure correlations, Infrared absorption bands, Instrumentation-IR spectrometer – sources of IR, Collimating systems, monochromators, sample cells, sample handling in IR spectroscopy and detectors-Thermocouple, Golay Cells, Thermistor, Bolometer, Pyroelectric detector, Applications of IR in pharmacy.

- **Fluorimetric Analysis:** Theory, luminescence, factors affecting fluorescence, quenching. Instrumentation, Applications, fluorescent indicators, study of pharmaceutically important compounds estimated by fluorimetry.
- b. **Flame Photometry:** Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceutical applications.
- c. **Atomic Absorption Spectrometry:** Introduction, Theory, types of electrodes, instrumentation and applications.
- d. **Atomic Emission Spectroscopy:** Spectroscopic sources, atomic emission spectrometers, photographic and photoelectric detection.
- e. **NMR & ESR (introduction only):** Introduction, theoretical aspects and applications.
- f. **Mass Spectroscopy: (Introduction only)** – Fragmentation, types of ions produced mass spectrum and applications.
- g. **Polarimetry: (Introduction only)** – Introduction to optical rotatory dispersion, circular dichroism, polarimeter.
- h. **X-RAY Diffraction: (Introduction only)** – Theory, reciprocal lattice concept, diffraction patterns and applications.
- i. **Thermal Analysis:** Introduction, instrumentation, applications, and DSC and DTA.

3.2 PHARMACEUTICAL ANALYSIS (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments:

1. Separation and identification of Amino Acids by Paper Chromatography.
2. Separation and identification of Sulpha drugs by TLC technique.
3. Effect of pH and solvent on the UV spectrum of given compound.
4. Comparison of the UV spectrum of a compound with that of its derivatives.
5. Determination of dissociation constant of indicators using UV-Visible spectroscopy.
6. Conductometric titration of mixture of acids with a strong base.
7. Potentiometric titration of a acid with a strong base.
8. Estimation of drugs by Fluorimetric technique.
9. Study of quenching effect in fluorimetry.
10. Colourimetric estimation of Supha drugs using BMR reagent.

11. Simultaneous estimation of two drugs present in given formulation.
12. Assay of Salicylic Acid by colourimetry.
13. Determination of Chlorides and Sulphates in Calcium gluconate by Nepheloturbidimetric Method.
14. Determination of Na/K by Flame Photometry.
15. Determination of pKa using pH meter.
16. Determination of specific rotation.
17. Comparison of the IR spectrum of a compound with that of its derivatives.
18. Demonstration of HPLC.
19. Demonstration of HPTLC.
20. Demonstration of GC-MS.
21. Demonstration of DSC.
22. Interpretation of NMR spectra of any one compound.

Reference Books:

1. Text Book of Pharm. Analysis by Higuchi. T and Hasen. E. B., New York Inter Science Publishers.
2. Quantitative Pharma. Analysis by Jenkins, The Blakiston division, New York.
3. Quantitative Drug Analysis, by Garrot. D, Chapman & Hall Ltd., London.
4. Undergraduate Instrumental Analysis by James. E., CBS Publishers.
5. Instrumental Analysis by Willard and Merritt, EWP, East West Press Ltd., Delhi/Madras.
6. Pharm Analysis by Skoog and West, Sounders Manipal College Publishing.
7. Text Book of Chemical Analysis, by A.I.Vogel, ELBS with Macmillan press, Hampshire.
8. Textbook of Pharm. Analysis by K.A.Connors, John Wiley & Sons, New York, Brisbane, Singapore.
9. Textbook of Pharm. Analysis (Practical) by Beckett & Stenlake, CBS Publishers, Delhi.
10. Textbook of Drug Analysis by P.D. Sethi., CBS Publishers, Delhi.
11. Spectroscopy by Silverstein, John & Wiley & Sons. Inc., Canada & Singapore.
12. How to practise GMP-A Plan for total quality control by P.P. Sharma, Vandana Publications, Agra.
13. The Science & Practice of Pharmacy by Remington Vol-I & II, Mack Publishing Co. Pennsylvania.
14. TLC by Stahl, Spring Verlay.
15. Text Book of Pharm. Chemistry by Chatten, CBS Publications.
16. Spectroscopy by William Kemp, ELBS with Macmillan Press, Hampshire.
17. I.P.-1996, The Controller of Publications, New Delhi.
18. BPC- Dept. of Health, U.K. for HMSO.
19. USP - Mack Publishing Co., Easton, PA.
20. The Extra Pharmacopoeia – The Pharm. Press, London.

Practicals

Title of the Experiment:

- 1 Study of agonistic and antagonistic effects of drugs using Guinea-pig ileum preparation.**
- 2 To study the effects of drugs on intestinal motility using frog's esophagus model*
- 3 To study the effects of drugs using rat uterus preparation.**
- 4 To study the anticonvulsant property of drugs (any one model).*
- 5 To study antihistaminic property of drug using histamine induced anaphylactic reaction in guinea pigs.
- 6 To study the apomorphine-induced compulsive behaviour (stereotypy) in mice.*
- 7 To study the muscle relaxant property of diazepam in mice using rotarod apparatus.*
- 8 To study the antiinflammatory property of indomethacin against carrageenan-induced paw oedema.**
- 9 To study the anxiolytic effect of diazepam in mice using mirrored-chamber apparatus.**
- 10 To demonstrate the effect of various drugs on the blood pressure and respiration of anaesthetized dog.
- 11 To study the effect of anthelmintics on earthworms.
- 12 To study the taming effect of chlorpromazine.*
- 13 To study the effects of drugs on vas deference of the male rat.**
- 14 To study the effect of drugs on pesticide toxicity using rats as model.
- 15 To study the effect of drugs on heavy metal toxicity.

** indicate major experiment & * indicate minor experiment

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.3 PHARMACOTHERAPEUTICS – II (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives of the Subject Upon completion of the subject student shall be able to –**
 - a. know the pathophysiology of selected disease states and the rationale for drug therapy
 - b. know the therapeutic approach to management of these diseases;
 - c. know the controversies in drug therapy;
 - d. know the importance of preparation of individualised therapeutic plans based on diagnosis; and
 - e. appreciate the needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text books (Theory)

Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication

Reference books (Theory)

- a. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange
- b. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
- c. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA]

3. Detailed syllabus and lecture wise schedule :

Etiopathogenesis and pharmacotherapy of diseases associated with following systems / diseases –

Title of the topic

1. **Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhoea and Syphilis
- 2 **Musculoskeletal disorders**
Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.
- 3 **Renal system**
Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders

- 4 **Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis
- 5 **Dermatology:** Psoriasis, Scabies, Eczema, Impetigo

3.3 PHARMACOTHERAPEUTICS – II (PRACTICAL)

Practical : 3 Hrs./Week

Practicals :

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.

The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.

A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment :

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination :

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.4 PHARMACEUTICAL JURISPRUDENCE (THEORY)

Theory : 2 Hrs. /Week

1. **Scope of the Subject:** (4-6 lines): This course exposes the student to several important legislations related to the profession of pharmacy in India. The Drugs and Cosmetics Act, along with its amendments are the core of this course. Other acts, which are covered, include the Pharmacy Act, dangerous drugs, medicinal and toilet preparation Act etc. Besides this the new drug policy, professional ethics, DPCO, patent and design Act will be discussed.
2. **Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, and appreciate) –
 - a. practice the Professional ethics;
 - b. understand the various concepts of the pharmaceutical legislation in India;
 - c. know the various parameters in the Drug and Cosmetic Act and rules;
 - d. know the Drug policy, DPCO, Patent and design act;
 - e. understand the labeling requirements and packaging guidelines for drugs and cosmetics;
 - f. be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and
 - g. other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

Text books (Theory)

Mithal , B M. Textbook of Forensic Pharmacy. Calcutta :National; 1988.

Reference books (Theory)

- a. Singh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad: Law Book House; 1984.
- b. Jain, NK. A Textbook of forensic pharmacy. Delhi: Vallabh prakashan ; 1995.
- c. Reports of the Pharmaceutical enquiry Committee
- d. I.D.M.A., Mumbai. DPCO 1995
- e. Various reports of Amendments.
- f. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
- g. Eastern Book Company .The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.

3. Detailed syllabus and lecture wise schedule:

Title of the topic

1. **Pharmaceutical Legislations** – A brief review.
2. Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI.
3. **Drugs and Cosmetics Act, 1940, and its rules 1945.**
Objectives, Legal definition, Study of Schedule's with reference to Schedule B, C&C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y.
Sales, Import, labeling and packaging of Drugs And Cosmetics
Provisions Relating to Indigenous Systems. Constitution and Functions of DTAB, DCC, CDL. Qualification and duties – Govt. analyst and Drugs Inspector.

4. **Pharmacy Act –1948.**
Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER.
5. **Medicinal and Toilet Preparation Act –1955.**
Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations.
6. **Narcotic Drugs and Psychotropic substances Act-1985 and Rules.** Objectives, Legal Definitions, General Study, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and regulations, Schedules to the Act.
7. **Study of Salient Features of Drugs and magic remedies Act and its rules.**
8. **Study of essential Commodities Act Relevant to drugs price control Order.**
9. **Drug Price control Order & National Drug Policy (Current).**
10. **Prevention Of Cruelty to animals Act-1960.**
11. **Patents & design Act-1970.**
12. **Brief study of prescription and Non-prescription Products.**

4. Assignments:

Format of the assignment

1. Minimum & Maximum number of pages
2. It shall be a computer draft copy
3. Reference(s) shall be included at the end.
4. Name and signature of the student
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min

Case studies relating to

1. Drugs and Cosmetics Act and rules along with its amendments, Dangerous Drugs Act, Medicinal and Toilet preparation Act, New Drug Policy, Professional Ethics, Drugs (Price control) Order, Patent and Design Act.
2. Various prescription and non-prescription products.
3. Medical and surgical accessories.
4. Diagnostic aids and appliances available in the market.

3.5 MEDICINAL CHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

1. Modern concept of rational drug design: A brief introduction to Quantitative Structure Activity Relationship (QSAR), prodrug, combinatorial chemistry and computer aided drug design (CADD) and concept of antisense molecules.

A study of the development of the following classes of drugs including SAR, mechanism of action, synthesis of important compounds, chemical nomenclature, brand names of important marketed products and their side effects.

2. Anti-infective agents
 - a) Local anti-infective agents
 - b) Preservatives
 - c) Antifungal agents
 - d) Urinary tract anti-infectives
 - e) Antitubercular agents
 - f) Antiviral agents and Anti AIDS agents
 - g) Antiprotozoal agents
 - h) Anthelmintics
 - i) Antiscabies and Antipedicular agents
3. Sulphonamides and sulphones
4. Antimalarials
5. Antibiotics
6. Antineoplastic agents
7. Cardiovascular agents
 - a) Antihypertensive agents
 - b) Antianginal agents and vasodilators
 - c) Antiarrhythmic agents
 - d) Antihyperlipidemic agents
 - e) Coagulants and Anticoagulants
 - f) Endocrine
8. Hypoglycemic agents
9. Thyroid and Antithyroid agents
10. Diuretics
11. Diagnostic agents
12. Steroidal Hormones and Adrenocorticoids

3.5 MEDICINAL CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

1. Assays of important drugs from the course content.
2. Preparation of medicinally important compounds or intermediates required for synthesis of drugs.
3. Monograph analysis of important drugs.
4. Determination of partition coefficients, dissociation constants and molar refractivity of compounds for QSAR analysis.

Reference Books:

- a. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.
- b. William.O.Foye, Principles of Medicinal Chemistry, B.I. Waverly Pvt. Ltd., New Delhi.
- c. Burgers, Medicinal Chemistry, M.E., Welly Med.Chemistry M.E. Walffed Johnwiley and Sons, Wiley-interscience Publication, New York, Toronto.
- d. A Text Book of Medicinal Chemistry Vol. I and II by Surendra N. Pandeya, S.G. Publisher, 6, Dildayal Nagar, Varanasi -10.
- e. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi - 54.
- f. Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19.
- g. Organic Drug Synthesis-Ledniser Mitzsher Vol. I and II.
- h. Pharmaceutical Chemistry drug Synthesis Vol. I and II by H. J. Roth and A. Kleemann.
- i. The Science and Practice of Pharmacy Vol. 1 and 2, Remington, MACK Publishing Company, Easton, Pennsylvania.

3.6 PHARMACEUTICAL FORMULATIONS (THEORY)

Theory : 2 Hrs. /Week

1. **Scope of the Subject:** Scope and objectives of the course: Subject deals with the formulation and evaluation of various pharmaceutical dosage forms.
2. **Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, appreciate) –
 - a. understand the principle involved in formulation of various pharmaceutical dosage forms;
 - b. prepare various pharmaceutical formulation;
 - c. perform evaluation of pharmaceutical dosage forms; and
 - d. understand and appreciate the concept of bioavailability and bioequivalence, their role in clinical situations.

Text books (Theory)

- a. Pharmaceutical dosage forms, Vol, I,II and III by lachman
- b. Rowlings Text book of Pharmaceutics
- c. Tutorial Pharmacy – Cooper & Gun

Reference books (Theory)

- a. Remington's Pharmaceutical Sciences
- b. USP/BP/IP

3. Detailed syllabus and lecture wise schedule:

Title of the topic

1. Pharmaceutical dosage form- concept and classification
2. **Tablets:** Formulation of different types of tablets, tablet excipients, granulation techniques quality control and evaluation of tablets. Tablet coating, Type of coating, quality control tests for coated tablet.
3. **Capsules;** Production and filling of hard gelatin capsules, Raw material for shell, finishing, quality control tests for capsules. Production and filling of soft gelatin capsules, quality control tests for soft gelatin capsules.
4. **Liquid orals:** Formulation and evaluation of suspensions, emulsions and solutions. Stability of these preparations
5. **Parenterals** Introduction Containers used for Parenterals (including official tests) Formulation of large and small volume Parenterals Sterilization
6. **Ophthalmic preparations (Semi – Solids):** Introduction and classification Factors affecting absorption and anatomy of skin Packaging storage and labeling, Ointments Types of Ointment Base Preparation of ointment, Jellies Types of jellies Formulation of jellies Suppositories, Method of preparation, Types Packaging
7. Definition and concept of **Controlled and novel Drug delivery systems** with available examples, viz. parenteral, trans dermal, buccal, rectal, nasal, implants, ocular

3.6 PHARMACEUTICAL FORMULATIONS (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments :

- 1. Manufacture of Tablets**
 - a. Ordinary compressed tablet-wet granulation
 - b. Tablets prepared by direct compression.
 - c. Soluble tablet.
 - d. Chewable tablet.
- 2. Formulation and filling of hard gelatin capsules**
- 3. Manufacture of parenterals**
 - a. Ascorbic acid injection
 - b. Calcium gluconate injection
 - c. Sodium chloride infusion.
 - d. Dextrose and Sodium chloride injection/ infusion.
- 4. Evaluation of Pharmaceutical formulations (QC tests)**
 - a. Tablets
 - b. Capsules
 - c. Injections
- 5. Formulation of two liquid oral preparations and evaluation by assay**
 - a. Solution: Paracetamol Syrup
 - b. Antacid suspensions- Aluminum hydroxide gel
- 6. Formulation of semisolids and evaluation by assay**
 - a. Salicylic acid and benzoic acid ointment
 - b. Gel formulation Diclofenac gel
- 7. Cosmetic preparations**
 - a. Lipsticks
 - b. Cold cream and vanishing cream
 - c. Clear liquid shampoo
 - d. Tooth paste and tooth powders.
- 8. Tablet coating (demonstration)**

Scheme of Practical Examination :

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Fourth Year

4.1 PHARMACOTHERAPEUTICS – III (THEORY)

Theory : 3 Hrs. /Week

1. **Scope :** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives:** At completion of this subject it is expected that students will be able to understand –
 - a. the pathophysiology of selected disease states and the rationale for drug therapy;
 - b. the therapeutic approach to management of these diseases;
 - c. the controversies in drug therapy;
 - d. the importance of preparation of individualised therapeutic plans based on diagnosis;
 - e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
 - f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
 - g. to summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
 - h. to discuss the controversies in drug therapy;
 - i. to discuss the preparation of individualised therapeutic plans based on diagnosis; and
 - j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

- a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication
- b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange

Reference Books

- a. Pathologic basis of disease - Robins SL, W.B.Saunders publication
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication
- c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
- e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature.

4.1 PHARMACOTHERAPEUTICS – III (PRACTICAL)

Practical : 3 Hrs./Week

Practicals:

Hospital postings for a period of at least 50 hours is required to understand the principles and practice involved in ward round participation and clinical discussion on selection of drug therapy. Students are required to maintain a record of 15 cases observed in the ward and the same should be submitted at the end of the course for evaluation. Each student should present at least two medical cases they have observed and followed in the wards.

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases:

Title of the topic

- 1 **Gastrointestinal system:** Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, Viral hepatitis including jaundice, and Drug induced liver disorders.
- 2 **Haematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.
- 3 **Nervous system:** Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,
- 4 **Psychiatry disorders:** Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders
- 5 Pain management including Pain pathways, neuralgias, headaches.
- 6 Evidence Based Medicine

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination :

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

4.2 HOSPITAL PHARMACY (THEORY)

Theory : 2 Hrs. /Week

1. **Scope:** In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug dispensing, manufacturing of parenteral preparations, drug information, patient counselling, and therapeutic drug monitoring for improved patient care.
2. **Objectives:** Upon completion of the course, the student shall be able to –
 - a. know various drug distribution methods;
 - b. know the professional practice management skills in hospital pharmacies;
 - c. provide unbiased drug information to the doctors;
 - d. know the manufacturing practices of various formulations in hospital set up;
 - e. appreciate the practice based research methods; and
 - f. appreciate the stores management and inventory control.

Text books: (latest editions)

- a. Hospital pharmacy by William .E. Hassan
- b. A text book of Hospital Pharmacy by S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh

References:

- a. WHO consultative group report.
- b. R.P.S. Vol.2. Part –B; Pharmacy Practice section.
- c. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.

3. Lecture wise programme :

Topics

- 1 **Hospital - its Organisation and functions**
- 2 **Hospital pharmacy-Organisation and management**
 - a) Organizational structure-Staff, Infrastructure & work load statistics
 - b) Management of materials and finance
 - c) Roles & responsibilities of hospital pharmacist
- 3 **The Budget – Preparation and implementation**
- 4 **Hospital drug policy**
 - a) Pharmacy and Therapeutic committee (PTC)
 - b) Hospital formulary
 - c) Hospital committees
 - Infection committee
 - Research and ethical committee
 - d) developing therapeutic guidelines
 - e) Hospital pharmacy communication - Newsletter

5 Hospital pharmacy services

- a) Procurement & warehousing of drugs and Pharmaceuticals
- b) Inventory control
Definition, various methods of Inventory Control
ABC, VED, EOQ, Lead time, safety stock
- c) Drug distribution in the hospital
 - i) Individual prescription method
 - ii) Floor stock method
 - iii) Unit dose drug distribution method
- d) Distribution of Narcotic and other controlled substances
- e) Central sterile supply services – Role of pharmacist

6 Manufacture of Pharmaceutical preparations

- a) Sterile formulations – large and small volume parenterals
- b) Manufacture of Ointments, Liquids, and creams
- c) Manufacturing of Tablets, granules, capsules, and powders
- d) Total parenteral nutrition

7 Continuing professional development programs

Education and training

8 Radio Pharmaceuticals – Handling and packaging**9 Professional Relations and practices of hospital pharmacist****4.2 HOSPITAL PHARMACY (PRACTICAL)****Practical : 3 Hrs./Week**

1. Assessment of drug interactions in the given prescriptions
2. Manufacture of parenteral formulations, powders.
3. Drug information queries.
4. Inventory control

List of Assignments:

1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.
2. Pharmacy and Therapeutics committee – Organization, functions, and limitations.
3. Development of a hospital formulary for 300 bedded teaching hospital
4. Preparation of ABC analysis of drugs sold in one month from the pharmacy.
5. Different phases of clinical trials with elements to be evaluated.
6. Various sources of drug information and systematic approach to provide unbiased drug information.
7. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.

Special requirements:

1. Each college should sign MoU with nearby local hospital having minimum 150 beds for providing necessary training to the students' on hospital pharmacy activities.
2. Well equipped with various resources of drug information.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

4.3 CLINICAL PHARMACY (THEORY)

Theory : 3 Hrs. /Week

1. Objectives of the Subject :

Upon completion of the subject student shall be able to (Know, do, appreciate) –

- a. monitor drug therapy of patient through medication chart review and clinical review;
- b. obtain medication history interview and counsel the patients;
- c. identify and resolve drug related problems;
- d. detect, assess and monitor adverse drug reaction;
- e. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and
- f. retrieve, analyse, interpret and formulate drug or medicine information.

Text books (Theory)

- a. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
- b. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
- c. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.
- d. A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi et al, Orient Orient Langram Pvt.Ltd. ISSN8125026

References

- a. Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
- b. Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
- c. Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

2. Detailed syllabus and lecture wise schedule:

Title of the topic

1. **Definitions, development and scope of clinical pharmacy**
2. **Introduction to daily activities of a clinical pharmacist**
 - a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
 - b. Ward round participation
 - c. Adverse drug reaction management
 - d. Drug information and poisons information
 - e. Medication history
 - f. Patient counseling
 - g. Drug utilisation evaluation (DUE) and review (DUR)
 - h. Quality assurance of clinical pharmacy services

3. **Patient data analysis**
The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.
4. **Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results**
 - a. Haematological, Liver function, Renal function, thyroid function tests
 - b. Tests associated with cardiac disorders
 - c. Fluid and electrolyte balance
 - d. Microbiological culture sensitivity tests
 - e. Pulmonary Function Tests
5. **Drug & Poison information**
 - a. Introduction to drug information resources available
 - b. Systematic approach in answering DI queries
 - c. Critical evaluation of drug information and literature
 - d. Preparation of written and verbal reports
 - e. Establishing a Drug Information Centre
 - f. Poisons information- organization & information resources
6. **Pharmacovigilance**
 - a. Scope, definition and aims of pharmacovigilance
 - b. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used]
 - c. Reporting, evaluation, monitoring, preventing & management of ADRs
 - d. Role of pharmacist in management of ADR.
7. Communication skills, including patient counselling techniques, medication history interview, presentation of cases.
8. Pharmaceutical care concepts
9. Critical evaluation of biomedical literature
10. Medication errors

4.3 CLINICAL PHARMACY (PRACTICAL)

Practical : 3 Hrs./Week

Students are expected to perform 15 practicals in the following areas covering the topics dealt in theory class.

- a. Answering drug information questions (4 Nos)
- b. Patient medication counselling (4 Nos)
- c. Case studies related to laboratory investigations (4 Nos)
- d. Patient medication history interview (3 Nos)

Assignment:

Students are expected to submit THREE written assignments (1500 – 2000 words) on the topics given to them covering the following areas dealt in theory class.

Drug information, Patient medication history interview, Patient medication counselling, Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

4.4 BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY)

Theory : 2 Hrs. /Week

1. Detailed syllabus and lecture wise schedule

1 Research Methodology

- a) Types of clinical study designs:
Case studies, observational studies, interventional studies,
- b) Designing the methodology
- c) Sample size determination and Power of a study
Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study
- d) Report writing and presentation of data

2 Biostatistics

2.1 a) Introduction

- b) Types of data distribution
- c) Measures describing the central tendency distributions- average, median, mode
- d) Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean.

2.2 Data graphics

Construction and labeling of graphs, histogram, piecharts, scatter plots, semilogarithmic plots

2.3 Basics of testing hypothesis

- a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals.
- b) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way)
- c) Level of significance (Non-parametric data)- Sign test, Wilcoxon's signed rank test, Wilcoxon rank sum test, Mann Whitney U test, Kruskal-Wallis test (one way ANOVA)
- d) Linear regression and correlation- Introduction, Pearson's and Spearman's correlation and correlation co-efficient.
- e) Introduction to statistical software: SPSS, Epi Info, SAS.

2.4 Statistical methods in epidemiology

Incidence and prevalence, relative risk, attributable risk

3. Computer applications in pharmacy

Computer System in Hospital Pharmacy: Patterns of Computer use in Hospital Pharmacy – Patient record database management, Medication order entry – Drug labels and list – Intravenous solution and admixture, patient medication profiles, Inventory control, Management report & Statistics.

Computer In Community Pharmacy

Computerizing the Prescription Dispensing process

Use of Computers for Pharmaceutical Care in community pharmacy

Accounting and General ledger system

Drug Information Retrieval & Storage :

Introduction – Advantages of Computerized Literature Retrieval

Use of Computerized Retrieval

Reference books:

- a. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3rd edition, publisher Marcel Dekker Inc. NewYork.
- b. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich , 3rd edition, McGraw Hill Publications 2006

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

Theory : 3 Hrs. /Week

1. Biopharmaceutics

1. Introduction to Biopharmaceutics
 - a. Absorption of drugs from gastrointestinal tract.
 - b. Drug Distribution.
 - c. Drug Elimination.

2. Pharmacokinetics

2. Introduction to Pharmacokinetics.
 - a. Mathematical model
 - b. Drug levels in blood.
 - c. Pharmacokinetic model
 - d. Compartment models
 - e. Pharmacokinetic study.
3. One compartment open model.
 - a. Intravenous Injection (Bolus)
 - b. Intravenous infusion.
4. Multicompartment models.
 - a. Two compartment open model.
 - b. IV bolus, IV infusion and oral administration
5. Multiple – Dosage Regimens.
 - a. Repetitive Intravenous injections – One Compartment Open Model
 - b. Repetitive Extravascular dosing – One Compartment Open model
 - c. Multiple Dose Regimen – Two Compartment Open Model
6. Nonlinear Pharmacokinetics.
 - a. Introduction
 - b. Factors causing Non-linearity.
 - c. Michaelis-menton method of estimating parameters.
7. Noncompartmental Pharmacokinetics.
 - a. Statistical Moment Theory.
 - b. MRT for various compartment models.
 - c. Physiological Pharmacokinetic model.
8. Bioavailability and Bioequivalence.
 - a. Introduction.
 - b. Bioavailability study protocol.
 - c. Methods of Assessment of Bioavailability

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

Practical : 3 Hrs./Week

1. Improvement of dissolution characteristics of slightly soluble drugs by some methods.
2. Comparison of dissolution studies of two different marketed products of same drug.
3. Influence of polymorphism on solubility and dissolution.
4. Protein binding studies of a highly protein bound drug and poorly protein bound drug.
5. Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.
6. Bioavailability studies of some commonly used drugs on animal/human model.
7. Calculation of K_a , K_e , $t_{1/2}$, C_{max} , AUC, AUMC, MRT etc. from blood profile data.
8. Calculation of bioavailability from urinary excretion data for two drugs.
9. Calculation of AUC and bioequivalence from the given data for two drugs.
10. In vitro absorption studies.
11. Bioequivalency studies on the different drugs marketed.(eg) Tetracycline, Sulphamethoxazole, Trimethoprim, Aspirin etc., on animals and human volunteers.
12. Absorption studies in animal inverted intestine using various drugs.
13. Effect on contact time on the plasma protein binding of drugs.
14. Studying metabolic pathways for different drugs based on elimination kinetics data.
15. Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data.
16. Determination of renal clearance.

References:

- a. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
- b. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania.
- c. Pharmacokinetics: By Milo Gibaldi Donald, R. Merckel Dekker Inc.
- d. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
- e. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
- f. Biopharmaceutics; By Swarbrick
- g. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmanekar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
- h. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozer, Lea and Febiger, Philadelphia, 1995.
- i. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
- j. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Robert F Notari Marcel Dekker Inc, New York and Basel, 1987.
- k. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

4.6 CLINICAL TOXICOLOGY (THEORY)

Theory : 2 Hrs. /Week

1. General principles involved in the management of poisoning
2. Antidotes and the clinical applications.
3. Supportive care in clinical Toxicology.
4. Gut Decontamination.
5. Elimination Enhancement.
6. Toxicokinetics.
7. Clinical symptoms and management of acute poisoning with the following agents –
 - a) Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.
 - b) Opiates overdose.
 - c) Antidepressants
 - d) Barbiturates and benzodiazepines.
 - e) Alcohol: ethanol, methanol.
 - f) Paracetamol and salicylates.
 - g) Non-steroidal anti-inflammatory drugs.
 - h) Hydrocarbons: Petroleum products and PEG.
 - i) Caustics: inorganic acids and alkali.
 - j) Radiation poisoning
8. Clinical symptoms and management of chronic poisoning with the following agents –
Heavy metals: Arsenic, lead, mercury, iron, copper
9. Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.
10. Plants poisoning. Mushrooms, Mycotoxins.
11. Food poisonings
12. Envenomations – Arthropod bites and stings.

Substance abuse:

Signs and symptoms of substance abuse and treatment of dependence

- a) CNS stimulants :amphetamine
- b) Opioids
- c) CNS depressants
- d) Hallucinogens: LSD
- e) Cannabis group
- f) Tobacco

References:

- a. Matthew J Ellenhorn. ELLENHORNS MEDICAL TOXICOLOGY – DIAGNOSIS AND TREATMENT OF POISONING. Second edition. Williams and Willkins publication, London
- b. V V Pillay. HANDBOOK OF FORENSIC MEDICINE AND TOXICOLOGY. Thirteenth edition 2003 Paras Publication, Hyderabad

Fifth year

5.1 CLINICAL RESEARCH (THEORY)

Theory : 3 Hrs. /Week

1. Drug development process:

Introduction

Various Approaches to drug discovery

1. Pharmacological
2. Toxicological
3. IND Application
4. Drug characterization
5. Dosage form

2. Clinical development of drug:

1. Introduction to Clinical trials
2. Various phases of clinical trial.
3. Methods of post marketing surveillance
4. Abbreviated New Drug Application submission.
5. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines
6. Challenges in the implementation of guidelines
7. Ethical guidelines in Clinical Research
8. Composition, responsibilities, procedures of IRB / IEC
9. Overview of regulatory environment in USA, Europe and India.
10. Role and responsibilities of clinical trial personnel as per ICH GCP
 - a. Sponsor
 - b. Investigators
 - c. Clinical research associate
 - d. Auditors
 - e. Contract research coordinators
 - f. Regulatory authority
11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)
12. Informed consent Process
13. Data management and its components
14. Safety monitoring in clinical trials.

References :

- a. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
- b. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
- c. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
- d. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
- e. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
- f. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
- g. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

5.2 PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS (THEORY)

Theory : 3 Hrs. /Week

1. **Pharmacoepidemiology :**

Definition and scope:

Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.

Measurement of outcomes in pharmacoepidemiology

Outcome measure and drug use measures

Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement

Concept of risk in pharmacoepidemiology

Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

Pharmacoepidemiological methods

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods

Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

Sources of data for pharmacoepidemiological studies

Ad Hoc data sources and automated data systems.

Selected special applications of pharmacoepidemiology

Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

2. **Phrmacoeconomics:**

Definition, history, needs of pharmacoeconomic evaluations

Role in formulary management decisions

Pharmacoeconomic evaluation

Outcome assessment and types of evaluation

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods:

Cost – minimization, cost- benefit, cost – effectiveness, cost utility

3. **Applications of Pharmacoeconomics**

Software and case studies

5.3 CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING (THEORY)

Theory : 2 Hrs. /Week

- 1. Introduction to Clinical pharmacokinetics.**
- 2. Design of dosage regimens:**
Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.
- 3. Pharmacokinetics of Drug Interaction:**
 - a. Pharmacokinetic drug interactions
 - b. Inhibition and Induction of Drug metabolism
 - c. Inhibition of Biliary Excretion.
- 4. Therapeutic Drug monitoring:**
 - a. Introduction
 - b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight, disease, Interacting drugs).
 - c. Indications for TDM. Protocol for TDM.
 - d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.
 - e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.
- 5. Dosage adjustment in Renal and hepatic Disease.**
 - a. Renal impairment
 - b. Pharmacokinetic considerations
 - c. General approach for dosage adjustment in Renal disease.
 - d. Measurement of Glomerular Filtration rate and creatinine clearance.
 - e. Dosage adjustment for uremic patients.
 - f. Extracorporeal removal of drugs.
 - g. Effect of Hepatic disease on pharmacokinetics.
- 6. Population Pharmacokinetics.**
 - a. Introduction to Bayesian Theory.
 - b. Adaptive method or Dosing with feed back.
 - c. Analysis of Population pharmacokinetic Data.
- 7. Pharmacogenetics**
 - a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.
 - b. Genetic Polymorphism in Drug Transport and Drug Targets.
 - c. Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations

APPENDIX-B

CONDITIONS TO BE FULFILLED BY THE ACADEMIC TRAINING INSTITUTION

- 1) Any authority or institution in India applying to the Pharmacy Council of India for approval of courses of study for Pharm.D. and Pharm.D. (Post Baccalaureate) under sub-section (1) of section 12 of the Pharmacy Act, 1948 shall comply with the infrastructural facilities as prescribed by the Pharmacy Council of India from time to time.
- 2) Pharm.D. and Pharm.D. (Post Baccalaureate) programmes shall be conducted only in those institutions which -
 - a) are approved by the Pharmacy Council of India for Pharm. D course as provided under section 12 of the Pharmacy Act, 1948;
 - b) have 300 bedded hospital attached to it.

(i) Hospital Details

1. Institution with their own hospital of minimum 300 beds.
2. Teaching hospital recognised by the Medical Council of India or University, or a Government hospital not below the level of district headquarter hospital with 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
3. Corporate type hospital with minimum 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
4. Number of institutions which can be attached to one hospital shall be restricted by the student pharmacist to bed ratio of 1:10.

(ii) Specialty

- a) Tertiary care hospitals are desirable
- b) Medicine[compulsory], and any three specialization of the following
 1. Surgery
 2. Pediatrics
 3. Gynecology and obstetrics
 4. Psychiatry
 5. Skin and VD
 6. Orthopedics

(iii) Location of the Hospital

Within the same limits of Corporation or Municipality or Campus with Medical Faculty involvement as adjunct faculty.

3) TEACHING STAFF REQUIREMENT

- i) Staff Pattern: All faculty shall be full time. However part time perceptors in hospital shall be allowed.
- ii) Subject wise specialization of the Teaching Staff :

S.No.	Subject	Specialization required
1.	Pharmacy Practice	M.Pharm in Pharmacy Practice or Pharmacology or Pharmaceutics.
2.	Human Anatomy & Physiology	M.Pharm in Pharmacology or Pharmacy practice
3.	Pharmaceutics (Dispensing & General Pharmacy)	M.Pharm in Pharmaceutics
4.	Pharmacognosy-I	M.Pharm in Pharmacognosy
5.	Pharmaceutical Organic Chemistry-I	M.Pharm in Pharmaceutical chemistry or Pharmaceutical Analysis or Quality assurance or Bulk Drug
6.	Pharmaceutical Inorganic Chemistry	M.Pharm in Pharmaceutical chemistry or Pharmaceutical Analysis or Quality assurance or Bulk Drug
7.	Pharmaceutical microbiology	M.Pharm in Pharmaceutics or Pharmaceutical Biotechnology
8.	Pathophysiology	M.Pharm Pharmacy practice or Pharmacology
9.	Applied Biochemistry & Clinical Chemistry	M.Pharm in Pharmacology or Pharmacy practice or Pharmaceutical chemistry
10.	Pharmacology-I	M.Pharm in Pharmacology or Pharmacy practice
11.	Pharmaceutical Jurisprudence	M.Pharm in Pharmaceutics
12.	Pharmacology-II	M.Pharm in Pharmacology or Pharmacy practice
13.	Pharmaceutical Dosage Forms	M.Pharm in Pharmaceutics or Industrial Pharmacy
14.	Pharmacotherapeutics –I, II and III	M.Pharm Pharmacy practice or Pharmacology
15.	Community Pharmacy	M.Pharm in Pharmacy practice or

		Pharmacology or Pharmaceutics
16.	Hospital Pharmacy	M.Pharm in Pharmacy practice or Pharmacology or Pharmaceutics
17.	Clinical Pharmacy	M.Pharm in Pharmacy practice
18.	Computer Science or Computer Application in pharmacy	MCA
19.	Mathematics	M.Sc. (Maths)

iii) Teaching Staff :

Department/Division	Name of the post	No.
Department of Pharmaceutics	Professor	1
	Asst. Professor	1
	Lecturer	2
Department of Pharmaceutical Chemistry (Including Pharmaceutical Analysis)	Professor	1
	Asst. Professor	1
	Lecturer	3
Department of Pharmacology	Professor	1
	Asst. Professor	1
	Lecturer	2
Department of Pharmacognosy	Professor	1
	Asst. Professor	1
	Lecturer	1
Department of Pharmacy Practice	Professor	1
	Asst. Professor	2
	Lecturer	3

iv) Prescribed qualifications and experience for Professor, Assistant Professor, Lecturer and others :

Sl. No.	CADRE	QUALIFICATIONS	EXPERIENCE
1.	Lecturer	i) Basic degree in pharmacy (B.Pharm.). ii) Registration as a pharmacist under the Pharmacy Act. iii) First Class Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm)	No minimum requirement.
2.	Assistant Professor	i) Basic degree in pharmacy (B.Pharm) ii) Registration as a pharmacist under the Pharmacy Act. iii) Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm) iv) Ph.D. degree (with First Class degree either at Bachelor's or Master's level) in the appropriate branch of specialization in Pharmacy.	Three years experience in Teaching or Research at the level of Lecturer or equivalent.
3.	Professor	i) Basic degree in pharmacy (B.Pharm) ii) Registration as a pharmacist under the Pharmacy Act. iii) Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm). iv) Ph.D. degree (with first Class either at	i) Ten years experience in Teaching or Research. ii) Out of which five years must be as Assistant Professor.

		Bachelor's or Master's level) in appropriate branch of specialization in Pharmacy.	
4.	Director or Principal or Head of institute	i) Basic degree in pharmacy (B. Pharm.) ii) Registration as a pharmacist under the Pharmacy Act. iii) Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm) iv) Ph.D. degree (with first Class degree either at Bachelor's or Master's level in the appropriate branch of specialization in Pharmacy.	i) Fifteen years experience in Teaching or Research. ii) Out of which five years must be as Professor or above in Pharmacy. Desirable : Administrative experience in responsible position. The maximum age for holding the post shall be 65 years.

Note : If a class or division is not awarded at Master's level, a minimum of 60% marks in aggregate or equivalent cumulative grade point average shall be considered equivalent to first class or division, as the case may be.

v) Workload of Faculty :

Professor – 8 hrs. per week

Assistant Professor – 12 hrs. per week

Lecturers – 16 hrs. per week

vi) Training of Pharmacy Practice Faculty:

a) Teaching staff will be trained as per the module prescribed by the Central Council.

b) Duration of training – Minimum 3 months.

c) Training sites – Institutions running pharmacy practice Programmes for at least five years.

d) Trainer – Professor or Assistant Professor with minimum of five years of clinical pharmacy teaching and practice experience.

4) NON-TEACHING STAFF:

Sl.No.	Designation	Required (Minimum)	Required Qualification
1	Laboratory Technician	1 for each Dept	D. Pharm
2	Laboratory Assistants or Laboratory Attenders	1 for each Lab (minimum)	SSLC
3	Office Superintendent	1	Degree
4	Accountant	1	Degree
5	Store keeper	1	D.Pharm or a Bachelor degree recognized by a University or institution.
6	Computer Data Operator	1	BCA or Graduate with Computer Course
7	Office Staff I	1	Degree
8	Office Staff II	2	Degree
9	Peon	2	SSLC
10	Cleaning personnel	Adequate	---
11	Gardener	Adequate	---

5) ACCOMMODATION :

Suitable and sufficient accommodation with adequate ventilation, lighting and other hygienic conditions should be provided to the rooms for Principal or the Head of the department, office, class rooms, library, staff, staff common room, students common room, museum, laboratories, stores, etc.

At least two lecture halls along with eight laboratories as specified below should be provided for :—

1. Pharmaceutics and Pharmacokinetics Lab	- 2
2. Life Science (Pharmacology, Physiology, Pathophysiology)	- 2
3. Phytochemistry or Pharmaceutical Chemistry	- 2
4. Pharmacy Practice	- 2

	Total = 8

In addition to the laboratories, balance room, aseptic room or cabinet, animal house and a machine room shall also be provided.

Floor area of the laboratory should not be less than 30 square feet per student required to work in the laboratory at any given time subject to a minimum of 750 square feet.

Laboratories should be fitted and constructed in a manner that these can be kept reasonably clean. Gas and water fittings, shelves, fuming cupboards be provided wherever necessary.

6. EQUIPMENT AND APPARATUS :

Department wise list of minimum equipments

A. DEPARTMENT OF PHARMACOLOGY :

I. Equipment:

S.No.	Name	Minimum required Nos.
1	Microscopes	15
2	Haemocytometer with Micropipettes	20
3	Sahli's haemocytometer	20
4	Hutchinson's spirometer	01

5	Spygmomanometer	05
6	Stethoscope	05
7	Permanent Slides for various tissues	One pair of each tissue Organs and endocrine glands One slide of each organ system
8	Models for various organs	One model of each organ system
9	Specimen for various organs and systems	One model for each organ system
10	Skeleton and bones	One set of skeleton and one spare bone
11	Different Contraceptive Devices and Models	One set of each device
12	Muscle electrodes	01
13	Lucas moist chamber	01
14	Myographic lever	01
15	Stimulator	01
16	Centrifuge	01
17	Digital Balance	01
18	Physical /Chemical Balance	01
19	Sherrington's Kymograph Machine or Polyrite	10
20	Sherrington Drum	10
21	Perspex bath assembly (single unit)	10
22	Aerators	10
23	Computer with LCD	01
24	Software packages for experiment	01
25	Standard graphs of various drugs	Adequate number
26	Actophotometer	01
27	Rotarod	01
28	Pole climbing apparatus	01
29	Analgesiometer (Eddy's hot plate and radiant heat methods)	01
30	Convulsiometer	01
31	Plethysmograph	01
32	Digital pH meter	01

II. Apparatus:

S.No	Name	Minimum required Nos.
1	Folin-Wu tubes	60
2	Dissection Tray and Boards	10
3	Haemostatic artery forceps	10
4	Hypodermic syringes and needles of size 15,24,26G	10
5	Levers, cannulae	20

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

B. DEPARTMENT OF PHARMACOGNOSY :**I. Equipment:**

S.No.	Name	Minimum required Nos.
1	Microscope with stage micrometer	15
2	Digital Balance	02
3	Autoclave	02
4	Hot air oven	02
5	B.O.D.incubator	01
6	Refrigerator	01
7	Laminar air flow	01
8	Colony counter	02
9	Zone reader	01
10	Digital pH meter	01
11	Sterility testing unit	01
12	Camera Lucida	15
13	Eye piece micrometer	15
14	Incinerator	01

15	Moisture balance	01
16	Heating mantle	15
17	Flourimeter	01
18	Vacuum pump	02
19	Micropipettes (Single and multi channeled)	02
20	Micro Centrifuge	01
21	Projection Microscope	01

II. Apparatus:

S.No.	Name	Minimum required Nos.
1	Reflux flask with condenser	20
2	Water bath	20
3	Clavengers apparatus	10
4	Soxhlet apparatus	10
6	TLC chamber and sprayer	10
7	Distillation unit	01

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

C. DEPARTMENT OF PHARMACEUTICAL CHEMISTRY :

I. Equipment:

S.No.	Name	Minimum required Nos.
1	Hot plates	05
2	Oven	03
3	Refrigerator	01
4	Analytical Balances for demonstration	05
5	Digital balance 10mg sensitivity	10
6	Digital Balance (1mg sensitivity)	01
7	Suction pumps	06

8	Muffle Furnace	01
9	Mechanical Stirrers	10
10	Magnetic Stirrers with Thermostat	10
11	Vacuum Pump	01
12	Digital pH meter	01
13	Microwave Oven	02

II. Apparatus:

S.No.	Name	Minimum required Nos.
1	Distillation Unit	02
2	Reflux flask and condenser single necked	20
3	Reflux flask and condenser double/ triple necked	20
4	Burettes	40
5	Arsenic Limit Test Apparatus	20
6	Nessler's Cylinders	40

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

D. DEPARTMENT OF PHARMACEUTICS:

I. Equipment:

S.No	Name	Minimum required Nos.
1	Mechanical stirrers	10
2	Homogenizer	05
3	Digital balance	05
4	Microscopes	05
5	Stage and eye piece micrometers	05
6	Brookfield's viscometer	01

7	Tray dryer	01
8	Ball mill	01
9	Sieve shaker with sieve set	01
10	Double cone blender	01
11	Propeller type mechanical agitator	05
12	Autoclave	01
13	Steam distillation still	01
14	Vacuum Pump	01
15	Standard sieves, sieve no. 8, 10, 12,22,24, 44, 66, 80	10 sets
16	Tablet punching machine	01
17	Capsule filling machine	01
18	Ampoule washing machine	01
19	Ampoule filling and sealing machine	01
20	Tablet disintegration test apparatus IP	01
21	Tablet dissolution test apparatus IP	01
22	Monsanto's hardness tester	01
23	Pfizer type hardness tester	01
24	Friability test apparatus	01
25	Clarity test apparatus	01
26	Ointment filling machine	01
27	Collapsible tube crimping machine	01
28	Tablet coating pan	01
29	Magnetic stirrer, 500ml and 1 liter capacity with speed control	05 EACH 10
30	Digital pH meter	01
31	All purpose equipment with all accessories	01
32	Aseptic Cabinet	01
33	BOD Incubator	02
34	Bottle washing Machine	01
35	Bottle Sealing Machine	01
36	Bulk Density Apparatus	02

37	Conical Percolator (glass/copper/ stainless steel)	10
38	Capsule Counter	02
39	Energy meter	02
40	Hot Plate	02
41	Humidity Control Oven	01
42	Liquid Filling Machine	01
43	Mechanical stirrer with speed regulator	02
44	Precision Melting point Apparatus	01
45	Distillation Unit	01

II. Apparatus:

S.No	Name	Minimum required Nos.
1	Ostwald's viscometer	15
2	Stalagmometer	15
3	Desiccator*	05
4	Suppository moulds	20
5	Buchner Funnels (Small, medium, large)	05 each
6	Filtration assembly	01
7	Permeability Cups	05
8	Andreason's Pipette	03
9	Lipstick moulds	10

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

E. DEPARTMENT OF PHARMACEUTICAL BIOTECHNOLOGY :

S.No.	Name	Minimum required Nos.
1	Orbital shaker incubator	01
2	Lyophilizer (Desirable)	01
3	Gel Electrophoresis (Vertical and Horizontal)	01
4	Phase contrast/Trinocular Microscope	01
5	Refrigerated Centrifuge	01
6	Fermenters of different capacity (Desirable)	01
7	Tissue culture station	01
8	Laminar airflow unit	01
9	Diagnostic kits to identify infectious agents	01
10	Rheometer	01
11	Viscometer	01
12	Micropipettes (single and multi channeled)	01 each
13	Sonicator	01
14	Respinometer	01
15	BOD Incubator	01
16	Paper Electrophoresis Unit	01
17	Micro Centrifuge	01
18	Incubator water bath	01
19	Autoclave	01
20	Refrigerator	01
21	Filtration Assembly	01
22	Digital pH meter	01

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

F. DEPARTMENT OF PHARMACY PRACTICE:**Equipment:**

S.No.	Name	Minimum required Nos.
1	Colorimeter	2
2	Microscope	Adequate
3	Permanent slides (skin, kidney, pancreas, smooth muscle, liver etc.,)	Adequate
4	Watch glass	Adequate
5	Centrifuge	1
6	Biochemical reagents for analysis of normal and pathological constituents in urine and blood facilities	Adequate
7	Filtration equipment	2
8	Filling Machine	1
9	Sealing Machine	1
10	Autoclave sterilizer	1
11	Membrane filter	1 Unit
12	Sintered glass funnel with complete filtering assemble	Adequate
13	Small disposable membrane filter for IV admixture filtration	Adequate
14	Laminar air flow bench	1
15	Vacuum pump	1
16	Oven	1
17	Surgical dressing	Adequate
18	Incubator	1
19	PH meter	1
20	Disintegration test apparatus	1
21	Hardness tester	1
22	Centrifuge	1
23	Magnetic stirrer	1
24	Thermostatic bath	1

NOTE:

1. **Computers and Internet connection (Broadband), six computers for students with internet and staff computers as required.**
2. **Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and the department.**

G. CENTRAL INSTRUMENTATION ROOM :

S.No.	Name	Minimum required Nos.
1	Colorimeter	01
2	Digital pH meter	01
3	UV- Visible Spectrophotometer	01
4	Flourimeter	01
5	Digital Balance (1mg sensitivity)	01
6	Nephelo Turbidity meter	01
7	Flame Photometer	01
8	Potentiometer	01
9	Conductivity meter	01
10	Fourier Transform Infra Red Spectrometer (Desirable)	01
11	HPLC	01
12	HPTLC (Desirable)	01
13	Atomic Absorption and Emission spectrophotometer (Desirable)	01
14	Biochemistry Analyzer (Desirable)	01
15	Carbon, Hydrogen, Nitrogen Analyzer (Desirable)	01
16	Deep Freezer (Desirable)	01
17	Ion- Exchanger	01
18	Lyophilizer (Desirable)	01

APPENDIX-C

INTERNSHIP

1) SPECIFIC OBJECTIVES:

- i) to provide patient care in cooperation with patients, prescribers, and other members of an interprofessional health care team based upon sound therapeutic principles and evidence-based data, taking into account relevant legal, ethical, social cultural, economic, and professional issues, emerging technologies, and evolving biomedical, pharmaceutical, social or behavioral or administrative, and clinical sciences that may impact therapeutic outcomes.
- ii) to manage and use resources of the health care system, in cooperation with patients, prescribers, other health care providers, and administrative and supportive personnel, to promote health; to provide, assess, and coordinate safe, accurate, and time-sensitive medication distribution; and to improve therapeutic outcomes of medication use.
- iii) to promote health improvement, wellness, and disease prevention in co-operation with patients, communities, at-risk population, and other members of an interprofessional team of health care providers.
- iv) to demonstrate skills in monitoring of the National Health Programmes and schemes, oriented to provide preventive and promotive health care services to the community.
- v) to develop leadership qualities to function effectively as a member of the health care team organised to deliver the health and family welfare services in existing socio-economic, political and cultural environment.
- vi) to communicate effectively with patients and the community.

2) OTHER DETAILS :

- i) All parts of the internship shall be done, as far as possible, in institutions in India. In case of any difficulties, the matter may be referred to the Pharmacy Council of India to be considered on merits.
- ii) Where an intern is posted to district hospital for training, there shall be a committee consisting of representatives of the college or university, and the district hospital administration, who shall regulate the training of such trainee. For such trainee a certificate of satisfactory completion of training shall be obtained from the relevant

administrative authorities which shall be countersigned by the Principal or Dean of College.

- iii) Every candidate shall be required, after passing the final Pharm.D. or Pharm.D. (Post Baccalaureate) examination as the case may be to undergo compulsory rotational internship to the satisfaction of the College authorities and University concerned for a period of twelve months so as to be eligible for the award of the degree of Pharm.D. or Pharm.D. (Post Baccalaureate) as the case may be.

3. ASSESSMENT OF INTERNSHIP :

- i) The intern shall maintain a record of work which is to be verified and certified by the preceptor (teacher practitioner) under whom he works. Apart from scrutiny of the record of work, assessment and evaluation of training shall be undertaken by an objective approach using situation tests in knowledge, skills and attitude during and at the end of the training. Based on the record of work and date of evaluation, the Dean or Principal shall issue certificate of satisfactory completion of training, following which the university shall award the degree or declare him eligible for it.
- ii) Satisfactory completion of internship shall be determined on the basis of the following:-

(1) Proficiency of knowledge required for each case management SCORE 0-5

(2) The competency in skills expected for providing Clinical

Pharmacy Services

SCORE 0-5

(3) Responsibility, punctuality, work up of case, involvement in patient care

SCORE 0-5

(4) Ability to work in a team (Behavior with other healthcare professionals including medical doctors, nursing staff and colleagues).

SCORE 0-5

(5) Initiative, participation in discussions, research aptitude.

SCORE 0-5

Poor	Fair	Below Average	Average	Above Average	Excellent
0	1	2	3	4	5

A Score of less than 3 in any of above items will represent unsatisfactory completion of internship.

**RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES, KARNATAKA (RGUHS),
BANGALORE – 560 041**

Pharm D Regulations 2008

1. ELIGIBILITY

1.1 Qualifying Examination

i) Candidates who have passed two year P.U.C. examination of Karnataka P.U.C. Board or an equivalent examination of any other approved Board or University established by law in India with English as one of the subject and Physics, Chemistry as compulsory subjects along with one of the following subject – Mathematics or Biology or P.C.M.B. Minimum eligibility should be based on the aggregate of P.C.M. or P.C.B. The candidates shall have passed subjects of English, Physics, Chemistry and Biology / Mathematics individually also.

ii) Candidates who have passed D.Pharm course from institutions approved by Pharmacy Council of India U/S 12 of Pharmacy Act, 1948, are only eligible to be admitted to first year Pharm. D course.

1.2 Age

The candidate should have completed 17 years of age on or before 31st day of December of the year of admission to the course.

2. Duration of the course

Pharm.D: The duration of the course shall be six academic years (five years of study and one year of internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of six years duration is divided into two phases –

Phase I – consisting of First, Second, Third, Fourth and Fifth academic year.

Phase II – consisting of internship or residency training during sixth year involving posting in speciality units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services and acquires skill under supervision so that he or she may become capable of functioning independently.

3. Medium of Instruction

Medium of Instruction and Examination Shall be English.

4. Attendance and Progress

A candidate is required to put in at least 80% attendance in theory and practical subjects separately in a recognized institution approved by Pharmacy council of India and affiliated to Rajiv Gandhi University of Health Sciences, Karnataka. The candidate shall complete prescribed course satisfactorily to be eligible to appear for the respective examination.

5. Course of study

a) The course of study for Pharm.D. shall include the subjects as given in the Tables below. The number of hours in a week, devoted to each subject for its teaching in theory, practical and tutorial shall not be less than that noted against it in columns (3), (4) and (5) below.

T A B L E S

First Year :

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
1.1	Human Anatomy and Physiology	3	3	1
1.2	Pharmaceutics	2	3	1
1.3	Medical Biochemistry	3	3	1
1.4	Pharmaceutical Organic Chemistry	3	3	1
1.5	Pharmaceutical Inorganic Chemistry	2	3	1
1.6	Remedial Mathematics/ Biology**	3	3*	1
	Total hours	16	18	6 = (40)

* For Biology

** For candidates who have studied PCMB in 10+2 course are exempted.

** Colleges to conduct the Examination.

Second Year:

S.No	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
2.1	Pathophysiology	4	-	1
2.2	Pharmaceutical Microbiology	4	4	1
2.3	Pharmacognosy & Phytopharmaceuticals	4	4	1
2.4	Pharmacology-I	4	-	1
2.5	Community Pharmacy	3	-	1
	Total Hours	19	8	5 = 32

Third Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
3.1	Pharmacology-II -	3	3	1
3.2	Pharmaceutical Analysis	3	3	1
3.3	Hospital Pharmacy	3	3	1
3.4	Pharmaceutical Jurisprudence	2	-	-
3.5	Medicinal Chemistry	3	3	1
3.6	Pharmaceutical Formulations	2	3	1
	Total hours	16	15	5 = 36

Fourth Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical/ Hospital	No. of hours of Tutorial

			Posting	
(1)	(2)	(3)	(4)	(5)
4.1	Pharmacotherapeutics-I	3	3	1
4.2	Pharmacotherapeutics-II	3	3	1
4.3	Clinical Pharmacy	3	3	1
4.4	Biostatistics & Research Methodology	2	-	1
4.5	Biopharmaceutics & Pharmacokinetics-	3	3	1
4.6	Clinical Toxicology	2	-	1
	Total hours	16	12	6 = 34

Fifth Year:

S.No	Name of Subject	No. of hours of Theory	No. of hours of Hospital posting *	No. of hours of Seminar
(1)	(2)	(3)	(4)	(5)
5.1	Pharmacotherapeutics-III	3	3	1
5.2	Clinical Research	3	-	1
5.3	Pharmacoepidemiology and Pharmacoeconomics	3	-	1
5.4	Clinical Pharmacokinetics & Therapeutic Drug Monitoring	2	-	1
5.5	Clerkship *	-	-	1
5.6	Project work (Six Months)	-	20	-
	Total hours	11	23	5 = 39

**** Attending ward rounds on daily basis.***

Sixth Year:

Internship or residency training including postings in specialty units. Student should independently provide the clinical pharmacy services under supervision of a preceptor to the

allotted wards. (i) Six months in General Medicine department, and (ii) Two months each in three other specialty departments

6. Approval of institution conducting the course of study

The regular course for Pharm.D. I, II, III, IV, V and VI year shall be conducted by an institution approved by Pharmacy Council of India and affiliated to Rajiv Gandhi University of Health Sciences, Karnataka. Institution running Pharm D regular courses only shall be permitted to start Pharm D (Post Baccalaureate) course. The approval and affiliation will be granted only if adequate arrangements for teaching-infrastructure facilities, accommodation, equipments, chemicals, glassware, library, teaching and non- teaching staff are provided as prescribed by Pharmacy Council of India and as required under the norms of Rajiv Gandhi University of Health Science, Karnataka(as prescribed in Appendix B).

7. Academic Work

The teaching staff of respective subjects shall maintain a regular record of attendance in both Theory and Practical.

Internal Assessment Marks

A. Theory: Three sessional examinations evenly spread during the academic year shall be conducted by the affiliated colleges. The average marks of the best two examinations shall be computed out of a maximum 30 marks and shall constitute the sessional marks in theory. Provided further the colleges may conduct one special theory sessional examination towards the end of the academic session for those who might have missed any one of the regular sessional examination on genuine grounds.

B. Practical: Students are expected to perform the number of experiments listed in the respective syllabus. Marks shall be awarded out of a maximum of 10 to each of the practical exercise and an average of those shall be computed out of maximum of 10 each marks. In addition, three practical sessional examinations evenly spread during academic year shall be conducted. The average marks of the best two practical examinations shall be computed out of a maximum of 20 marks. A total of 30 marks shall constitute the sessional award in practical. While awarding the sessional marks of practical experiments, the following considerations should be taken into account.

1. Preparation of the candidate.
2. Manipulative skills.
3. Results of the experiment.
4. Knowledge of the experiment
5. Viva voce pertaining to the experiments only.

The College shall maintain the sessional books of the students and the record of sessional marks of the students.

A regular record of both theory and practical class work and sessional examinations conducted in an institution imparting the course shall be maintained for each student in the institution.

8. Examination for Pharm D

- (1) Every year there shall be an examination to examine the students.
- (2) Each examination may be held twice every year. The first examination in a year shall be the annual examination and the second examination shall be supplementary examination.
- (3) The examinations shall be of written and practical (including oral nature) carrying maximum marks for each part of a subject as indicated in Tables below :

Scheme of Examination for Pharm D Course

First Year:

Sl.No.		Name of Subject	Maximum marks for Theory	Maximum marks for Practical				
			Examination	Sessional	Total	Examination	Sessional	Total
1.1	Human Anatomy and Physiology		70	30	100	70	30	100
1.2	Pharmaceutics		70	30	100	70	30	100
1.3	Medicinal Biochemistry		70	30	100	70	30	100
1.4	Pharmaceutical Organic Chemistry		70	30	100	70	30	100
1.5	Pharmaceutical Inorganic Chemistry		70	30	100	70	30	100
1.6	Remedial Mathematics/Biology**		70	30	100	70*	30*	100*
					600			600 = 1200

* For Biology.

** Colleges to conduct the examination.

Second Year :

Sl.No.		Name of Subject	Maximum marks for Theory	Maximum marks for Practical					
			Examination	Sessional	Total	Examination	Sessional	Total	

2.1	Pathophysiology	70	30	100	-	-	-
2.2	Pharmaceutical Microbiology	70	30	100	70	30	100
2.3	Pharmacognosy & Phytopharmaceuticals	70	30	100	70	30	100
2.4	Pharmacology-I	70	30	100	-	-	-
2.5	Community Pharmacy	70	30	100	-	-	-
				500			200 = 700

Third Year:

Sl.No.		Name of Subject	Maximum marks for Theory	Maximum marks for Practical				
			Examination	Sessional	Total	Examination	Sessional	Total
3.1	Pharmacology-II -		70	30	100	70	30	100
3.2	Pharmaceutical Analysis		70	30	100	70	30	100
3.3	Hospital Pharmacy		70	30	100	70	30	100
3.4	Pharmaceutical Jurisprudence		70	30	100	-	-	-
3.5	Medicinal Chemistry		70	30	100	70	30	100
3.6	Pharmaceutical Formulations		70	30	100	70	30	100
					600			500 = 1100

Fourth Year:

Sl.No.		Name of Subject	Maximum marks for Theory	Maximum marks for Practical					
				Examination	Sessional	Total	Examination	Sessional	Total

4.1	Pharmacotherapeutics-I	70	30	100	70	30	100
4.2	Pharmacotherapeutics-II	70	30	100	70	30	100
4.3	Clinical Pharmacy	70	30	100	70	30	100
4.4	Biostatistics & Research Methodology	70	30	100	-	-	-
4.5	Biopharmaceutics & Pharmacokinetics-	70	30	100	70	30	100
4.6	Clinical Toxicology	70	30	100	-	-	-
				600			400 = 1000

Fifth Year :

Sl.No.		Name of Subject	Maximum marks for Theory	Maximum marks for Practical				
			Examination	Sessional	Total	Examination	Sessional	Total
5.1	Pharmacotherapeutics-III		70	30	100	70	30	100
5.2	Clinical Research		70	30	100	-	-	-
5.3	Pharmacoepidemiology and Pharmacoeconomics		70	30	100	-	-	-
5.4	Clinical Pharmacokinetics & Therapeutic Drug Monitoring		70	30	100	-	-	-
5.5	Clerkship *		-	-	-	70	30	100
5.6	Project work (Six Months)		-	-	-	100**	-	100
					400			300 = 700

* Attending ward rounds on daily basis.

** 30 marks – viva-voce (oral)

70 marks – Thesis work

9. Mode of examinations

(1) Theory examination shall be of three hours and practical examination shall be of four hours duration.

(2) Practical examination shall also consist of a viva –voce (Oral) examination.

(3) Clerkship examination – Oral examination shall be conducted after the completion of clerkship of students. An external and an internal examiner will evaluate the student. Students may be asked to present the allotted medical cases followed by discussion. Students' capabilities in delivering clinical pharmacy services, pharmaceutical care planning and knowledge of therapeutics shall be assessed.

10. Criteria for Pass

a) Candidates who have secured a minimum of 50% marks in the Theory (including sessional) and Practical (including sessional) separately in any subject or subjects shall be declared to have passed in that subject/ and exempted from appearing in that subject/s at subsequent examination.

b) Theory and Practical of a particular subject are considered as individual subjects for the purpose of pass criteria.

11. Eligibility for promotion to next year

All students who have appeared for all the subjects and passed the first year annual examination are eligible for promotion to the second year and, so on. However, failure in more than two subjects shall debar him or her from promotion to the next year classes.

12. Declaration of Class

Class shall be awarded at the end of I, II, III, IV, V and final year of Pharm. D examination as shown below:

1) Distinction	75%
2) First class	60% and above and less than 75%
3) Second Class	50% and above and less than 60%

Pass class shall be awarded to such of the candidates who would have passed the examination in more than one attempt. However, this shall not be applicable to candidates who are exempted in Remedial Biology and Remedial Mathematics by the RGUHS Karnataka, Bangalore.

13. Internship

- (1) Internship is a phase of training wherein a student is expected to conduct actual practice of pharmacy and health care and acquires skills under the supervision so that he or she may become capable of functioning independently.
- (2) A student shall be permitted to start the internship only after having passed in theory and practical of all subjects of all the previous years.
- (3) Every student has to undergo one-year internship as per Appendix-C to these regulations.

14. Award of Degree

a) A candidate who has passed in all the subjects of Pharm.D course has successfully completed the Internship (as described in appendix C) will be eligible for the award of Pharm. D degree.

15. Practical training

1. **Hospital posting** — Every student shall be posted in constituent hospital for a period of not less than seventy five hours to be covered in not less than 200 working days in each of second, third & fourth year course. Each student shall submit report duly certified by the preceptor and duly attested by the Head of the Department or Institution as prescribed. In the fifth year, every student shall spend half a day in the morning hours attending ward rounds on daily basis as a part of clerkship. Theory teaching may be scheduled in the afternoon.
2. **Project work** — (1) To allow the student to develop data collection and reporting skills in the area of community, hospital and clinical pharmacy, a project work shall be carried out under the supervision of a teacher. The project topic must be approved by the Head of the Department or Head of the Institution. The same shall be announced to students within one month of commencement of the fifth year classes. Project work shall be presented in a written report and as a seminar at the end of the year. External and the internal examiners shall do the assessment of the project work.
(2) Project work shall comprise of objectives of the work, methodology, results, discussions and conclusions.
3. **Objectives of project work** — The main objectives of the project work is to—
 - (i) show the evidence of having made accurate description of published work of others and of having recorded the findings in an impartial manner; and
 - (ii) develop the students in data collection, analysis and reporting and interpretation skills.
4. **Methodology** — To complete the project work following methodology shall be adopted, namely:—
 - (i) students shall work in groups of not less than *two* and not more than *four* under an authorised teacher;
 - (ii) project topic shall be approved by the Head of the Department or Head of the Institution;
 - (iii) project work chosen shall be related to the pharmacy practice in community, hospital and clinical setup. It shall be patient and treatment (Medicine) oriented, like drug utilization reviews, Pharmacoepidemiology, pharmacovigilance or pharmacoeconomics;
 - (iv) project work shall be approved by the institutional ethics committee;
 - (v) student shall present at least three seminars, one in the beginning, one at middle and one at the end of the project work; and
 - (vi) two-page write-up of the project indicating title, objectives, methodology anticipated benefits and references shall be submitted to the Head of the Department or Head of the Institution.

5. **Reporting** — (1) Student working on the project shall submit jointly to the Head of the Department or Head of the Institution a project report of about 40-50 pages. Project report should include a certificate issued by the RGUHS recognized teacher, Head of the Department as well as by the Head of the Institution
- (2) Project report shall be computer typed in double space using Times Roman font on A4 paper. The title shall be in bold with font size 18, subtitles in bold with font size 14 and the text with font size 12. The cover page of the project report shall contain details about the name of the student and the name of the authorized teacher with font size 14.
- (3) Submission of the project report shall be done at least one month prior to the commencement of annual or supplementary examination.
6. **Evaluation**— The following methodology shall be adopted for evaluating the project work—
- (i) Project work shall be evaluated by internal and external examiners.
- (ii) Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of four students).
- (iii) Three seminars presented by students shall be evaluated for twenty marks each and the average of best two shall be forwarded to the university with marks of other subjects.
- (iv) Evaluation shall be done on the following items:
- | | Marks |
|-------------------------------|-------------------|
| a) Write up of the seminar | (7.5) |
| b) Presentation of work | (7.5) |
| c) Communication skills | (7.5) |
| d) Question and answer skills | (7.5) |
| Total | (30 marks) |

(v) Final evaluation of project work shall be done on the following items:	Marks
a) Write up of the seminar	(17.5)
b) Presentation of work	(17.5)
c) Communication skills	(17.5)
d) Question and answer skills	(17.5)
Total	(70 marks)

Explanation.— For the purposes of differentiation in the evaluation in case of topic being the same for the group of students, the same shall be done based on item numbers b, c and d mentioned above.

16. No. of Admissions

Pharm. D: 30 students

SYLLABUS FOR PHARM. D.

First Year

1.1 HUMAN ANATOMY & PHYSIOLOGY (THEORY)

Theory : 3 Hrs. /Week

1. Scope and Objectives: This course is designed to impart a fundamental knowledge on the structure and functions of the human body. It also helps in understanding both homeostasis mechanisms and homeostatic imbalances of various body systems. Since a medicament, which is produced by pharmacist, is used to correct the deviations in human body, it enhances the understanding of how the drugs act on the various body systems in correcting the disease state of the organs.

2. Upon completion of the course the student shall be able to:

- describe the structure (gross and histology) and functions of various organs of the human body;
- describe the various homeostatic mechanisms and their imbalances of various systems;
- identify the various tissues and organs of the different systems of the human body;
- perform the hematological tests and also record blood pressure, heart rate, pulse and Respiratory volumes;
- appreciate coordinated working pattern of different organs of each system; and
- appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body

3. Course materials:

Text books

- Tortora Gerard J. and Nicholas, P. Principles of anatomy and physiology Publisher Harpercollins college New York.
- Wilson, K.J.W. Ross and Wilson's foundations of anatomy and physiology. Publisher: Churchill Livingstone, Edinburg.

Reference books

- Guyton arthur, C. *Physiology of human body*. Publisher: Holtsaunders.
 - Chatterjee,C.C. *Human physiology*. Volume 1&11. Publisher: medical allied agency, Calcutta.
- Peter L. Williams, Roger Warwick, Mary Dyson and Lawrence, H.
- Gray's anatomy*. Publisher:Churchill Livingstone, London.

4. Lecture wise program:

Topics

- 1 Scope of anatomy and physiology, basic terminologies used in this subject
(Description of the body as such planes and terminologies)
- 2 Structure of cell – its components and their functions.
- 3 Elementary tissues of the human body: epithelial, connective, Muscular and nervous tissues-their sub-types and characteristics
- 4 a) Osseous system - structure, composition and functions of the Skeleton. (done in practical classes - 6hrs)
b) Classification of joints, Types of movements of joints and disorders of joints
(Definitions only)
- 5 Haemopoetic System
a) Composition and functions of blood
b) Haemopoiesis and disorders of blood components (definition of disorder)
c) Blood groups
d) Clotting factors and mechanism
e) Platelets and disorders of coagulation
- 6 Lymph
a) Lymph and lymphatic system, composition, formation and circulation.
b) Spleen: structure and functions, Disorders
c) Disorders of lymphatic system (definition only)
- 7 Cardiovascular system
a) Anatomy and functions of heart
b) Blood vessels and circulation (Pulmonary, coronary and systemic circulation)
c) Electrocardiogram (ECG)
d) Cardiac cycle and heart sounds
e) Blood pressure – its maintenance and regulation
f) Definition of the following disorders
Hypertension, Hypotension,
Arteriosclerosis, Atherosclerosis,

Angina, Myocardial infarction,
Congestive heart failure, Cardiac
arrhythmias

8 Respiratory system

- a) Anatomy of respiratory organs and functions
- b) Mechanism / physiology of respiration and regulation of respiration
- c) Transport of respiratory gases
- d) Respiratory volumes and capacities, and Definition of: Hypoxia, Asphyxia, Dybarism, Oxygen therapy and resuscitation.

9 Digestive system

- a) Anatomy and physiology of GIT
- b) Anatomy and functions of accessory glands of GIT
- c) Digestion and absorption
- d) Disorders of GIT (definitions only)

10 Nervous system

- a) Definition and classification of nervous system
- b) Anatomy, physiology and functional areas of cerebrum
- c) Anatomy and physiology of cerebellum
- d) Anatomy and physiology of mid brain
- e) Thalamus, hypothalamus and Basal Ganglia
- f) Spinal cord: Structure & reflexes – mono-poly-planter
- g) Cranial nerves – names and functions
- h) ANS – Anatomy & functions of sympathetic & parasympathetic N.S.

11 Urinary system

- a) Anatomy and physiology of urinary system
- b) Formation of urine
- c) Renin Angiotensin system – Juxtaglomerular apparatus - acid base Balance
- d) Clearance tests and micturition

12 Endocrine system

- a) Pituitary gland
- b) Adrenal gland
- c) Thyroid and Parathyroid glands

d) Pancreas and gonads

- 13 Reproductive system
 - a) Male and female reproductive system
 - b) Their hormones – Physiology of menstruation
 - c) Spermatogenesis & Oogenesis
 - d) Sex determination (genetic basis)
 - e) Pregnancy and maintenance and parturition
 - f) Contraceptive devices
- 14 Sense organs
 - a) Eye
 - b) Ear
 - c) Skin
 - d) Tongue & Nose
- 15 Skeletal muscles
 - a) Histology
 - b) Physiology of Muscle contraction
 - c) Physiological properties of skeletal muscle and their disorders (definitions)
- 16 Sports physiology
 - a) Muscles in exercise, Effect of athletic training on muscles and muscle performance,
 - b) Respiration in exercise, CVS in exercise, Body heat in exercise, Body fluids and salts in exercise,
 - c) Drugs and athletics

1.1 HUMAN ANATOMY & PHYSIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

General Requirements: Dissection box, Laboratory Napkin, muslin cloth, record, Observation book(100pages), Stationary items, Blood lancet.

Course materials:

Text books

Goyal, R. K, Natvar M.P, and Shah S.A, Practical anatomy, physiology and biochemistry, latest edition, Publisher: B.S Shah Prakashan, Ahmedabad.

Reference books

Ranade VG, Text book of practical physiology, Latest edition, Publisher: PVG, Pune
Anderson Experimental Physiology, Latest edition, Publisher: NA

List of Experiments:

1. Study of tissues of human body
 - (a) Epithelial tissue.
 - (b) Muscular tissue.
2. Study of tissues of human body
 - (a) Connective tissue.
 - (b) Nervous tissue.
3. Study of appliances used in hematological experiments.
4. Determination of W.B.C. count of blood.
5. Determination of R.B.C. count of blood.
6. Determination of differential count of blood.
7. Determination of
 - (a) Erythrocyte Sedimentation Rate.
 - (b) Hemoglobin content of Blood.
 - (c) Bleeding time & Clotting time.
8. Determination of
 - (a) Blood Pressure.
 - (b) Blood group.
9. Study of various systems with the help of charts, models & specimens
 - (a) Skeleton system part I-axial skeleton.
 - (b) Skeleton system part II- appendicular skeleton.
 - (c) Cardiovascular system.
 - (d) Respiratory system.
 - (e) Digestive system.
 - (f) Urinary system.
 - (g) Nervous system.
 - (h) Special senses.
 - (i) Reproductive system.
10. Study of different family planning appliances.
11. To perform pregnancy diagnosis test.
12. Study of appliances used in experimental physiology.
13. To record simple muscle curve using gastrocnemius sciatic nerve preparation.
14. To record simple summation curve using gastrocnemius sciatic nerve preparation.

15. To record simple effect of temperature using gastrocnemius sciatic nerve preparation.
16. To record simple effect of load & after load using gastrocnemius sciatic nerve preparation.
17. To record simple fatigue curve using gastrocnemius sciatic nerve preparation.

Scheme of Practical Examination:

	Sessionals	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.2 PHARMACEUTICS (THEORY)

Theory : 2 Hrs. /Week

- 1. Scope and objectives:** This course is designed to impart a fundamental knowledge on the art and science of formulating different dosage forms. It prepares the students for most basics of the applied field of pharmacy.
- 2. Upon the completion of the course the student should be able to:**
 - a. know the formulation aspects of different dosage forms;

- b. do different pharmaceutical calculation involved in formulation;
- c. formulate different types of dosage forms; and
- d. appreciate the importance of good formulation for effectiveness.

3. Course materials:

Text books

- a. Cooper and Gunns Dispensing for pharmacy students.
- b. A text book Professional Pharmacy by N.K.Jain and S.N.Sharma.

Reference books

- a. Introduction to Pharmaceutical dosage forms by Howard C. Ansel.
- b. Remington's Pharmaceutical Sciences.
- c. Register of General Pharmacy by Cooper and Gunn.
- d. General Pharmacy by M.L.Schroff.

4. Lecture wise programme:

Topics

- 1
 - a. Introduction to dosage forms - classification and definitions
 - b. Prescription: definition, parts and handling
 - c. Posology: Definition, Factors affecting dose selection. Calculation of children and infant doses.
- 2 Historical back ground and development of profession of pharmacy and pharmaceutical industry in brief.
- 3 Development of Indian Pharmacopoeia and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.
- 4 Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc.
- 5 Powders and Granules: Classification advantages and disadvantages, Preparation of simple, compound powders, Insufflations, Dusting powders, Eutectic and Explosive powders, Tooth powder and effervescent powders and granules.
- 6 Monophasic Dosage forms: Theoretical aspects of formulation including adjuvant like stabilizers, colorants, flavours with examples. Study of Monophasic liquids like gargles, mouth washes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions.

- 7 Biphasic dosage forms: Suspensions and emulsions, Definition, advantages and disadvantages, classification, test for the type of emulsion, formulation, stability and evaluation.
- 8 Suppositories and pessaries: Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation.
- 9 Galenicals: Definition, equipment for different extraction processes like infusion, Decoction, Maceration and Percolation, methods of preparation of spirits, tinctures and extracts.
- 10 Pharmaceutical calculations.
- 11 Surgical aids: Surgical dressings, absorbable gelatin sponge, sutures, ligatures and medicated bandages.
- 12 Incompatibilities: Introduction, classification and methods to overcome the incompatibilities.

1.2 PHARMACEUTICS (PRACTICAL)

Practical: 3 Hrs./Week

List of Experiments:

1. Syrups

- a. Simple Syrup I.P
- b. Syrup of Ephedrine Hcl NF
- c. Syrup Vasaka IP
- d. Syrup of ferrous Phosphate IP
- e. Orange Syrup

2. Elixir

- a. Piperizine citrate elixir BP
- b. Cascara elixir BPC
- c. Paracetamol elixir BPC

3. Linctus

- a. Simple Linctus BPC
- b. Pediatric simple Linctus BPC

4. Solutions

- a. Solution of cresol with soap IP
- b. Strong solution of ferric chloride BPC
- c. Aqueous Iodine Solution IP
- d. Strong solution of Iodine IP
- e. Strong solution of ammonium acetate IP

5. Liniments

- a. Liniment of turpentine IP*
- b. Liniment of camphor IP

6. Suspensions*

- a. Calamine lotion
- b. Magnesium Hydroxide mixture BP

7. Emulsions*

- a. Cod liver oil emulsion
- b. Liquid paraffin emulsion

8. Powders*

- a. Eutectic powder
- b. Explosive powder
- c. Dusting powder
- d. Insufflations

9. Suppositories*

- a. Boric acid suppositories
- b. Chloral suppositories

10. Incompatibilities

- a. Mixtures with Physical
- b. Chemical & Therapeutic incompatibilities

* colourless bottles required for dispensing * Paper envelope (white), butter paper and white paper required for dispensing.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.3 MEDICAL BIOCHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

1. Scope of the Subject: Applied biochemistry deals with complete understanding of the molecular level of the chemical process associated with living cells. Clinical chemistry deals with the study of chemical aspects of human life in health and illness and the application of chemical laboratory methods to diagnosis, control of treatment, and prevention of diseases.

2. Objectives of the Subject (Know, do, appreciate) :

The objective of the present course is providing biochemical facts and the principles to the students of pharmacy. Upon completion of the subject student shall be able to –

- a. understand the catalytic activity of enzymes and importance of isoenzymes in diagnosis of diseases;
- b. know the metabolic process of biomolecules in health and illness (metabolic disorders);
- c. understand the genetic organization of mammalian genome; protein synthesis; replication; mutation and repair mechanism;
- d. know the biochemical principles of organ function tests of kidney, liver and endocrine gland; and
- e. do the qualitative analysis and determination of biomolecules in the body fluids.

Text books (Theory)

- a. Harpers review of biochemistry - Martin
- b. Text book of clinical chemistry- Alex Kaplan & Laverne L. Szabo
- c. Text book of biochemistry -- Ramarao

Reference books (Theory)

- a. Principles of biochemistry -- Lehninger
- b. Practical Biochemistry-David T. Plummer.
- c. Practical Biochemistry-Pattabhiraman.

3. Lecture wise programme:

Topics

- 1 Introduction to biochemistry:** Cell and its biochemical organization, transport process across the cell membranes. Energy rich compounds; ATP, Cyclic AMP and their biological significance.
- 2 Enzymes:** Definition; Nomenclature; IUB classification; Factor affecting enzyme activity; Enzyme action; enzyme inhibition. Isoenzymes and their therapeutic and diagnostic applications; Coenzymes and their biochemical role and deficiency diseases.

- 3 **Carbohydrate metabolism:** Glycolysis, Citric acid cycle (TCA cycle), HMP shunt, Glycogenolysis, gluconeogenesis, glycogenesis. Metabolic disorders of carbohydrate metabolism (diabetes mellitus and glycogen storage diseases); Glucose, Galactose tolerance test and their significance; hormonal regulation of carbohydrate metabolism.

- 4 **Lipid metabolism:** Oxidation of saturated (β -oxidation); Ketogenesis and ketolysis; biosynthesis of fatty acids, lipids; metabolism of cholesterol; Hormonal regulation of lipid metabolism. Defective metabolism of lipids (Atherosclerosis, fatty liver, hypercholesterolemia).
- 5 **Biological oxidation:** Coenzyme system involved in Biological oxidation. Electron transport chain (its mechanism in energy capture; regulation and inhibition); Uncouplers of ETC; Oxidative phosphorylation;
- 6 **Protein and amino acid metabolism:** protein turn over; nitrogen balance; Catabolism of Amino acids (Transamination, deamination & decarboxylation). Urea cycle and its metabolic disorders; production of bile pigments; hyperbilirubinemia, porphoria, jaundice. Metabolic disorder of Amino acids.
- 7 **Nucleic acid metabolism:** Metabolism of purine and pyrimidine nucleotides; Protein synthesis; Genetic code; inhibition of protein synthesis; mutation and repair mechanism; DNA replication (semiconservative /onion peel models) and DNA repair mechanism.
- 8 **Introduction to clinical chemistry: Cell;** composition; malfunction; Roll of the clinical chemistry laboratory.
- 9 **The kidney function tests:** Role of kidney; Laboratory tests for normal function includes-
 - a) Urine analysis (macroscopic and physical examination, quantitative and semiquantitative tests.)
 - b) Test for NPN constituents. (Creatinine /urea clearance, determination of blood and urine creatinine, urea and uric acid)
 - c) Urine concentration test
 - d) Urinary tract calculi. (stones)
- 10 **Liver function tests:** Physiological role of liver, metabolic, storage, excretory, protective, circulatory functions and function in blood coagulation.
 - a) Test for hepatic dysfunction-Bile pigments metabolism.
 - b) Test for hepatic function test- Serum bilirubin, urine bilirubin, and urine urobilinogen.
 - c) Dye tests of excretory function.
 - d) Tests based upon abnormalities of serum proteins.
 Selected enzyme tests.
- 11 **Lipid profile tests:** Lipoproteins, composition, functions. Determination of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides.
- 12 **Immunochemical techniques** for determination of hormone levels and protein levels in serum for endocrine diseases and infectious diseases.
Radio immuno assay (RIA) and Enzyme Linked Immuno Sorbent Assay (ELISA)

- 13 **Electrolytes:** Body water, compartments, water balance, and electrolyte distribution. Determination of sodium, calcium, potassium, chlorides, bicarbonates in the body fluids.

1.3 MEDICINAL BIOCHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

Title of the Experiment:

- 1 Qualitative analysis of normal constituents of urine.*
- 2 Qualitative analysis of abnormal constituents of urine.*
- 3 Quantitative estimation of urine sugar by Benedict's reagent method.**
- 4 Quantitative estimation of urine chlorides by Volhard's method.**
- 5 Quantitative estimation of urine creatinine by Jaffe's method.**
- 6 Quantitative estimation of urine calcium by precipitation method.**
- 7 Quantitative estimation of serum cholesterol by Libermann Burchard's method.**
- 8 Preparation of Folin Wu filtrate from blood.*
- 9 Quantitative estimation of blood creatinine.**
- 10 Quantitative estimation of blood sugar Folin-Wu tube method.**
- 11 Estimation of SGOT in serum.**
- 12 Estimation of SGPT in serum.**
- 13 Estimation of Urea in Serum.**
- 14 Estimation of Proteins in Serum.**
- 15 Determination of serum bilirubin**
- 16 Determination of Glucose by means of Glucose oxidase.**
- 17 Enzymatic hydrolysis of Glycogen/Starch by Amylases.**
- 18 Study of factors affecting Enzyme activity. (pH & Temp.)**
- 19 Preparation of standard buffer solutions and its pH measurements (any two)*
- 20 Experiment on lipid profile tests**
- 21 Determination of sodium, calcium and potassium in serum.**

** indicate major experiments & * indicate minor experiments

Assignments:

Format of the assignment

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.4 PHARMACEUTICAL ORGANIC CHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

- 1. Scope and objectives:** This course is designed to impart a very good knowledge about
- IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds;
 - Some important physical properties of organic compounds;
 - Free radical/ nucleophilic [alkyl/ acyl/ aryl] /electrophilic substitution, free radical/ nucleophilic / electrophilic addition, elimination, oxidation and reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability of compounds;
 - Some named organic reactions with mechanisms; and
 - Methods of preparation, test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.

2. Course materials:

Text books

- T.R.Morrison and R. Boyd - Organic chemistry,
- Bentley and Driver-Text book of Pharmaceutical chemistry
- I.L.Finlar- Organic chemistry, the fundamentals of chemistry

Reference books

- Organic chemistry – J.M.Cram and D.J.Cram
- Organic chemistry- Brown
- Advanced organic chemistry- Jerry March, Wiley
- Organic chemistry- Cram and Hammered, Pine Hendrickson

3. Lecture wise programme :

Topics

- Structures and Physical properties:
 - Polarity of bonds, polarity of molecules, M.P, Inter molecular forces, B.P, Solubility, non ionic solutes and ionic solutes, protic and aprotic Solvents, ion pairs,
 - Acids and bases, Lowry bronsted and Lewis theories
 - Isomerism
- Nomenclature of organic compound belonging to the following classes Alkanes, Alkenes, Dienes, Alkynes, Alcohols, Aldehydes, Ketones, Amides, Amines, Phenols, Alkyl Halides, Carboxylic Acid, Esters, Acid Chlorides And Cycloalkanes.

- 3 Free radicals chain reactions of alkane : Mechanism, relative reactivity and stability
- 4 Alicyclic compounds : Preparations of cyclo alkanes, Bayer strain theory and orbital picture of angle strain.
- 5 Nucleophilic aliphatic substitution mechanism: Nucleophiles and leaving groups, kinetics of second and first order reaction, mechanism and kinetics of SN_2 reactions. Stereochemistry and steric hindrance, role of solvents, phase transfer catalysis, mechanism and kinetics of SN_1 reactions, stereochemistry, carbocation and their stability, rearrangement of carbocation, role of solvents in SN_1 reaction, Ion dipole bonds, SN_2 versus SN_1 solvolyses, nucleophilic assistance by the solvents.
- 6 Dehydro halogenation of alkyl halides: 1,2 elimination, kinetics, E_2 and E_1 mechanism, elimination via carbocation, evidence for E_2 mechanism, absence of rearrangement isotope effect, absence hydrogen exchange, the element effect, orientation and reactivity, E_2 versus E_1 , elimination versus substitution, dehydration of alcohol, ease of dehydration, acid catalysis, reversibility, orientation.
- 7 Electrophilic and free radicals addition: Reactions at carbon-carbon, double bond, electrophile, hydrogenation, heat of hydrogenation and stability of alkenes, markownikoff rule, addition of hydrogen halides, addition of hydrogen bromides, peroxide effect, electrophilic addition, mechanism, rearrangement, absence of hydrogen exchange, orientation and reactivity, addition of halogen, mechanism, halohydrin formation, mechanism of free radicals addition, mechanism of peroxide initiated addition of hydrogen bromide, orientation of free addition, additions of carbene to alkene, cyclo addition reactions.
- 8 Theory of resonance: Allyl radical as a resonance hybrid, stability, orbital picture, resonance stabilisation of allyl cations, hyper conjugation, stability of conjugated dienes, mechanisms of 1,4- addition, 1,2 addition
- 9 Electrophilic aromatic substitution: Effect of substituent groups, determination of orientation, determination of relative reactivity, classification of substituent group, mechanism of nitration, sulphonation, halogenation, friedel craft alkylation, friedel craft acylation, reactivity and orientation, activating and deactivating o, p, m directing groups, electron release via resonance, effect of halogen on electrophilic aromatic substitution in alkyl benzene, side chain halogenation of alkyl benzene, resonance stabilization of benzyl radical.

- 10 Nucleophilic addition reaction: Mechanism of aldol condensation, claisen condensation, cannizzaro reaction, crossed aldol condensation, crossed cannizzaro reaction, benzoin condensation, perkin condensation. Knoevenagel, Reformatsky reaction, Wittig reaction, Michael addition.
- 11 Nucleophilic acyl substitution in carboxylic acid derivatives, comparison with nucleophilic addition reaction, ionization of carboxylic acids, acidity of acids, structure of carboxylate ion, effect of substituent on acidity, conversion acids to acid chloride, amide, ester and anhydride
- 12 Study of the following official compounds- preparation, test for purity, assay and medicinal uses of Chlorbutol, Dimercaprol, Glyceryl trinitrate, Urea, Ethylene diamine dihydrate, Vanillin, Paraldehyde, Ethylene chloride, Lactic acid, Tartaric acid, citric acid, salicylic acid, aspirin, methyl salicylate, ethyl benzoate, benzyl benzoate, dimethyl phthalate, sodium lauryl sulphate, saccharin sodium, mephensin.

1.4 PHARMACEUTICAL ORGANIC CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

I. Introduction to the various laboratory techniques through demonstration involving synthesis of the following compounds (at least 8 compounds to be synthesised):

1. Acetanilide / aspirin (Acetylation)
2. Benzanilide / Phenyl benzoate (Benzoylation)
3. P-bromo acetanilide / 2,4,6 – tribromo aniline (Bromination)
4. Dibenzylidene acetone (Condensation)
5. 1-Phenylazo-2-naphthol (Diazotisation and coupling)
6. Benzoic acid / salicylic acid (Hydrolysis of ester)
7. M-dinitro benzene (Nitration)
8. 9, 10 – Anthraquinone (Oxidation of anthracene) / preparation of benzoic acid from toluene or benzaldehyde
9. M-phenylene diamine (Reduction of M-dinitrobenzene) / Aniline from nitrobenzene
10. Benzophenone oxime
11. Nitration of salicylic acid
12. Preparation of picric acid
13. Preparation of O-chlorobenzoic acid from O-chlorotoluene
14. Preparation of cyclohexanone from cyclohexanol

II. Identification of organic compounds belonging to the following classes by :

Systematic qualitative organic analysis including preparation of derivatives Phenols, amides, carbohydrates, amines, carboxylic acids, aldehyde and ketones, Alcohols, esters, hydrocarbons, anilides, nitrocompounds.

III. Introduction to the use of stereo models:

Methane, Ethane, Ethylene, Acetylene, Cis alkene, Trans alkene, inversion of configuration.

Scheme of Practical Examination:

	Sessional	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.5 PHARMACEUTICAL INORGANIC CHEMISTRY (THEORY)

Theory : 2 Hrs. /Week..... Comment (al): Please include the complete syllabus of RGUHS

- 1. Scope and objectives:** This course mainly deals with fundamentals of Analytical chemistry and also the study of inorganic pharmaceuticals regarding their monographs and also the course deals with basic knowledge of analysis of various pharmaceuticals.
- 2. Upon completion of the course student shall be able to:**
 - a. understand the principles and procedures of analysis of drugs and also regarding the application of inorganic pharmaceuticals;
 - b. know the analysis of the inorganic pharmaceuticals their applications; and
 - c. appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.
- 3. Course materials:**
 1. M.L. Schroff, Inorganic Pharmaceutical Chemistry.
 2. Bentley and Driver's Textbook of Pharmaceutical Chemistry by L.M. Atherden.
 3. I.P. 1985 and 1996, Govt. of India, Ministry of Health, 3rd Edition, 1985 4th Edition 1996.
 4. A.H.Beckett & J.B. Stenlake's Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London, 4th edition.
 5. D.A. Skoog, D.M. West, Fundamental of Analytical chemistry, 6th edition.
- 3. Lecture wise Programme:.....Comment (GP2) RGUHS syllabus**
topics to be included as in the latest syllabus Page number 36-37

Sources and effects of impurities in pharmacopoeial substances, importance of limit test, general principles and procedures for tests for chloride, sulphate, iron, arsenic, lead and heavy metals, Special procedures for limit tests.

General methods of preparation assays* , storage condition & medicinal uses of inorganic compounds belonging to the following classes, (Assays*)

2.1 Medicinal Gases: oxygen Nitrous oxide, Carbon dioxide

2.2 Gastrointestinal agents

Acidifiers: dill HCl

Antacids: Aluminium hydroxide gel Calcium carbonate, Sodium Bicarbonate* . Magnesium trisilicate, Magnesium carbonate (Light and heavy), Magnesium hydroxide mixture* and Zinc oxide*,

Protective and adsorbents: Kaolin and Talc,

Cathartics Magnesium sulphate*, Sodium orthophosphate Sodium sulphate.

2.3 Major intra and extra cellular electrolytes, major physiological ions and electrolytes used for the replacement therapy, physiological acid base balance, electrolyte combination therapy ORS, Sodium chloride injection, Dextrose and Sodium chloride injection, Calcium gluconate injection.

2.4 Topical agents and dermatological preparations:

Protective Talc, Zinc oxide, Zinc stearate, Titanium dioxide.

Antimicrobials: Potassium Permanganate*, chlorinated lime*, Iodine preparations, Boric acid*, Borax.

2.5 Dental products: Dentifrices, anticaries agents, desensitizing agents, calcium carbonate, sodium fluoride, Stannous fluoride, Zinc chloride, Zinc eugenol cement.

2.6 Miscellaneous agents:

Expectorants: Ammonium chloride (Formal method), Potassium iodide Haematinics: Ferrous sulfate*, Ferrous gluconate, Ferrous Fumarate, Iron dextran injection, Iron and Ammonium citrate.

Emetics : Copper sulphate*.

Poisons and Antidotes : Sodium thiosulphate, Charcoal (activated)

Pharmaceutical Aids : Bentonite, Sodium metabisulphite,
Barium sulphate*

3. Sources of errors, types of errors, methods of minimizing errors, accuracy, precision.

4. Fundamentals of volumetric analysis, theory of indicators and methods of expressing concentration, Primary and secondary standards. Preparation, standardization and storage of various volumetric solutions like oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulfate, potassium permanganate and Iodine solution.

4.1 Principles of redox titrations: Concepts of oxidation and reduction. Redox reactions, strength and equivalent weights of oxidizing and reducing agents, theory of redox titrations, iodometry, iodometry, bromometry, titrations with potassium iodate, potassium bromate, titanous chloride, 2,6-dichlorophenol.

4.2 Theory of nonaqueous titrations: classification of solvents used in nonaqueous titrations, estimation of Sodium Benzoate by nonaqueous titrations.

4.3 Principles of precipitation titrations: different methods-Mohr's Modified Mohr's, Volhard's, Modified Volhard's Fajans with example. Estimation of sodium chloride.

4.4 Principles of complexometric titrations: different types of complexometric titrations, methods of detecting the endpoints in complexometric titrations with example and estimation of calcium Gluconate

1.5 PHARMACEUTICAL INORGANIC CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

1. Limit test (6 exercises)

- a. Limit test for chlorides
- b. Limit test for sulphates
- c. Limit test for iron
- d. Limit test for heavy metals
- e. Limit test for arsenic
- f. Modified limit tests for chlorides and sulphates

2. Assays (10 exercises)

- a. Ammonium chloride- Acid-base titration
- b. Ferrous sulphate- Cerimetry
- c. Copper sulphate- Iodometry
- d. Calcilugluconate- Complexometry
- e. Hydrogen peroxide – Permanganometry
- f. Sodium benzoate – Nonaqueous titration
- g. Sodium chloride – Modified volhard's method
- h. Assay of KI – KIO_3 titration
- i. Gravimetric estimation of barium as barium sulphate
- j. Sodium antimony gluconate or antimony potassium tartarate

3. Estimation of mixture (Any two exercises)

- a. Sodium hydroxide and sodium carbonate
- b. Boric acid and Borax
- c. Oxalic acid and sodium oxalate

4. Test for identity (Any three exercises)

- a. Sodium bicarbonate
- b. Barium sulphate
- c. Ferrous sulphate
- d. Potassium chloride

5. Test for purity (Any two exercises)

- a. Swelling power in Bentonite
- b. Acid neutralising capacity in aluminium hydroxide gel
- c. Ammonium salts in potash alum
- d. Adsorption power heavy Kaolin
- e. Presence of Iodates in KI

6. Preparations (Any two exercises)

- a. Boric acids
- b. Potash alum
- c. Calcium lactate
- d. Magnesium sulphate

Scheme of Practical Examination :

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment1&2	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.6 REMEDIAL MATHEMATICS/BIOLOGY (THEORY)

Theory : 3 Hrs. /Week

REMEDIAL MATHEMATICS :

- 1. Scope and objectives:** This is an introductory course in mathematics. This subjects deals with the introduction to matrices, determinants, trigonometry, analytical geometry, differential calculus, integral calculus, differential equations, laplace transform.
- 2. Upon completion of the course the student shall be able to : –**
 - a. Know Trigonometry, Analytical geometry, Matrices, Determinant, Integration, Differential equation, Laplace transform and their applications;
 - b. solve the problems of different types by applying theory; and
 - c. appreciate the important applications of mathematics in pharmacy.

3. Course materials:

Text books

- a. Differential calculus By Shantinakaran
- b. Text book of Mathematics for second year pre-university by Prof.B.M.Sreenivas

Reference books

- a. Integral calculus By Shanthinarayan
- b. Engineering mathematics By B.S.Grewal
- c. Trigonometry Part-I By S.L.Loney

4. Lecture wise programme :

Topics

- 1 **Algebra** : Determinants, Matrices
- 2 **Trigonometry** : Sides and angles of a triangle, solution of triangles
- 3 **Analytical Geometry** :Points, Straight line, circle, parabola
- 4 **Differential calculus**: Limit of a function, Differential calculus, Differentiation of a sum, Product, Quotient Composite, Parametric, exponential, trigonometric and Logarithmic function. Successive differentiation, Leibnitz's theorem, Partial differentiation, Euler's theorem on homogeneous functions of two variables.
- 5 **Integral Calculus**: Definite integrals, integration by substitution and by parts, Properties of definite integrals.
- 6 **Differential equations**: Definition, order, degree, variable separable, homogeneous, Linear, heterogeneous, linear, differential equation with constant coefficient, simultaneous linear equation of second order.
- 7 **Laplace transform**: Definition, Laplace transform of elementary functions, Properties of linearity and shifting.

BIOLOGY :

1. **Scope and objectives**: This is an introductory course in Biology, which gives detailed study of natural sources such as plant and animal origin. This subject has been introduced to the pharmacy course in order to make the student aware of various naturally occurring drugs and its history, sources, classification, distribution and the characters of the plants and animals. This subject gives basic foundation to Pharmacognosy.

2. Course materials:

Text books

- a. Text book of Biology by S.B.Gokhale
- b. A Text book of Biology by Dr.Thulajappa and Dr. Seetaram.

Reference books

- a. A Text book of Biology by B.V.Sreenivasa Naidu

- b. A Text book of Biology by Naidu and Murthy
- c. Botany for Degree students By A.C.Dutta.
- d. Outlines of Zoology by M.Ekambaranatha ayyer and T.N.Ananthakrishnan.
- e. A manual for pharmaceutical biology practical by S.B.Gokhale and C.K.Kokate.

3. Lecture wise programme :

Topic

PART – A

- 01 Introduction
- 02 General organization of plants and its inclusions
- 03 Plant tissues
- 04 Plant kingdom and its classification
- 05 Morphology of plants
- 06 Root, Stem, Leaf and Its modifications
- 07 Inflorescence and Pollination of flowers
- 08 Morphology of fruits and seeds
- 09 Plant physiology
- 10 Taxonomy of Leguminosae, umbelliferae, Solanaceae, Lilliacae, Zinziberaceae, Rubiaceae
- 11 Study of Fungi, Yeast, Penicillin and Bacteria

PART-B

- 01 Study of Animal cell
- 02 Study animal tissues
- 03 Detailed study of frog
- 04 Study of Pisces, Raptiles, Aves
- 05 Geneeral organization of mammals
- 06 Study of poisonous animals

1.6 BIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

Title:

- 1. Introduction of biology experiments
- 2. Study of cell wall constituents and cell inclusions
- 3. Study of Stem modifications
- 4. Study of Root modifications
- 5. Study of Leaf modifications
- 6. Identification of Fruits and seeds
- 7. Preparation of Permanent slides
- 8. T.S. of Senna, Cassia, Ephedra, Podophyllum.
- 9. Simple plant physiological experiments

10. Identification of animals
11. Detailed study of Frog
12. Computer based tutorials

Scheme of Practical Examination :

	Sessionals	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance.

Second year

2.1 PATHOPHYSIOLOGY (THEORY)

Theory :4 Hrs. /Week

- 1. Scope of the Subject:** This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic Pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge of its application in other subject of pharmacy.
- 2. Objectives of the Subject :** Upon completion of the subject student shall be able to –
 - a. describe the etiology and pathogenesis of the selected disease states;
 - b. name the signs and symptoms of the diseases; and
 - c. mention the complications of the diseases.

Text books (Theory)

- a. Pathologic basis of disease by- Cotran, Kumar, Robbins
- b. Text book of Pathology- Harsh Mohan
- c. Text book of Pathology- Y.M. Bhide

Reference books (Theory)

- a. Clinical Pharmacy and Therapeutics; Second edition; Roger Walker; Churchill Livingstone publication

3. Detailed syllabus and lecture wise schedule :

Chapter

1 Basic principles of cell injury and Adaptation

- a) Causes, Pathogenesis and morphology of cell injury
- b) Abnormalities in lipoproteinaemia, glycogen infiltration and glycogen infiltration and glycogen infiltration and glycogen storage diseases

2 Inflammation

- a) Pathogenesis of acute inflammation, Chemical mediators in inflammation, Types of chronic inflammation
- b) Repairs of wounds in the skin, factors influencing healing of wounds

3 Diseases of Immunity

- a) Introduction to T and B cells
- b) MHC proteins or transplantation antigens
- c) Immune tolerance
 - Hypersensitivity
Hypersensitivity type I, II, III, IV, Biological significance, Allergy due to food, chemicals and drugs
 - Autoimmunity
Criteria for autoimmunity, Classifications of autoimmune diseases in man, mechanism of autoimmunity, Transplantation and immunologic tolerance, allograft rejections, transplantation antigens, mechanism of rejection of allograft.
 - Acquired immune deficiency syndrome (AIDS)
 - Amyloidosis

4 Cancer: differences between benign and malignant tumors, Histological diagnosis of malignancy, invasions and metastasis, patterns of spread, disturbances of growth of cells, classification of tumors, general biology of tumors, spread of malignant tumors, etiology and pathogenesis of cancer.

5 Types of shock, mechanisms, stages and management

6 Biological effects of radiation

7 Environmental and nutritional diseases

- i) Air pollution and smoking- SO₂, NO, NO₂, and CO
- ii) Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation.

- 8 Pathophysiology of common diseases
 - a. Parkinsonism
 - b. Schizophrenia
 - c. Depression and mania
 - d. Hypertension,
 - e. Stroke (ischaemic and hemorrhage)
 - f. Angina, CCF, Atherosclerosis, Myocardial infarction
 - g. Diabetes Mellitus
 - h. Peptic ulcer and inflammatory bowel diseases
 - i. Cirrhosis and Alcoholic liver diseases
 - j. Acute and chronic renal failure
 - k. Asthma and chronic obstructive airway diseases
- 9 Infectious diseases :
Sexually transmitted diseases (HIV, Syphilis, Gonorrhea), Urinary tract infections, Pneumonia, Typhoid, Tuberculosis, Leprosy, Malaria Dysentery (bacterial and amoebic), Hepatitis-infective hepatitis.

4. Assignments :

Title of the Experiment

- 1 Chemical Mediators of inflammation
- 2 Drug Hypersensitivity
- 3 Cigarette smoking & its ill effects
- 4 Biological Effects of Radiation
- 5 Etiology and hazards of obesity
- 6 Complications of diabetes
- 7 Diagnosis of cancer
- 8 Disorders of vitamins
- 9 Methods in Pathology-Laboratory values of clinical significance
- 10 Pathophysiology of Dengue Hemorrhagic Fever (DHF)

Format of the assignment

- 1 Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy.
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

2.2 PHARMACEUTICAL MICROBIOLOGY (THEORY)

Theory : 4 Hrs. /Week

1. **Scope of the Subject:** Microbiology has always been an essential component of pharmacy curriculum. This is because of the relevance of microbiology to pharmaceutical sciences and more specifically to pharmaceutical industry. Pharmaceutical biotechnology is the logical extension of pharmaceutical microbiology, which is expected to change the complete drug product scenario in the future.

This course deals with the various aspects of microorganisms, its classification, morphology, laboratory cultivation identification and maintenance. It also discusses with sterilization of pharmaceutical products, equipment, media etc. The course further discusses the immunological preparations, diseases its transmission, diagnosis, control and immunological tests.

2. Objectives of the Subject :

Upon completion of the subject student shall be able to –

- a. know the anatomy, identification, growth factors and sterilization of microorganisms;
- b. know the mode of transmission of disease causing microorganism, symptoms of disease, and treatment aspect;
- c. do estimation of RNA and DNA and there by identifying the source;
- d. do cultivation and identification of the microorganisms in the laboratory;
- e. do identification of diseases by performing the diagnostic tests; and
- f. appreciate the behavior of motility and behavioral characteristics of microorganisms.

Text books (Theory)

- a. Vanitha Kale and Kishor Bhusari “ Applied Microbiology ” Himalaya Publishing house Mumbai.
- b. Mary Louis Turgeon “ Immunology and Serology in Laboratory Medicines” 2nd edition, 1996 Mosby- Year book inc St. Louis Missouri 63146.
- c. Harsh Mohan, “ Text book of Pathology” 3rd edition, 1998, B-3 Ansari road Darya ganj N. Delhi.

Reference books (Theory)

- a. Prescott L.M., Jarley G.P Klein D.A “Microbiology” 2nd- edition Mc Graw Hill Company Inc
- b. Rawlins E.A.”Bentley’s Text Book of Pharmaceutics” B ailliere Tindals 24-28 London 1988
- c. Forbisher “ Fundamentals of Microbiology” Philadelphia W.B. Saunders.
- d. Prescott L.M. Jarley G.P., Klein.D.A. “ Microbiology.”2nd edition WMC Brown Publishers, Oxford. 1993

- e. War Roitt, Jonathan Brostoff, David male, “ Immunology”3rd edition 1996, Mosby-year book Europe Ltd, London.
- f. Pharmacopoeia of India, Govt of India, 1996.

3. Detailed syllabus and lecture wise schedule :

Title of the topic

- 1 Introduction to the science of microbiology. Major divisions of microbial world and Relationship among them.
- 2 Different methods of classification of microbes and study of Bacteria, Fungi, virus, Rickettsiae, Spirochetes.
- 3 Nutritional requirements, growth and cultivation of bacteria and virus. Study of different important media required for the growth of aerobic and anaerobic bacteria & fungi. Differential media, enriched media and selective media, maintenance of lab cultures.
- 4 Different methods used in isolation and identification of bacteria with emphasis to different staining techniques and biochemical reactions. Counting of bacteria -Total and Viable counting techniques.
- 5 Detailed study of different methods of sterilization including their merits and demerits. Sterilization methods for all pharmaceutical products. Detailed study of sterility testing of different pharmaceutical preparations . Brief information on Validation.
- 6 Disinfectants- Study of disinfectants, antiseptics, fungicidal and virucidal agents factors affecting their activation and mechanism of action. Evaluation of bactericidal, bacteristatic, , virucidal activities, evaluation of preservatives in pharmaceutical preparations.
- 7 Immunology- Immunity, Definition, Classification, General principles of natural immunity, Phagocytosis, acquired immunity(active and passive) . Antigens, chemical nature of antigens structure and formation of Antibodies, Antigen-Antibody reactions. Bacterial exotoxins and endotoxins. Significance of toxoids in active immunity, Immunization programme, and importance of booster dose.
- 8 Diagnostic tests : Schick's Test, Elisa test, Western Blot test, Southern Blot PCR Widal, QBC, Mantaux Peripheral smear. Study of malarial parasite.
- 9 Microbial culture sensitivity Testing: Interpretation of results Principles and methods of different microbiological assays, microbiological assay of Penicillin, Streptomycin and vitamin B₂ and B₁₂. Standardisation of vaccines and sera.
- 10 Study of infectious diseases: Typhoid, Tuberculosis, Malaria, Cholera, Hepatitis, Meningitis, Syphilis & Gonorrhea and HIV.

2.2 PHARMACEUTICAL MICROBIOLOGY (PRACTICAL)

Practical : 4 Hrs./Week

Title of the Experiment:

- 1 Study of apparatus used in experimental microbiology*.
- 2 Sterilisation of glass ware's. Preparation of media and sterilisation.*
- 3 Staining techniques – Simple staining ; Gram's staining ; Negative staining**
- 4 Study of motility characters*.
- 5 Enumeration of micro-organisms (Total and Viable)*
- 6 Study of the methods of isolation of pure culture.*
- 7 Bio chemical testing for the identification of micro*-organisms.
- 8 Cultural sensitivity testing for some micro-organisms.*
- 9 Sterility testing for powders and liquids.*
- 10 Determination of minimum inhibitory concentration.*
- 11 Microbiological assay of antibiotics by cup plate method.*
- 12 Microbiological assay of vitamins by Turbidometric method**
- 13 Determination of RWC.**
- 14 Diagnostic tests for some common diseases, Widal, malarial parasite.**

* Indicate minor experiment & ** indicate major experiment

Assignments:

- 1 Visit to some pathological laboratories & study the activities and equipment/instruments used and reporting the same.
2. Visit to milk dairies (Pasturization) and microbial laboratories(other sterization methods) & study the activities and equipment/instruments used and reporting the same.
3. Library assignments
 - a. Report of recent microbial techniques developed in diagnosing some common diseases.
 - b. Latest advancement developed in identifying, cultivating & handling of microorganisms.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

2.3 PHARMACOGNOSY & PHYTOPHARMACEUTICALS (THEORY)**Theory : 4 Hrs. /Week**

- 1. Scope and objectives:** This subject has been introduced for the pharmacy course in order to make the student aware of medicinal uses of various naturally occurring drugs its history, sources, distribution, method of cultivation, active constituents, medicinal uses, identification tests, preservation methods, substitutes and adulterants.
- 2. Upon completion of the course student shall be able to:**
 - a. under stand the basic principles of cultivation, collection and storage of crude drugs;
 - b. know the source, active constituents and uses of crude drugs; and
 - c. appreciate the applications of primary and secondary metabolites of the plant.
- 3. Course materials:**

Text books

 - a. Pharmacognosy by G.E. Trease & W.C.Evans.
 - b. Pharmacognosy by C.K.Kokate,Gokhale & A.C.Purohit.

Reference books

 - a. Pharmacognosy by Brady &Tyler.E.
 - b. Pharmacognosy by T.E.Wallis.
 - c. Pharmacognosy by C.S. Shah & Qadery.

d. Pharmacognosy by M.A. Iyengar.

4. Lecture wise programme:

Topics

- 1 Introduction.
- 2 Definition, history and scope of Pharmacognosy.
- 3 Classification of crude drugs.
- 4 Cultivation, collection, processing and storage of crude drugs.
- 5 Detailed method of cultivation of crude drugs.
- 6 Study of cell wall constituents and cell inclusions.
- 7 Microscopical and powder Microscopical study of crude drugs.
- 8 Study of natural pesticides.
- 9 Detailed study of various cell constituents.
- 10 Carbohydrates and related products.
- 11 Detailed study carbohydrates containing drugs.(11 drugs)
- 12 Definition sources, method extraction, chemistry and method of analysis of lipids.
- 13 Detailed study of oils.
- 14 Definition, classification, chemistry and method of analysis of protein.
- 15 Study of plants fibers used in surgical dressings and related products.
- 16 Different methods of adulteration of crude drugs.

2.3 PHARMACOGNOSY & PHYTOPHARMACEUTICALS (PRACTICAL)

Practical : 4 Hrs./Week

General Requirements: Laboratory Napkin, Observation Book 150 pages Zero brush, Needle, Blade, Match box.

List of experiments:

- 1 Introduction of Pharmacognosy laboratory and experiments.
- 2 Study of cell wall constituents and cell inclusions.
- 3 Macro, powder and microscopic study of Datura.
- 4 Macro, powder and microscopic study of Senna.
- 5 Macro, powder and microscopic study of Cassia.cinnamon.
- 6 Macro, powder and microscopic study of Cinchona.
- 7 Macro, powder and microscopic study of Ephedra.
- 8 Macro, powder and microscopic study of Quassia.
- 9 Macro, powder and microscopic study of Clove
- 10 Macro, powder and microscopic study of Fennel.
- 11 Macro, powder and microscopic study of Coriander.
- 12 Macro, powder and microscopic study of Isapgol.
- 13 Macro, powder and microscopic study of Nux vomica.
- 14 Macro, powder and microscopic study of Rauwolfia.
- 15 Macro, powder and microscopic study of Liquorice.
- 16 Macro, powder and microscopic study of Ginger.
- 17 Macro, powder and microscopic study of Podophyllum.
- 18 Determination of Iodine value.
- 19 Determination of Saponification value and unsaponifiable matter.
- 20 Determination of ester value.
- 21 Determination of Acid value.
- 22 Chemical tests for Acacia.
- 23 Chemical tests for Tragacanth.
- 24 Chemical tests for Agar.
- 25 Chemical tests for Starch.
- 26 Chemical tests for Lipids.(castor oil,sesame oil, shark liver oil,bees wax)
- 27 Chemical tests for Gelatin.

Scheme of Practical Examination:

	Sessionals	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance.

2.4 PHARMACOLOGY – I (THEORY)

Theory : 4 Hrs. /Week

- 1. Scope of the Subject:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, apart from general pharmacology, drugs acting on autonomic nervous system, cardiovascular system, central nervous system, blood and blood forming agents and renal system will be taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.
- 2. Objectives of the Subject :** Upon completion of the subject student shall be able to (Know, do, appreciate) –
 - a. understand the pharmacological aspects of drugs falling under the above mentioned chapters;
 - b. handle and carry out the animal experiments;
 - c. appreciate the importance of pharmacology subject as a basis of therapeutics; and
 - d. correlate and apply the knowledge therapeutically.

Text books (Theory) (Author, Title, Edition, Publication Place, Publisher, Year of Publication)

- a. Tripathi, K. D. Essentials of medical pharmacology. 4th Ed, 1999. Publisher: Jaypee, Delhi.
- b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
- c. Rang, H.P. & Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory)(Author, Title, Edition, Publication Place, Publisher, Publication Year)

- a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th Ed, 1996. Publisher Mc Graw Hill, Pergamon press.
- b. Craig, C.R.&Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown.Co
- c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, Int.
- d. Shargel and Leon. Applied Biopharmaceutics and pharmacokinetics. Latest edition. Publisher: Prentice Hall, London.

Text books (Practical) :

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

Reference books (Practical)

- a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.
- b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
- c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
- d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

3. Detailed syllabus and lecture wise schedule :**Title of the topic**

1.

General Pharmacology

- a) Introduction, definitions and scope of pharmacology
- b) Routes of administration of drugs
- c) Pharmacokinetics (absorption, distribution, metabolism and excretion)
- d) Pharmacodynamics
- e) Factors modifying drug effects
- f) Drug toxicity - Acute, sub-acute and chronic toxicity.
- g) Pre-clinical evaluations
- h) Drug interactions

Note: The term Pharmacology used here refers to the classification, mechanism of action, pharmacokinetics, pharmacodynamics, adverse effects, contraindications, Therapeutic uses, interactions and dose and route of administration.

2.

Pharmacology of drugs acting on ANS

- a) Adrenergic and antiadrenergic drugs
- b) Cholinergic and anticholinergic drugs
- c) Neuromuscular blockers
- d) Mydriatics and miotics
- e) Drugs used in myasthenia gravis
- f) Drugs used in Parkinsonism

3. **Pharmacology of drugs acting on cardiovascular system**
- a) Antihypertensives
 - b) Anti-anginal drugs
 - c) Anti-arrhythmic drugs
 - d) Drugs used for therapy of Congestive Heart Failure
 - e) Drugs used for hyperlipidaemias
4. **Pharmacology of drugs acting on Central Nervous System**
- a) General anesthetics
 - b) Sedatives and hypnotics
 - c) Anticonvulsants
 - d) Analgesic and anti-inflammatory agents
 - e) *Psychotropic drugs*
 - f) Alcohol and methyl alcohol
 - g) CNS stimulants and cognition enhancers
 - h) Pharmacology of local anaesthetics
5. **Pharmacology of Drugs acting on Respiratory tract**
- a) Bronchodilators
 - b) Mucolytics
 - c) Expectorants
 - d) Antitussives
 - e) Nasal Decongestants
6. **Pharmacology of Hormones and Hormone antagonists**
- a) Thyroid and Antithyroid drugs
 - b) Insulin, Insulin analogues and oral hypoglycemic agents
 - c) Sex hormones and oral contraceptives
 - d) Oxytocin and other stimulants and relaxants
7. **Pharmacology of autocoids and their antagonists**
- a) Histamines and Antihistaminics
 - b) 5-Hydroxytryptamine and its antagonists
 - c) Lipid derived autocoids and platelet activating factor

2.5 COMMUNITY PHARMACY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope:** In the changing scenario of pharmacy practice in India, Community Pharmacists are expected to offer various pharmaceutical care services. In order to meet this demand, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling, health screening services for improved patient care in the community set up.
2. **Objectives:** Upon completion of the course, the student shall be able to –
 - a. know pharmaceutical care services;
 - b. know the business and professional practice management skills in community pharmacies;
 - c. do patient counselling & provide health screening services to public in community pharmacy;
 - d. respond to minor ailments and provide appropriate medication;
 - e. show empathy and sympathy to patients; and
 - f. appreciate the concept of Rational drug therapy.

Text Books:

- a. Health Education and Community Pharmacy by N.S.Parmar.
- b. WHO consultative group report.
- c. Drug store & Business management by Mohammed Ali & Jyoti.

Reference books:

- a. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.
- b. Comprehensive Pharmacy Review – Edt. Leon Shargel. Lippincott Williams & Wilkins.

Special requirements:

1. Either the college is having model community pharmacy (meeting the schedule N requirement) or sign MoU with at least 4-5 community pharmacies nearby to the college for training the students on dispensing and counselling activities.
2. Special equipments like B.P apparatus, Glucometer, Peak flow meter, and apparatus for cholesterol estimation.

3. Scheme of evaluation (80 Marks)

1. Synopsis	10
2. Major Experiment	30
(Counselling of patients with specific diseases – emphasis should be given on Counselling introduction, content, process and conclusion)	

3. Minor Experiment(Ability to measure B.P/ CBG / Lung function)	15
4. Prescription Analysis (Analyzing the prescriptions for probable drug interaction and ability to tell the management)	15
5. Viva – Voce	10

4. Lecture wise programme :

Topics

1 Definition, scope, of community pharmacy Roles and responsibilities of Community pharmacist

2 Community Pharmacy Management

- a) Selection of site, Space layout, and design
- b) Staff, Materials- coding, stocking
- c) Legal requirements
- d) Maintenance of various registers
- e) Use of Computers: Business and health care soft wares

3 Prescriptions – parts of prescription, legality & identification of medication related problems like drug interactions.

4 Inventory control in community pharmacy

Definition, various methods of Inventory Control
ABC, VED, EOQ, Lead time, safety stock

5 Pharmaceutical care

Definition and Principles of Pharmaceutical care.

6 Patient counselling

Definition, outcomes, various stages, barriers, Strategies to overcome barriers
Patient information leaflets- content, design, & layouts, advisory labels

7 Patient medication adherence

Definition, Factors affecting medication adherence, role of pharmacist in improving the adherence.

8 Health screening services

Definition, importance, methods for screening
Blood pressure/ blood sugar/ lung function
and Cholesterol testing

9 OTC Medication- Definition, OTC medication list & Counselling

10 Health Education

WHO Definition of health, and health promotion, care for children, pregnant & breast feeding women, and geriatric patients.

Commonly occurring Communicable Diseases, causative agents,

Clinical presentations and prevention of communicable diseases – Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy,

Syphilis, Gonorrhea and AIDS

Balance diet, and treatment & prevention of deficiency disorders

Family planning – role of pharmacist

11 Responding to symptoms of minor ailments

Relevant pathophysiology, common drug therapy to,

Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Pyrexia, Ophthalmic symptoms, worms infestations.

12 Essential Drugs concept and Rational Drug Therapy

Role of community pharmacist

13 Code of ethics for community pharmacists

Third Year

3.1 PHARMACOLOGY – II (THEORY)

Theory : 3 Hrs. /Week

- 1. Scope of the Subject:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, drugs acting on autacoids, respiratory system, GIT, immune system and hormones, and pharmacology of autacoids and hormones will be concentrated. In addition, pharmacology of chemotherapeutic agents, vitamins, essential minerals and principles of toxicology are also taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.
- 2. Objectives of the Subject Upon completion of the subject student shall be able to:**
 - a. understand the pharmacological aspects of drugs falling under the above mentioned chapters,
 - b. carry out the animal experiments confidently,
 - c. appreciate the importance of pharmacology subject as a basis of therapeutics, and
 - d. correlate and apply the knowledge therapeutically.

Text books (Theory)

- a. Tripathi, K. D. Essentials of medical pharmacology. 4th edition, 1999. Publisher: Jaypee, Delhi.
- b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
- c. Rang, H.P. and Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory)

- a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th edition, 1996. Publisher: Mc Graw Hill, Pergamon press.
- b. Craig, C.R. and Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown and company.
- c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, International.
- d. Gupta, P.K. and Salunkhe, D.K. Modern Toxicology. Volume I, II and III. Latest edition. Publisher: B.V. Gupta, Metropolitan Book Co. (p) Ltd, New Delhi.

Text books (Practical)

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

Reference books (Practical) :

- a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.

- b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
- c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
- d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

3. Detailed syllabus and lecture wise schedule:

Title of the topic

- 1. **Pharmacology of Drugs acting on Blood and blood forming agents**
 - Anticoagulants
 - Thrombolytics and antiplatelet agents
 - Haemopoietics and plasma expanders

2. **Pharmacology of drugs acting on Renal System**

- a) Diuretics
- b) Antidiuretics

3. **Chemotherapy**

- a) Introduction
- b) Sulfonamides and co-trimoxazole
- c) Penicillins and Cephalosporins
- d) Tetracyclins and Chloramphenicol
- e) Macrolides, Aminoglycosides, Polyene & Polypeptide antibiotics
- f) Quinolines and Fluroquinolines
- g) Antifungal antibiotics
- h) Antiviral agents
- i) Chemotherapy of tuberculosis and leprosy
- j) Chemotherapy of Malaria
- k) Chemotherapy of protozoal infections (amoebiasis, Giardiasis)
- l) Pharmacology of Anthelmintic drugs
- m) Chemotherapy of cancer (Neoplasms)

- 4 **Immunopharmacology**
Pharmacology of immunosuppressants and stimulants

5. **Principles of Animal toxicology**
Acute, sub acute and chronic toxicity

6. **The dynamic cell: The structures and functions of the components of the cell**
- a) Cell and macromolecules: Cellular classification, subcellular organelles, macromolecules, large macromolecular assemblies
 - b) Chromosome structure: Pro and eukaryotic chromosome structures, chromatin structure, genome complexity, the flow of genetic information.
 - c) DNA replication: General, bacterial and eukaryotic DNA replication.
 - d) The cell cycle: Restriction point, cell cycle regulators and modifiers.
 - e) Cell signaling: Communication between cells and their environment, ion-channels, signal transduction pathways (MAP kinase, P38 kinase, JNK, Ras and PI3-kinase pathways, biosensors.

The Gene: Genome structure and function:

- a) Gene structure: Organization and elucidation of genetic code.
- b) Gene expression: Expression systems (pro and eukaryotic), genetic elements that control gene expression (nucleosomes, histones, acetylation, HDACS, DNA binding protein families.
- c) Transcription and Transcription factors: Basic principles of transcription in pro and eukaryotes. Transcription factors that regulate transcription in pro and eukaryotes.

RNA processing: rRNA, tRNA and mRNA processing.

Protein synthesis: Mechanisms of protein synthesis, initiation in eukaryotes, translation control and post-translation events

Altered gene functions: Mutations, deletions, amplifications, LOH, traslocations, trinucleotide repeats and other genetic abnormalities. Oncogenes and tumor suppressor genes.

The gene sequencing, mapping and cloning of human disease genes.

Introduction to gene therapy and targeting.

Recombinant DNA technology: principles. Processes (gene transfer technology) and applications

Books:

- 1 Molecular Biology of the Cell by Alberts B., Bray, D., Lewis, J., Raff M., Roberts, K and Watson, JD, 3rd edition.
- 2 Molecular Cell Biology By Lodish, H., Baltimore, D., Berk, A et al., 5th edition.
- 3 Molecular Biology by Turner, PC., McLennan, AG., Bates, AD and White MRH 2nd edition.
- 4 Genes VIII by Lewin, B., (2004)

- 5 Pharmaceutical Biotechnology, by Crommelin, DJA and Sindelar RD (1997)
- 6 Recombinant DNA by Watson, JD., Gilman, M., et al., (1996)
- 7 Biopharmaceutical: Biochemistry and Biotechnology by Walsh, G., (1998)

3.1 PHARMACOLOGY – II (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments:

1. Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea pigs, e. Rabbits).
2. Study of physiological salt solutions used in experimental pharmacology.
3. Study of laboratory appliances used in experimental pharmacology.
4. Study of use of anesthetics in laboratory animals.
5. To record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.
6. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.
7. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three point method.
8. To record the dose response curve of Histamine using isolated guinea-pig ileum preparation.
9. Study of agonistic and antagonistic effects of drugs using isolated guinea-pig ileum preparation.
10. To carry out bioassay of Histamine using isolated guinea-pig ileum preparation by interpolation method.
11. To carry out bioassay of Histamine using guinea-pig ileum preparation by three point method.
12. To study the routes of administration of drugs in animals (Rats, Mice, Rabbits).
13. Study of theory, principle, procedure involved and interpretation of given results for the following experiments:
 - a) Analgesic property of drug using analgesiometer.
 - b) Antiinflammatory effect of drugs using rat-paw edema method.
 - c) Anticonvulsant activity of drugs using maximal electroshock and pentylene tetrazole methods.
 - d) Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods.
 - e) Locomotor activity evaluation of drugs using actophotometer and rotorod.
 - f) Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.

Scheme of Practical Examination:

	Sessionals	Annual
Identification	02	10
Synopsis	04	10
Major Experiment (Bioassay)	08	30
Minor Experiment (Interpretation of given Graph or simulated experiment)	04	10
Viva	02	10
Max Marks	20	70
Duration	3hrs	4hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.2 PHARMACEUTICAL ANALYSIS (THEORY)

Theory : 3 Hrs. /Week

1. Quality Assurance:

- a. Introduction, sources of quality variation, control of quality variation.
- b. Concept of statistical quality control.
- c. Validation methods- quality of equipment, validation of equipment and validation of analytical instruments and calibration.
- d. GLP, ISO 9000.
- e. Total quality management, quality review and documentation.
- f. ICH- international conference for harmonization-guidelines.
- g. Regulatory control.

2. Chromatography:

Introduction, history, classification, separation techniques, choice of methods. The following techniques be discussed with relevant examples of pharmaceutical products involving principles and techniques of separation of drugs from excipients.

- a. **Column Chromatography:** Adsorption column chromatography, Operational technique, frontal analysis and elution analysis. Factors affecting column efficiency, applications and partition chromatography.
- b. **TLC:** Introduction, principle, techniques, R_f value and applications.
- c. **PC:** Introduction, principle, types of paper chromatography, preparation techniques, development techniques, applications.
- d. **Ion-exchange chromatography:** Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications.
- e. **HPLC:** Introduction, theory, instrumentation, and applications.
- f. **HPTLC:** Introduction, theory, instrumentation, and applications.
- g. **Gas Chromatography:** Introduction, theory, instrumentation-carrier gases, types of columns, stationary phases in GLC & GSC. Detectors-Flame ionization detectors, electron capture detector, thermal conductivity detector. Typical gas chromatogram, derivatisation techniques, programmed temperature gas chromatography, applications.
- h. **Electrophoresis:** Principles of separation, equipment for paper and gel electrophoresis, and application.
- i. **Gel filtration and affinity chromatography:** Introduction, technique, applications.

3. Electrometric Methods:

Theoretical aspects, instrumentation, interpretation of data/spectra and analytical applications be discussed on the following topics.

- a. **Potentiometry:** Electrical potential, electrochemical cell, reference electrodes, indicator electrodes, measurement of potential and pH, construction and working of electrodes, Potentiometric titrations, methods of detecting end point, Karl Fischer titration.
- b. **Conductometry:** Introduction, conductivity cell, conductometric titrations and applications.

4. **Spectroscopy:**

Theoretical aspects, instrumentation, elements of interpretation of data/spectra and application of analytical techniques be discussed on:

- a. **Absorption Spectroscopy:**
 - Theory of electronic, atomic and molecular spectra. Fundamental laws of photometry, Beer-Lambert's Law, application and its deviation, limitation of Beer law, application of the law to single and multiple component analysis, measurement of equilibrium constant and rate constant by spectroscopy. Spectra of isolated chromophores, auxochromes, batho-chromic shift, hypsochromic shift, hyperchromic and hypochromic effect, effect of solvent on absorption spectra, molecular structure and infrared spectra.
Instrumentation – Photometer, U.V.-Visible spectrophotometer – sources of U.V.-Visible radiations, collimating systems, monochromators, samples cells and following detectors-Photocell, Barrier layer cell, Phototube, Diode array, applications of U.V.-Visible spectroscopy in pharmacy and spectrophotometric titrations.
 - **Infrared Spectroscopy:** Vibrational transitions, frequency – structure correlations, Infrared absorption bands, Instrumentation–IR spectro-meter – sources of IR, Collimating systems, monochromators, sample cells, sample handling in IR spectroscopy and detectors–Thermocouple, Golay Cells, Thermistor, Bolometer, Pyroelectric detector, Applications of IR in pharmacy.
 - **Fluorimetric Analysis:** Theory, luminescence, factors affecting fluorescence, quenching. Instrumentation, Applications, fluorescent indicators, study of pharmaceutically important compounds estimated by fluorimetry.
- b. **Flame Photometry:** Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceutical applications.
- c. **Atomic Absorption Spectrometry:** Introduction, Theory, types of electrodes, instrumentation and applications.
- d. **Atomic Emission Spectroscopy:** Spectroscopic sources, atomic emission spectrometers, photographic and photoelectric detection.

3.2 PHARMACEUTICAL ANALYSIS (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments:

1. Separation and identification of Amino Acids by Paper Chromatography.
2. Separation and identification of Sulpha drugs by TLC technique.
3. Effect of pH and solvent on the UV spectrum of given compound.
4. Comparison of the UV spectrum of a compound with that of its derivatives.
5. Determination of dissociation constant of indicators using UV-Visible spectroscopy.
6. Conductometric titration of mixture of acids with a strong base.
7. Potentiometric titration of a acid with a strong base.
8. Estimation of drugs by Fluorimetric technique.
9. Study of quenching effect in fluorimetry.
10. Colourimetric estimation of Supha drugs using BMR reagent.
11. Simultaneous estimation of two drugs present in given formulation.
12. Assay of Salicylic Acid by colourimetry.
13. Determination of Chlorides and Sulphates in Calcium gluconate by Nepheloturbidimetric Method.
14. Determination of Na/K by Flame Photometry.
15. Determination of pKa using pH meter.
16. Determination of specific rotation.
17. Comparison of the IR spectrum of a compound with that of its derivatives.
18. Demonstration of HPLC.
19. Demonstration of HPTLC.
20. Demonstration of GC-MS.
21. Demonstration of DSC.
22. Interpretation of NMR spectra of any one compound.

Reference Books:

1. Text Book of Pharm. Analysis by Higuchi. T and Hasen. E. B., New York Inter Science Publishers.
2. Quantitative Pharma. Analysis by Jenkins, The Blakiston division, New York.
3. Quantitative Drug Analysis, by Garrot. D, Chapman & Hall Ltd., London.
4. Undergraduate Instrumental Analysis by James. E., CBS Publishers.
5. Instrumental Analysis by Willard and Merritt, EWP, East West Press Ltd., Delhi/Madras.
6. Pharm Analysis by Skoog and West, Sounders Manipal College Publishing.

7. Text Book of Chemical Analysis, by A.I.Vogel, ELBS with Macmillan press, Hampshire.
8. Textbook of Pharm. Analysis by K.A.Connors, John Wiley & Sons, New York, Brisbane, Singapore.
9. Textbook of Pharm. Analysis (Practical) by Beckett & Stenlake, CBS Publishers, Delhi.
10. Textbook of Drug Analysis by P.D. Sethi., CBS Publishers, Delhi.
11. Spectroscopy by Silverstein, John & Wiley & Sons. Inc., Canada & Singapore.
12. How to practise GMP-A Plan for total quality control by P.P. Sharma, Vandana Publications, Agra.
13. The Science & Practice of Pharmacy by Remington Vol-I & II, Mack Publishing Co. Pennsylvania.
14. TLC by Stahl, Spring Verlay.
15. Text Book of Pharm. Chemistry by Chatten, CBS Publications.
16. Spectroscopy by William Kemp, ELBS with Macmillan Press, Hampshire.
17. I.P.-1996, The Controller of Publications, New Delhi.
18. BPC- Dept. of Health, U.K. for HMSO.
19. USP - Mack Publishing Co., Easton, PA.
20. The Extra Pharmacopoeia – The Pharm. Press, London.

Practicals

Title of the Experiment:

- 1 Study of agonistic and antagonistic effects of drugs using Guinea-pig ileum preparation.**
- 2 To study the effects of drugs on intestinal motility using frog's esophagus model*
- 3 To study the effects of drugs using rat uterus preparation.**
- 4 To study the anticonvulsant property of drugs (any one model).*
- 5 To study antihistaminic property of drug using histamine induced anaphylactic reaction in guinea pigs.
- 6 To study the apomorphine-induced compulsive behaviour (stereotypy) in mice.*
- 7 To study the muscle relaxant property of diazepam in mice using rotarod apparatus.*
- 8 To study the antiinflammatory property of indomethacin against carrageenan-induced paw oedema.**
- 9 To study the anxiolytic effect of diazepam in mice using mirrored-chamber apparatus.**
- 10 To demonstrate the effect of various drugs on the blood pressure and respiration of anaesthetized dog.
- 11 To study the effect of anthelmintics on earthworms.
- 12 To study the taming effect of chlorpromazine.*
- 13 To study the effects of drugs on vas deference of the male rat.**
- 14 To study the effect of drugs on pesticide toxicity using rats as model.
- 15 To study the effect of drugs on heavy metal toxicity.

** indicate major experiment & * indicate minor experiment

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.3 HOSPITAL PHARMACY (THEORY)

Theory: 2 Hrs. /Week

1. **Scope:** In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug dispensing, manufacturing of parenteral preparations, drug information, patient counselling, and therapeutic drug monitoring for improved patient care.
2. **Objectives:** Upon completion of the course, the student shall be able to –
 - a. know various drug distribution methods;
 - b. know the professional practice management skills in hospital pharmacies;
 - c. provide unbiased drug information to the doctors;
 - d. know the manufacturing practices of various formulations in hospital set up;
 - e. appreciate the practice based research methods; and
 - f. appreciate the stores management and inventory control.

Text books: (latest editions)

- a. Hospital pharmacy by William .E. Hassan
- b. A text book of Hospital Pharmacy by S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh

References:

- a. WHO consultative group report.
- b. R.P.S. Vol.2. Part –B; Pharmacy Practice section.
- c. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.

3. Lecture wise programme:

Topics

- 1 **Hospital - its Organisation and functions**
- 2 **Hospital pharmacy-Organisation and management**
 - a) Organizational structure-Staff, Infrastructure & work load statistics
 - b) Management of materials and finance
 - c) Roles & responsibilities of hospital pharmacist
- 3 **The Budget – Preparation and implementation**
- 4 **Hospital drug policy**
 - a) Pharmacy and Therapeutic committee (PTC)
 - b) Hospital formulary
 - c) Hospital committees
 - Infection committee
 - Research and ethical committee
 - d) Developing therapeutic guidelines
 - e) Hospital pharmacy communication - Newsletter

5 Hospital pharmacy services

- a) Procurement & warehousing of drugs and Pharmaceuticals
- b) Inventory control
Definition, various methods of Inventory Control
ABC, VED, EOQ, Lead time, safety stock
- c) Drug distribution in the hospital
 - i) Individual prescription method
 - ii) Floor stock method
 - iii) Unit dose drug distribution method
- d) Distribution of Narcotic and other controlled substances
- e) Central sterile supply services – Role of pharmacist

6 Manufacture of Pharmaceutical preparations

- a) Sterile formulations – large and small volume parenterals
- b) Manufacture of Ointments, Liquids, and creams
- c) Manufacturing of Tablets, granules, capsules, and powders
- d) Total parenteral nutrition

7 Continuing professional development programs

Education and training

8 Radio Pharmaceuticals – Handling and packaging

9 Professional Relations and practices of hospital pharmacist

3.3 HOSPITAL PHARMACY (PRACTICAL)

Practical : 3 Hrs./Week

1. Assessment of drug interactions in the given prescriptions
2. Manufacture of parenteral formulations, powders.
3. Drug information queries.
4. Inventory control

List of Assignments:

- 1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.*
- 2. Pharmacy and Therapeutics committee – Organization, functions, and limitations.*
- 3. Development of a hospital formulary for 300 bedded teaching hospital*
- 4. Preparation of ABC analysis of drugs sold in one month from the pharmacy.*
- 5. Different phases of clinical trials with elements to be evaluated.*

6. Various sources of drug information and systematic approach to provide unbiased drug information.

7. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.

Special requirements:

1. Each college should sign MoU with nearby local hospital having minimum 300 beds for providing necessary training to the students' on hospital pharmacy activities.
2. Well equipped with various resources of drug information.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.4 PHARMACEUTICAL JURISPRUDENCE (THEORY)

Theory : 2 Hrs. /Week

- 1. Scope of the Subject:** (4-6 lines): This course exposes the student to several important legislations related to the profession of pharmacy in India. The Drugs and Cosmetics Act, along with its amendments are the core of this course. Other acts, which are covered, include the Pharmacy Act, dangerous drugs, medicinal and toilet preparation Act etc. Besides this the new drug policy, professional ethics, DPCO, patent and design Act will be discussed.
- 2. Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, and appreciate) –
 - a. practice the Professional ethics;
 - b. understand the various concepts of the pharmaceutical legislation in India;

- c. know the various parameters in the Drug and Cosmetic Act and rules;
- d. know the Drug policy, DPCO, Patent and design act;
- e. understand the labeling requirements and packaging guidelines for drugs and cosmetics;
- f. be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and
- g. other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

Text books (Theory)

Mithal, B M. Textbook of Forensic Pharmacy. Calcutta :National; 1988._____

Reference books (Theory)

- a. Singh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad: Law Book House; 1984.
- b. Jain, NK. A Textbook of forensic pharmacy. Delhi: Vallabh prakashan ; 1995.
- c. Reports of the Pharmaceutical enquiry Committee
- d. I.D.M.A., Mumbai. DPCO 1995
- e. Various reports of Amendments.
- f. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
- g. Eastern Book Company .The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.

3. Detailed syllabus and lecture wise schedule:

Title of the topic

1. **Pharmaceutical Legislations – A brief review.**
2. Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI.
3. **Drugs and Cosmetics Act, 1940, and its rules 1945.**
Objectives, Legal definition, Study of Schedule's with reference to Schedule B, C&C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y.
Sales, Import, labeling and packaging of Drugs And Cosmetics
Provisions Relating to Indigenous Systems.
Constitution and Functions of DTAB, DCC, CDL.
Qualification and duties –Govt. analyst and Drugs Inspector.
4. **Pharmacy Act –1948.**
Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER.
5. **Medicinal and Toilet Preparation Act –1955.**
Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations.
6. **Narcotic Drugs and Psychotropic substances Act-1985 and Rules.** Objectives, Legal Definitions, General Study, Constitution and Functions of narcotic &

Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and regulations, Schedules to the Act.

7. **Study of Salient Features of Drugs and magic remedies Act and its rules.**
8. **Study of essential Commodities Act Relevant to drugs price control Order.**
9. **Drug Price control Order & National Drug Policy (Current).**
10. **Prevention Of Cruelty to animals Act-1960.**
11. **Patents & design Act-1970.**
12. **Brief study of prescription and Non-prescription Products.**

4. Assignments:

Format of the assignment

1. Minimum & Maximum number of pages
2. It shall be a computer draft copy
3. Reference(s) shall be included at the end.
4. Name and signature of the student
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min

Case studies relating to

1. Drugs and Cosmetics Act and rules along with its amendments, Dangerous Drugs Act, Medicinal and Toilet preparation Act, New Drug Policy, Professional Ethics, Drugs (Price control) Order, Patent and Design Act.
2. Various prescription and non-prescription products.
3. Medical and surgical accessories.
4. Diagnostic aids and appliances available in the market.

3.5 MEDICINAL CHEMISTRY (THEORY)

Theory: 3 Hrs. /Week

1. Modern concept of rational drug design: A brief introduction to Quantitative Structure Activity Relationship (QSAR), prodrug, combinatorial chemistry and computer aided drug design (CADD) and concept of antisense molecules.

A study of the development of the following classes of drugs including SAR, mechanism of action, synthesis of important compounds, chemical nomenclature, brand names of important marketed products and their side effects.

2. Anti-infective agents
 - a) Local anti-infective agents
 - b) Preservatives
 - c) Antifungal agents
 - d) Urinary tract anti-infectives
 - e) Antitubercular agents
 - f) Antiviral agents and Anti AIDS agents
 - g) Antiprotozoal agents
 - h) Anthelmintics
 - i) Antiscabies and Antipedicular agents
3. Sulphonamides and sulphones
4. Antimalarials
5. Antibiotics
6. Antineoplastic agents
7. Cardiovascular agents
 - a) Antihypertensive agents
 - b) Antianginal agents and vasodilators

- c) Antiarrhythmic agents
 - d) Antihyperlipidemic agents
 - e) Coagulants and Anticoagulants
 - f) Endocrine
8. Hypoglycemic agents
 9. Thyroid and Antithyroid agents
 10. Diuretics
 11. Diagnostic agents
 12. Steroidal Hormones and Adrenocorticoids

3.5 MEDICINAL CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

1. Assays of important drugs from the course content.
2. Preparation of medicinally important compounds or intermediates required for synthesis of drugs.
3. Monograph analysis of important drugs.
4. Determination of partition coefficients, dissociation constants and molar refractivity of compounds for QSAR analysis.

Reference Books:

- a. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.
- b. William.O.Foye, Principles of Medicinal Chemistry, B.I. Waverly Pvt. Ltd., New Delhi.
- c. Burgers, Medicinal Chemistry, M.E., Welly Med.Chemistry M.E. Walfed Johnwilley and Sons, Wiley-interscience Publication, New York, Toranto.
- d. A Text Book of Medicinal Chemistry Vol. I and II by Surendra N. Pandeya, S.G. Publisher, 6, Dildayal Nagar, Varanasi -10.
- e. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi - 54.
- f. Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19.
- g. Organic Drug Synthesis-Ledniser Mitzsher Vol. I and II.
- h. Pharmaceutical Chemistry drug Synthesis Vol. I and II by H. J. Roth and A. Kleemann.
- i. The Science and Practice of Pharmacy Vol. 1 and 2, Remington, MACK Publishing Company, Easton, Pennsylvania.

3.6 PHARMACEUTICAL FORMULATIONS (THEORY)

Theory : 2 Hrs. /Week

1. **Scope of the Subject:** Scope and objectives of the course: Subject deals with the formulation and evaluation of various pharmaceutical dosage forms.
2. **Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, appreciate) –
 - a. understand the principle involved in formulation of various pharmaceutical dosage forms;
 - b. prepare various pharmaceutical formulation;
 - c. perform evaluation of pharmaceutical dosage forms; and
 - d. understand and appreciate the concept of bioavailability and bioequivalence, their role in clinical situations.

Text books (Theory)

- a. Pharmaceutical dosage forms, Vol, I,II and III by lachman
- b. Rowlings Text book of Pharmaceutics
- c. Tutorial Pharmacy – Cooper &Gun

Reference books (Theory)

- a. Remington's Pharmaceutical Sciences
- b. USP/BP/IP

3. Detailed syllabus and lecture wise schedule:

Title of the topic

1. Pharmaceutical dosage form- concept and classification
2. **Tablets:** Formulation of different types of tablets, tablet excipients, granulation techniques quality control and evaluation of tablets. Tablet coating, Type of coating, quality control tests for coated tablet.
3. **Capsules;** Production and filling of hard gelatin capsules, Raw material for shell, finishing, quality control tests for capsules. Production and filling of soft gelatin capsules, quality control tests for soft gelatin capsules.
4. **Liquid orals:** Formulation and evaluation of suspensions, emulsions and solutions. Stability of these preparations
5. **Parenterals** Introduction Containers used for Parenterals (including official tests) Formulation of large and small volume Parenterals Sterilization
6. **Ophthalmic preparations (Semi – Solids):** Introduction and classification Factors affecting absorption and anatomy of skin Packaging storage and labeling, Ointments Types of Ointment Base Preparation of ointment, Jellies Types of jellies Formulation of jellies Suppositories, Method of preparation, Types Packaging

7. Definition and concept of **Controlled and novel Drug delivery systems** with available examples, viz. parenteral, trans dermal, buccal, rectal, nasal, implants, ocular

3.6 PHARMACEUTICAL FORMULATIONS (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments :

- 1. Manufacture of Tablets**
 - a. Ordinary compressed tablet-wet granulation
 - b. Tablets prepared by direct compression.
 - c. Soluble tablet.
 - d. Chewable tablet.
- 2. Formulation and filling of hard gelatin capsules**
- 3. Manufacture of parenterals**
 - a. Ascorbic acid injection
 - b. Calcium gluconate injection
 - c. Sodium chloride infusion.
 - d. Dextrose and Sodium chloride injection/ infusion.
- 4. Evaluation of Pharmaceutical formulations (QC tests)**
 - a. Tablets
 - b. Capsules
 - c. Injections
- 5. Formulation of two liquid oral preparations and evaluation by assay**
 - a. Solution: Paracetamol Syrup
 - b. Antacid suspensions- Aluminum hydroxide gel
- 6. Formulation of semisolids and evaluation by assay**
 - a. Salicylic acid and benzoic acid ointment
 - b. Gel formulation Diclofenac gel
- 7. Cosmetic preparations**
 - a. Lipsticks
 - b. Cold cream and vanishing cream
 - c. Clear liquid shampoo
 - d. Tooth paste and tooth powders.
- 8. Tablet coating (demonstration)**

Scheme of Practical Examination :

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Fourth Year

4.1 PHARMACOTHERAPEUTICS - I (THEORY)

Theory : 3 Hrs. /Week

- 1. Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
- 2. Objectives:** At completion of this subject it is expected that students will be able to understand –
 - a. the pathophysiology of selected disease states and the rationale for drug therapy;
 - b. the therapeutic approach to management of these diseases;
 - c. the controversies in drug therapy;
 - d. the importance of preparation of individualised therapeutic plans based on diagnosis;
 - e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
 - f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
 - g. summarise the therapeutic approach to management of these diseases including reference to the latest available evidence;
 - h. discuss the controversies in drug therapy;
 - i. discuss the preparation of individualised therapeutic plans based on diagnosis; and
 - j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

- a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.
- b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange.

Reference Books

- a. Pathologic basis of disease - Robins SL, W.B.Saunders publication.
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication.
- c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication.
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
- e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature.

3. Detailed syllabus and lecture wise schedule :

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

Title of the topic

- 1 **Cardiovascular system:** Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, , Hyperlipidaemias , Electrophysiology of heart and Arrhythmias
- 2 **Respiratory system :** Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases
Endocrine system : Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis
- 3 **General prescribing guidelines for**
 - a. Paediatric patients
 - b. Geriatric patients
 - c. Pregnancy and breast feeding
- 4 **Ophthalmology:** Glaucoma, Conjunctivitis- viral & bacterial
- 5 **Introduction to rational drug use**
Definition, Role of pharmacist Essential drug concept Rational drug formulations

4.1 PHARMACOTHERAPEUTICS - I (PRACTICAL)

Practical : 3 Hrs./Week

Practicals :

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

4.2 PHARMACOTHERAPEUTICS – II (THEORY)

Theory : 3 Hrs. /Week

- 1. Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
- 2. Objectives of the Subject Upon completion of the subject student shall be able to –**
 - a. know the pathophysiology of selected disease states and the rationale for drug therapy
 - b. know the therapeutic approach to management of these diseases;
 - c. know the controversies in drug therapy;
 - d. know the importance of preparation of individualised therapeutic plans based on diagnosis; and
 - e. appreciate the needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text books (Theory)

Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication

Reference books (Theory)

- a. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange
- b. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
- c. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA]

3. Detailed syllabus and lecture wise schedule :

Etiopathogenesis and pharmacotherapy of diseases associated with following systems / diseases –

Title of the topic

- 1. Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhoea

and Syphilis

2 Musculoskeletal disorders

Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.

3 Renal system

Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders

- 4 **Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis
- 5 **Dermatology:** Psoriasis, Scabies, Eczema, Impetigo

4.2 PHARMACOTHERAPEUTICS – II (PRACTICAL)

Practical : 3 Hrs./Week

Practicals :

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.

The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.

A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment :

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination :

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

4.3 CLINICAL PHARMACY (THEORY)

Theory: 3 Hrs. /Week

1. Objectives:

Upon completion of the subject student shall be able to (Know, do, appreciate) –

- a. monitor drug therapy of patient through medication chart review and clinical review;
- b. obtain medication history interview and counsel the patients;
- c. identify and resolve drug related problems;
- d. detect, assess and monitor adverse drug reaction;
- e. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and
- f. retrieve, analyse, interpret and formulate drug or medicine information.

Text books (Theory)

- a. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
- b. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
- c. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.
- d. A textbook of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi, Karin Nyfort-Hansen and Milap Nahata Orient Langman Pvt.Ltd. ISSBN8125026

References

- a. Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
- b. Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
- c. Pharmaceutical Statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

2. Detailed syllabus and lecture wise schedule:

Title of the topic

1. **Definitions, development and scope of clinical pharmacy**
2. **Introduction to daily activities of a clinical pharmacist**
 - a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)

- b. Ward round participation
- c. Adverse drug reaction management
- d. Drug information and poisons information
- e. Medication history
- f. Patient counseling
- g. Drug utilisation evaluation (DUE) and review (DUR)
- h. Quality assurance of clinical pharmacy services

3. **Patient data analysis**

The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.

4. **Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results**

- a. Haematological, Liver function, Renal function, thyroid function tests
- b. Tests associated with cardiac disorders
- c. Fluid and electrolyte balance
- d. Microbiological culture sensitivity tests
- e. Pulmonary Function Tests

5. **Drug & Poison information**

- a. Introduction to drug information resources available
- b. Systematic approach in answering DI queries
- c. Critical evaluation of drug information and literature
- d. Preparation of written and verbal reports
- e. Establishing a Drug Information Centre
- f. Poisons information- organization & information resources

6. **Pharmacovigilance**

- a. Scope, definition and aims of pharmacovigilance
- b. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used]
- c. Reporting, evaluation, monitoring, preventing & management of ADRs
- d. Role of pharmacist in management of ADR.

7. **Communication skills, including patient counselling techniques, medication history interview, presentation of cases.**

8. **Pharmaceutical care concepts**

9. **Critical evaluation of biomedical literature**

10. **Medication errors**

4.3 CLINICAL PHARMACY (PRACTICAL)

Practical: 3 Hrs./Week

Students are expected to perform 15 practicals in the following areas covering the topics dealt in theory class.

- a. Answering drug information questions (4 Nos)
- b. Patient medication counselling (4 Nos)
- c. Case studies related to laboratory investigations (4 Nos)
- d. Patient medication history interview (3 Nos)

Assignment:

Students are expected to submit THREE written assignments (1500 – 2000 words) on the topics given to them covering the following areas dealt in theory class.

Drug information, Patient medication history interview, Patient medication counselling, Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

4.4 BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY)

Theory: 2 Hrs. /Week

1. Detailed syllabus and lecture wise schedule

1 Research Methodology

- a) Types of clinical study designs:
Case studies, observational studies, interventional studies,
- b) Designing the methodology
- c) Sample size determination and Power of a study
Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study
- d) Report writing and presentation of data

2 Biostatistics

2.1 a) Introduction

- b) Types of data distribution
- c) Measures describing the central tendency distributions- average, median, mode
- d) Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean.

2.2 Data graphics

Construction and labeling of graphs, histogram, piecharts, scatter plots, semilogarithmic plots

2.3 Basics of testing hypothesis

- a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals.
- b) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way)
- c) Level of significance (Non-parametric data)- Sign test, Wilcoxon's signed rank test, Wilcoxon rank sum test, Mann Whitney U test, Kruskal-Wallis test (one way ANOVA)
- d) Linear regression and correlation- Introduction, Pearson's and Spearman's correlation and correlation co-efficient.
- e) Introduction to statistical software: SPSS, Epi Info, SAS.

2.4 Statistical methods in epidemiology

Incidence and prevalence, relative risk, attributable risk

3. Computer applications in pharmacy

Computer System in Hospital Pharmacy: Patterns of Computer use in Hospital Pharmacy
– Patient record database management, Medication order entry – Drug labels and list –
Intravenous solution and admixture, patient medication profiles, Inventory control,
Management report & Statistics.

Computer In Community Pharmacy

Computerizing the Prescription Dispensing process

Use of Computers for Pharmaceutical Care in community pharmacy

Accounting and General ledger system

Drug Information Retrieval & Storage :

Introduction – Advantages of Computerized Literature Retrieval

Use of Computerized Retrieval

Reference books:

- a. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3rd edition, publisher Marcel Dekker Inc. NewYork.
- b. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich , 3rd edition, McGraw Hill Publications 2006

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

Theory: 3 Hrs. /Week

Goal: To train the students in the area of Biopharmaceutics and pharmacokinetics to work efficiently in the in clinical research and pharma industry.

Objectives: Upon completion of the course, the candidate shall have the ability to calculate Pharmacokinetic parameters from the given data, apply principles of pharmacokinetics in the design of new formulations and conduct bioavailability and bioequivalence studies.

1. Biopharmaceutics

1. Introduction to Biopharmaceutics
 - a. Absorption of drugs from gastrointestinal tract.
 - b. Drug Distribution.
 - c. Drug Elimination.

2. Pharmacokinetics

2. Introduction to Pharmacokinetics.
 - a. Mathematical model
 - b. Drug levels in blood.
 - c. Pharmacokinetic model
 - d. Compartment models
 - e. Pharmacokinetic study.
3. One compartment open model.
 - a. Intravenous Injection (Bolus)
 - b. Intravenous infusion.
4. Multicompartment models.
 - a. Two compartment open model.
 - b. IV bolus, IV infusion and oral administration
5. Multiple – Dosage Regimens.
 - a. Repetitive Intravenous injections – One Compartment Open Model
 - b. Repetitive Extravascular dosing – One Compartment Open model
 - c. Multiple Dose Regimen – Two Compartment Open Model
6. Nonlinear Pharmacokinetics.
 - a. Introduction
 - b. Factors causing Non-linearity.
 - c. Michaelis-menton method of estimating parameters.
7. Noncompartmental Pharmacokinetics.
 - a. Statistical Moment Theory.
 - b. MRT for various compartment models.

- c. Physiological Pharmacokinetic model.
- 8. Bioavailability and Bioequivalence.
 - a. Introduction.
 - b. Bioavailability study protocol.
 - c. Methods of Assessment of Bioavailability

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

Practical : 3 Hrs./Week

1. Improvement of dissolution characteristics of slightly soluble drugs by some methods.
2. Comparison of dissolution studies of two different marketed products of same drug.
3. Influence of polymorphism on solubility and dissolution.
4. Protein binding studies of a highly protein bound drug and poorly protein bound drug.
5. Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.
6. Bioavailability studies of some commonly used drugs on animal/human model.
7. Calculation of K_a , K_e , $t_{1/2}$, C_{max} , AUC, AUMC, MRT etc. from blood profile data.
8. Calculation of bioavailability from urinary excretion data for two drugs.
9. Calculation of AUC and bioequivalence from the given data for two drugs.
10. In vitro absorption studies.
11. Bioequivalency studies on the different drugs marketed.(eg) Tetracycline, Sulphamethoxazole, Trimethoprim, Aspirin etc., on animals and human volunteers.
12. Absorption studies in animal inverted intestine using various drugs.
13. Effect on contact time on the plasma protein binding of drugs.
14. Studying metabolic pathways for different drugs based on elimination kinetics data.
15. Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data.
16. Determination of renal clearance.

References:

- a. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
- b. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania.
- c. Pharmacokinetics: By Milo Gibaldi Donald, R. Mercel Dekker Inc.
- d. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
- e. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
- f. Biopharmaceutics; By Swarbrick
- g. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmanekar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
- h. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
- i. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.

- j. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Robert F Notari Marcel Dekker Inc, New York and Basel, 1987.
- k. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

4.6 CLINICAL TOXICOLOGY (THEORY)

Theory: 2 Hrs. /Week

1. General principles involved in the management of poisoning
2. Antidotes and the clinical applications.
3. Supportive care in clinical Toxicology.
4. Gut Decontamination.
5. Elimination Enhancement.
6. Toxicokinetics.
7. Clinical symptoms and management of acute poisoning with the following agents –
 - a) Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.
 - b) Opiates overdose.
 - c) Antidepressants
 - d) Barbiturates and benzodiazepines.
 - e) Alcohol: ethanol, methanol.
 - f) Paracetamol and salicylates.
 - g) Non-steroidal anti-inflammatory drugs.
 - h) Hydrocarbons: Petroleum products and PEG.
 - i) Caustics: inorganic acids and alkali.
 - j) Radiation poisoning
8. Clinical symptoms and management of chronic poisoning with the following agents –
Heavy metals: Arsenic, lead, mercury, iron, copper
9. Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.
10. Plants poisoning. Mushrooms, Mycotoxins.
11. Food poisonings
12. Envenomations – Arthropod bites and stings.

Substance abuse:

Signs and symptoms of substance abuse and treatment of dependence

- a) CNS stimulants :amphetamine
- b) Opioids
- c) CNS depressants
- d) Hallucinogens: LSD
- e) Cannabis group
- f) Tobacco

References:

- a. Matthew J Ellenhorn. ELLENHORNS MEDICAL TOXICOLOGY – DIAGNOSIS AND TREATMENT OF POISONING. Second edition. Williams and Willkins publication, London

- b. V V Pillay. HANDBOOK OF FORENSIC MEDICINE AND TOXICOLOGY. Thirteenth edition 2003 Paras Publication, Hyderabad



भारत का राजपत्र The Gazette of India

साप्ताहिक/WEEKLY

प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं० 19] नई दिल्ली, शनिवार, मई 10—मई 16, 2008 (वैशाख 20, 1930)
No. 19] NEW DELHI, SATURDAY, MAY 10—MAY 16, 2008 (VAISAKHA 20, 1930)

इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।
(Separate paging is given to this Part in order that it may be filed as a separate compilation)

भाग III—खण्ड 4

[PART III—SECTION 4]

[सांविधिक निकायों द्वारा जारी की गई विविध अधिसूचनाएं जिसमें कि आदेश, विज्ञापन और सूचनाएं सम्मिलित हैं]
[Miscellaneous Notifications including Notifications, Orders, Advertisements and Notices issued by
Statutory Bodies]

भारतीय रिज़र्व बैंक

मुंबई-400001, दिनांक 9 अप्रैल 2008

संदर्भ : बैंपवि. सं. आईबीडी.-14241/23.13.048/2007-08--भारतीय रिज़र्व बैंक अधिनियम, 1934 (1934 का 2) की धारा 42 की उप-धारा (6) के खण्ड (ग) के अनुसरण में भारतीय रिज़र्व बैंक इसके द्वारा निदेश देता है कि उक्त अधिनियम की दूसरी अनुसूची में निम्नलिखित परिवर्तन किये जाएं :--

“अरब बांग्लादेश बैंक लिमिटेड” शब्दों के स्थान पर “एबी बैंक लिमिटेड” शब्द होंगे।

आनन्द सिन्हा
कार्यपालक निदेशक

[PUBLISHED IN THE GAZETTE OF INDIA, No.19, PART III, SECTION 4]

Ministry of Health and Family Welfare
(Pharmacy Council of India)

New Delhi, 10th May, 2008.

Pharm.D. Regulations 2008

Regulations framed under section 10 of the Pharmacy Act, 1948 (8 of 1948).

(As approved by the Government of India, Ministry of Health vide, letter No.V.13013/1/2007-PMS, dated the 13th March, 2008 and notified by the Pharmacy Council of India).

No.14-126/2007-PCI.— In exercise of the powers conferred by section 10 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government, hereby makes the following regulations, namely:-

CHAPTER-I

1. Short title and commencement. – (1) These regulations may be called the Pharm.D. Regulations 2008.
(2) They shall come into force from the date of their publication in the official Gazette.
2. Pharm.D. shall consist of a certificate, having passed the course of study and examination as prescribed in these regulations, for the purpose of registration as a pharmacist to practice the profession under the Pharmacy Act, 1948.

CHAPTER-II

3. Duration of the course. –

- a) Pharm.D: The duration of the course shall be six academic years (five years of study and one year of internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of six years duration is divided into two phases –

Phase I – consisting of First, Second, Third, Fourth and Fifth academic year.

Phase II – consisting of internship or residency training during sixth year involving posting in speciality units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services and acquires skill under supervision so that he or she may become capable of functioning independently.

- b) Pharm.D. (Post Baccalaureate): The duration of the course shall be for three academic years (two years of study and one year internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of three years duration is divided into two phases –

Phase I – consisting of First and Second academic year.

Phase II – consisting of Internship or residency training during third year involving posting in speciality units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services, and acquires skill under supervision so that he or she may become capable of functioning independently.

4. Minimum qualification for admission to. –

- a) Pharm.D. Part-I Course – A pass in any of the following examinations -

(1) 10+2 examination with Physics and Chemistry as compulsory subjects along with one of the following subjects:

Mathematics or Biology.

(2) A pass in D.Pharm course from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act.

(3) Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examinations.

Provided that a student should complete the age of 17 years on or before 31st December of the year of admission to the course.

Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.

b) Pharm.D. (Post Baccalaureate) Course -

A pass in B.Pharm from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act:

Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.

5. Number of admissions in the above said programmes shall be as prescribed by the Pharmacy Council of India from time to time and presently be restricted as below –
 - i) Pharm.D. Programme – 30 students.
 - ii) Pharm.D. (Post Baccalaureate) Programme – 10 students.
6. Institutions running B.Pharm programme approved under section 12 of the Pharmacy Act, will only be permitted to run Pharm.D. programme. Pharm.D. (Post Baccalaureate) programme will be permitted only in those institutions which are permitted to run Pharm.D. programme.
7. Course of study. – The course of study for Pharm.D. shall include the subjects as given in the Tables below. The number of hours in a week, devoted to each subject for its teaching in theory, practical and tutorial shall not be less than that noted against it in columns (3), (4) and (5) below.

T A B L E S

First Year :

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
1.1	Human Anatomy and Physiology	3	3	1
1.2	Pharmaceutics	2	3	1
1.3	Medicinal Biochemistry	3	3	1
1.4	Pharmaceutical Organic Chemistry	3	3	1
1.5	Pharmaceutical Inorganic Chemistry	2	3	1
1.6	Remedial Mathematics/ Biology	3	3*	1
	Total hours	16	18	6 = (40)

* For Biology

Second Year:

S.No	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
2.1	Pathophysiology	3	-	1
2.2	Pharmaceutical Microbiology	3	3	1
2.3	Pharmacognosy & Phytopharmaceuticals	3	3	1
2.4	Pharmacology-I	3	-	1
2.5	Community Pharmacy	2	-	1
2.6	Pharmacotherapeutics-I	3	3	1
	Total Hours	17	9	6 = 32

Third Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
3.1	Pharmacology-II	3	3	1
3.2	Pharmaceutical Analysis	3	3	1
3.3	Pharmacotherapeutics-II	3	3	1
3.4	Pharmaceutical Jurisprudence	2	-	-
3.5	Medicinal Chemistry	3	3	1
3.6	Pharmaceutical Formulations	2	3	1
	Total hours	16	15	5 = 36

Fourth Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical/Hospital Posting	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
4.1	Pharmacotherapeutics-III	3	3	1
4.2	Hospital Pharmacy	2	3	1
4.3	Clinical Pharmacy	3	3	1
4.4	Biostatistics & Research Methodology	2	-	1
4.5	Biopharmaceutics & Pharmacokinetics	3	3	1
4.6	Clinical Toxicology	2	-	1
	Total hours	15	12	6 = 33

Fifth Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Hospital posting*	No. of hours of Seminar
(1)	(2)	(3)	(4)	(5)
5.1	Clinical Research	3	-	1
5.2	Pharmacoepidemiology and Pharmacoeconomics	3	-	1
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	2	-	1
5.4	Clerkship *	-	-	1
5.5	Project work (Six Months)	-	20	-
	Total hours	8	20	4 = 32

* Attending ward rounds on daily basis.

Sixth Year:

Internship or residency training including postings in speciality units. Student should independently provide the clinical pharmacy services to the allotted wards.

- (i) Six months in General Medicine department, and
- (ii) Two months each in three other speciality departments

8. Syllabus. – The syllabus for each subject of study in the said Tables shall be as specified in Appendix -A to these regulations.
9. Approval of the authority conducting the course of study. – (1) No person, institution, society or university shall start and conduct Pharm.D or Pharm.D. (Post Baccalaureate) programme without the prior approval of the Pharmacy Council of India.
 - (2) Any person or pharmacy college for the purpose of obtaining permission under sub-section (1) of section 12 of the Pharmacy Act, shall submit a scheme as prescribed by the Pharmacy Council of India.
 - (3) The scheme referred to in sub-regulation (2) above, shall be in such form and contain such particulars and be preferred in such manner and be accompanied with such fee as may be prescribed:

Provided that the Pharmacy Council of India shall not approve any institution under these regulations unless it provides adequate arrangements for teaching in regard to building, accommodation, labs., equipments, teaching staff, non-teaching staff, etc., as specified in Appendix-B to these regulations.
10. Examination. – (1) Every year there shall be an examination to examine the students.
 - (2) Each examination may be held twice every year. The first examination in a year shall be the annual examination and the second examination shall be supplementary examination.
 - (3) The examinations shall be of written and practical (including oral nature) carrying maximum marks for each part of a subject as indicated in Tables below :

T A B L E S**First Year examination :**

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
1.1	Human Anatomy and Physiology	70	30	100	70	30	100
1.2	Pharmaceutics	70	30	100	70	30	100
1.3	Medicinal Biochemistry	70	30	100	70	30	100
1.4	Pharmaceutical Organic Chemistry	70	30	100	70	30	100
1.5	Pharmaceutical Inorganic Chemistry	70	30	100	70	30	100
1.6	Remedial Mathematics/Biology	70	30	100	70*	30*	100*
				600			600 = 1200

* for Biology.

Second Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
2.1	Pathophysiology	70	30	100	-	-	-
2.2	Pharmaceutical Microbiology	70	30	100	70	30	100
2.3	Pharmacognosy & Phytopharmaceuticals	70	30	100	70	30	100
2.4	Pharmacology-I	70	30	100	-	-	-
2.5	Community Pharmacy	70	30	100	-	-	-
2.6	Pharmacotherapeutics-I	70	30	100	70	30	100
				600			300 = 900

Third Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
3.1	Pharmacology-II	70	30	100	70	30	100
3.2	Pharmaceutical Analysis	70	30	100	70	30	100
3.3	Pharmacotherapeutics-II	70	30	100	70	30	100
3.4	Pharmaceutical Jurisprudence	70	30	100	-	-	-
3.5	Medicinal Chemistry	70	30	100	70	30	100
3.6	Pharmaceutical Formulations	70	30	100	70	30	100
				600			500 = 1100

Fourth Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
4.1	Pharmacotherapeutics-III	70	30	100	70	30	100
4.2	Hospital Pharmacy	70	30	100	70	30	100
4.3	Clinical Pharmacy	70	30	100	70	30	100
4.4	Biostatistics & Research Methodology	70	30	100	-	-	-
4.5	Biopharmaceutics & Pharmacokinetics	70	30	100	70	30	100
4.6	Clinical Toxicology	70	30	100	-	-	-
				600			400 = 1000

Fifth Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
5.1	Clinical Research	70	30	100	-	-	-
5.2	Pharmacoepidemiology and Pharmacoeconomics	70	30	100	-	-	-
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	70	30	100	-	-	-
5.4	Clerkship *	-	-	-	70	30	100
5.5	Project work (Six Months)	-	-	-	100**	-	100
				300			200 = 500

* Attending ward rounds on daily basis.

** 30 marks – viva-voce (oral)

70 marks – Thesis work

11. Eligibility for appearing Examination.— Only such students who produce certificate from the Head of the Institution in which he or she has undergone the Pharm.D. or as the case may be, the Pharm.D. (Post Baccalaureate) course, in proof of his or her having regularly and satisfactorily undergone the course of study by attending not less than 80% of the classes held both in theory and in practical separately in each subject shall be eligible for appearing at examination.

12. Mode of examinations.— (1) Theory examination shall be of three hours and practical examination shall be of four hours duration.

(2) A Student who fails in theory or practical examination of a subject shall re-appear both in theory and practical of the same subject.

(3) Practical examination shall also consist of a viva –voce (Oral) examination.

(4) Clerkship examination – Oral examination shall be conducted after the completion of clerkship of students. An external and an internal examiner will evaluate the student. Students may be asked to present the allotted medical cases followed by discussion. Students' capabilities in delivering clinical pharmacy services, pharmaceutical care planning and knowledge of therapeutics shall be assessed.

13. Award of sessional marks and maintenance of records.— (1) A regular record of both theory and practical class work and examinations conducted in an institution imparting training for Pharm.D. or as the case may be, Pharm.D. (Post Baccalaureate) course, shall be maintained for each student in the institution and 30 marks for each theory and 30 marks for each practical subject shall be allotted as sessional.

(2) There shall be at least two periodic sessional examinations during each academic year and the highest aggregate of any two performances shall form the basis of calculating sessional marks.

(3) The sessional marks in practicals shall be allotted on the following basis:-

(i) Actual performance in the sessional examination (20 marks);

(ii) Day to day assessment in the practical class work, promptness, viva-voce record maintenance, etc. (10 marks).

14. Minimum marks for passing examination.— A student shall not be declared to have passed examination unless he or she secures at least 50% marks in each of the subjects separately in the theory examinations, including sessional marks and at least 50% marks in each of the practical examinations including sessional marks. The students securing 60% marks or above in aggregate in all subjects in a single attempt at the Pharm.D. or as the case may be, Pharm. D. (Post Baccalaureate) course examination shall be declared to have passed in first class. Students securing 75% marks or above in any subject or subjects shall be declared to have passed with distinction in the subject or those subjects provided he or she passes in all the subjects in a single attempt.
15. Eligibility for promotion to next year.— All students who have appeared for all the subjects and passed the first year annual examination are eligible for promotion to the second year and, so on. However, failure in more than two subjects shall debar him or her from promotion to the next year classes.
16. Internship.— (1) Internship is a phase of training wherein a student is expected to conduct actual practice of pharmacy and health care and acquires skills under the supervision so that he or she may become capable of functioning independently.
(2) Every student has to undergo one year internship as per Appendix-C to these regulations.
17. Approval of examinations.— Examinations mentioned in regulations 10 to 12 and 14 shall be held by the examining authority hereinafter referred to as the university, which shall be approved by the Pharmacy Council of India under sub-section (2) of section 12 of the Pharmacy Act, 1948. Such approval shall be granted only if the examining authority concerned fulfills the conditions as specified in Appendix-D to these regulations.
18. Certificate of passing examination.— Every student who has passed the examinations for the Pharm.D. (Doctor of Pharmacy) or Pharm.D. (Post Baccalaureate) (Doctor of Pharmacy) as the case may be, shall be granted a certificate by the examining authority.

CHAPTER-III

Practical training

19. Hospital posting.— Every student shall be posted in constituent hospital for a period of not less than fifty hours to be covered in not less than 200 working days in each of second, third & fourth year course. Each student shall submit report duly certified by the preceptor and duly attested by the Head of the Department or Institution as prescribed. In the fifth year, every student shall spend half a day in the morning hours attending ward rounds on daily basis as a part of clerkship. Theory teaching may be scheduled in the afternoon.

20. Project work.— (1) To allow the student to develop data collection and reporting skills in the area of community, hospital and clinical pharmacy, a project work shall be carried out under the supervision of a teacher. The project topic must be approved by the Head of the Department or Head of the Institution. The same shall be announced to students within one month of commencement of the fifth year classes. Project work shall be presented in a written report and as a seminar at the end of the year. External and the internal examiners shall do the assessment of the project work.
 (2) Project work shall comprise of objectives of the work, methodology, results, discussions and conclusions.

21. Objectives of project work.— The main objectives of the project work is to—
 - (i) show the evidence of having made accurate description of published work of others and of having recorded the findings in an impartial manner; and
 - (ii) develop the students in data collection, analysis and reporting and interpretation skills.

22. Methodology.— To complete the project work following methodology shall be adopted, namely:—
 - (i) students shall work in groups of not less than *two* and not more than *four* under an authorised teacher;
 - (ii) project topic shall be approved by the Head of the Department or Head of the Institution;
 - (iii) project work chosen shall be related to the pharmacy practice in community, hospital and clinical setup. It shall be patient and treatment (Medicine) oriented, like drug utilisation reviews, pharmacoepidemiology, pharmacovigilance or pharmacoeconomics;
 - (iv) project work shall be approved by the institutional ethics committee;
 - (v) student shall present at least three seminars, one in the beginning, one at middle and one at the end of the project work; and
 - (vi) two-page write-up of the project indicating title, objectives, methodology anticipated benefits and references shall be submitted to the Head of the Department or Head of the Institution.

23. Reporting .— (1) Student working on the project shall submit jointly to the Head of the Department or Head of the Institution a project report of about 40-50 pages. Project report should include a certificate issued by the authorised teacher, Head of the Department as well as by the Head of the Institution

(2) Project report shall be computer typed in double space using Times Roman font on A4 paper. The title shall be in bold with font size 18, sub-titles in bold with font size 14 and the text with font size 12. The cover page of the project report shall contain details about the name of the student and the name of the authorised teacher with font size 14.

(3) Submission of the project report shall be done at least one month prior to the commencement of annual or supplementary examination.

24. Evaluation.— The following methodology shall be adopted for evaluating the project work—

(i) Project work shall be evaluated by internal and external examiners.

(ii) Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of four students).

(iii) Three seminars presented by students shall be evaluated for twenty marks each and the average of best two shall be forwarded to the university with marks of other subjects.

(iv) Evaluation shall be done on the following items:	Marks
a) Write up of the seminar	(7.5)
b) Presentation of work	(7.5)
c) Communication skills	(7.5)
d) Question and answer skills	(7.5)
Total	(30 marks)
(v) Final evaluation of project work shall be done on the following items:	Marks
a) Write up of the seminar	(17.5)
b) Presentation of work	(17.5)
c) Communication skills	(17.5)
d) Question and answer skills	(17.5)
Total	(70 marks)

Explanation.— For the purposes of differentiation in the evaluation in case of topic being the same for the group of students, the same shall be done based on item numbers b, c and d mentioned above.

APPENDIX-A

(See regulation 8)

PHARM.D. SYLLABUS

First Year

1.1 HUMAN ANATOMY & PHYSIOLOGY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope and Objectives:** This course is designed to impart a fundamental knowledge on the structure and functions of the human body. It also helps in understanding both homeostasis mechanisms and homeostatic imbalances of various body systems. Since a medicament, which is produced by pharmacist, is used to correct the deviations in human body, it enhances the understanding of how the drugs act on the various body systems in correcting the disease state of the organs.
2. **Upon completion of the course the student shall be able to:**
 - a. describe the structure (gross and histology) and functions of various organs of the human body;
 - b. describe the various homeostatic mechanisms and their imbalances of various systems;
 - c. identify the various tissues and organs of the different systems of the human body;
 - d. perform the hematological tests and also record blood pressure, heart rate, pulse and Respiratory volumes;
 - e. appreciate coordinated working pattern of different organs of each system; and
 - f. appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body

3. Course materials:

Text books

- a. Tortora Gerard J. and Nicholas, P. Principles of anatomy and physiology
Publisher Harpercollins college New York.
- b. Wilson, K.J.W. Ross and Wilson's foundations of anatomy and physiology.
Publisher: Churchill Livingstone, Edinburg.

Reference books

- a. Guyton arthur, C. *Physiology of human body*. Publisher: Holtsaunders.
- b. Chatterjee,C.C. *Human physiology*. Volume 1&11. Publisher: medical allied agency, Calcutta.
- c. Peter L. Williams, Roger Warwick, Mary Dyson and Lawrence, H.
- d. *Gray's anatomy*. Publisher:Churchill Livingstone, London.

4. Lecture wise program :

Topics

- 1 Scope of anatomy and physiology, basic terminologies used in this subject
(Description of the body as such planes and terminologies)
- 2 Structure of cell – its components and their functions.
- 3 Elementary tissues of the human body: epithelial, connective, Muscular and nervous tissues-their sub-types and characteristics
- 4 a) Osseous system - structure, composition and functions of the Skeleton. (done in practical classes - 6hrs)
b) Classification of joints, Types of movements of joints and disorders of joints
(Definitions only)
- 5 Haemopoetic System
a) Composition and functions of blood
b) Haemopoiesis and disorders of blood components (definition of disorder)
c) Blood groups
d) Clotting factors and mechanism
e) Platelets and disorders of coagulation
- 6 Lymph
a) Lymph and lymphatic system, composition, formation and circulation.
b) Spleen: structure and functions, Disorders
c) Disorders of lymphatic system (definition only)
- 7 Cardiovascular system
a) Anatomy and functions of heart
b) Blood vessels and circulation (Pulmonary, coronary and systemic circulation)
c) Electrocardiogram (ECG)
d) Cardiac cycle and heart sounds
e) Blood pressure – its maintenance and regulation
f) Definition of the following disorders
Hypertension, Hypotension, Arteriosclerosis, Atherosclerosis, Angina, Myocardial infarction, Congestive heart failure, Cardiac arrhythmias
- 8 Respiratory system
a) Anatomy of respiratory organs and functions
b) Mechanism / physiology of respiration and regulation of respiration
c) Transport of respiratory gases
d) Respiratory volumes and capacities, and Definition of: Hypoxia, Asphyxia, Dybarism, Oxygen therapy and resuscitation.
- 9 Digestive system
a) Anatomy and physiology of GIT
b) Anatomy and functions of accessory glands of GIT
c) Digestion and absorption
d) Disorders of GIT (definitions only)

10 Nervous system

- a) Definition and classification of nervous system
- b) Anatomy, physiology and functional areas of cerebrum
- c) Anatomy and physiology of cerebellum
- d) Anatomy and physiology of mid brain
- e) Thalamus, hypothalamus and Basal Ganglia
- f) Spinal cord: Structure & reflexes – mono-poly-planter
- g) Cranial nerves – names and functions
- h) ANS – Anatomy & functions of sympathetic & parasympathetic N.S.

11 Urinary system

- a) Anatomy and physiology of urinary system
- b) Formation of urine
- c) Renin Angiotensin system – Juxtaglomerular apparatus - acid base Balance
- d) Clearance tests and micturition

12 Endocrine system

- a) Pituitary gland
- b) Adrenal gland
- c) Thyroid and Parathyroid glands
- d) Pancreas and gonads

13 Reproductive system

- a) Male and female reproductive system
- b) Their hormones – Physiology of menstruation
- c) Spermatogenesis & Oogenesis
- d) Sex determination (genetic basis)
- e) Pregnancy and maintenance and parturition
- f) Contraceptive devices

14 Sense organs

- a) Eye
- b) Ear
- c) Skin
- d) Tongue & Nose

15 Skeletal muscles

- a) Histology
- b) Physiology of Muscle contraction
- c) Physiological properties of skeletal muscle and their disorders (definitions)

16 Sports physiology

- a) Muscles in exercise, Effect of athletic training on muscles and muscle performance,
- b) Respiration in exercise, CVS in exercise, Body heat in exercise, Body fluids and salts in exercise,
- c) Drugs and athletics

1.1 HUMAN ANATOMY & PHYSIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

General Requirements: Dissection box, Laboratory Napkin, muslin cloth, record, Observation book(100pages), Stationary items, Blood lancet.

Course materials:

Text books

Goyal, R. K, Natvar M.P, and Shah S.A, Practical anatomy, physiology and biochemistry, latest edition, Publisher: B.S Shah Prakashan, Ahmedabad.

Reference books

Ranade VG, Text book of practical physiology, Latest edition, Publisher: PVG, Pune
Anderson Experimental Physiology, Latest edition, Publisher: NA

List of Experiments:

1. Study of tissues of human body
 - (a) Epithelial tissue.
 - (b) Muscular tissue.
2. Study of tissues of human body
 - (a) Connective tissue.
 - (b) Nervous tissue.
3. Study of appliances used in hematological experiments.
4. Determination of W.B.C. count of blood.
5. Determination of R.B.C. count of blood.
6. Determination of differential count of blood.
7. Determination of
 - (a) Erythrocyte Sedimentation Rate.
 - (b) Hemoglobin content of Blood.
 - (c) Bleeding time & Clotting time.
8. Determination of
 - (a) Blood Pressure.
 - (b) Blood group.
9. Study of various systems with the help of charts, models & specimens
 - (a) Skeleton system part I-axial skeleton.
 - (b) Skeleton system part II- appendicular skeleton.
 - (c) Cardiovascular system.
 - (d) Respiratory system.

- (e) Digestive system.
- (f) Urinary system.
- (g) Nervous system.
- (h) Special senses.
- (i) Reproductive system.

10. Study of different family planning appliances.
11. To perform pregnancy diagnosis test.
12. Study of appliances used in experimental physiology.
13. To record simple muscle curve using gastrocnemius sciatic nerve preparation.
14. To record simple summation curve using gastrocnemius sciatic nerve preparation.
15. To record simple effect of temperature using gastrocnemius sciatic nerve preparation.
16. To record simple effect of load & after load using gastrocnemius sciatic nerve preparation.
17. To record simple fatigue curve using gastrocnemius sciatic nerve preparation.

Scheme of Practical Examination:

	Sessionals	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.2 PHARMACEUTICS (THEORY)

Theory : 2 Hrs. /Week

1. Scope and objectives: This course is designed to impart a fundamental knowledge on the art and science of formulating different dosage forms. It prepares the students for most basics of the applied field of pharmacy.

2. Upon the completion of the course the student should be able to:

- a. know the formulation aspects of different dosage forms;
- b. do different pharmaceutical calculation involved in formulation;
- c. formulate different types of dosage forms; and
- d. appreciate the importance of good formulation for effectiveness.

3. Course materials:

Text books

- a. Cooper and Gunns Dispensing for pharmacy students.
- b. A text book Professional Pharmacy by N.K.Jain and S.N.Sharma.

Reference books

- a. Introduction to Pharmaceutical dosage forms by Howard C. Ansel.
- b. Remington's Pharmaceutical Sciences.
- c. Register of General Pharmacy by Cooper and Gunn.
- d. General Pharmacy by M.L.Schroff.

4. Lecture wise programme:

Topics

- 1
 - a. Introduction to dosage forms - classification and definitions
 - b. Prescription: definition, parts and handling
 - c. Posology: Definition, Factors affecting dose selection. Calculation of children and infant doses.
- 2 Historical back ground and development of profession of pharmacy and pharmaceutical industry in brief.
- 3 Development of Indian Pharmacopoeia and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.
- 4 Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc.
- 5 Powders and Granules: Classification advantages and disadvantages, Preparation of simple, compound powders, Insufflations, Dusting powders, Eutectic and Explosive powders, Tooth powder and effervescent powders and granules.
- 6 Monophasic Dosage forms: Theoretical aspects of formulation including adjuvant like stabilizers, colorants, flavours with examples. Study of Monophasic liquids like gargles, mouth washes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions.

- 7 Biphasic dosage forms: Suspensions and emulsions, Definition, advantages and disadvantages, classification, test for the type of emulsion, formulation, stability and evaluation.
- 8 Suppositories and pessaries: Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation.
- 9 Galenicals: Definition, equipment for different extraction processes like infusion, Decoction, Maceration and Percolation, methods of preparation of spirits, tinctures and extracts.
- 10 Pharmaceutical calculations.
- 11 Surgical aids: Surgical dressings, absorbable gelatin sponge, sutures, ligatures and medicated bandages.
- 12 Incompatibilities: Introduction, classification and methods to overcome the incompatibilities.

1.2 PHARMACEUTICS (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments:

- 1. Syrups**
 - a. Simple Syrup I.P
 - b. Syrup of Ephedrine Hcl NF
 - c. Syrup Vasaka IP
 - d. Syrup of ferrous Phosphate IP
 - e. Orange Syrup
- 2. Elixir**
 - a. Piperizine citrate elixir BP
 - b. Cascara elixir BPC
 - c. Paracetamol elixir BPC
- 3. Linctus**
 - a. Simple Linctus BPC
 - b. Pediatric simple Linctus BPC
- 4. Solutions**
 - a. Solution of cresol with soap IP
 - b. Strong solution of ferric chloride BPC
 - c. Aqueous Iodine Solution IP
 - d. Strong solution of Iodine IP
 - e. Strong solution of ammonium acetate IP

- 5. Liniments**
 - a. Liniment of turpentine IP*
 - b. Liniment of camphor IP
- 6. Suspensions***
 - a. Calamine lotion
 - b. Magnesium Hydroxide mixture BP
- 7. Emulsions***
 - a. Cod liver oil emulsion
 - b. Liquid paraffin emulsion
- 8. Powders***
 - a. Eutectic powder
 - b. Explosive powder
 - c. Dusting powder
 - d. Insufflations
- 9. Suppositories***
 - a. Boric acid suppositories
 - b. Chloral suppositories
- 10. Incompatibilities**
 - a. Mixtures with Physical
 - b. Chemical & Therapeutic incompatibilities

* colourless bottles required for dispensing * Paper envelope (white), butter paper and white paper required for dispensing.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.3 MEDICINAL BIOCHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

1. Scope of the Subject: Applied biochemistry deals with complete understanding of the molecular level of the chemical process associated with living cells. Clinical chemistry deals with the study of chemical aspects of human life in health and illness and the application of chemical laboratory methods to diagnosis, control of treatment, and prevention of diseases.

2. Objectives of the Subject (Know, do, appreciate) :

The objective of the present course is providing biochemical facts and the principles to the students of pharmacy. Upon completion of the subject student shall be able to –

- a. understand the catalytic activity of enzymes and importance of isoenzymes in diagnosis of diseases;
- b. know the metabolic process of biomolecules in health and illness (metabolic disorders);
- c. understand the genetic organization of mammalian genome; protein synthesis; replication; mutation and repair mechanism;
- d. know the biochemical principles of organ function tests of kidney, liver and endocrine gland; and
- e. do the qualitative analysis and determination of biomolecules in the body fluids.

Text books (Theory)

- a. Harpers review of biochemistry - Martin
- b. Text book of biochemistry – D.Satyanarayana
- c. Text book of clinical chemistry- Alex kaplan & Laverve L.Szabo

Reference books (Theory)

- a. Principles of biochemistry -- Lehninger
- b. Text book of biochemistry -- Ramarao
- c. Practical Biochemistry-David T.Plummer.
- d. Practical Biochemistry-Pattabhiraman.

3. Lecture wise programme:

Topics

- 1 **Introduction to biochemistry:** Cell and its biochemical organization, transport process across the cell membranes. Energy rich compounds; ATP, Cyclic AMP and their biological significance.
- 2 **Enzymes:** Definition; Nomenclature; IUB classification; Factor affecting enzyme activity; Enzyme action; enzyme inhibition. Isoenzymes and their therapeutic and diagnostic applications; Coenzymes and their biochemical role and deficiency diseases.
- 3 **Carbohydrate metabolism:** Glycolysis, Citric acid cycle (TCA cycle), HMP shunt, Glycogenolysis, gluconeogenesis, glycogenesis. Metabolic disorders of carbohydrate metabolism (diabetes mellitus and glycogen storage diseases); Glucose, Galactose tolerance test and their significance; hormonal regulation of carbohydrate metabolism.

- 4 **Lipid metabolism:** Oxidation of saturated (β -oxidation); Ketogenesis and ketolysis; biosynthesis of fatty acids, lipids; metabolism of cholesterol; Hormonal regulation of lipid metabolism. Defective metabolism of lipids (Atherosclerosis, fatty liver, hypercholesterolemia).
- 5 **Biological oxidation:** Coenzyme system involved in Biological oxidation. Electron transport chain (its mechanism in energy capture; regulation and inhibition); Uncouplers of ETC; Oxidative phosphorylation;
- 6 **Protein and amino acid metabolism:** protein turn over; nitrogen balance; Catabolism of Amino acids (Transamination, deamination & decarboxylation). Urea cycle and its metabolic disorders; production of bile pigments; hyperbilirubinemia, porphoria, jaundice. Metabolic disorder of Amino acids.
- 7 **Nucleic acid metabolism:** Metabolism of purine and pyrimidine nucleotides; Protein synthesis; Genetic code; inhibition of protein synthesis; mutation and repair mechanism; DNA replication (semiconservative /onion peel models) and DNA repair mechanism.
- 8 **Introduction to clinical chemistry: Cell;** composition; malfunction; Roll of the clinical chemistry laboratory.
- 9 **The kidney function tests:** Role of kidney; Laboratory tests for normal function includes-
 - a) Urine analysis (macroscopic and physical examination, quantitative and semiquantitative tests.)
 - b) Test for NPN constituents. (Creatinine /urea clearance, determination of blood and urine creatinine, urea and uric acid)
 - c) Urine concentration test
 - d) Urinary tract calculi. (stones)
- 10 **Liver function tests:** Physiological role of liver, metabolic, storage, excretory, protective, circulatory functions and function in blood coagulation.
 - a) Test for hepatic dysfunction-Bile pigments metabolism.
 - b) Test for hepatic function test- Serum bilirubin, urine bilirubin, and urine urobilinogen.
 - c) Dye tests of excretory function.
 - d) Tests based upon abnormalities of serum proteins.
 Selected enzyme tests.
- 11 **Lipid profile tests:** Lipoproteins, composition, functions. Determination of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides.
- 12 **Immunochemical techniques** for determination of hormone levels and protein levels in serum for endocrine diseases and infectious diseases.
Radio immuno assay (RIA) and Enzyme Linked Immuno Sorbent Assay (ELISA)
- 13 **Electrolytes:** Body water, compartments, water balance, and electrolyte distribution. Determination of sodium, calcium potassium, chlorides, bicarbonates in the body fluids.

1.3 MEDICINAL BIOCHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

Title of the Experiment:

- 1 Qualitative analysis of normal constituents of urine.*
 - 2 Qualitative analysis of abnormal constituents of urine.*
 - 3 Quantitative estimation of urine sugar by Benedict's reagent method.**
 - 4 Quantitative estimation of urine chlorides by Volhard's method.**
 - 5 Quantitative estimation of urine creatinine by Jaffe's method.**
 - 6 Quantitative estimation of urine calcium by precipitation method.**
 - 7 Quantitative estimation of serum cholesterol by Libermann Burchard's method.**
 - 8 Preparation of Folin Wu filtrate from blood.*
 - 9 Quantitative estimation of blood creatinine.**
 - 10 Quantitative estimation of blood sugar Folin-Wu tube method.**
 - 11 Estimation of SGOT in serum.**
 - 12 Estimation of SGPT in serum.**
 - 13 Estimation of Urea in Serum.**
 - 14 Estimation of Proteins in Serum.**
 - 15 Determination of serum bilirubin**
 - 16 Determination of Glucose by means of Glucoseoxidase.**
 - 17 Enzymatic hydrolysis of Glycogen/Starch by Amylases.**
 - 18 Study of factors affecting Enzyme activity. (pH & Temp.)**
 - 19 Preparation of standard buffer solutions and its pH measurements (any two)*
 - 20 Experiment on lipid profile tests**
 - 21 Determination of sodium, calcium and potassium in serum.**
- ** indicate major experiments & * indicate minor experiments

Assignments:

Format of the assignment

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.4 PHARMACEUTICAL ORGANIC CHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

- 1. Scope and objectives:** This course is designed to impart a very good knowledge about
 - a. IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds;
 - b. Some important physical properties of organic compounds;
 - c. Free radical/ nucleophilic [alkyl/ acyl/ aryl] /electrophilic substitution, free radical/ nucleophilic / electrophilic addition, elimination, oxidation and reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability of compounds;
 - d. Some named organic reactions with mechanisms; and
 - e. Methods of preparation, test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.

2. Course materials:

Text books

- a. T.R.Morrison and R. Boyd - Organic chemistry,
- b. Bentley and Driver-Text book of Pharmaceutical chemistry
- c. I.L.Finer- Organic chemistry, the fundamentals of chemistry

Reference books

- a. Organic chemistry – J.M.Cram and D.J.Cram
- b. Organic chemistry- Brown
- c. Advanced organic chemistry- Jerry March, Wiley
- d. Organic chemistry- Cram and Hammered, Pine Hendrickson

3. Lecture wise programme :

Topics

- 1 Structures and Physical properties:
 - a. Polarity of bonds, polarity of molecules, M.P, Inter molecular forces, B.P, Solubility, non ionic solutes and ionic solutes, protic and aprotic Solvents, ion pairs,
 - b. Acids and bases, Lowry bronsted and Lewis theories
 - c. Isomerism
- 2 Nomenclature of organic compound belonging to the following classes Alkanes, Alkenes, Dienes, Alkynes, Alcohols, Aldehydes, Ketones, Amides, Amines, Phenols, Alkyl Halides, Carboxylic Acid, Esters, Acid Chlorides And Cycloalkanes.
- 3 Free radicals chain reactions of alkane : Mechanism, relative reactivity and stability
- 4 Alicyclic compounds : Preparations of cyclo alkanes, Bayer strain theory and orbital picture of angle strain.
- 5 Nucleophilic aliphatic substitution mechanism: Nucleophiles and leaving groups, kinetics of second and first order reaction, mechanism and kinetics of SN_2 reactions. Stereochemistry and steric hindrance, role of solvents, phase transfer catalysis, mechanism and kinetics of SN_1 reactions, stereochemistry, carbocation and their stability, rearrangement of carbocation, role of solvents in SN_1 reaction, Ion dipole bonds, SN_2 versus SN_1 solvolyses, nucleophilic assistance by the solvents.

- 6 Dehydro halogenation of alkyl halides: 1,2 elimination, kinetics, E2 and E1 mechanism, elimination via carbocation, evidence for E2 mechanism, absence of rearrangement isotope effect, absence hydrogen exchange, the element effect, orientation and reactivity, E2 versus E1, elimination versus substitution, dehydration of alcohol, ease of dehydration, acid catalysis, reversibility, orientation.
- 7 Electrophillic and free radicals addition: Reactions at carbon-carbon, double bond, electrophile, hydrogenation, heat of hydrogenation and stability of alkenes, markownikoff rule, addition of hydrogen halides, addition of hydrogen bromides, peroxide effect, electrophillic addition, mechanism, rearrangement, absence of hydrogen exchange, orientation and reactivity, addition of halogen, mechanism, halohydrin formation, mechanism of free radicals additon, mechanism of peroxide initiated addition of hydrogen bromide, orientation of free addition, additions of carbene to alkene, cyclo addition reactions.
- 8 Carbon-carbon double bond as substituents: Free radical halogenations of alkenes, comparision of free radical substitution with free radical addition, free radical substitution in alkenes, orientation and reactivity, allylic rearrangements.
- 9 Theory of resonance: Allyl radical as a resonance hybrid, stability, orbital picture, resonance stabilisation of allyl radicals, hyper conjugation, allyl cation as a resonance hybrid, nucleophyllic substitution in allylic substrate, SN1 reactivity, allylic rearrangement, resonance stabilisation of allyl cation, hyper conjugation, nucleophilic substitution in allylic substrate, SN2 nucleophilic substituion in vinylic substrate, vinylic cation, stability of conjugated dienes, resonance in alkenes, hyper conjugation, ease of formation of conjugated dienes, orientation of elimination, electrophilic addition to conjugated dienes, 1,4- addition, 1,2-versus 1,4-addition, rate versus equilibrium, orientation and reactivity of free radical addition to conjugated dienes.
- 10 Electrophilic aromatic substitution: Effect of substituent groups, determination of orientation, determination of relative reactivity, classification of substituent group, mechanism of nitration, sulphonation, halogenation, friedel craft alkylation, friedel craft acylation, reactivity and orientation, activating and deactivating O,P,M directing groups, electron release via resonance, effect of halogen on electrophilic aromatic substitution in alkyl benzene, side chain halogination of alkyl benzene, resonance stabilization of benzyl radical.
- 11 Nucleophilic addition reaction: Mechanism, ionisation of carboxylic acids, acidity constants, acidity of acids, structure of carboxylate ions, effect of substituent on acidity, nucleophilic acyl substitution reaction, conversion of acid to acid chloride, esters, amide and anhydride. Role of caboxyl group, comparison of alkyl nucleophilic substitution with acyl nucleophilic substitution.

- 12 Mechanism of aldol condensation, claisen condensation, cannizzaro reaction, crossed aldol condensation, crossed cannizzaro reaction, benzoin condensation, perkin condensation. Knoevenagel, Reformatsky reaction, Wittig reaction, Michael addition.
- 13 Hoffman rearrangement: Migration to electron deficient nitrogen, Sandmeyer's reaction, basicity of amines, diazotisation and coupling, acidity of phenols, Williamson synthesis, Fries rearrangement, Kolbe reaction, Reimer tieman's reactions.
- 14 Nucleophilic aromatic substitution: Bimolecular displacement mechanisms, orientation, comparison of aliphatic nucleophilic substitution with that of aromatic.
- 15 Oxidation reduction reaction.
- 16 Study of the following official compounds- preparation, test for purity, assay and medicinal uses of Chlorbutol, Dimercaprol, Glyceryl trinitrate, Urea, Ethylene diamine dihydrate, Vanillin, Paraldehyde, Ethylene chloride, Lactic acid, Tartaric acid, citric acid, salicylic acid, aspirin, methyl salicylate, ethyl benzoate, benzyl benzoate, dimethyl phthalate, sodium lauryl sulphate, saccharin sodium, mephensin.

1.4 PHARMACEUTICAL ORGANIC CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

I. Introduction to the various laboratory techniques through demonstration involving synthesis of the following compounds (at least 8 compounds to be synthesised):

1. Acetanilide / aspirin (Acetylation)
2. Benzanilide / Phenyl benzoate (Benzoylation)
3. P-bromo acetanilide / 2,4,6 – tribromo aniline (Bromination)
4. Dibenzylidene acetone (Condensation)
5. 1-Phenylazo-2-naphthol (Diazotisation and coupling)
6. Benzoic acid / salicylic acid (Hydrolysis of ester)
7. M-dinitro benzene (Nitration)
8. 9, 10 – Anthraquinone (Oxidation of anthracene) / preparation of benzoic acid from toluene or benzaldehyde
9. M-phenylene diamine (Reduction of M-dinitrobenzene) / Aniline from nitrobenzene
10. Benzophenone oxime
11. Nitration of salicylic acid
12. Preparation of picric acid
13. Preparation of O-chlorobenzoic acid from O-chlorotoluene
14. Preparation of cyclohexanone from cyclohexanol

II. Identification of organic compounds belonging to the following classes by :

Systematic qualitative organic analysis including preparation of derivatives
Phenols, amides, carbohydrates, amines, carboxylic acids, aldehyde and ketones,
Alcohols, esters, hydrocarbons, anilides, nitrocompounds.

III. Introduction to the use of stereo models:

Methane, Ethane, Ethylene, Acetylene, Cis alkene, Trans alkene, inversion of configuration.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.5 PHARMACEUTICAL INORGANIC CHEMISTRY (THEORY)

Theory : 2 Hrs. /Week

1. **Scope and objectives:** This course mainly deals with fundamentals of Analytical chemistry and also the study of inorganic pharmaceuticals regarding their monographs and also the course deals with basic knowledge of analysis of various pharmaceuticals.
2. **Upon completion of the course student shall be able to:**
 - a. under stand the principles and procedures of analysis of drugs and also regarding the application of inorganic pharmaceuticals;
 - b. know the analysis of the inorganic pharmaceuticals their applications; and
 - c. appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.

3. Course materials:

Text books

- a. A text book Inorganic medicinal chemistry by Surendra N. Pandeya
- b. A. H. Beckett and J. B. Stanlake's Practical Pharmaceutical chemistry Vol-I & Vol-II
- c. Inorganic Pharmaceutical Chemistry III-Edition P.Gundu Rao

Reference books

- a. Inorganic Pharmaceutical Chemistry by Anand & Chetwal
- b. Pharmaceutical Inorganic chemistry by Dr.B.G.Nagavi
- c. Analytical chemistry principles by John H. Kennedy
- d. I.P.1985 and 1996, Govt. of India, Ministry of health

4. Lecture wise programme:

Topics

- 1 Errors
- 2 Volumetric analysis
- 3 Acid-base titrations
- 4 Redox titrations
- 5 Non aqueous titrations
- 6 Precipitation titrations
- 7 Complexometric titrations
- 8 Theory of indicators
- 9 Gravimetry
- 10 Limit tests
- 11 Medicinal gases
- 12 Acidifiers
- 13 Antacids
- 14 Cathartics
- 15 Electrolyte replenishers

- 16 Essential Trace elements
- 17 Antimicrobials
- 18 Pharmaceutical aids
- 19 Dental Products
- 20 Miscellaneous compounds
- 21 Radio Pharmaceuticals

1.5 PHARMACEUTICAL INORGANIC CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

1. Limit test (6 exercises)

- a. Limit test for chlorides
- b. Limit test for sulphates
- c. Limit test for iron
- d. Limit test for heavy metals
- e. Limit test for arsenic
- f. Modified limit tests for chlorides and sulphates

2. Assays (10 exercises)

- a. Ammonium chloride- Acid-base titration
- b. Ferrous sulphate- Cerimetry
- c. Copper sulphate- Iodometry
- d. Calcium gluconate- Complexometry
- e. Hydrogen peroxide – Permanganometry
- f. Sodium benzoate – Nonaqueous titration
- g. Sodium chloride – Modified volhard's method
- h. Assay of KI – KIO_3 titration
- i. Gravimetric estimation of barium as barium sulphate
- j. Sodium antimony gluconate or antimony potassium tartarate

3. Estimation of mixture (Any two exercises)

- a. Sodium hydroxide and sodium carbonate
- b. Boric acid and Borax
- c. Oxalic acid and sodium oxalate

4. Test for identity (Any three exercises)

- a. Sodium bicarbonate
- b. Barium sulphate
- c. Ferrous sulphate
- d. Potassium chloride

5. Test for purity (Any two exercises)

- a. Swelling power in Bentonite
- b. Acid neutralising capacity in aluminium hydroxide gel
- c. Ammonium salts in potash alum
- d. Adsorption power heavy Kaolin
- e. Presence of Iodates in KI

6. Preparations (Any two exercises)

- a. Boric acids
- b. Potash alum
- c. Calcium lactate
- d. Magnesium sulphate

Scheme of Practical Examination :

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment1&2	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.6 REMEDIAL MATHEMATICS/BIOLOGY (THEORY)

Theory : 3 Hrs. /Week

REMEDIAL MATHEMATICS :

1. **Scope and objectives:** This is an introductory course in mathematics. This subjects deals with the introduction to matrices, determinants, trigonometry, analytical geometry, differential calculus, integral calculus, differential equations, laplace transform.
2. **Upon completion of the course the student shall be able to : –**
 - a. Know Trigonometry, Analytical geometry, Matrices, Determinant, Integration, Differential equation, Laplace transform and their applications;
 - b. solve the problems of different types by applying theory; and
 - c. appreciate the important applications of mathematics in pharmacy.

3. Course materials:

Text books

- a. Differential calculus By Shantinakaran
- b. Text book of Mathematics for second year pre-university by Prof.B.M.Sreenivas

Reference books

- a. Integral calculus By Shanthinarayan
- b. Engineering mathematics By B.S.Grewal
- c. Trigonometry Part-I By S.L.Loney

4. Lecture wise programme :

Topics

- 1 **Algebra :** Determinants, Matrices
- 2 **Trigonometry :** Sides and angles of a triangle, solution of triangles
- 3 **Analytical Geometry :**Points, Straight line, circle, parabola
- 4 **Differential calculus:** Limit of a function, Differential calculus, Differentiation of a sum, Product, Quotient Composite, Parametric, exponential, trigonometric and Logarithmic function. Successive differentiation, Leibnitz's theorem, Partial differentiation, Euler's theorem on homogeneous functions of two variables
- 5 **Integral Calculus:** Definite integrals, integration by substitution and by parts, Properties of definite integrals.
- 6 **Differential equations:** Definition, order, degree, variable separable, homogeneous, Linear, heterogeneous, linear, differential equation with constant coefficient, simultaneous linear equation of second order.
- 7 **Laplace transform:** Definition, Laplace transform of elementary functions, Properties of linearity and shifting.

BIOLOGY :

1. **Scope and objectives:** This is an introductory course in Biology, which gives detailed study of natural sources such as plant and animal origin. This subject has been introduced to the pharmacy course in order to make the student aware of various naturally occurring drugs and its history, sources, classification, distribution and the characters of the plants and animals. This subject gives basic foundation to Pharmacognosy.

2. **Course materials:**

Text books

- a. Text book of Biology by S.B.Gokhale
- b. A Text book of Biology by Dr.Thulajappa and Dr. Seetaram.

Reference books

- a. A Text book of Biology by B.V.Sreenivasa Naidu
- b. A Text book of Biology by Naidu and Murthy
- c. Botany for Degree students By A.C.Dutta.
- d. Outlines of Zoology by M.Ekambaramanatha ayyer and T.N.Ananthakrishnan.
- e. A manual for pharmaceutical biology practical by S.B.Gokhale and C.K.Kokate.

3. **Lecture wise programme :**

Topic

PART – A

- 01 Introduction
- 02 General organization of plants and its inclusions
- 03 Plant tissues
- 04 Plant kingdom and its classification
- 05 Morphology of plants
- 06 Root, Stem, Leaf and Its modifications
- 07 Inflorescence and Pollination of flowers
- 08 Morphology of fruits and seeds
- 09 Plant physiology
- 10 Taxonomy of Leguminosae, umbelliferae, Solanaceae, Liliaceae, Zinziberaceae, Rubiaceae
- 11 Study of Fungi, Yeast, Penicillin and Bacteria

PART-B

- 01 Study of Animal cell
- 02 Study animal tissues
- 03 Detailed study of frog
- 04 Study of Pisces, Raptiles, Aves
- 05 General organization of mammals
- 06 Study of poisonous animals

1.6 BIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

Title:

1. Introduction of biology experiments
2. Study of cell wall constituents and cell inclusions
3. Study of Stem modifications
4. Study of Root modifications
5. Study of Leaf modifications
6. Identification of Fruits and seeds
7. Preparation of Permanent slides
8. T.S. of Senna, Cassia, Ephedra, Podophyllum.
9. Simple plant physiological experiments
10. Identification of animals
11. Detailed study of Frog
12. Computer based tutorials

Scheme of Practical Examination :

	Sessionals	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance.

Second year

2.1 PATHOPHYSIOLOGY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic Pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge of its application in other subject of pharmacy.
2. **Objectives of the Subject :** Upon completion of the subject student shall be able to –
 - a. describe the etiology and pathogenesis of the selected disease states;
 - b. name the signs and symptoms of the diseases; and
 - c. mention the complications of the diseases.

Text books (Theory)

- a. Pathologic basis of disease by- Cotran, Kumar, Robbins
- b. Text book of Pathology- Harsh Mohan
- c. Text book of Pathology- Y.M. Bhide

Reference books (Theory)

- a. Clinical Pharmacy and Therapeutics; Second edition; Roger Walker; Churchill Livingstone publication

3. Detailed syllabus and lecture wise schedule :

Chapter

- 1 **Basic principles of cell injury and Adaptation**
 - a) Causes, Pathogenesis and morphology of cell injury
 - b) Abnormalities in lipoproteinaemia, glycogen infiltration and glycogen infiltration and glycogen infiltration and glycogen storage diseases
- 2 **Inflammation**
 - a) Pathogenesis of acute inflammation, Chemical mediators in inflammation, Types of chronic inflammation
 - b) Repairs of wounds in the skin, factors influencing healing of wounds
- 3 **Diseases of Immunity**
 - a) Introduction to T and B cells
 - b) MHC proteins or transplantation antigens
 - c) Immune tolerance
 - Hypersensitivity
 - Hypersensitivity type I, II, III, IV, Biological significance, Allergy due to food, chemicals and drugs
 - Autoimmunity
 - Criteria for autoimmunity, Classifications of autoimmune diseases in man, mechanism of autoimmunity, Transplantation and immunologic tolerance, allograft rejections, transplantation antigens, mechanism of rejection of allograft.
 - Acquired immune deficiency syndrome (AIDS)

- Amylodosis

- 4 **Cancer:** differences between benign and malignant tumors, Histological diagnosis of malignancy, invasions and metastasis, patterns of spread, disturbances of growth of cells, classification of tumors, general biology of tumors, spread of malignant tumors, etiology and pathogenesis of cancer.
- 5 Types of shock, mechanisms, stages and management
- 6 Biological effects of radiation
- 7 Environmental and nutritional diseases
 - i) Air pollution and smoking- SO₂, NO, NO₂, and CO
 - ii) Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation.
- 8 Pathophysiology of common diseases
 - a. Parkinsonism
 - b. Schizophrenia
 - c. Depression and mania
 - d. Hypertension,
 - e. Stroke (ischaemic and hemorrhage)
 - f. Angina, CCF, Atherosclerosis, Myocardial infarction
 - g. Diabetes Mellitus
 - h. Peptic ulcer and inflammatory bowel diseases
 - i. Cirrhosis and Alcoholic liver diseases
 - j. Acute and chronic renal failure
 - k. Asthma and chronic obstructive airway diseases
- 9 Infectious diseases :
Sexually transmitted diseases (HIV, Syphilis, Gonorrhea), Urinary tract infections, Pneumonia, Typhoid, Tuberculosis, Leprosy, Malaria Dysentery (bacterial and amoebic), Hepatitis- infective hepatitis.

4. Assignments :

Title of the Experiment

- 1 Chemical Mediators of inflammation
- 2 Drug Hypersensitivity
- 3 Cigarette smoking & its ill effects
- 4 Biological Effects of Radiation
- 5 Etiology and hazards of obesity
- 6 Complications of diabetes
- 7 Diagnosis of cancer
- 8 Disorders of vitamins
- 9 Methods in Pathology-Laboratory values of clinical significance
- 10 Pathophysiology of Dengue Hemorrhagic Fever (DHF)

Format of the assignment

- 1 Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy.
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

2.2 PHARMACEUTICAL MICROBIOLOGY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** Microbiology has always been an essential component of pharmacy curriculum. This is because of the relevance of microbiology to pharmaceutical sciences and more specifically to pharmaceutical industry. Pharmaceutical biotechnology is the logical extension of pharmaceutical microbiology, which is expected to change the complete drug product scenario in the future.

This course deals with the various aspects of microorganisms, its classification, morphology, laboratory cultivation identification and maintenance. It also discusses with sterilization of pharmaceutical products, equipment, media etc. The course further discusses the immunological preparations, diseases its transmission, diagnosis, control and immunological tests.

2. **Objectives of the Subject :**

Upon completion of the subject student shall be able to –

- a. know the anatomy, identification, growth factors and sterilization of microorganisms;
- b. know the mode of transmission of disease causing microorganism, symptoms of disease, and treatment aspect;
- c. do estimation of RNA and DNA and there by identifying the source;
- d. do cultivation and identification of the microorganisms in the laboratory;
- e. do identification of diseases by performing the diagnostic tests; and
- f. appreciate the behavior of motility and behavioral characteristics of microorganisms.

Text books (Theory)

- a. Vanitha Kale and Kishor Bhusari “ Applied Microbiology ” Himalaya Publishing house Mumbai.
- b. Mary Louis Turgeon “ Immunology and Serology in Laboratory Medicines” 2nd edition, 1996 Mosby- Year book inc St. Louis Missouri 63146.
- c. Harsh Mohan, “ Text book of Pathology” 3rd edition, 1998, B-3 Ansari road Darya ganj N. Delhi.

Reference books (Theory)

- a. Prescott L.M., Jarley G.P Klein D.A “Microbiology” 2nd- edition Mc Graw Hill Company Inc
- b. Rawlins E.A.”Bentley’s Text Book of Pharmaceutics” B ailliere Tindals 24-28 London 1988
- c. Forbisher “ Fundamentals of Microbiology” Philadelphia W.B. Saunders.
- d. Prescott L.M. Jarley G.P., Klein.D.A. “ Microbiology.”2nd edition WMC Brown Publishers, Oxford. 1993
- e. War Roitt, Jonathan Brostoff, David male, “ Immunology”3rd edition 1996, Mosby-year book Europe Ltd, London.
- f. Pharmacopoeia of India, Govt of India, 1996.

3. Detailed syllabus and lecture wise schedule :

Title of the topic

- 1 Introduction to the science of microbiology. Major divisions of microbial world and Relationship among them.
- 2 Different methods of classification of microbes and study of Bacteria, Fungi, virus, Rickettsiae, Spirochetes.
- 3 Nutritional requirements, growth and cultivation of bacteria and virus. Study of different important media required for the growth of aerobic and anaerobic bacteria & fungi. Differential media, enriched media and selective media, maintenance of lab cultures.
- 4 Different methods used in isolation and identification of bacteria with emphasis to different staining techniques and biochemical reactions. Counting of bacteria -Total and Viable counting techniques.
- 5 Detailed study of different methods of sterilization including their merits and demerits. Sterilization methods for all pharmaceutical products. Detailed study of sterility testing of different pharmaceutical preparations . Brief information on Validation.
- 6 Disinfectants- Study of disinfectants, antiseptics, fungicidal and virucidal agents factors affecting their activation and mechanism of action. Evaluation of bactericidal, bacteristatic, , virucidal activities, evaluation of preservatives in pharmaceutical preparations.
- 7 Immunology- Immunity, Definition, Classification, General principles of natural immunity, Phagocytosis, acquired immunity(active and passive) . Antigens, chemical nature of antigens structure and formation of Antibodies, Antigen-Antibody reactions. Bacterial exotoxins and endotoxins. Significance of toxoids in active immunity, Immunization programme, and importance of booster dose.
- 8 Diagnostic tests : Schick's Test, Elisa test, Western Blot test, Southern Blot PCR Widal, QBC, Mantoux Peripheral smear. Study of malarial parasite.
- 9 Microbial culture sensitivity Testing: Interpretation of results Principles and methods of different microbiological assays, microbiological assay of Penicillin, Streptomycin and vitamin B₂ and B₁₂. Standardisation of vaccines and sera.
- 10 Study of infectious diseases: Typhoid, Tuberculosis, Malaria, Cholera, Hepatitis, Meningitis, Syphilis & Gonorrhea and HIV.

2.2 PHARMACEUTICAL MICROBIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

Title of the Experiment:

- 1 Study of apparatus used in experimental microbiology*.
- 2 Sterilisation of glass ware's. Preparation of media and sterilisation.*
- 3 Staining techniques – Simple staining ; Gram's staining ; Negative staining**
- 4 Study of motility characters*.
- 5 Enumeration of micro-organisms (Total and Viable)*
- 6 Study of the methods of isolation of pure culture.*
- 7 Bio chemical testing for the identification of micro*-organisms.

- 8 Cultural sensitivity testing for some micro-organisms.*
- 9 Sterility testing for powders and liquids.*
- 10 Determination of minimum inhibitory concentration.*
- 11 Microbiological assay of antibiotics by cup plate method.*
- 12 Microbiological assay of vitamins by Turbidometric method**
- 13 Determination of RWC.**
- 14 Diagnostic tests for some common diseases, Widal, malarial parasite.**

* Indicate minor experiment & ** indicate major experiment

Assignments:

- 1 Visit to some pathological laboratories & study the activities and equipment/instruments used and reporting the same.
2. Visit to milk dairies (Pasturization) and microbial laboratories (other sterilization methods) & study the activities and equipment/instruments used and reporting the same.
3. Library assignments
 - a. Report of recent microbial techniques developed in diagnosing some common diseases.
 - b. Latest advancement developed in identifying, cultivating & handling of microorganisms.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

2.3 PHARMACOGNOSY & PHYTOPHARMACEUTICALS (THEORY)

Theory : 3 Hrs. /Week

1. **Scope and objectives:** This subject has been introduced for the pharmacy course in order to make the student aware of medicinal uses of various naturally occurring drugs its history, sources, distribution, method of cultivation, active constituents, medicinal uses, identification tests, preservation methods, substitutes and adulterants.
2. **Upon completion of the course student shall be able to:**
 - a. under stand the basic principles of cultivation, collection and storage of crude drugs;
 - b. know the source, active constituents and uses of crude drugs; and
 - c. appreciate the applications of primary and secondary metabolites of the plant.

3. Course materials:

Text books

- a. Pharmacognosy by G.E. Trease & W.C.Evans.
- b. Pharmacognosy by C.K.Kokate,Gokhale & A.C.Purohit.

Reference books

- a. Pharmacognosy by Brady &Tyler.E.
- b. Pharmacognosy by T.E.Wallis.
- c. Pharmacognosy by C.S. Shah & Qadery.
- d. Pharmacognosy by M.A. Iyengar.

4. Lecture wise programme:

Topics

- 1 Introduction.
- 2 Definition, history and scope of Pharmacognosy.
- 3 Classification of crude drugs.
- 4 Cultivation, collection, processing and storage of crude drugs.
- 5 Detailed method of cultivation of crude drugs.
- 6 Study of cell wall constituents and cell inclusions.
- 7 Microscopical and powder Microscopical study of crude drugs.
- 8 Study of natural pesticides.
- 9 Detailed study of various cell constituents.
- 10 Carbohydrates and related products.
- 11 Detailed study carbohydrates containing drugs.(11 drugs)
- 12 Definition sources, method extraction, chemistry and method of analysis of lipids.
- 13 Detailed study of oils.
- 14 Definition, classification, chemistry and method of analysis of protein.
- 15 Study of plants fibers used in surgical dressings and related products.
- 16 Different methods of adulteration of crude drugs.

2.3 PHARMACOGNOSY & PHYTOPHARMACEUTICALS (PRACTICAL)

Practical : 3 Hrs./Week

General Requirements: Laboratory Napkin, Observation Book 150 pages Zero brush, Needle, Blade, Match box.

List of experiments:

- 1 Introduction of Pharmacognosy laboratory and experiments.
- 2 Study of cell wall constituents and cell inclusions.
- 3 Macro, powder and microscopic study of Datura.
- 4 Macro, powder and microscopic study of Senna.
- 5 Macro, powder and microscopic study of Cassia.cinnamon.
- 6 Macro, powder and microscopic study of Cinchona.
- 7 Macro, powder and microscopic study of Ephedra.
- 8 Macro, powder and microscopic study of Quassia.
- 9 Macro, powder and microscopic study of Clove
- 10 Macro, powder and microscopic study of Fennel.
- 11 Macro, powder and microscopic study of Coriander.
- 12 Macro, powder and microscopic study of Isapgol.
- 13 Macro, powder and microscopic study of Nux vomica.
- 14 Macro, powder and microscopic study of Rauwolfia.
- 15 Macro, powder and microscopic study of Liquorice.
- 16 Macro, powder and microscopic study of Ginger.
- 17 Macro, powder and microscopic study of Podophyllum.
- 18 Determination of Iodine value.
- 19 Determination of Saponification value and unsaponifiable matter.
- 20 Determination of ester value.
- 21 Determination of Acid value.
- 22 Chemical tests for Acacia.
- 23 Chemical tests for Tragacanth.
- 24 Chemical tests for Agar.
- 25 Chemical tests for Starch.
- 26 Chemical tests for Lipids.(castor oil,sesame oil, shark liver oil,bees wax)
- 27 Chemical tests for Gelatin.

Scheme of Practical Examination:

	Sessionals	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance.

2.4 PHARMACOLOGY – I (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, apart from general pharmacology, drugs acting on autonomic nervous system, cardiovascular system, central nervous system, blood and blood forming agents and renal system will be taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.
2. **Objectives of the Subject :** Upon completion of the subject student shall be able to (Know, do, appreciate) –
 - a. understand the pharmacological aspects of drugs falling under the above mentioned chapters;
 - b. handle and carry out the animal experiments;
 - c. appreciate the importance of pharmacology subject as a basis of therapeutics; and
 - d. correlate and apply the knowledge therapeutically.

Text books (Theory) (Author, Title, Edition, Publication Place, Publisher, Year of Publication)

- a. Tripathi, K. D. Essentials of medical pharmacology. 4th Ed, 1999. Publisher: Jaypee, Delhi.
- b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
- c. Rang, H.P. & Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory)(Author, Title, Edition, Publication Place, Publisher, Publication Year)

- a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th Ed, 1996. Publisher Mc Graw Hill, Pergamon press.
- b. Craig, C.R.&Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown.Co
- c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, Int.
- d. Shargel and Leon. Applied Biopharmaceutics and pharmacokinetics. Latest edition. Publisher: Prentice Hall, London.

Text books (Practical) :

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

Reference books (Practical)

- a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.

- b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
- c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
- d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

3. Detailed syllabus and lecture wise schedule :

Title of the topic

1. General Pharmacology

- a) Introduction, definitions and scope of pharmacology
- b) Routes of administration of drugs
- c) Pharmacokinetics (absorption, distribution, metabolism and excretion)
- d) Pharmacodynamics
- e) Factors modifying drug effects
- f) Drug toxicity - Acute, sub- acute and chronic toxicity.
- g) Pre-clinical evaluations
- h) Drug interactions

Note: The term Pharmacology used here refers to the classification, mechanism of action, pharmacokinetics, pharmacodynamics, adverse effects, contraindications, Therapeutic uses, interactions and dose and route of administration.

2. Pharmacology of drugs acting on ANS

- a) Adrenergic and antiadrenergic drugs
- b) Cholinergic and anticholinergic drugs
- c) Neuromuscular blockers
- d) Mydriatics and miotics
- e) Drugs used in myasthenia gravis
- f) Drugs used in Parkinsonism

3. Pharmacology of drugs acting on cardiovascular system

- a) Antihypertensives
- b) Anti-anginal drugs
- c) Anti-arrhythmic drugs
- d) Drugs used for therapy of Congestive Heart Failure
- e) Drugs used for hyperlipidaemias

4. **Pharmacology of drugs acting on Central Nervous System**
 - a) General anesthetics
 - b) Sedatives and hypnotics
 - c) Anticonvulsants
 - d) Analgesic and anti-inflammatory agents
 - e) *Psychotropic drugs*
 - f) Alcohol and methyl alcohol
 - g) CNS stimulants and cognition enhancers
 - h) Pharmacology of local anaesthetics
5. **Pharmacology of Drugs acting on Respiratory tract**
 - a) Bronchodilators
 - b) Mucolytics
 - c) Expectorants
 - d) Antitussives
 - e) NasalDecongestants
6. **Pharmacology of Hormones and Hormone antagonists**
 - a) Thyroid and Antithyroid drugs
 - b) Insulin, Insulin analogues and oral hypoglycemic agents
 - c) Sex hormones and oral contraceptives
 - d) Oxytocin and other stimulants and relaxants
7. **Pharmacology of autocooids and their antagonists**
 - a) Histamines and Antihistaminics
 - b) 5-Hydroxytryptamine and its antagonists
 - c) Lipid derived autocooids and platelet activating factor

2.5 COMMUNITY PHARMACY (THEORY)

Theory : 2 Hrs. /Week

1. **Scope:** In the changing scenario of pharmacy practice in India, Community Pharmacists are expected to offer various pharmaceutical care services. In order to meet this demand, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling, health screening services for improved patient care in the community set up.
2. **Objectives:** Upon completion of the course, the student shall be able to –
 - a. know pharmaceutical care services;
 - b. know the business and professional practice management skills in community pharmacies;
 - c. do patient counselling & provide health screening services to public in community pharmacy;
 - d. respond to minor ailments and provide appropriate medication;
 - e. show empathy and sympathy to patients; and
 - f. appreciate the concept of Rational drug therapy.

Text Books:

- a. Health Education and Community Pharmacy by N.S.Parmar.
- b. WHO consultative group report.
- c. Drug store & Business management by Mohammed Ali & Jyoti.

Reference books:

- a. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.
- b. Comprehensive Pharmacy Review – Edt. Leon Shargel. Lippincott Williams & Wilkins.

Special requirements:

1. Either the college is having model community pharmacy (meeting the schedule N requirement) or sign MoU with at least 4-5 community pharmacies nearby to the college for training the students on dispensing and counselling activities.
2. Special equipments like B.P apparatus, Glucometer, Peak flow meter, and apparatus for cholesterol estimation.

3. Scheme of evaluation (80 Marks)

1. Synopsis	10
2. Major Experiment	30
(Counselling of patients with specific diseases – emphasis should be given on Counselling introduction, content, process and conclusion)	
3. Minor Experiment(Ability to measure B.P/ CBG / Lung function)	15
4. Prescription Analysis (Analyzing the prescriptions for probable drug interaction and ability to tell the management)	15
5. Viva – Voce	10

4. Lecture wise programme :

Topics

- 1 Definition, scope, of community pharmacy
Roles and responsibilities of Community pharmacist**
- 2 Community Pharmacy Management**
 - a) Selection of site, Space layout, and design
 - b) Staff, Materials- coding, stocking
 - c) Legal requirements
 - d) Maintenance of various registers
 - e) Use of Computers: Business and health care soft wares
- 3 Prescriptions** – parts of prescription, legality & identification of medication related problems like drug interactions.
- 4 Inventory control in community pharmacy**
Definition, various methods of Inventory Control
ABC, VED, EOQ, Lead time, safety stock
- 5 Pharmaceutical care**
Definition and Principles of Pharmaceutical care.
- 6 Patient counselling**
Definition, outcomes, various stages, barriers, Strategies to overcome barriers
Patient information leaflets- content, design, & layouts, advisory labels
- 7 Patient medication adherence**
Definition, Factors affecting medication adherence, role of pharmacist in improving the adherence.
- 8 Health screening services**
Definition, importance, methods for screening
Blood pressure/ blood sugar/ lung function
and Cholesterol testing
- 9 OTC Medication- Definition, OTC medication list & Counselling**
- 10 Health Education**
WHO Definition of health, and health promotion, care for children, pregnant & breast feeding women, and geriatric patients.
Commonly occurring Communicable Diseases, causative agents,
Clinical presentations and prevention of communicable diseases – Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy, Syphilis, Gonorrhea and AIDS
Balance diet, and treatment & prevention of deficiency disorders
Family planning – role of pharmacist
- 11 Responding to symptoms of minor ailments**
Relevant pathophysiology, common drug therapy to,
Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Pyrexia, Ophthalmic symptoms, worms infestations.
- 12 Essential Drugs concept and Rational Drug Therapy
Role of community pharmacist**
- 13 Code of ethics for community pharmacists**

2.6 PHARMACOTHERAPEUTICS - I (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives:** At completion of this subject it is expected that students will be able to understand –
 - a. the pathophysiology of selected disease states and the rationale for drug therapy;
 - b. the therapeutic approach to management of these diseases;
 - c. the controversies in drug therapy;
 - d. the importance of preparation of individualised therapeutic plans based on diagnosis;
 - e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
 - f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
 - g. summarise the therapeutic approach to management of these diseases including reference to the latest available evidence;
 - h. discuss the controversies in drug therapy;
 - i. discuss the preparation of individualised therapeutic plans based on diagnosis; and
 - j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

- a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.
- b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange.

Reference Books

- a. Pathologic basis of disease - Robins SL, W.B.Saunders publication.
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication.
- c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication.
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
- e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature.

3. Detailed syllabus and lecture wise schedule :

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

Title of the topic

- 1 **Cardiovascular system:** Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, , Hyperlipidaemias , Electrophysiology of heart and Arrhythmias
- 2 **Respiratory system :** Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases
Endocrine system : Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis
- 3 **General prescribing guidelines for**
 - a. Paediatric patients
 - b. Geriatric patients
 - c. Pregnancy and breast feeding
- 4 **Ophthalmology:** Glaucoma, Conjunctivitis- viral & bacterial
- 5 **Introduction to rational drug use**
Definition, Role of pharmacist Essential drug concept Rational drug formulations

2.6 PHARMACOTHERAPEUTICS - I (PRACTICAL)

Practical : 3 Hrs./Week

Practicals :

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Third Year

3.1 PHARMACOLOGY – II (THEORY)

Theory : 3 Hrs. /Week

- 1. Scope of the Subject:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, drugs acting on autacoids, respiratory system, GIT, immune system and hormones, and pharmacology of autacoids and hormones will be concentrated. In addition, pharmacology of chemotherapeutic agents, vitamins, essential minerals and principles of toxicology are also taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.
- 2. Objectives of the Subject Upon completion of the subject student shall be able to:**
 - a. understand the pharmacological aspects of drugs falling under the above mentioned chapters,
 - b. carry out the animal experiments confidently,
 - c. appreciate the importance of pharmacology subject as a basis of therapeutics, and
 - d. correlate and apply the knowledge therapeutically.

Text books (Theory)

- a. Tripathi, K. D. Essentials of medical pharmacology. 4th edition, 1999. Publisher: Jaypee, Delhi.
- b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
- c. Rang, H.P. and Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory)

- a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th edition, 1996. Publisher: Mc Graw Hill, Pergamon press.
- b. Craig, C.R. and Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown and company.
- c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, International.
- d. Gupta, P.K. and Salunkhe, D.K. Modern Toxicology. Volume I, II and III. Latest edition. Publisher: B.V. Gupta, Metropolitan Book Co. (p) Ltd, New Delhi.

Text books (Practical)

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

Reference books (Practical) :

- a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.
- b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
- c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
- d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

3. Detailed syllabus and lecture wise schedule:**Title of the topic**

1. **Pharmacology of Drugs acting on Blood and blood forming agents**
 - a) Anticoagulants
 - b) Thrombolytics and antiplatelet agents
 - c) Haemopoietics and plasma expanders
2. **Pharmacology of drugs acting on Renal System**
 - a) Diuretics
 - b) Antidiuretics
3. **Chemotherapy**
 - a) Introduction
 - b) Sulfonamides and co-trimoxazole
 - c) Penicillins and Cephalosporins
 - d) Tetracyclins and Chloramphenicol
 - e) Macrolides, Aminoglycosides, Polyene & Polypeptide antibiotics
 - f) Quinolines and Fluroquinolines
 - g) Antifungal antibiotics
 - h) Antiviral agents
 - i) Chemotherapy of tuberculosis and leprosy
 - j) Chemotherapy of Malaria
 - k) Chemotherapy of protozoal infections (amoebiasis, Giardiasis)
 - l) Pharmacology of Anthelmintic drugs
 - m) Chemotherapy of cancer (Neoplasms)
4. **Immunopharmacology**
Pharmacology of immunosuppressants and stimulants
5. **Principles of Animal toxicology**
Acute, sub acute and chronic toxicity

6. The dynamic cell: The structures and functions of the components of the cell

- a) Cell and macromolecules: Cellular classification, subcellular organelles, macromolecules, large macromolecular assemblies
- b) Chromosome structure: Pro and eukaryotic chromosome structures, chromatin structure, genome complexity, the flow of genetic information.
- c) DNA replication: General, bacterial and eukaryotic DNA replication.
- d) The cell cycle: Restriction point, cell cycle regulators and modifiers.
- e) Cell signaling: Communication between cells and their environment, ion-channels, signal transduction pathways (MAP kinase, P38 kinase, JNK, Ras and PI3-kinase pathways, biosensors.

The Gene: Genome structure and function:

- a) Gene structure: Organization and elucidation of genetic code.
- b) Gene expression: Expression systems (pro and eukaryotic), genetic elements that control gene expression (nucleosomes, histones, acetylation, HDACS, DNA binding protein families.
- c) Transcription and Transcription factors: Basic principles of transcription in pro and eukaryotes. Transcription factors that regulate transcription in pro and eukaryotes.

RNA processing: rRNA, tRNA and mRNA processing.

Protein synthesis: Mechanisms of protein synthesis, initiation in eukaryotes, translation control and post-translation events

Altered gene functions: Mutations, deletions, amplifications, LOH, traslocations, trinucleotide repeats and other genetic abnormalities.

Oncogenes and tumor suppressor genes.

The gene sequencing, mapping and cloning of human disease genes.

Introduction to gene therapy and targeting.

Recombinant DNA technology: principles. Processes (gene transfer technology) and applications

Books:

- 1 Molecular Biology of the Cell by Alberts B., Bray, D., Lewis, J., Raff M., Roberts, K and Watson, JD, 3rd edition.
- 2 Molecular Cell Biology By Lodish, H., Baltimore, D., Berk, A et al., 5th edition.
- 3 Molecular Biology by Turner, PC., McLennan, AG., Bates, AD and White MRH 2nd edition.
- 4 Genes VIII by Lewin, B., (2004)
- 5 Pharmaceutical Biotechnology, by Crommelin, DJA and Sindelar RD (1997)
- 6 Recombinant DNA by Watson, JD., Gilman, M., et al., (1996)
- 7 Biopharmaceutical: Biochemistry and Biotechnology by Walsh, G., (1998)

3.1 PHARMACOLOGY – II (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments:

1. Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea pigs, e. Rabbits).
2. Study of physiological salt solutions used in experimental pharmacology.
3. Study of laboratory appliances used in experimental pharmacology.
4. Study of use of anesthetics in laboratory animals.
5. To record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.
6. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.
7. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three point method.
8. To record the dose response curve of Histamine using isolated guinea-pig ileum preparation.
9. Study of agonistic and antagonistic effects of drugs using isolated guinea-pig ileum preparation.
10. To carry out bioassay of Histamine using isolated guinea-pig ileum preparation by interpolation method.
11. To carry out bioassay of Histamine using guinea-pig ileum preparation by three point method.
12. To study the routes of administration of drugs in animals (Rats, Mice, Rabbits).
13. Study of theory, principle, procedure involved and interpretation of given results for the following experiments:
 - a) Analgesic property of drug using analgesiometer.
 - b) Antiinflammatory effect of drugs using rat-paw edema method.
 - c) Anticonvulsant activity of drugs using maximal electroshock and pentylenetetrazole methods.
 - d) Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods.
 - e) Locomotor activity evaluation of drugs using actophotometer and rotarod.
 - f) Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.

Scheme of Practical Examination:

	Sessionals	Annual
Identification	02	10
Synopsis	04	10
Major Experiment (Bioassay)	08	30
Minor Experiment (Interpretation of given Graph or simulated experiment)	04	10
Viva	02	10
Max Marks	20	70
Duration	3hrs	4hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.2 PHARMACEUTICAL ANALYSIS (THEORY)

Theory : 3 Hrs. /Week

1. Quality Assurance:

- a. Introduction, sources of quality variation, control of quality variation.
- b. Concept of statistical quality control.
- c. Validation methods- quality of equipment, validation of equipment and validation of analytical instruments and calibration.
- d. GLP, ISO 9000.
- e. Total quality management, quality review and documentation.
- f. ICH- international conference for harmonization-guidelines.
- g. Regulatory control.

2. Chromatography:

Introduction, history, classification, separation techniques, choice of methods. The following techniques be discussed with relevant examples of pharmaceutical products involving principles and techniques of separation of drugs from excipients.

- a. **Column Chromatography:** Adsorption column chromatography, Operational technique, frontal analysis and elution analysis. Factors affecting column efficiency, applications and partition chromatography.
- b. **TLC:** Introduction, principle, techniques, R_f value and applications.
- c. **PC:** Introduction, principle, types of paper chromatography, preparation techniques, development techniques, applications.
- d. **Ion-exchange chromatography:** Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications.
- e. **HPLC:** Introduction, theory, instrumentation, and applications.
- f. **HPTLC:** Introduction, theory, instrumentation, and applications.
- g. **Gas Chromatography:** Introduction, theory, instrumentation-carrier gases, types of columns, stationary phases in GLC & GSC. Detectors- Flame ionization detectors, electron capture detector, thermal conductivity detector. Typical gas chromatogram, derivatisation techniques, programmed temperature gas chromatography, applications.
- h. **Electrophoresis:** Principles of separation, equipment for paper and gel electrophoresis, and application.
- i. **Gel filtration and affinity chromatography:** Introduction, technique, applications.

3. **Electrometric Methods:**

Theoretical aspects, instrumentation, interpretation of data/spectra and analytical applications be discussed on the following topics.

- a. **Potentiometry:** Electrical potential, electrochemical cell, reference electrodes, indicator electrodes, measurement of potential and pH, construction and working of electrodes, Potentiometric titrations, methods of detecting end point, Karl Fischer titration.
- b. **Conductometry:** Introduction, conductivity cell, conductometric titrations and applications.
- c. **Polarography:** Instrumentation, DME, residual current, diffusion current and limiting current, polarographic wave, Ilkovic's equation, Effect of oxygen on polarographic wave, Polarographic maxima and suppressors and applications.
- d. **Amperometric Titrations:** Introduction, types of electrodes used, reference and indicator electrode, instrumentation, titration procedure, advantages and disadvantages of Amperometry over potentiometry. Pharma applications.

4. **Spectroscopy:**

Theoretical aspects, instrumentation, elements of interpretation of data/spectra and application of analytical techniques be discussed on:

a. **Absorption Spectroscopy:**

- Theory of electronic, atomic and molecular spectra. Fundamental laws of photometry, Beer-Lambert's Law, application and its deviation, limitation of Beer law, application of the law to single and multiple component analysis, measurement of equilibrium constant and rate constant by spectroscopy. Spectra of isolated chromophores, auxochromes, batho-chromic shift, hypsochromic shift, hyperchromic and hypochromic effect, effect of solvent on absorption spectra, molecular structure and infrared spectra.

Instrumentation – Photometer, U.V.-Visible spectrophotometer – sources of U.V.-Visible radiations, collimating systems, monochromators, samples cells and following detectors-Photocell, Barrier layer cell, Phototube, Diode array, applications of U.V.-Visible spectroscopy in pharmacy and spectrophotometric titrations.

- **Infrared Spectroscopy:** Vibrational transitions, frequency – structure correlations, Infrared absorption bands, Instrumentation–IR spectrometer – sources of IR, Collimating systems, monochromators, sample cells, sample handling in IR spectroscopy and detectors–Thermocouple, Golay Cells, Thermistor, Bolometer, Pyroelectric detector, Applications of IR in pharmacy.

- **Fluorimetric Analysis:** Theory, luminescence, factors affecting fluorescence, quenching. Instrumentation, Applications, fluorescent indicators, study of pharmaceutically important compounds estimated by fluorimetry.
- b. **Flame Photometry:** Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceutical applications.
- c. **Atomic Absorption Spectrometry:** Introduction, Theory, types of electrodes, instrumentation and applications.
- d. **Atomic Emission Spectroscopy:** Spectroscopic sources, atomic emission spectrometers, photographic and photoelectric detection.
- e. **NMR & ESR (introduction only):** Introduction, theoretical aspects and applications.
- f. **Mass Spectroscopy: (Introduction only)** – Fragmentation, types of ions produced mass spectrum and applications.
- g. **Polarimetry: (Introduction only)** – Introduction to optical rotatory dispersion, circular dichroism, polarimeter.
- h. **X-RAY Diffraction: (Introduction only)** – Theory, reciprocal lattice concept, diffraction patterns and applications.
- i. **Thermal Analysis:** Introduction, instrumentation, applications, and DSC and DTA.

3.2 PHARMACEUTICAL ANALYSIS (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments:

1. Separation and identification of Amino Acids by Paper Chromatography.
2. Separation and identification of Sulpha drugs by TLC technique.
3. Effect of pH and solvent on the UV spectrum of given compound.
4. Comparison of the UV spectrum of a compound with that of its derivatives.
5. Determination of dissociation constant of indicators using UV-Visible spectroscopy.
6. Conductometric titration of mixture of acids with a strong base.
7. Potentiometric titration of an acid with a strong base.
8. Estimation of drugs by Fluorimetric technique.
9. Study of quenching effect in fluorimetry.
10. Colourimetric estimation of Sulpha drugs using BMR reagent.

11. Simultaneous estimation of two drugs present in given formulation.
12. Assay of Salicylic Acid by colourimetry.
13. Determination of Chlorides and Sulphates in Calcium gluconate by Nepheloturbidimetric Method.
14. Determination of Na/K by Flame Photometry.
15. Determination of pKa using pH meter.
16. Determination of specific rotation.
17. Comparison of the IR spectrum of a compound with that of its derivatives.
18. Demonstration of HPLC.
19. Demonstration of HPTLC.
20. Demonstration of GC-MS.
21. Demonstration of DSC.
22. Interpretation of NMR spectra of any one compound.

Reference Books:

1. Text Book of Pharm. Analysis by Higuchi. T and Hasen. E. B., New York Inter Science Publishers.
2. Quantitative Pharma. Analysis by Jenkins, The Blakiston division, New York.
3. Quantitative Drug Analysis, by Garrot. D, Chapman & Hall Ltd., London.
4. Undergraduate Instrumental Analysis by James. E., CBS Publishers.
5. Instrumental Analysis by Willard and Merritt, EWP, East West Press Ltd., Delhi/Madras.
6. Pharm Analysis by Skoog and West, Sounders Manipal College Publishing.
7. Text Book of Chemical Analysis, by A.I.Vogel, ELBS with Macmillan press, Hampshire.
8. Textbook of Pharm. Analysis by K.A.Connors, John Wiley & Sons, New York, Brisbane, Singapore.
9. Textbook of Pharm. Analysis (Practical) by Beckett & Stenlake, CBS Publishers, Delhi.
10. Textbook of Drug Analysis by P.D. Sethi., CBS Publishers, Delhi.
11. Spectroscopy by Silverstein, John & Wiley & Sons. Inc., Canada & Singapore.
12. How to practise GMP-A Plan for total quality control by P.P. Sharma, Vandana Publications, Agra.
13. The Science & Practice of Pharmacy by Remington Vol-I & II, Mack Publishing Co. Pennsylvania.
14. TLC by Stahl, Spring Verlay.
15. Text Book of Pharm. Chemistry by Chatten, CBS Publications.
16. Spectroscopy by William Kemp, ELBS with Macmillan Press, Hampshire.
17. I.P.-1996, The Controller of Publications, New Delhi.
18. BPC- Dept. of Health, U.K. for HMSO.
19. USP - Mack Publishing Co., Easton, PA.
20. The Extra Pharmacopoeia – The Pharm. Press, London.

Practicals

Title of the Experiment:

- 1 Study of agonistic and antagonistic effects of drugs using Guinea-pig ileum preparation.**
- 2 To study the effects of drugs on intestinal motility using frog's esophagus model*
- 3 To study the effects of drugs using rat uterus preparation.**
- 4 To study the anticonvulsant property of drugs (any one model).*
- 5 To study antihistaminic property of drug using histamine induced anaphylactic reaction in guinea pigs.
- 6 To study the apomorphine-induced compulsive behaviour (stereotypy) in mice.*
- 7 To study the muscle relaxant property of diazepam in mice using rotarod apparatus.*
- 8 To study the antiinflammatory property of indomethacin against carrageenan-induced paw oedema.**
- 9 To study the anxiolytic effect of diazepam in mice using mirrored-chamber apparatus.**
- 10 To demonstrate the effect of various drugs on the blood pressure and respiration of anaesthetized dog.
- 11 To study the effect of anthelmintics on earthworms.
- 12 To study the taming effect of chlorpromazine.*
- 13 To study the effects of drugs on vas deferense of the male rat.**
- 14 To study the effect of drugs on pesticide toxicity using rats as model.
- 15 To study the effect of drugs on heavy metal toxicity.

** indicate major experiment & * indicate minor experiment

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.3 PHARMACOTHERAPEUTICS – II (THEORY)

Theory : 3 Hrs. /Week

- 1. Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
- 2. Objectives of the Subject Upon completion of the subject student shall be able to –**
 - a. know the pathophysiology of selected disease states and the rationale for drug therapy
 - b. know the therapeutic approach to management of these diseases;
 - c. know the controversies in drug therapy;
 - d. know the importance of preparation of individualised therapeutic plans based on diagnosis; and
 - e. appreciate the needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text books (Theory)

Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication

Reference books (Theory)

- a. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange
- b. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
- c. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA]

3. Detailed syllabus and lecture wise schedule :

Etiopathogenesis and pharmacotherapy of diseases associated with following systems / diseases –

Title of the topic

- 1. Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhoea and Syphilis
- 2 Musculoskeletal disorders**
Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.
- 3 Renal system**
Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders

- 4 **Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis
- 5 **Dermatology:** Psoriasis, Scabies, Eczema, Impetigo

3.3 PHARMACOTHERAPEUTICS – II (PRACTICAL)

Practical : 3 Hrs./Week

Practicals :

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.

The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.

A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment :

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination :

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.4 PHARMACEUTICAL JURISPRUDENCE (THEORY)

Theory : 2 Hrs. /Week

1. **Scope of the Subject:** (4-6 lines): This course exposes the student to several important legislations related to the profession of pharmacy in India. The Drugs and Cosmetics Act, along with its amendments are the core of this course. Other acts, which are covered, include the Pharmacy Act, dangerous drugs, medicinal and toilet preparation Act etc. Besides this the new drug policy, professional ethics, DPCO, patent and design Act will be discussed.
2. **Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, and appreciate) –
 - a. practice the Professional ethics;
 - b. understand the various concepts of the pharmaceutical legislation in India;
 - c. know the various parameters in the Drug and Cosmetic Act and rules;
 - d. know the Drug policy, DPCO, Patent and design act;
 - e. understand the labeling requirements and packaging guidelines for drugs and cosmetics;
 - f. be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and
 - g. other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

Text books (Theory)

Mithal , B M. Textbook of Forensic Pharmacy. Calcutta :National; 1988.

Reference books (Theory)

- a. Singh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad: Law Book House; 1984.
- b. Jain, NK. A Textbook of forensic pharmacy. Delhi: Vallabh prakashan ; 1995.
- c. Reports of the Pharmaceutical enquiry Committee
- d. I.D.M.A., Mumbai. DPCO 1995
- e. Various reports of Amendments.
- f. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
- g. Eastern Book Company .The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.

3. Detailed syllabus and lecture wise schedule:

Title of the topic

1. **Pharmaceutical Legislations** – A brief review.
2. Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI.
3. **Drugs and Cosmetics Act, 1940, and its rules 1945.**
 Objectives, Legal definition, Study of Schedule's with reference to Schedule B, C&C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y.
 Sales, Import, labeling and packaging of Drugs And Cosmetics
 Provisions Relating to Indigenous Systems.
 Constitution and Functions of DTAB, DCC, CDL.
 Qualification and duties –Govt. analyst and Drugs Inspector.

4. **Pharmacy Act –1948.**
Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER.
5. **Medicinal and Toilet Preparation Act –1955.**
Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations.
6. **Narcotic Drugs and Psychotropic substances Act-1985 and Rules.** Objectives, Legal Definitions, General Study, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and regulations, Schedules to the Act.
7. **Study of Salient Features of Drugs and magic remedies Act and its rules.**
8. **Study of essential Commodities Act Relevant to drugs price control Order.**
9. **Drug Price control Order & National Drug Policy (Current).**
10. **Prevention Of Cruelty to animals Act-1960.**
11. **Patents & design Act-1970.**
12. **Brief study of prescription and Non-prescription Products.**

4. Assignments:

Format of the assignment

1. Minimum & Maximum number of pages
2. It shall be a computer draft copy
3. Reference(s) shall be included at the end.
4. Name and signature of the student
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min

Case studies relating to

1. Drugs and Cosmetics Act and rules along with its amendments, Dangerous Drugs Act, Medicinal and Toilet preparation Act, New Drug Policy, Professional Ethics, Drugs (Price control) Order, Patent and Design Act.
2. Various prescription and non-prescription products.
3. Medical and surgical accessories.
4. Diagnostic aids and appliances available in the market.

3.5 MEDICINAL CHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

1. Modern concept of rational drug design: A brief introduction to Quantitative Structure Activity Relationship (QSAR), prodrug, combinatorial chemistry and computer aided drug design (CADD) and concept of antisense molecules.

A study of the development of the following classes of drugs including SAR, mechanism of action, synthesis of important compounds, chemical nomenclature, brand names of important marketed products and their side effects.

2. Anti-infective agents
 - a) Local anti-infective agents
 - b) Preservatives
 - c) Antifungal agents
 - d) Urinary tract anti-infectives
 - e) Antitubercular agents
 - f) Antiviral agents and Anti AIDS agents
 - g) Antiprotozoal agents
 - h) Anthelmintics
 - i) Antiscabies and Antipedicular agents
3. Sulphonamides and sulphones
4. Antimalarials
5. Antibiotics
6. Antineoplastic agents
7. Cardiovascular agents
 - a) Antihypertensive agents
 - b) Antianginal agents and vasodilators
 - c) Antiarrhythmic agents
 - d) Antihyperlipidemic agents
 - e) Coagulants and Anticoagulants
 - f) Endocrine
8. Hypoglycemic agents
9. Thyroid and Antithyroid agents
10. Diuretics
11. Diagnostic agents
12. Steroidal Hormones and Adrenocorticoids

3.5 MEDICINAL CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

1. Assays of important drugs from the course content.
2. Preparation of medicinally important compounds or intermediates required for synthesis of drugs.
3. Monograph analysis of important drugs.
4. Determination of partition coefficients, dissociation constants and molar refractivity of compounds for QSAR analysis.

Reference Books:

- a. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.
- b. William.O.Foye, Principles of Medicinal Chemistry, B.I. Waverly Pvt. Ltd., New Delhi.
- c. Burgers, Medicinal Chemistry, M.E., Welly Med.Chemistry M.E. Walffed Johnwiley and Sons, Wiley-interscience Publication, New York, Toranto.
- d. A Text Book of Medicinal Chemistry Vol. I and II by Surendra N. Pandeya, S.G. Publisher, 6, Dildayal Nagar, Varanasi -10.
- e. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi - 54.
- f. Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19.
- g. Organic Drug Synthesis-Ledniser Mitzsher Vol. I and II.
- h. Pharmaceutical Chemistry drug Synthesis Vol. I and II by H. J. Roth and A. Kleemann.
- i. The Science and Practice of Pharmacy Vol. 1 and 2, Remington, MACK Publishing Company, Easton, Pennsylvania.

3.6 PHARMACEUTICAL FORMULATIONS (THEORY)

Theory : 2 Hrs. /Week

1. **Scope of the Subject:** Scope and objectives of the course: Subject deals with the formulation and evaluation of various pharmaceutical dosage forms.
2. **Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, appreciate) –
 - a. understand the principle involved in formulation of various pharmaceutical dosage forms;
 - b. prepare various pharmaceutical formulation;
 - c. perform evaluation of pharmaceutical dosage forms; and
 - d. understand and appreciate the concept of bioavailability and bioequivalence, their role in clinical situations.

Text books (Theory)

- a. Pharmaceutical dosage forms, Vol, I,II and III by lachman
- b. Rowlings Text book of Pharmaceutics
- c. Tutorial Pharmacy – Cooper & Gun

Reference books (Theory)

- a. Remington's Pharmaceutical Sciences
- b. USP/BP/IP

3. Detailed syllabus and lecture wise schedule:

Title of the topic

1. Pharmaceutical dosage form- concept and classification
2. **Tablets:** Formulation of different types of tablets, tablet excipients, granulation techniques quality control and evaluation of tablets. Tablet coating, Type of coating, quality control tests for coated tablet.
3. **Capsules;** Production and filling of hard gelatin capsules, Raw material for shell, finishing, quality control tests for capsules. Production and filling of soft gelatin capsules, quality control tests for soft gelatin capsules.
4. **Liquid orals:** Formulation and evaluation of suspensions, emulsions and solutions. Stability of these preparations
5. **Parenterals** Introduction Containers used for Parenterals (including official tests) Formulation of large and small volume Parenterals Sterilization
6. **Ophthalmic preparations (Semi – Solids):** Introduction and classification Factors affecting absorption and anatomy of skin Packaging storage and labeling, Ointments Types of Ointment Base Preparation of ointment, Jellies Types of jellies Formulation of jellies Suppositories, Method of preparation, Types Packaging
7. Definition and concept of **Controlled and novel Drug delivery systems** with available examples, viz. parenteral, trans dermal, buccal, rectal, nasal, implants, ocular

3.6 PHARMACEUTICAL FORMULATIONS (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments :

- 1. Manufacture of Tablets**
 - a. Ordinary compressed tablet-wet granulation
 - b. Tablets prepared by direct compression.
 - c. Soluble tablet.
 - d. Chewable tablet.
- 2. Formulation and filling of hard gelatin capsules**
- 3. Manufacture of parenterals**
 - a. Ascorbic acid injection
 - b. Calcium gluconate injection
 - c. Sodium chloride infusion.
 - d. Dextrose and Sodium chloride injection/ infusion.
- 4. Evaluation of Pharmaceutical formulations (QC tests)**
 - a. Tablets
 - b. Capsules
 - c. Injections
- 5. Formulation of two liquid oral preparations and evaluation by assay**
 - a. Solution: Paracetamol Syrup
 - b. Antacid suspensions- Aluminum hydroxide gel
- 6. Formulation of semisolids and evaluation by assay**
 - a. Salicylic acid and benzoic acid ointment
 - b. Gel formulation Diclofenac gel
- 7. Cosmetic preparations**
 - a. Lipsticks
 - b. Cold cream and vanishing cream
 - c. Clear liquid shampoo
 - d. Tooth paste and tooth powders.
- 8. Tablet coating (demonstration)**

Scheme of Practical Examination :

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Fourth Year

4.1 PHARMACOTHERAPEUTICS – III (THEORY)

Theory : 3 Hrs. /Week

1. **Scope :** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives:** At completion of this subject it is expected that students will be able to understand –
 - a. the pathophysiology of selected disease states and the rationale for drug therapy;
 - b. the therapeutic approach to management of these diseases;
 - c. the controversies in drug therapy;
 - d. the importance of preparation of individualised therapeutic plans based on diagnosis;
 - e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
 - f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
 - g. to summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
 - h. to discuss the controversies in drug therapy;
 - i. to discuss the preparation of individualised therapeutic plans based on diagnosis; and
 - j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

- a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication
- b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange

Reference Books

- a. Pathologic basis of disease - Robins SL, W.B.Saunders publication
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication
- c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
- e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature.

4.1 PHARMACOTHERAPEUTICS – III (PRACTICAL)

Practical : 3 Hrs./Week

Practicals:

Hospital postings for a period of at least 50 hours is required to understand the principles and practice involved in ward round participation and clinical discussion on selection of drug therapy. Students are required to maintain a record of 15 cases observed in the ward and the same should be submitted at the end of the course for evaluation. Each student should present at least two medical cases they have observed and followed in the wards.

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases:

Title of the topic

- 1 **Gastrointestinal system:** Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, Viral hepatitis including jaundice, and Drug induced liver disorders.
- 2 **Haematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.
- 3 **Nervous system:** Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,
- 4 **Psychiatry disorders:** Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders
- 5 Pain management including Pain pathways, neuralgias, headaches.
- 6 Evidence Based Medicine

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination :

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

4.2 HOSPITAL PHARMACY (THEORY)

Theory : 2 Hrs. /Week

1. **Scope:** In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug dispensing, manufacturing of parenteral preparations, drug information, patient counselling, and therapeutic drug monitoring for improved patient care.
2. **Objectives:** Upon completion of the course, the student shall be able to –
 - a. know various drug distribution methods;
 - b. know the professional practice management skills in hospital pharmacies;
 - c. provide unbiased drug information to the doctors;
 - d. know the manufacturing practices of various formulations in hospital set up;
 - e. appreciate the practice based research methods; and
 - f. appreciate the stores management and inventory control.

Text books: (latest editions)

- a. Hospital pharmacy by William .E. Hassan
- b. A text book of Hospital Pharmacy by S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh

References:

- a. WHO consultative group report.
- b. R.P.S. Vol.2. Part –B; Pharmacy Practice section.
- c. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.

3. Lecture wise programme :

Topics

- 1 **Hospital - its Organisation and functions**
- 2 **Hospital pharmacy-Organisation and management**
 - a) Organizational structure-Staff, Infrastructure & work load statistics
 - b) Management of materials and finance
 - c) Roles & responsibilities of hospital pharmacist
- 3 **The Budget – Preparation and implementation**
- 4 **Hospital drug policy**
 - a) Pharmacy and Therapeutic committee (PTC)
 - b) Hospital formulary
 - c) Hospital committees
 - Infection committee
 - Research and ethical committee
 - d) developing therapeutic guidelines
 - e) Hospital pharmacy communication - Newsletter

5 Hospital pharmacy services

- a) Procurement & warehousing of drugs and Pharmaceuticals
- b) Inventory control
Definition, various methods of Inventory Control
ABC, VED, EOQ, Lead time, safety stock
- c) Drug distribution in the hospital
 - i) Individual prescription method
 - ii) Floor stock method
 - iii) Unit dose drug distribution method
- d) Distribution of Narcotic and other controlled substances
- e) Central sterile supply services – Role of pharmacist

6 Manufacture of Pharmaceutical preparations

- a) Sterile formulations – large and small volume parenterals
- b) Manufacture of Ointments, Liquids, and creams
- c) Manufacturing of Tablets, granules, capsules, and powders
- d) Total parenteral nutrition

7 Continuing professional development programs

Education and training

8 Radio Pharmaceuticals – Handling and packaging**9 Professional Relations and practices of hospital pharmacist****4.2 HOSPITAL PHARMACY (PRACTICAL)****Practical : 3 Hrs./Week**

1. Assessment of drug interactions in the given prescriptions
2. Manufacture of parenteral formulations, powders.
3. Drug information queries.
4. Inventory control

List of Assignments:

1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.
2. Pharmacy and Therapeutics committee – Organization, functions, and limitations.
3. Development of a hospital formulary for 300 bedded teaching hospital
4. Preparation of ABC analysis of drugs sold in one month from the pharmacy.
5. Different phases of clinical trials with elements to be evaluated.
6. Various sources of drug information and systematic approach to provide unbiased drug information.
7. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.

Special requirements:

1. Each college should sign MoU with nearby local hospital having minimum 150 beds for providing necessary training to the students' on hospital pharmacy activities.
2. Well equipped with various resources of drug information.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

4.3 CLINICAL PHARMACY (THEORY)

Theory : 3 Hrs. /Week

1. Objectives of the Subject :

Upon completion of the subject student shall be able to (Know, do, appreciate) –

- a. monitor drug therapy of patient through medication chart review and clinical review;
- b. obtain medication history interview and counsel the patients;
- c. identify and resolve drug related problems;
- d. detect, assess and monitor adverse drug reaction;
- e. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and
- f. retrieve, analyse, interpret and formulate drug or medicine information.

Text books (Theory)

- a. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
- b. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
- c. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.
- d. A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi et al, Orient Orient Langram Pvt.Ltd. ISSN8125026

References

- a. Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
- b. Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
- c. Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

2. Detailed syllabus and lecture wise schedule:

Title of the topic

1. **Definitions, development and scope of clinical pharmacy**
2. **Introduction to daily activities of a clinical pharmacist**
 - a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
 - b. Ward round participation
 - c. Adverse drug reaction management
 - d. Drug information and poisons information
 - e. Medication history
 - f. Patient counseling
 - g. Drug utilisation evaluation (DUE) and review (DUR)
 - h. Quality assurance of clinical pharmacy services

3. **Patient data analysis**
The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.
4. **Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results**
 - a. Haematological, Liver function, Renal function, thyroid function tests
 - b. Tests associated with cardiac disorders
 - c. Fluid and electrolyte balance
 - d. Microbiological culture sensitivity tests
 - e. Pulmonary Function Tests
5. **Drug & Poison information**
 - a. Introduction to drug information resources available
 - b. Systematic approach in answering DI queries
 - c. Critical evaluation of drug information and literature
 - d. Preparation of written and verbal reports
 - e. Establishing a Drug Information Centre
 - f. Poisons information- organization & information resources
6. **Pharmacovigilance**
 - a. Scope, definition and aims of pharmacovigilance
 - b. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used]
 - c. Reporting, evaluation, monitoring, preventing & management of ADRs
 - d. Role of pharmacist in management of ADR.
7. Communication skills, including patient counselling techniques, medication history interview, presentation of cases.
8. Pharmaceutical care concepts
9. Critical evaluation of biomedical literature
10. Medication errors

4.3 CLINICAL PHARMACY (PRACTICAL)

Practical : 3 Hrs./Week

Students are expected to perform 15 practicals in the following areas covering the topics dealt in theory class.

- a. Answering drug information questions (4 Nos)
- b. Patient medication counselling (4 Nos)
- c. Case studies related to laboratory investigations (4 Nos)
- d. Patient medication history interview (3 Nos)

Assignment:

Students are expected to submit THREE written assignments (1500 – 2000 words) on the topics given to them covering the following areas dealt in theory class.

Drug information, Patient medication history interview, Patient medication counselling, Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

4.4 BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY)

Theory : 2 Hrs. /Week

1. Detailed syllabus and lecture wise schedule

1 Research Methodology

- a) Types of clinical study designs:
Case studies, observational studies, interventional studies,
- b) Designing the methodology
- c) Sample size determination and Power of a study
Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study
- d) Report writing and presentation of data

2 Biostatistics

2.1 a) Introduction

- b) Types of data distribution
- c) Measures describing the central tendency distributions- average, median, mode
- d) Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean.

2.2 Data graphics

Construction and labeling of graphs, histogram, piecharts, scatter plots, semilogarithmic plots

2.3 Basics of testing hypothesis

- a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals.
- b) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way)
- c) Level of significance (Non-parametric data)- Sign test, Wilcoxon's signed rank test, Wilcoxon rank sum test, Mann Whitney U test, Kruskal-Wallis test (one way ANOVA)
- d) Linear regression and correlation- Introduction, Pearson's and Spearman's correlation and correlation co-efficient.
- e) Introduction to statistical software: SPSS, Epi Info, SAS.

2.4 Statistical methods in epidemiology

Incidence and prevalence, relative risk, attributable risk

3. Computer applications in pharmacy

Computer System in Hospital Pharmacy: Patterns of Computer use in Hospital Pharmacy – Patient record database management, Medication order entry – Drug labels and list – Intravenous solution and admixture, patient medication profiles, Inventory control, Management report & Statistics.

Computer In Community Pharmacy

Computerizing the Prescription Dispensing process

Use of Computers for Pharmaceutical Care in community pharmacy

Accounting and General ledger system

Drug Information Retrieval & Storage :

Introduction – Advantages of Computerized Literature Retrieval

Use of Computerized Retrieval

Reference books:

- a. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3rd edition, publisher Marcel Dekker Inc. NewYork.
- b. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich , 3rd edition, McGraw Hill Publications 2006

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

Theory : 3 Hrs. /Week

1. Biopharmaceutics

1. Introduction to Biopharmaceutics
 - a. Absorption of drugs from gastrointestinal tract.
 - b. Drug Distribution.
 - c. Drug Elimination.

2. Pharmacokinetics

2. Introduction to Pharmacokinetics.
 - a. Mathematical model
 - b. Drug levels in blood.
 - c. Pharmacokinetic model
 - d. Compartment models
 - e. Pharmacokinetic study.
3. One compartment open model.
 - a. Intravenous Injection (Bolus)
 - b. Intravenous infusion.
4. Multicompartment models.
 - a. Two compartment open model.
 - b. IV bolus, IV infusion and oral administration
5. Multiple – Dosage Regimens.
 - a. Repetitive Intravenous injections – One Compartment Open Model
 - b. Repetitive Extravascular dosing – One Compartment Open model
 - c. Multiple Dose Regimen – Two Compartment Open Model
6. Nonlinear Pharmacokinetics.
 - a. Introduction
 - b. Factors causing Non-linearity.
 - c. Michaelis-menton method of estimating parameters.
7. Noncompartmental Pharmacokinetics.
 - a. Statistical Moment Theory.
 - b. MRT for various compartment models.
 - c. Physiological Pharmacokinetic model.
8. Bioavailability and Bioequivalence.
 - a. Introduction.
 - b. Bioavailability study protocol.
 - c. Methods of Assessment of Bioavailability

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

Practical : 3 Hrs./Week

1. Improvement of dissolution characteristics of slightly soluble drugs by some methods.
2. Comparison of dissolution studies of two different marketed products of same drug.
3. Influence of polymorphism on solubility and dissolution.
4. Protein binding studies of a highly protein bound drug and poorly protein bound drug.
5. Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.
6. Bioavailability studies of some commonly used drugs on animal/human model.
7. Calculation of K_a , K_e , $t_{1/2}$, C_{max} , AUC, AUMC, MRT etc. from blood profile data.
8. Calculation of bioavailability from urinary excretion data for two drugs.
9. Calculation of AUC and bioequivalence from the given data for two drugs.
10. In vitro absorption studies.
11. Bioequivalency studies on the different drugs marketed.(eg) Tetracycline, Sulphamethoxazole, Trimethoprim, Aspirin etc., on animals and human volunteers.
12. Absorption studies in animal inverted intestine using various drugs.
13. Effect on contact time on the plasma protein binding of drugs.
14. Studying metabolic pathways for different drugs based on elimination kinetics data.
15. Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data.
16. Determination of renal clearance.

References:

- a. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
- b. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania.
- c. Pharmacokinetics: By Milo Gibaldi Donald, R. Merckel Dekker Inc.
- d. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
- e. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
- f. Biopharmaceutics; By Swarbrick
- g. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmanekar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
- h. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febiger, Philadelphia, 1995.
- i. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
- j. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Robert F Notari Marcel Dekker Inc, New York and Basel, 1987.
- k. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

4.6 CLINICAL TOXICOLOGY (THEORY)

Theory : 2 Hrs. /Week

1. General principles involved in the management of poisoning
2. Antidotes and the clinical applications.
3. Supportive care in clinical Toxicology.
4. Gut Decontamination.
5. Elimination Enhancement.
6. Toxicokinetics.
7. Clinical symptoms and management of acute poisoning with the following agents –
 - a) Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.
 - b) Opiates overdose.
 - c) Antidepressants
 - d) Barbiturates and benzodiazepines.
 - e) Alcohol: ethanol, methanol.
 - f) Paracetamol and salicylates.
 - g) Non-steroidal anti-inflammatory drugs.
 - h) Hydrocarbons: Petroleum products and PEG.
 - i) Caustics: inorganic acids and alkali.
 - j) Radiation poisoning
8. Clinical symptoms and management of chronic poisoning with the following agents –
Heavy metals: Arsenic, lead, mercury, iron, copper
9. Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.
10. Plants poisoning. Mushrooms, Mycotoxins.
11. Food poisonings
12. Envenomations – Arthropod bites and stings.

Substance abuse:

Signs and symptoms of substance abuse and treatment of dependence

- a) CNS stimulants :amphetamine
- b) Opioids
- c) CNS depressants
- d) Hallucinogens: LSD
- e) Cannabis group
- f) Tobacco

References:

- a. Matthew J Ellenhorn. ELLENHORNS MEDICAL TOXICOLOGY – DIAGNOSIS AND TREATMENT OF POISONING. Second edition. Williams and Willkins publication, London
- b. V V Pillay. HANDBOOK OF FORENSIC MEDICINE AND TOXICOLOGY. Thirteenth edition 2003 Paras Publication, Hyderabad

Fifth year

5.1 CLINICAL RESEARCH (THEORY)

Theory : 3 Hrs. /Week

1. Drug development process:

Introduction

Various Approaches to drug discovery

1. Pharmacological
2. Toxicological
3. IND Application
4. Drug characterization
5. Dosage form

2. Clinical development of drug:

1. Introduction to Clinical trials
2. Various phases of clinical trial.
3. Methods of post marketing surveillance
4. Abbreviated New Drug Application submission.
5. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines
6. Challenges in the implementation of guidelines
7. Ethical guidelines in Clinical Research
8. Composition, responsibilities, procedures of IRB / IEC
9. Overview of regulatory environment in USA, Europe and India.
10. Role and responsibilities of clinical trial personnel as per ICH GCP
 - a. Sponsor
 - b. Investigators
 - c. Clinical research associate
 - d. Auditors
 - e. Contract research coordinators
 - f. Regulatory authority
11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)
12. Informed consent Process
13. Data management and its components
14. Safety monitoring in clinical trials.

References :

- a. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
- b. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
- c. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
- d. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
- e. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
- f. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
- g. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

5.2 PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS (THEORY)

Theory : 3 Hrs. /Week

1. **Pharmacoepidemiology :**

Definition and scope:

Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.

Measurement of outcomes in pharmacoepidemiology

Outcome measure and drug use measures

Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement

Concept of risk in pharmacoepidemiology

Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

Pharmacoepidemiological methods

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods

Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

Sources of data for pharmacoepidemiological studies

Ad Hoc data sources and automated data systems.

Selected special applications of pharmacoepidemiology

Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

2. **Pharmacoeconomics:**

Definition, history, needs of pharmacoeconomic evaluations

Role in formulary management decisions

Pharmacoeconomic evaluation

Outcome assessment and types of evaluation

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods:

Cost – minimization, cost- benefit, cost – effectiveness, cost utility

3. **Applications of Pharmacoeconomics**

Software and case studies

5.3 CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING (THEORY)

Theory : 2 Hrs. /Week

- 1. Introduction to Clinical pharmacokinetics.**
- 2. Design of dosage regimens:**
Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.
- 3. Pharmacokinetics of Drug Interaction:**
 - a. Pharmacokinetic drug interactions
 - b. Inhibition and Induction of Drug metabolism
 - c. Inhibition of Biliary Excretion.
- 4. Therapeutic Drug monitoring:**
 - a. Introduction
 - b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight, disease, Interacting drugs).
 - c. Indications for TDM. Protocol for TDM.
 - d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.
 - e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.
- 5. Dosage adjustment in Renal and hepatic Disease.**
 - a. Renal impairment
 - b. Pharmacokinetic considerations
 - c. General approach for dosage adjustment in Renal disease.
 - d. Measurement of Glomerular Filtration rate and creatinine clearance.
 - e. Dosage adjustment for uremic patients.
 - f. Extracorporeal removal of drugs.
 - g. Effect of Hepatic disease on pharmacokinetics.
- 6. Population Pharmacokinetics.**
 - a. Introduction to Bayesian Theory.
 - b. Adaptive method or Dosing with feed back.
 - c. Analysis of Population pharmacokinetic Data.
- 7. Pharmacogenetics**
 - a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.
 - b. Genetic Polymorphism in Drug Transport and Drug Targets.
 - c. Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations

APPENDIX-B

(See regulation 9)

CONDITIONS TO BE FULFILLED BY THE ACADEMIC TRAINING INSTITUTION

- 1) Any authority or institution in India applying to the Pharmacy Council of India for approval of courses of study for Pharm.D. and Pharm.D. (Post Baccalaureate) under sub-section (1) of section 12 of the Pharmacy Act, 1948 shall comply with the infrastructural facilities as prescribed by the Pharmacy Council of India from time to time.
- 2) Pharm.D. and Pharm.D. (Post Baccalaureate) programmes shall be conducted only in those institutions which -
 - a) are approved by the Pharmacy Council of India for B.Pharm course as provided under section 12 of the Pharmacy Act, 1948;
 - b) have 300 bedded hospital attached to it.

(i) Hospital Details

1. Institution with their own hospital of minimum 300 beds.
2. Teaching hospital recognised by the Medical Council of India or University, or a Government hospital not below the level of district headquarter hospital with 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
3. Corporate type hospital with minimum 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
4. Number of institutions which can be attached to one hospital shall be restricted by the student pharmacist to bed ratio of 1:10.

(ii) Speciality

- a) Tertiary care hospitals are desirable
- b) Medicine[compulsory], and any three specialization of the following
 1. Surgery
 2. Pediatrics
 3. Gynecology and obstetrics
 4. Psychiatry
 5. Skin and VD
 6. Orthopedics

(iii) Location of the Hospital

Within the same limits of Corporation or Municipality or Campus with Medical Faculty involvement as adjunct faculty.

3) TEACHING STAFF REQUIREMENT

- i) Staff Pattern : All faculty shall be full time. However part time perceptors in hospital shall be allowed.
- ii) Subject wise specialisation of the Teaching Staff :

S.No.	Subject	Specialisation required
1.	Pharmacy Practice	M.Pharm in Pharmacy Practice or Pharmacology or Pharmaceutics.
2.	Human Anatomy & Physiology	M.Pharm in Pharmacology or Pharmacy practice
3.	Pharmaceutics (Dispensing & General Pharmacy)	M.Pharm in Pharmaceutics
4.	Pharmacognosy-I	M.Pharm in Pharmacognosy
5.	Pharmaceutical Organic Chemistry-I	M.Pharm in Pharmaceutical chemistry or Pharmaceutical Analysis or Quality assurance or Bulk Drug
6.	Pharmaceutical Inorganic Chemistry	M.Pharm in Pharmaceutical chemistry or Pharmaceutical Analysis or Quality assurance or Bulk Drug
7.	Pharmaceutical microbiology	M.Pharm in Pharmaceutics or Pharmaceutical Biotechnology
8.	Pathophysiology	M.Pharm Pharmacy practice or Pharmacology
9.	Applied Biochemistry & Clinical Chemistry	M.Pharm in Pharmacology or Pharmacy practice or Pharmaceutical chemistry
10.	Pharmacology-I	M.Pharm in Pharmacology or Pharmacy practice
11.	Pharmaceutical Jurisprudence	M.Pharm in Pharmaceutics
12.	Pharmacology-II	M.Pharm in Pharmacology or Pharmacy practice
13.	Pharmaceutical Dosage Forms	M.Pharm in Pharmaceutics or Industrial Pharmacy
14.	Pharmacotherapeutics –I, II and III	M.Pharm Pharmacy practice or Pharmacology
15.	Community Pharmacy	M.Pharm in Pharmacy practice or Pharmacology or Pharmaceutics
16.	Hospital Pharmacy	M.Pharm in Pharmacy practice or Pharmacology or Pharmaceutics
17.	Clinical Pharmacy	M.Pharm in Pharmacy practice
18.	Computer Science or Computer Application in pharmacy	MCA
19.	Mathematics	M.Sc. (Maths)

iii) Teaching Staff :

Department/Division	Name of the post	No.
Department of Pharmaceutics	Professor	1
	Asst. Professor	1
	Lecturer	2
Department of Pharmaceutical Chemistry (Including Pharmaceutical Analysis)	Professor	1
	Asst. Professor	1
	Lecturer	3
Department of Pharmacology	Professor	1
	Asst. Professor	1
	Lecturer	2
Department of Pharmacognosy	Professor	1
	Asst. Professor	1
	Lecturer	1
Department of Pharmacy Practice	Professor	1
	Asst. Professor	2
	Lecturer	3

iv) Prescribed qualifications and experience for Professor, Assistant Professor, Lecturer and others :

Sl. No.	CADRE	QUALIFICATIONS	EXPERIENCE
1.	Lecturer	i) Basic degree in pharmacy (B.Pharm). ii) Registration as a pharmacist under the Pharmacy Act. iii) First Class Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm)	No minimum requirement.
2.	Assistant Professor	i) Basic degree in pharmacy (B.Pharm). ii) Registration as a pharmacist under the Pharmacy Act. iii) Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm)	Three years experience in Teaching or Research at the level of Lecturer or equivalent.

		iv) Ph.D. degree (with First Class degree either at Bachelor's or Master's level) in the appropriate branch of specialization in Pharmacy.	
3.	Professor	i) Basic degree in pharmacy (B.Pharm). ii) Registration as a pharmacist under the Pharmacy Act. iii) Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm). iv) Ph.D. degree (with first Class either at Bachelor's or Master's level) in appropriate branch of specialization in Pharmacy.	i) Ten years experience in Teaching or Research. ii) Out of which five years must be as Assistant Professor.
4.	Director or Principal or Head of institute	i) Basic degree in pharmacy (B.Pharm). ii) Registration as a pharmacist under the Pharmacy Act. iii) Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm) iv) Ph.D. degree (with first Class degree either at Bachelor's or Master's level in the appropriate branch of specialization in Pharmacy.	i) Fifteen years experience in Teaching or Research. ii) Out of which five years must be as Professor or above in Pharmacy. Desirable : Administrative experience in responsible position. The maximum age for holding the post shall be 65 years.

Note : If a class or division is not awarded at Master's level, a minimum of 60% marks in aggregate or equivalent cumulative grade point average shall be considered equivalent to first class or division, as the case may be.

v) Workload of Faculty :

Professor – 8 hrs. per week

Assistant Professor – 12 hrs. per week

Lecturers – 16 hrs. per week

vi) Training of Pharmacy Practice Faculty :

a) Teaching staff will be trained as per the module prescribed by the Central Council.

b) Duration of training – Minimum 3 months.

c) Training sites – Institutions running pharmacy practice or Programmes for atleast five years.

d) Trainer – Professor or Assistant Professor with minimum of five years of clinical pharmacy teaching and practice experience.

4) NON-TEACHING STAFF :

Sl.No.	Designation	Required (Minimum)	Required Qualification
1	Laboratory Technician	1 for each Dept	D. Pharm
2	Laboratory Assistants or Laboratory Attenders	1 for each Lab (minimum)	SSLC
3	Office Superintendent	1	Degree
4	Accountant	1	Degree
5	Store keeper	1	D.Pharm or a Bachelor degree recognized by a University or institution.
6	Computer Data Operator	1	BCA or Graduate with Computer Course
7	Office Staff I	1	Degree
8	Office Staff II	2	Degree
9	Peon	2	SSLC
10	Cleaning personnel	Adequate	---
11	Gardener	Adequate	---

5) ACCOMMODATION :

Suitable and sufficient accommodation with adequate ventilation, lighting and other hygienic conditions should be provided to the rooms for Principal or the Head of the department, office, class rooms, library, staff, staff common room, students common room, museum, laboratories, stores, etc.

At least two lecture halls alongwith eight laboratories as specified below should be provided for: —

1. Pharmaceutics and Pharmacokinetics Lab	- 2
2. Life Science (Pharmacology, Physiology, Pathophysiology)	- 2
3. Phytochemistry or Pharmaceutical Chemistry	- 2
4. Pharmacy Practice	- 2

Total =	8

In addition to the laboratories, balance room, aseptic room or cabinet, animal house and a machine room shall also be provided.

Floor area of the laboratory should not be less than 30 square feet per student required to work in the laboratory at any given time subject to a minimum of 750 square feet.

Laboratories should be fitted and constructed in a manner that these can be kept reasonably clean. Gas and water fittings, shelves, fuming cupboards be provided wherever necessary.

6. EQUIPMENT AND APPARATUS :

Department wise list of minimum equipments

A. DEPARTMENT OF PHARMACOLOGY :

I. Equipment:

S.No.	Name	Minimum required Nos.
1	Microscopes	15
2	Haemocytometer with Micropipettes	20
3	Sahli's haemocytometer	20
4	Hutchinson's spirometer	01
5	Spygmomanometer	05
6	Stethoscope	05
7	Permanent Slides for various tissues	One pair of each tissue Organs and endocrine glands One slide of each organ system
8	Models for various organs	One model of each organ system
9	Specimen for various organs and systems	One model for each organ system
10	Skeleton and bones	One set of skeleton and one spare bone

11	Different Contraceptive Devices and Models	One set of each device
12	Muscle electrodes	01
13	Lucas moist chamber	01
14	Myographic lever	01
15	Stimulator	01
16	Centrifuge	01
17	Digital Balance	01
18	Physical /Chemical Balance	01
19	Sherrington's Kymograph Machine or Polyrite	10
20	Sherrington Drum	10
21	Perspex bath assembly (single unit)	10
22	Aerators	10
23	Computer with LCD	01
24	Software packages for experiment	01
25	Standard graphs of various drugs	Adequate number
26	Actophotometer	01
27	Rotarod	01
28	Pole climbing apparatus	01
29	Analgesiometer (Eddy's hot plate and radiant heat methods)	01
30	Convulsiometer	01
31	Plethysmograph	01
32	Digital pH meter	01

II. Apparatus:

S.No	Name	Minimum required Nos.
1	Folin-Wu tubes	60
2	Dissection Tray and Boards	10
3	Haemostatic artery forceps	10
4	Hypodermic syringes and needles of size 15,24,26G	10
5	Levers, cannulae	20

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

B. DEPARTMENT OF PHARMACOGNOSY :

I. Equipment:

S.No.	Name	Minimum required Nos.
1	Microscope with stage micrometer	15
2	Digital Balance	02
3	Autoclave	02

4	Hot air oven	02
5	B.O.D.incubator	01
6	Refrigerator	01
7	Laminar air flow	01
8	Colony counter	02
9	Zone reader	01
10	Digital pH meter	01
11	Sterility testing unit	01
12	Camera Lucida	15
13	Eye piece micrometer	15
14	Incinerator	01
15	Moisture balance	01
16	Heating mantle	15
17	Flourimeter	01
18	Vacuum pump	02
19	Micropipettes (Single and multi channeled)	02
20	Micro Centrifuge	01
21	Projection Microscope	01

II. Apparatus:

S.No.	Name	Minimum required Nos.
1	Reflux flask with condenser	20
2	Water bath	20
3	Clavengers apparatus	10
4	Soxhlet apparatus	10
6	TLC chamber and sprayer	10
7	Distillation unit	01

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

C. DEPARTMENT OF PHARMACEUTICAL CHEMISTRY :

I. Equipment:

S.No.	Name	Minimum required Nos.
1	Hot plates	05
2	Oven	03
3	Refrigerator	01
4	Analytical Balances for demonstration	05
5	Digital balance 10mg sensitivity	10
6	Digital Balance (1mg sensitivity)	01
7	Suction pumps	06
8	Muffle Furnace	01

9	Mechanical Stirrers	10
10	Magnetic Stirrers with Thermostat	10
11	Vacuum Pump	01
12	Digital pH meter	01
13	Microwave Oven	02

II. Apparatus:

S.No.	Name	Minimum required Nos.
1	Distillation Unit	02
2	Reflux flask and condenser single necked	20
3	Reflux flask and condenser double/triple necked	20
4	Burettes	40
5	Arsenic Limit Test Apparatus	20
6	Nessler's Cylinders	40

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

D. DEPARTMENT OF PHARMACEUTICS :

I. Equipment:

S.No	Name	Minimum required Nos.
1	Mechanical stirrers	10
2	Homogenizer	05
3	Digital balance	05
4	Microscopes	05
5	Stage and eye piece micrometers	05
6	Brookfield's viscometer	01
7	Tray dryer	01
8	Ball mill	01
9	Sieve shaker with sieve set	01
10	Double cone blender	01
11	Propeller type mechanical agitator	05
12	Autoclave	01
13	Steam distillation still	01
14	Vacuum Pump	01
15	Standard sieves, sieve no. 8, 10, 12, 22, 24, 44, 66, 80	10 sets
16	Tablet punching machine	01
17	Capsule filling machine	01
18	Ampoule washing machine	01
19	Ampoule filling and sealing machine	01

20	Tablet disintegration test apparatus IP	01
21	Tablet dissolution test apparatus IP	01
22	Monsanto's hardness tester	01
23	Pfizer type hardness tester	01
24	Friability test apparatus	01
25	Clarity test apparatus	01
26	Ointment filling machine	01
27	Collapsible tube crimping machine	01
28	Tablet coating pan	01
29	Magnetic stirrer, 500ml and 1 liter capacity with speed control	05 EACH 10
30	Digital pH meter	01
31	All purpose equipment with all accessories	01
32	Aseptic Cabinet	01
33	BOD Incubator	02
34	Bottle washing Machine	01
35	Bottle Sealing Machine	01
36	Bulk Density Apparatus	02
37	Conical Percolator (glass/copper/stainless steel)	10
38	Capsule Counter	02
39	Energy meter	02
40	Hot Plate	02
41	Humidity Control Oven	01
42	Liquid Filling Machine	01
43	Mechanical stirrer with speed regulator	02
44	Precision Melting point Apparatus	01
45	Distillation Unit	01

II. Apparatus:

S.No	Name	Minimum required Nos.
1	Ostwald's viscometer	15
2	Stalagmometer	15
3	Desiccator*	05
4	Suppository moulds	20
5	Buchner Funnels (Small, medium, large)	05 each
6	Filtration assembly	01
7	Permeability Cups	05
8	Andreason's Pipette	03
9	Lipstick moulds	10

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

E. DEPARTMENT OF PHARMACEUTICAL BIOTECHNOLOGY :

S.No.	Name	Minimum required Nos.
1	Orbital shaker incubator	01
2	Lyophilizer (Desirable)	01
3	Gel Electrophoresis (Vertical and Horizontal)	01
4	Phase contrast/Trinocular Microscope	01
5	Refrigerated Centrifuge	01
6	Fermenters of different capacity (Desirable)	01
7	Tissue culture station	01
8	Laminar airflow unit	01
9	Diagnostic kits to identify infectious agents	01
10	Rheometer	01
11	Viscometer	01
12	Micropipettes (single and multi channeled)	01 each
13	Sonicator	01
14	Respinometer	01
15	BOD Incubator	01
16	Paper Electrophoresis Unit	01
17	Micro Centrifuge	01
18	Incubator water bath	01
19	Autoclave	01
20	Refrigerator	01
21	Filtration Assembly	01
22	Digital pH meter	01

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

F. DEPARTMENT OF PHARMACY PRACTICE :**Equipment:**

S.No.	Name	Minimum required Nos.
1	Colorimeter	2
2	Microscope	Adequate
3	Permanent slides (skin, kidney, pancreas, smooth muscle, liver etc.,)	Adequate
4	Watch glass	Adequate
5	Centrifuge	1
6	Biochemical reagents for analysis of normal and pathological constituents in urine and blood facilities	Adequate
7	Filtration equipment	2
8	Filling Machine	1
9	Sealing Machine	1

10	Autoclave sterilizer	1
11	Membrane filter	1 Unit
12	Sintered glass funnel with complete filtering assemble	Adequate
13	Small disposable membrane filter for IV admixture filtration	Adequate
14	Laminar air flow bench	1
15	Vacuum pump	1
16	Oven	1
17	Surgical dressing	Adequate
18	Incubator	1
19	PH meter	1
20	Disintegration test apparatus	1
21	Hardness tester	1
22	Centrifuge	1
23	Magnetic stirrer	1
24	Thermostatic bath	1

NOTE:

1. **Computers and Internet connection (Broadband), six computers for students with internet and staff computers as required.**
2. **Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and the department.**

G. CENTRAL INSTRUMENTATION ROOM :

S.No.	Name	Minimum required Nos.
1	Colorimeter	01
2	Digital pH meter	01
3	UV- Visible Spectrophotometer	01
4	Flourimeter	01
5	Digital Balance (1mg sensitivity)	01
6	Nephelo Turbidity meter	01
7	Flame Photometer	01
8	Potentiometer	01
9	Conductivity meter	01
10	Fourier Transform Infra Red Spectrometer (Desirable)	01
11	HPLC	01
12	HPTLC (Desirable)	01
13	Atomic Absorption and Emission spectrophotometer (Desirable)	01
14	Biochemistry Analyzer (Desirable)	01
15	Carbon, Hydrogen, Nitrogen Analyzer (Desirable)	01
16	Deep Freezer (Desirable)	01
17	Ion- Exchanger	01
18	Lyophilizer (Desirable)	01

APPENDIX-C

(See regulation 16)

INTERNSHIP

1) SPECIFIC OBJECTIVES :

- i) to provide patient care in cooperation with patients, prescribers, and other members of an interprofessional health care team based upon sound therapeutic principles and evidence-based data, taking into account relevant legal, ethical, social cultural, economic, and professional issues, emerging technologies, and evolving biomedical, pharmaceutical, social or behavioral or administrative, and clinical sciences that may impact therapeutic outcomes.
- ii) to manage and use resources of the health care system, in cooperation with patients, prescribers, other health care providers, and administrative and supportive personnel, to promote health; to provide, assess, and coordinate safe, accurate, and time-sensitive medication distribution; and to improve therapeutic outcomes of medication use.
- iii) to promote health improvement, wellness, and disease prevention in co-operation with patients, communities, at-risk population, and other members of an interprofessional team of health care providers.
- iv) to demonstrate skills in monitoring of the National Health Programmes and schemes, oriented to provide preventive and promotive health care services to the community.
- v) to develop leadership qualities to function effectively as a member of the health care team organised to deliver the health and family welfare services in existing socio-economic, political and cultural environment.
- vi) to communicate effectively with patients and the community.

2) OTHER DETAILS :

- i) All parts of the internship shall be done, as far as possible, in institutions in India. In case of any difficulties, the matter may be referred to the Pharmacy Council of India to be considered on merits.
- ii) Where an intern is posted to district hospital for training, there shall be a committee consisting of representatives of the college or university, and the district hospital administration, who shall regulate the training of such trainee. For such trainee a certificate of satisfactory completion of training shall be obtained from the relevant administrative authorities which shall be countersigned by the Principal or Dean of College.

- iii) Every candidate shall be required, after passing the final Pharm.D. or Pharm.D. (Post Baccalaureate) examination as the case may be to undergo compulsory rotational internship to the satisfaction of the College authorities and University concerned for a period of twelve months so as to be eligible for the award of the degree of Pharm.D. or Pharm.D. (Post Baccalaureate) as the case may be.

3. ASSESSMENT OF INTERNSHIP :

- i) The intern shall maintain a record of work which is to be verified and certified by the preceptor (teacher practitioner) under whom he works. Apart from scrutiny of the record of work, assessment and evaluation of training shall be undertaken by an objective approach using situation tests in knowledge, skills and attitude during and at the end of the training. Based on the record of work and date of evaluation, the Dean or Principal shall issue certificate of satisfactory completion of training, following which the university shall award the degree or declare him eligible for it.
- ii) Satisfactory completion of internship shall be determined on the basis of the following:-
- (1) Proficiency of knowledge required for each case management SCORE 0-5
 - (2) The competency in skills expected for providing Clinical Pharmacy Services SCORE 0-5
 - (3) Responsibility, punctuality, work up of case, involvement in patient care SCORE 0-5
 - (4) Ability to work in a team (Behavior with other healthcare professionals including medical doctors, nursing staff and colleagues). SCORE 0-5
 - (5) Initiative, participation in discussions, research aptitude. SCORE 0-5

Poor	Fair	Below Average	Average	Above Average	Excellent
0	1	2	3	4	5

A Score of less than 3 in any of above items will represent unsatisfactory completion of internship.

APPENDIX-D
(See regulation 17)
CONDITIONS TO BE FULFILLED BY
THE EXAMINING AUTHORITY

1. The Examining Authority shall be a statutory Indian University constituted by the Central Government/State Government/Union Territory Administration. It shall ensure that discipline and decorum of the examinations are strictly observed at the examination centers.
2. It shall permit the Inspector or Inspectors of the Pharmacy Council of India to visit and inspect the examinations.
3. It shall provide:-
 - (a) adequate rooms with necessary furniture for holding written examinations;
 - (b) well-equipped laboratories for holding practical examinations;
 - (c) an adequate number of qualified and responsible examiners and staff to conduct and invigilate the examinations; and
 - (d) such other facilities as may be necessary for efficient and proper conduct of examinations.
4. It shall, if so required by a candidate, furnish the statement of marks secured by a candidate in the examinations after payment of prescribed fee, if any, to the Examining Authority.
5. It shall appoint examiners whose qualifications should be similar to those of the teachers in the respective subjects as shown in Appendix-B.
6. In pursuance of sub-section (3) of section 12 of the Pharmacy Act, 1948, the Examining Authority shall communicate to the Secretary, Pharmacy Council of India, not less than six weeks in advance the dates fixed for examinations, the time-table for such examinations, so as to enable the Council to arrange for inspection of the examinations.
7. The Examining Authority shall ensure that examiners for conducting examination for Pharm.D. and Pharm.D. (Post Baccalaureate) programmes shall be persons possessing pharmacy qualification and are actually involved in the teaching of the Pharm.D. and Pharm.D. (Post Baccalaureate) programmes in an approved institution.

(ARCHNA MUDGAL)
Registrar-cum-Secretary
Pharmacy Council of India
New Delhi – 110002

**RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES, KARNATAKA
(RGUHS), BANGALORE – 560 041**

**Pharm D & Pharm D (Post Baccalaureate) Revised Regulations 2008
(Effective from 2012-2013)**

1. Minimum Qualification for Admission to -

1.1. Pharm.D Course First Year –

1.1.1. A pass in any of the following examinations –

- i. Students who have passed two years P.U.C. examination of Karnataka P.U.C. Board or an equivalent examination of any other approved Board or University established by law in India with English as one of the subject and Physics, Chemistry as compulsory subjects along with one of the following subject – Mathematics or Biology or P.C.M.B.
- ii. Students who have passed D. Pharm course from institutions approved by Pharmacy Council of India U/S 12 of Pharmacy Act, 1948
- iii. Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examinations.

1.1.2. Age – Provided that a student should complete the age of 17 years on or before 31st December of the year of admission to the course.

1.2. Pharm.D Post Baccalaureate course –

- 1.2.1. A pass in B Pharm degree examination of Rajiv Gandhi University of Health Sciences or B Pharm examination of any other Indian University established by law in India or any other degree courses in Pharmacy recognized as equivalent to B Pharm by RGUHS and Pharmacy Council of India.**

2. Duration of the course –

2.1. Pharm.D:

The duration of the course shall be six academic years (five years of study and one year of internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of six years duration is divided into two phases –

Phase I – consisting of First, Second, Third, Fourth and Fifth academic year.

Phase II – consisting of internship or residency training during sixth year involving posting in speciality units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services and acquires skill under supervision so that he or she may become capable of functioning independently.

2.2. Pharm.D. (Post Baccalaureate):

Eligible B Pharm graduates shall be admitted to the first year of the Pharm.D (Post Baccalaureate) course

The duration of the course shall be for three academic years (two years of study and one year internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of three years duration is divided into two phases –

Phase I – consisting of First and Second academic year.

Phase II – consisting of Internship or residency training during third year involving posting in speciality units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services, and acquires skill under supervision so that he or she may become capable of functioning independently.

3. Medium of Instruction

The medium of instruction and examination of Pharm.D & Pharm.D (Post Baccalaureate) courses shall be English.

4. Number of admissions in the above said courses shall be as prescribed by the Pharmacy Council of India from time to time and presently be restricted as below –

4.1. Pharm.D. Course – 30 students.

4.2. Pharm.D. (Post Baccalaureate) Course – 10 students.

5. Institutions running B.Pharm course approved under section 12 of the Pharmacy Act, will only be permitted to run Pharm.D. course. Pharm.D. (Post Baccalaureate) course will be permitted only in those institutions which are permitted to run Pharm.D. course.

6. Course of study –

6.1. **Pharm.D Course** - The course of study for Pharm.D. shall include the subjects as given in the Tables below. The number of hours in a week, devoted to each subject for its teaching in theory, practical and tutorial shall not be less than that noted against it in columns (3), (4) and (5) below.

6.2. The total number of years taken by the candidate to complete the Pharm.D course shall not exceed 10 years from the date of admission.

TABLES

First Year:

S. No	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
1.1	Human Anatomy and Physiology	3	3	1
1.2	Pharmaceutics	2	3	1
1.3	Medicinal Biochemistry	3	3	1
1.4	Pharmaceutical Organic Chemistry	3	3	1
1.5	Pharmaceutical Inorganic Chemistry	2	3	1
1.6	Remedial Mathematics/ Biology**	3	3*	1
	Total Hours	16	18	6 = (40)

* For Biology

** For candidates who have studied PCMB in 10+2 course are exempted.

** Colleges to conduct the Examination.

Second Year:

S. No	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
2.1	Pathophysiology	3	-	1
2.2	Pharmaceutical Microbiology	3	3	1
2.3	Pharmacognosy & Phytopharmaceuticals	3	3	1
2.4	Pharmacology-I	3	3	1
2.5	Community Pharmacy	2	-	1
2.6	Pharmacotherapeutics-I	3	3	1
	Total Hours	17	12	6 = (32)

Third Year:

S. No	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial

(1)	(2)	(3)	(4)	(5)
3.1	Pharmacology-II	3	3	1
3.2	Pharmaceutical Analysis	3	3	1
3.3	Pharmacotherapeutics-II	3	3	1
3.4	Pharmaceutical Jurisprudence	2	-	-
3.5	Medicinal Chemistry	3	3	1
3.6	Pharmaceutical Formulations	2	3	1
	Total Hours	16	15	6 = (36)

Fourth Year:

S. No	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
4.1	Pharmacotherapeutics-III	3	3	1
4.2	Hospital Pharmacy	2	3	1
4.3	Clinical Pharmacy	3	3	1
4.4	Biostatistics & Research Methodology	2	-	1
4.5	Biopharmaceutics & Pharmacokinetics	3	3	1
4.6	Clinical Toxicology	2	-	1
	Total Hours	15	12	6 = (33)

Fifth Year:

S. No	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
5.1	Clinical Research	3	-	1
5.2	Pharmacoepidemiology and Pharmacoeconomics	3	-	1
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	2	-	1
5.4	Clerkship *	-	-	1

5.5	Project Work (Six Months)	-	20	-
	Total Hours	8	20	4 = (32)

* Attending ward rounds on daily basis.

Sixth Year:

Internship or residency training including postings in speciality units. Student should independently provide the clinical pharmacy services to the allotted wards.

- (i) Six months in General Medicine department, and
- (ii) Two months each in three other speciality departments

6.3. Pharm.D (Post Baccalaureate) Course - The course of study for Pharm.D (Post Baccalaureate) shall include the subjects as given in the Tables below. The number of hours in a week, devoted to each subject for its teaching in theory, practical and tutorial shall not be less than that noted against it in columns (3), (4) and (5) below.

6.4. The total number of years taken by the candidate to complete the Pharm.D (Post Baccalaureate) course shall not exceed 6 years from the date of admission.

T A B L E S

First Year (Post Baccalaureate):

S. No	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
1.1	Pharmacotherapeutics- I & II	3	3	1
1.2	Hospital & Community Pharmacy	3	3	1
1.3	Clinical Pharmacy	3	3	1
1.4	Biostatistics & Research Methodology	2	-	1
1.5	Clinical Toxicology	2	-	1
1.6	Pharmacotherapeutics-III	3	3	1
1.7	Biopharmaceutics & Pharmacokinetics	3	3	1
	Total Hours	19	15	7 = (41)

Second Year (Post Baccalaureate):

S. No	Name of Subject	No. of	No. of	No. of

		hours of Theory	hours of Practical	hours of Tutorial
(1)	(2)	(3)	(4)	(5)
2.1	Clinical Research	3	-	1
2.2	Pharmacoepidemiology and Pharmacoeconomics	3	-	1
2.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	2	-	1
2.4	Clerkship *	-	-	1
2.5	Project Work (Six Months)	-	20	-
	Total Hours	8	20	4 = (32)

* Attending ward rounds on daily basis.

Third Year:

Internship or residency training including postings in speciality units. Student should independently provide the clinical pharmacy services to the allotted wards.

(iii) Six months in General Medicine department, and

(iv) Two months each in three other speciality departments

7. Syllabus. – The syllabus for each subject of study in the said Tables shall be as specified in Appendix -A to these regulations.
8. Approval of institution conducting the course of study –
 - 8.1. The regular course for Pharm.D. I, II, III, IV, V and VI year shall be conducted by an institution approved by Pharmacy Council of India and affiliated to Rajiv Gandhi University of Health Sciences, Karnataka.
 - 8.2. Institution conducting Pharm D regular courses only shall be permitted to start Pharm D (Post Baccalaureate) course.
 - 8.3. The approval and affiliation will be granted only if adequate arrangements for teaching-infrastructural facilities, hospital, accommodation, equipments, chemicals, glassware, library, teaching and non- teaching staff are provided as prescribed by Pharmacy Council of India and as required under the norms of Rajiv Gandhi University of Health Science, Karnataka (as prescribed in Appendix B).
9. Examination –
 - 9.1. Every year there shall be an examination to examine the students.
 - 9.2. Each examination may be held twice every year. The first examination in a year shall be the annual examination and the second examination shall be supplementary examination.
 - 9.3. The examinations shall be of written and practical (including oral nature) carrying maximum marks for each part of a subject as indicated in Tables below:

T A B L E S

First Year Pharm.D examination:

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
1.1	Human Anatomy and Physiology	70	30	100	70	30	100
1.2	Pharmaceutics	70	30	100	70	30	100
1.3	Medicinal Biochemistry	70	30	100	70	30	100
1.4	Pharmaceutical Organic Chemistry	70	30	100	70	30	100
1.5	Pharmaceutical Inorganic Chemistry	70	30	100	70	30	100
1.6	Remedial Mathematics/Biology**	70	30	100	70*	30*	100*
				600			600 = 1200

*for Biology.

Second Year Pharm.D examination:

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
2.1	Pathophysiology	70	30	100	-	-	-
2.2	Pharmaceutical Microbiology	70	30	100	70	30	100
2.3	Pharmacognosy & Phytopharmaceuticals	70	30	100	70	30	100
2.4	Pharmacology-I	70	30	100	70	30	100
2.5	Community Pharmacy	70	30	100	-	-	-
2.6	Pharmacotherapeutics-I	70	30	100	70	30	100
				600			400 = 1000

Third Year Pharm.D examination:

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
3.1	Pharmacology-II	70	30	100	70	30	100
3.2	Pharmaceutical Analysis	70	30	100	70	30	100
3.3	Pharmacotherapeutics-II	70	30	100	70	30	100
3.4	Pharmaceutical Jurisprudence	70	30	100	-	-	-

3.5	Medicinal Chemistry	70	30	100	70	30	100
3.6	Pharmaceutical Formulations	70	30	100	70	30	100
				600			500 = 1100

Fourth Year Pharm.D examination:

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
4.1	Pharmacotherapeutics-III	70	30	100	70	30	100
4.2	Hospital Pharmacy	70	30	100	70	30	100
4.3	Clinical Pharmacy	70	30	100	70	30	100
4.4	Biostatistics & Research Methodology	70	30	100	-	-	-
4.5	Biopharmaceutics & Pharmacokinetics	70	30	100	70	30	100
4.6	Clinical Toxicology	70	30	100	-	-	-
				600			400 = 1000

Fifth Year Pharm.D examination:

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
5.1	Clinical Research	70	30	100	-	-	-
5.2	Pharmacoepidemiology and Pharmacoeconomics	70	30	100	-	-	-
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	70	30	100	-	-	-
5.4	Clerkship *	-	-	-	70	30	100
5.5	Project Work (Six Months)	-	-	-	100**	-	100
				300			200 = 500

*Attending ward rounds on daily basis.

**30 marks – viva-voce (oral); 70 marks – Thesis work

First Year Pharm.D (Post Baccalaureate) examination:

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
1.1	Pharmacotherapeutics-I & II	70	30	100	70	30	100
1.2	Hospital & Community Pharmacy	70	30	100	70	30	100
1.3	Clinical Pharmacy	70	30	100	70	30	100
1.4	Biostatistics & Research Methodology	70	30	100	-	-	-
1.5	Clinical Toxicology	70	30	100	-	-	-
1.6	Pharmacotherapeutics-III	70	30	100	70	30	100

1.7	Biopharmaceutics & Pharmacokinetics	70	30	100	70	30	100
				700			500 = 1200

Second Year Pharm.D (Post Baccalaureate) examination:

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
2.1	Clinical Research	70	30	100	-	-	-
2.2	Pharmacoepidemiology and Pharmacoeconomics	70	30	100	-	-	-
2.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	70	30	100	-	-	-
2.4	Clerkship *	-	-	-	70	30	100
2.5	Project Work (Six Months)	-	-	-	100**	-	100
				300			200 = 500

*Attending ward rounds on daily basis.

**30 marks – viva-voce (oral); 70 marks – Thesis work

10. Eligibility for appearing Examination – Only such students who produce certificate from the Head of the Institution in which he or she has undergone the Pharm.D. or as the case may be, the Pharm.D. (Post Baccalaureate) course, in proof of his or her having regularly and satisfactorily undergone the course of study by attending not less than 80% of the classes held both in theory and in practical separately in each subject shall be eligible for appearing at examination.

11. Mode of Examinations –

11.1. Theory examination shall be of three hours

11.2. Practical examination shall be as below:

11.2.1. Four hours duration for Pharm.D – I, II and III year course

11.2.2. Six hours duration for Pharm.D – IV and V year, and for Pharm.D (Post Baccalaureate) – I and II year.

11.3. Practical examination shall also consist of a viva –voce (Oral) examination.

11.4. Clerkship examination – Oral examination shall be conducted after the completion of clerkship of students. An external and an internal examiner will evaluate the student. Students' capabilities in delivering clinical pharmacy services, pharmaceutical care planning and knowledge of therapeutics shall be assessed.

12. Award of sessional marks and maintenance of records –

12.1. A regular record of both theory and practical class work and examinations conducted in an institution imparting training for Pharm.D. or as the case may be, Pharm.D. (Post Baccalaureate) course, shall be maintained for each student in the institution

and 30 marks for each theory and 30 marks for each practical subject shall be allotted as sessional.

12.2. There shall be at least two periodic sessional examinations during each academic year and the highest aggregate of any two performances shall form the basis of calculating sessional marks.

12.3. The sessional marks in practicals shall be allotted on the following basis-

- (i) Actual performance in the sessional examination (20 marks);
- (ii) Day to day assessment in the practical class work, promptness, viva-voce record maintenance, etc. (10 marks).

13. Minimum marks for passing examination —

13.1. A student shall not be declared to have passed examination unless he or she secures at least 50% marks in each of the subjects separately in the theory examinations, including sessional marks and at least 50% marks in each of the practical examinations including sessional marks.

13.2. A Student who fails in theory or practical examination of a subject shall re-appear both in theory and practical of the same subject.

13.3. The students securing 60% marks or above in aggregate in all subjects in a single attempt at the Pharm.D. or as the case may be, Pharm. D. (Post Baccalaureate) course examination shall be declared to have passed in first class. Students securing 75% marks or above in any subject or subjects shall be declared to have passed with distinction in the subject or those subjects provided he or she passes in all the subjects in a single attempt.

14. Eligibility for promotion to next year –

14.1. Failure in more than three subjects shall debar him or her from promotion to the next year classes.

14.2. The candidates who become eligible after clearing subject/subjects in the supplementary examination shall only be eligible to get admission to the next higher class along with the students of annual pattern of examination.

14.3. Students of I Pharm.D who have appeared for all the subjects are permitted to carryover not more than three failed subjects to II Pharm.D and appear for II Pharm.D examination concurrently along with failed subjects of I Pharm.D However, these Students have to pass all the failed subjects of I Pharm.D to become eligible to proceed to III Pharm.D.

14.4. Students of II Pharm.D who have appeared for all the subjects are permitted to carryover not more than three failed subjects to III Pharm.D and appear for III Pharm.D examination concurrently along with failed subjects of II Pharm.D However, these Students have to pass all the failed subjects of II Pharm.D to become eligible to proceed to IV Pharm.D.

14.5. Students of III Pharm.D who have appeared for all the subjects are permitted to carryover not more than three failed subjects to IV Pharm.D and appear for IV Pharm.D examination concurrently along with failed subjects of III Pharm.D

However, these Students have to pass all the failed subjects of III Pharm.D to become eligible to proceed to V Pharm.D.

- 14.6. Students of IV Pharm.D who have appeared for all the subjects are permitted to carryover not more than three failed subjects to V Pharm.D and appear for V Pharm.D examination concurrently along with failed subjects of IV Pharm.D
- 14.7. Students of I Pharm.D (Post Baccalaureate) who have appeared for all the subjects are permitted to carryover not more than three failed subjects to II Pharm.D (Post Baccalaureate) and appear for II Pharm.D (Post Baccalaureate) examination concurrently along with failed subjects of I Pharm.D (Post Baccalareate).
- 14.8. Students shall have to pass all the examinations of Pharm.D, or Pharm.D (Post Baccalaureate) as may be applicable, to be eligible to undergo Internship.

15. Internship –

- 15.1. Internship is a phase of training wherein a student is expected to conduct actual practice of pharmacy and health care and acquires skills under the supervision so that he or she may become capable of functioning independently.
- 15.2. Every student has to undergo one-year internship as per Appendix-C to these regulations.

16. Award of Degree –

- 16.1. Every student who has passed the examinations for the Pharm.D or Pharm.D. (Post Baccalaureate) as the case may be, and has successfully completed one year internship, shall be eligible for the award of degree.

17. Practical training

- 17.1. Hospital posting — Every student shall be posted in constituent hospital for a period of not less than seventy five hours to be covered in not less than 200 working days in each of second, third & fourth year course. Each student shall submit report duly certified by the preceptor and duly attested by the Head of the Department or Institution as prescribed. In the fifth year, every student shall spend half a day in the morning hours attending ward rounds on daily basis as a part of clerkship. Theory teaching may be scheduled in the afternoon.
- 17.2. Project work—
 - 17.2.1. To allow the student to develop data collection and reporting skills in the area of community, hospital and clinical pharmacy, a project work shall be carried out under the supervision of a teacher. The project topic must be approved by the Head of the Department or Head of the Institution. The same shall be announced to students within one month of commencement of the fifth year classes. Project work shall be presented in a written report and as a seminar at the end of the year. External and the internal examiners shall do the assessment of the project work.
 - 17.2.2. Project work shall comprise of objectives of the work, methodology, results, discussions and conclusions.
- 17.3. Objectives of project work— The main objectives of the project work is to—

- (i) show the evidence of having made accurate description of published work of others and of having recorded the findings in an impartial manner; and
 - (ii) develop the students in data collection, analysis and reporting and interpretation skills.
- 17.4. Methodology— To complete the project work following methodology shall be adopted, namely:—
- (i) students shall work in groups of not more than four under an authorised teacher;
 - (ii) The Head of the Department or Head of the Institution shall approve project topic;
 - (iii) project work chosen shall be related to the pharmacy practice in community, hospital and clinical setup. It shall be patient and treatment (Medicine) oriented, like drug utilisation reviews, pharmacoepidemiology, pharmacovigilance or pharmacoeconomics;
 - (iv) The institutional ethics committee shall approve project work;
 - (v) student shall present at least three seminars, one in the beginning, one at middle and one at the end of the project work; and
 - (vi) two-page write-up of the project indicating title, objectives, methodology anticipated benefits and references shall be submitted to the Head of the Department or Head of the Institution.
- 17.5. Reporting—
- 17.5.1. Student working on the project shall submit jointly to the Head of the Department or Head of the Institution a project report of about 40-50 pages. Project report should include a certificate issued by the authorised teacher, Head of the Department as well as by the Head of the Institution
- 17.5.2. Project report shall be computer typed in double space using Times Roman font on A4 paper. The title shall be in bold with font size 18, sub-titles in bold with font size 14 and the text with font size 12. The cover page of the project report shall contain details about the name of the student and the name of the authorised teacher with font size 14.
- 17.5.3. Submission of the project report shall be done at least one month prior to the commencement of annual or supplementary examination.
- 17.6. Evaluation— The following methodology shall be adopted for evaluating the project work—
- (i) Project work shall be evaluated by internal and external examiners.
 - (ii) Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of four students).
 - (iii) Three seminars presented by students shall be evaluated for thirty marks each and the average of best two shall be forwarded to the university with marks of other subjects.
 - (iv) Evaluation shall be done on the following items:

	Marks
a) Write up of the seminar	(7.5)
b) Presentation of work	(7.5)

	c) Communication skills	(7.5)
	d) Question and answer skills	(7.5)
	Total	(30 marks)
(v)	Final evaluation of project work shall be done on the following items: Marks	
	a) Write up of the seminar	(17.5)
	b) Presentation of work	(17.5)
	c) Communication skills	(17.5)
	d) Question and answer skills	(17.5)
	Total	(70 marks)

Explanation.— For the purposes of differentiation in the evaluation in case of topic being the same for the group of students, the same shall be done based on item numbers b, c and d mentioned above.

APPENDIX-A

PHARM.D. SYLLABUS

First Year

1.1 HUMAN ANATOMY & PHYSIOLOGY (THEORY)

Theory : 3 Hrs. /Week

- 1. Scope and Objectives:** This course is designed to impart a fundamental knowledge on the structure and functions of the human body. It also helps in understanding both homeostasis mechanisms and homeostatic imbalances of various body systems. Since a medicament, which is produced by pharmacist, is used to correct the deviations in human body, it enhances the understanding of how the drugs act on the various body systems in correcting the disease state of the organs.
- 2. Upon completion of the course the student shall be able to:**
 - a. describe the structure (gross and histology) and functions of various organs of the human body;
 - b. describe the various homeostatic mechanisms and their imbalances of various systems;
 - c. identify the various tissues and organs of the different systems of the human body;
 - d. perform the hematological tests and also record blood pressure, heart rate, pulse and Respiratory volumes;
 - e. appreciate coordinated working pattern of different organs of each system; and
 - f. appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body
- 3. Course materials:**

Text books

 - a. Tortora Gerard J. and Nicholas, P. Principles of anatomy and physiology Publisher Harpercollins college New York.
 - b. Wilson, K.J.W. Ross and Wilson's foundations of anatomy and physiology. Publisher: Churchill Livingstone, Edinburg.

Reference books

 - a. Guyton arthur, C. Physiology of human body. Publisher: Holtsaunders.
 - b. Chatterjee,C.C. Human physiology. Volume 1&11. Publisher: medical allied agency, Calcutta.
 - c. Peter L. Williams, Roger Warwick, Mary Dyson and Lawrence, H.

d. Gray's anatomy. Publisher:Churchill Livingstone, London.

4. Lecture wise program: Topics

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Scope of anatomy and physiology, basic terminologies used in this subject (Description of the body as such planes and terminologies)	1 Hour
2	Structure of cell – its components and their functions.	1 Hour
3	Elementary tissues of the human body: epithelial, connective, Muscular and nervous tissues-their sub-types and characteristics	2 Hours
4	Osseous System a) Structure , composition of Bones and functions of the skeleton. b) Classification of joints, Types of movements of joints and disorders of joints (Definitions only)	2 Hours
5	Haemopoietic system a) Composition and functions of blood b) Haemopoiesis and disorders of blood components (definition of disorder) c) Blood groups a) d)Clotting factors and mechanism d) Platelets and disorders of coagulation	6 Hours
6	Lymph a) Lymph and lymphatic system, composition, formation and circulation. b) Spleen: structure and functions, Disorders c) Disorders of lymphatic system (definition only)	3 Hours
7	Cardiovascular system a) Anatomy and functions of heart b) Blood vessels and circulation (Pulmonary, coronary and systemic circulation) c) Electrocardiogram (ECG) d) Cardiac cycle and heart sounds e) Blood pressure – its maintenance and regulation f) Definition of the following disorders: Hypertension, Hypotension, Arteriosclerosis, Atherosclerosis, Angina, Myocardial infarction, Congestive heart failure, Cardiac arrhythmias	8 Hours
8	Respiratory system a) Anatomy of respiratory organs and functions b) Mechanism / physiology of respiration and regulation of respiration c) Transport of respiratory gases d) Respiratory volumes and capacities, and Definition of: Hypoxia, Asphyxia, Dybarism, Oxygen therapy and resuscitation.	5 Hours
9	Digestive system	7 Hours

	a) Anatomy and physiology of GIT b) Anatomy and functions of accessory glands of GIT c) Digestion and absorption d) Disorders of GIT (definitions only)	
10	Nervous system a) Definition and classification of nervous system b) Anatomy, physiology and functional areas of cerebrum c) Anatomy and physiology of cerebellum d) Anatomy and physiology of mid brain e) Thalamus, hypothalamus and Basal Ganglia f) Spinal cord: Structure & reflexes – mono-poly-planter g) Cranial nerves – names and functions h) ANS – Anatomy & functions of sympathetic & parasympathetic N.S.	12 Hours
11	Urinary system a) Anatomy and physiology of urinary system b) Formation of urine c) Renin Angiotensin system – Juxtaglomerular apparatus - acid base Balance a) d) Clearance tests and micturition	6 Hours
12	Endocrine system a) Pituitary gland b) Adrenal gland c) Thyroid and Parathyroid glands b) d) Pancreas and gonads	5 Hours
13	Reproductive system a) Male and female reproductive system b) Their hormones – Physiology of menstruation c) Spermatogenesis & Oogenesis d) Sex determination (genetic basis) e) Pregnancy and maintenance and parturition c) f) Contraceptive devices	7 Hours
14	Sense organs a) Eye b) Ear c) Skin d) d) Tongue & Nose	6 Hours
15	Skeletal muscles a) Histology b) Physiology of Muscle contraction c) Physiological properties of skeletal muscle and their disorders (definitions)	2 Hours

16	Sports physiology a) Muscles in exercise, Effect of athletic training on muscles and muscle performance, b) Respiration in exercise, CVS in exercise, Body heat in exercise, Body fluids and salts in exercise, c) Drugs and athletics	2 Hours

1.1 HUMAN ANATOMY & PHYSIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

General Requirements: Dissection box, Laboratory Napkin, muslin cloth, record, Observation book(100pages), Stationary items, Blood lancet.

Course materials:

Text books

Goyal, R. K, Natvar M.P, and Shah S.A, Practical anatomy, physiology and biochemistry, latest edition, Publisher: B.S Shah Prakashan, Ahmedabad.

Reference books

Ranade VG, Text book of practical physiology, Latest edition, Publisher: PVG, Pune
 Anderson Experimental Physiology, Latest edition, Publisher: NA

List of Experiments:

- Study of tissues of human body
 - Epithelial tissue.
 - Muscular tissue.
- Study of tissues of human body
 - Connective tissue
 - Nervous tissue.
- Study of appliances used in hematological experiments.
- Determination of W.B.C. count of blood.
- Determination of R.B.C. count of blood.
- Determination of differential count of blood.
- Determination of
 - Erythrocyte Sedimentation Rate.
 - Hemoglobin content of Blood.
 - Bleeding time & Clotting time.
- Determination of
 - Blood Pressure.
 - Blood group.
- Study of various systems with the help of charts, models & specimens
 - Skeleton system part I-axial skeleton.

- (b) Skeleton system part II- appendicular skeleton.
 - (c) Cardiovascular system.
 - (d) Respiratory system.
 - (e) Digestive system.
 - (f) Urinary system.
 - (g) Nervous system.
 - (h) Special senses.
 - (i) Reproductive system.
10. Study of different family planning appliances.
 11. To perform pregnancy diagnosis test.
 12. Study of appliances used in experimental physiology.
 13. To record simple muscle curve using gastrocnemius sciatic nerve preparation.
 14. To record simple summation curve using gastrocnemius sciatic nerve preparation.
 15. To record simple effect of temperature using gastrocnemius sciatic nerve preparation.
 16. To record simple effect of load & after load using gastrocnemius sciatic nerve preparation.
 17. To record simple fatigue curve using gastrocnemius sciatic nerve preparation.

Scheme of Practical Examination:

	Sessionals	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.2 PHARMACEUTICS (THEORY)

Theory: 2 Hrs. /Week

- 1. Scope and objectives:** This course is designed to impart a fundamental knowledge on the art and science of formulating different dosage forms. It prepares the students for most basics of the applied field of pharmacy.
- 2. Upon the completion of the course the student should be able to:**
 - a. know the formulation aspects of different dosage forms;
 - b. do different pharmaceutical calculation involved in formulation;
 - c. formulate different types of dosage forms; and
 - d. appreciate the importance of good formulation for effectiveness.

3. Course materials:

Text books

- a. Cooper and Gunns Dispensing for pharmacy students.
- b. A text book Professional Pharmacy by N.K.Jain and S.N.Sharma.

Reference books

- a. Introduction to Pharmaceutical dosage forms by Howard C. Ansel.
- b. Remington's Pharmaceutical Sciences.
- c. Register of General Pharmacy by Cooper and Gunn.
- d. General Pharmacy by M.L.Schroff.

4. Lecture wise programme:

Topics

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	a. Introduction to dosage forms - classification and definitions b. Prescription: definition, parts and handling c. Posology: Definition, Factors affecting dose selection. Calculation of children and infant doses.	8 Hours
2	Historical back ground and development of profession of pharmacy and pharmaceutical industry in brief.	2 Hours
3	Development of Indian Pharmacopoeia and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.	2 Hours

4	Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc.	2 Hours
5	Powders and Granules: Classification advantages and disadvantages, Preparation of simple, compound powders, Insufflations, Dusting powders, Eutectic and Explosive powders, Tooth powder and effervescent powders and granules.	4 Hours
6	Monophasic Dosage forms: Theoretical aspects of formulation including adjuvant like stabilizers, colorants, flavours with examples. Study of Monophasic liquids like gargles, mouth washes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions.	5 Hours
7	Biphasic dosage forms: Suspensions and emulsions, Definition, advantages and disadvantages, classification, test for the type of emulsion, formulation, stability and evaluation.	8 Hours
8	Suppositories and pessaries: Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation.	5 Hours
9	Galenicals: Definition, equipment for different extraction processes like infusion, Decoction, Maceration and Percolation, methods of preparation of spirits, tinctures and extracts.	5 Hours
10	Pharmaceutical calculations.	2 Hours
11	Surgical aids: Surgical dressings, absorbable gelatin sponge, sutures, ligatures and medicated bandages.	4 Hours
12	Incompatibilities: Introduction, classification and methods to overcome the incompatibilities.	3 Hours

1.2 PHARMACEUTICS (PRACTICAL)

Practical: 3 Hrs./Week

List of Experiments:

1. Syrups

- a) Simple Syrup I.P
- b) Syrup of Ephedrine Hcl NF
- c) Syrup Vasaka IP
- d) Syrup of ferrous Phosphate IP
- e) Orange Syrup

2. Elixir

- a) Piperizine citrate elixir BP
- b) Cascara elixir BPC
- c) Paracetamol elixir BPC

3. Linctus

- a) Simple Linctus BPC
- b) Pediatric simple Linctus BPC

4. Solutions

- a) Solution of cresol with soap IP
- b) Strong solution of ferric chloride BPC
- c) Aqueous Iodine Solution IP
- d) Strong solution of Iodine IP
- e) Strong solution of ammonium acetate IP

5. Liniments

- a) Liniment of turpentine IP*
- b) Liniment of camphor IP

6. Suspensions*

- a) Calamine lotion
- b) Magnesium Hydroxide mixture BP

7. Emulsions*

- a) Cod liver oil emulsion
- b) Liquid paraffin emulsion

8. Powders

- a) Eutectic powder
- b) Explosive powder
- c) Dusting powder

d) Insufflations

9. Suppositories_

- a) Boric acid suppositories
- b) Chloral suppositories

10. Incompatibilities

- a) Mixtures with Physical
- b) Chemical & Therapeutic incompatibilities

* colourless bottles required for dispensing - Paper envelope (white), butter paper and white paper required for dispensing.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.3 MEDICINAL BIOCHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

1. Scope of the Subject: Applied biochemistry deals with complete understanding of the molecular level of the chemical process associated with living cells. Clinical chemistry deals with the study of chemical aspects of human life in health and illness and the application of chemical laboratory methods to diagnosis, control of treatment, and prevention of diseases.

2. Objectives of the Subject (Know, do, appreciate):

The objective of the present course is providing biochemical facts and the principles to the students of pharmacy. Upon completion of the subject student shall be able to –

- a. understand the catalytic activity of enzymes and importance of isoenzymes in diagnosis of diseases;
- b. know the metabolic process of biomolecules in health and illness (metabolic disorders);
- c. understand the genetic organization of mammalian genome; protein synthesis; replication; mutation and repair mechanism;
- d. know the biochemical principles of organ function tests of kidney, liver and endocrine gland; and
- e. do the qualitative analysis and determination of biomolecules in the body fluids.

Text books (Theory)

- a. Harpers review of biochemistry - Martin
- b. Text book of biochemistry – D.Satyanarayana
- c. Text book of clinical chemistry- Alex kaplan &Laverve L.Szabo

Reference books (Theory)

- a. Principles of biochemistry -- Lehninger
- b. Text book of biochemistry -- Ramarao
- c. Practical Biochemistry-David T.Plummer.
- d. Practical Biochemistry-Pattabhiraman.

3. Lecture wise programme:

Topics

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Introduction to biochemistry: Cell and its biochemical organization, transport process across the cell membranes. Energy rich compounds; ATP, Cyclic AMP and their biological significance.	3 Hours
2	Enzymes: Definition; Nomenclature; IUB classification; Factor affecting enzyme activity; Enzyme action; enzyme inhibition. Isoenzymes and their therapeutic and diagnostic applications; Coenzymes and their biochemical role and deficiency diseases.	12 hours
3	Carbohydrate metabolism: Glycolysis, Citric acid cycle (TCA cycle), HMP shunt, Glycogenolysis, gluconeogenesis, glycogenesis. Metabolic disorders of carbohydrate metabolism (diabetes mellitus and glycogen storage diseases); Glucose, Galactose tolerance test and their significance; hormonal regulation of carbohydrate metabolism.	13 Hours
4	Lipid metabolism: Oxidation of saturated (β -oxidation); Ketogenesis and ketolysis; biosynthesis of fatty acids, lipids; metabolism of cholesterol; Hormonal regulation of lipid metabolism. Defective metabolism of lipids (Atherosclerosis, fatty liver, hypercholesterolemia).	10 Hours
5	Biological oxidation: Coenzyme system involved in Biological oxidation. Electron transport chain (its mechanism in energy capture; regulation and inhibition); Uncouplers of ETC; Oxidative phosphorylation;	5 Hours
6	Protein and amino acid metabolism: protein turn over; nitrogen balance; Catabolism of Amino acids (Transamination, deamination & decarboxylation). Urea cycle and its metabolic disorders; production of bile pigments; hyperbilirubinemia, porphoria, jaundice. Metabolic disorder of Amino acids.	12 Hours
7	Nucleic acid metabolism: Metabolism of purine and pyrimidine nucleotides; Protein synthesis; Genetic code; inhibition of protein synthesis; mutation and repair mechanism; DNA replication (semiconservative /onion peel models) and DNA repair mechanism.	12 Hours
8	Introduction to clinical chemistry: Cell; composition; malfunction; Roll of the clinical chemistry laboratory.	2 Hours
9	The kidney function tests: Role of kidney; Laboratory tests for normal function includes a) Urine analysis (macroscopic and physical examination, quantitative and semiquantitative tests.) b) Test for NPN constituents. (Creatinine /urea clearance, determination of blood and urine creatinine, urea and uric acid)	2 Hours

	c) Urine concentration test d) Urinary tract calculi. (stones)	
10	Liver function tests: Physiological role of liver, metabolic, storage, excretory, protective, circulatory functions and function in blood coagulation. a) Test for hepatic dysfunction-Bile pigments metabolism. b) Test for hepatic function test- Serum bilirubin, urine bilirubin, and urine urobilinogen. c) Dye tests of excretory function. d) Tests based upon abnormalities of serum proteins. Selected enzyme tests.	2 Hours
11	Lipid profile tests: Lipoproteins, composition, functions. Determination of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides.	2 Hours
12	Immunochemical techniques for determination of hormone levels and protein levels in serum for endocrine diseases and infectious diseases. Radio immuno assay (RIA) and Enzyme Linked Immuno Sorbent Assay (ELISA)	2 Hours
13	Electrolytes: Body water, compartments, water balance, and electrolyte distribution. Determination of sodium, calcium potassium, chlorides, bicarbonates in the body fluids.	2 Hours

1.3 MEDICINAL BIOCHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

Title of the Experiment:

1. Qualitative analysis of normal constituents of urine.*
2. Qualitative analysis of abnormal constituents of urine.*
3. Quantitative estimation of urine sugar by Benedict's reagent method.**
4. Quantitative estimation of urine chlorides by Volhard's method.**
5. Quantitative estimation of urine creatinine by Jaffe's method.**
6. Quantitative estimation of urine calcium by precipitation method.**
7. Quantitative estimation of serum cholesterol by Libermann Burchard's method.**
8. Preparation of Folin Wu filtrate from blood.*
9. Quantitative estimation of blood creatinine.**
10. Quantitative estimation of blood sugar Folin-Wu tube method.**
11. Estimation of SGOT in serum.**
12. Estimation of SGPT in serum.**

13. Estimation of Urea in Serum.**
 14. Estimation of Proteins in Serum.**
 15. Determination of serum bilirubin**
 16. Determination of Glucose by means of Glucoseoxidase.**
 17. Enzymatic hydrolysis of Glycogen/Starch by Amylases.**
 18. Study of factors affecting Enzyme activity. (pH & Temp.)**
 19. Preparation of standard buffer solutions and its pH measurements (any two)*
 20. Experiment on lipid profile tests**
 21. Determination of sodium,calcium and potassium in serum.**
- ** indicate major experiments & * indicate minor experiments

Assignments:

Format of the assignment

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.4 PHARMACEUTICAL ORGANIC CHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

- 1. Scope and objectives:** This course is designed to impart a very good knowledge about
 - a. IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds;
 - b. Some important physical properties of organic compounds;
 - c. Free radical/ nucleophilic [alkyl/ acyl/ aryl] / electrophilic substitution, free radical/ nucleophilic / electrophilic addition, elimination, oxidation and reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability of compounds;
 - d. Some named organic reactions with mechanisms; and
 - e. Methods of preparation, test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.

2. Course materials:

Text books

- a. T.R.Morrison and R. Boyd - Organic chemistry,
- b. Bentley and Driver-Text book of Pharmaceutical chemistry
- c. I.L.Finer- Organic chemistry, the fundamentals of chemistry

Reference books

- a. Organic chemistry – J.M.Cram and D.J.Cram
- b. Organic chemistry- Brown
- c. Advanced organic chemistry- Jerry March, Wiley
- d. Organic chemistry- Cram and Hammered, Pine Hendrickson

3. Lecture wise programme :

Topics

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Structures and Physical properties: a) Polarity of bonds, polarity of molecules, M.P, Inter molecular forces, B.P, Solubility, non ionic solutes and ionic solutes, protic and aprotic Solvents, ion pairs, b) Acids and bases, Lowry bronsted and Lewis theories c) Isomerism	3 Hours

2	Nomenclature of organic compound belonging to the following classes Alkanes, Alkenes, Dienes, Alkynes, Alcohols, Aldehydes, Ketones, Amides, Amines, Phenols, Alkyl Halides, Carboxylic Acid, Esters, Acid Chlorides And Cycloalkanes.	8 Hours
3	Free radicals chain reactions of alkane : Mechanism, relative reactivity and stability	3 Hours
4	Alicyclic compounds : Preparations of cyclo alkanes, Bayer strain theory and orbital picture of angle strain.	3 Hours
5	Nucleophilic aliphatic substitution mechanism: Nucleophiles and leaving groups, kinetics of second and first order reaction, mechanism and kinetics of SN2 reactions. Stereochemistry and steric hindrance, role of solvents, phase transfer catalysis, mechanism and kinetics of SN1 reactions, stereochemistry, carbocation and their stability, rearrangement of carbocation, role of solvents in SN1 reaction, Ion dipole bonds, SN2 versus SN1 solvolyses, nucleophilic assistance by the solvents.	8 Hours
6	Dehydro halogenation of alkyl halides: 1,2 elimination, kinetics, E2 and E1 mechanism, elimination via carbocation, evidence for E2 mechanism, absence of rearrangement isotope effect, absence hydrogen exchange, the element effect, orientation and reactivity, E2 versus E1, elimination versus substitution, dehydration of alcohol, ease of dehydration, acid catalysis, reversibility, orientation.	7 Hours
7	Electrophilic and free radicals addition: Reactions at carbon -carbon, double bond, electrophile, hydrogenation, heat of hydrogenation and stability of alkenes, markownikoff rule, addition of hydrogen halides, addition of hydrogen bromides, peroxide effect, electrophilic addition, mechanism, rearrangement, absence of hydrogen exchange, orientation and reactivity, addition of halogen, mechanism, halohydrin formation, mechanism of free radicals addition, mechanism of peroxide initiated addition of hydrogen bromide, orientation of free addition, additions of carbene to alkene, cyclo addition reactions.	5 Hours
8	Carbon-carbon double bond as substituents: Free radical halogenations of alkenes, comparison of free radical substitution with free radical addition, free radical substitution in alkenes, orientation and reactivity, allylic rearrangements.	2 Hours
9	Theory of resonance: Allyl radical as a resonance hybrid, stability, orbital picture, resonance stabilisation of allyl radicals, hyper conjugation, allyl cation as a resonance hybrid, nucleophilic substitution in allylic substrate, SN1 reactivity, allylic rearrangement, resonance stabilisation of allyl cation, hyper conjugation, nucleophilic substitution in allylic substrate,	6 Hours

	SN2 nucleophilic substitution in vinylic substrate, vinylic cation, stability of conjugated dienes, resonance in alkenes, hyper conjugation, ease of formation of conjugated dienes, orientation of elimination, electrophilic addition to conjugated dienes, 1,4 - addition, 1,2-versus 1,4-addition, rate versus equilibrium, orientation and reactivity of free radical addition to conjugated dienes.	
10	Electrophilic aromatic substitution: Effect of substituent groups, determination of orientation, determination of relative reactivity, classification of substituent group, mechanism of nitration, sulphonation, halogenation, Friedel-Craft alkylation, Friedel-Craft acylation, reactivity and orientation, activating and deactivating O,P,M directing groups, electron release via resonance, effect of halogen on electrophilic aromatic substitution in alkyl benzene, side chain halogenation of alkyl benzene, resonance stabilization of benzyl radical.	8 Hours
11	Nucleophilic addition reaction: Mechanism, ionisation of carboxylic acids, acidity constants, acidity of acids, structure of carboxylate ions, effect of substituent on acidity, nucleophilic acyl substitution reaction, conversion of acid to acid chloride, esters, amide and anhydride. Role of carboxyl group, comparison of alkyl nucleophilic substitution with acyl nucleophilic substitution.	4 Hours
12	Mechanism of aldol condensation, Claisen condensation, Cannizzaro reaction, crossed aldol condensation, crossed Cannizzaro reaction, Benzoin condensation, Perkin condensation. Knoevenagel, Reformatsky reaction, Wittig reaction, Michael addition.	4 Hours
13	Hoffman rearrangement: Migration to electron deficient nitrogen, Sandmeyer's reaction, basicity of amines, diazotisation and coupling, acidity of phenols, Williamson synthesis, Fries rearrangement, Kolbe reaction, Reimer-Tiemann's reactions.	5 hours
14	Nucleophilic aromatic substitution: Bimolecular displacement mechanisms, orientation, comparison of aliphatic nucleophilic substitution with that of aromatic.	2 Hours
15	Oxidation reduction reaction.	2 Hours
16	Study of the following official compounds- preparation, test for purity, assay and medicinal uses of Chlorbutol, Dimercaprol, Glyceryl trinitrate, Urea, Ethylene diamine dihydrate, Vanillin, Paraldehyde, Ethylene chloride, Lactic acid, Tartaric acid, citric acid, salicylic acid, aspirin, methyl salicylate, ethyl benzoate, benzyl benzoate, dimethyl phthalate, sodium lauryl sulphate, saccharin sodium, mephensin.	5 Hours

1.4 PHARMACEUTICAL ORGANIC CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

I. Introduction to the various laboratory techniques through demonstration involving synthesis of the following compounds (at least 8 compounds to be synthesised):

1. Acetanilide / aspirin (Acetylation)
2. Benzanilide / Phenyl benzoate (Benzoylation)
3. P-bromo acetanilide / 2,4,6 – tribromo aniline (Bromination)
4. Dibenzylidene acetone (Condensation)
5. 1-Phenylazo-2-naphthol (Diazotisation and coupling)
6. Benzoic acid / salicylic acid (Hydrolysis of ester)
7. M-dinitro benzene (Nitration)
8. 9, 10 – Anthraquinone (Oxidation of anthracene) / preparation of benzoic acid from toluene or benzaldehyde
9. M-phenylene diamine (Reduction of M-dinitrobenzene) / Aniline from nitrobenzene
10. Benzophenone oxime
11. Nitration of salicylic acid
12. Preparation of picric acid
13. Preparation of O-chlorobenzoic acid from O-chlorotoluene
14. Preparation of cyclohexanone from cyclohexanol

II. Identification of organic compounds belonging to the following classes by :

Systematic qualitative organic analysis including preparation of derivatives Phenols, amides, carbohydrates, amines, carboxylic acids, aldehyde and ketones, Alcohols, esters, hydrocarbons, anilides, nitrocompounds.

III. Introduction to the use of stereo models:

Methane, Ethane, Ethylene, Acetylene, Cis alkene, Trans alkene, inversion of configuration.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15

Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.5 PHARMACEUTICAL INORGANIC CHEMISTRY (THEORY)

Theory : 2 Hrs./Week

- 1. Scope and objectives:** This course mainly deals with fundamentals of Analytical chemistry and also the study of inorganic pharmaceuticals regarding their monographs and also the course deals with basic knowledge of analysis of various pharmaceuticals.
- 2. Upon completion of the course student shall be able to:**
 - a. understand the principles and procedures of analysis of drugs and also regarding the application of inorganic pharmaceuticals;
 - b. know the analysis of the inorganic pharmaceuticals their applications; and
 - c. appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.

3. Course materials:

Text books

- a. A text book Inorganic medicinal chemistry by Surendra N. Pandeya
- b. A. H. Beckett and J. B. Stanlake's Practical Pharmaceutical chemistry Vol –I & Vol-II
- c. Inorganic Pharmaceutical Chemistry III-Edition P.Gundu Rao

Reference books

- a. Inorganic Pharmaceutical Chemistry by Anand & Chetwal
- b. Pharmaceutical Inorganic chemistry by Dr.B.G.Nagavi
- c. Analytical chemistry principles by John H. Kennedy
- d. I.P.1985 and 1996, Govt. of India, Ministry of health

4. Lecture wise programme:

Topics

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Errors: Errors in quantitative analysis, classification of errors, concept of	3 Hours

	accuracy and precision, treatment of analytical	
2	Volumetric analysis: Principle of volumetric analysis, different methods of analysis, different methods of expressing concentrations of solutions, Primary and secondary standards.	4 Hours
3	Acid-base titrations: Acid-base concepts, relative strength of acids and bases, law of mass action, common ion effect, ionic product of water, Henderson-Hasselbalch equation, buffer solutions, theory of indicators, neutralization curves, choice of indicators, mixed and universal indicators.	3 Hours
4	Redox titrations: Concepts of oxidation and reduction reactions. Redox reactions, theory of redox titrations, redox indicators, iodometry, iodimetry, titrations involving ceric sulphate, potassium iodate, potassium bromate, titanous chloride, Potassium permanganate.	3 Hours
5	Non aqueous titrations: Theoretical basis, types of solvents, preparations and standardization of titrant solutions, titration of weak acid, weak bases and indicators. Standardization of perchloric acid, lithium and sodium methoxide, tetrabutyl ammonium hydroxide.	2 Hours
6	Precipitation titrations: Introduction, types of precipitation titrations, end point detection.	2 Hours
7	Complexometric titrations: Introduction, principle, types of titrations, end-point detection.	2 Hours
8	Theory of Indicators	1 Hour
9	Gravimetry: Basic concepts, precipitation techniques, co-precipitations, post-precipitation, various steps involved in gravimetric analysis, pharmaceutical applications.	2 Hours
10	Limit tests: Definition, importance, general procedure for limit test for chlorides, sulphates, iron, arsenic, lead and heavy metals	4 Hours
11	Medicinal gases: Preparation and uses of the following oxygen, carbon dioxide, Helium, Nitrogen and Nitrous oxide.	2 Hours
Method of preparation, assay, storage conditions and uses of Inorganic compounds listed in IP belonging to the following categories.		
12	Acidifiers: Dilute HCl, Sodium Phosphate, Ammonium chloride.	1 Hour
13	Antacids: Classification, qualities of an ideal antacid, side effects, advantages, combination therapy, acid neutralizing capacity, sodium bicarbonate, Potassium citrate, Aluminium hydroxide gel, Dried Aluminium hydroxide gel, magnesium hydroxide, Light and Heavy	3 Hours

	magnesium trisilicate, Light and Heavy magnesium carbonate, Calcium carbonate, Magaldrate and Bismuth carbonate.	
14	Cathartics: Magnesium hydroxide, Magnesium sulphate, Magnesium carbonate, Sodium phosphate.	2 Hours
15	Electrolyte replenishers: Electrolytes used for replacement therapy: sodium chloride, potassium chloride, calcium chloride, calcium gluconate. Electrolytes used in acid-base therapy: Sodium acetate, potassium acetate, sodium bicarbonate, potassium bicarbonate, sodium citrate, sodium lactate, ammonium chloride, Electrolyte combination therapy, compound sodium chloride solution, sodium chloride injection and oral rehydration salt.	3 Hours
16	Essential Trace elements: Definition, physiological role of Iron, Copper, Zinc, Chromium, Manganese, Molybdenum, Selenium, Sulphur and Iodine.	2 Hours
17	Antimicrobials: Hydrogen peroxide, Potassium permanganate, Chlorinated Lime, Iodine, Boric acid, Silver nitrate, Selenium Sulphide.	2 Hours
18	Pharmaceutical Aids: Sodium bisulphate, sodium metabisulphite, bentonite, magnesium stearate, zinc stearate, aluminium sulphate, sodium carboxy methylcellulose, purified water, water for injection and sterile water for injection.	2 Hours
19	Dental Products: Anti-caries agents: Role of Fluorides as anti-caries agents, Sodium Fluoride. Dentifrices: Calcium carbonate, dibasic calcium phosphate, Zinc chloride.	2 Hours
20	Miscellaneous compounds Sclerosing agents: Hypertonic saline, Sodium tetra decyl sulphate. Expectorants: Potassium citrate and Potassium iodide. Sedative: Potassium bromide. Antidotes: Sodium nitrite, Sodium thiosulphate and Charcoal Respiratory stimulant: Ammonium carbonate.	3 Hours
21	Radio Pharmaceuticals: Introduction, measurement of radioactivity, clinical applications and dosage, hazards and precautions.	2 Hours

1.5 PHARMACEUTICAL INORGANIC CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

1. Limit test (6 exercises)

- a. Limit test for chlorides
- b. Limit test for sulphates
- c. Limit test for iron
- d. Limit test for heavy metals
- e. Limit test for arsenic
- f. Modified limit tests for chlorides and sulphates

2. Assays (10 exercises)

- a. Ammonium chloride- Acid-base titration
- b. Ferrous sulphate- Cerimetry
- c. Copper sulphate- Iodometry
- d. Calcium gluconate- Complexometry
- e. Hydrogen peroxide – Permanganometry
- f. Sodium benzoate – Nonaqueous titration
- g. Sodium chloride – Modified volhard's method
- h. Assay of KI – KIO₃ titration
- i. Gravimetric estimation of barium as barium sulphate
- j. Sodium antimony gluconate or antimony potassium tartarate

3. Estimation of mixture (Any two exercises)

- a. Sodium hydroxide and sodium carbonate
- b. Boric acid and Borax
- c. Oxalic acid and sodium oxalate

4. Test for identity (Any three exercises)

- a. Sodium bicarbonate
- b. Barium sulphate
- c. Ferrous sulphate
- d. Potassium chloride

5. Test for purity (Any two exercises)

- a. Swelling power in Bentonite
- b. Acid neutralising capacity in aluminium hydroxide gel
- c. Ammonium salts in potash alum
- d. Adsorption power heavy Kaolin
- e. Presence of Iodates in KI

6. Preparations (Any two exercises)

- a. Boric acids
- b. Potash alum
- c. Calcium lactate
- d. Magnesium sulphate

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.6 REMEDIAL MATHEMATICS/BIOLOGY (THEORY)

Theory: 3 Hrs. /Week

REMEDIAL MATHEMATICS:

1. **Scope and objectives:** This is an introductory course in mathematics. This subjects deals with the introduction to matrices, determinants, trigonometry, analytical geometry, differential calculus, integral calculus, differential equations, laplace transform.
2. **Upon completion of the course the student shall be able to : –**
 - a. Know Trigonometry, Analytical geometry, Matrices, Determinant, Integration, Differential equation, Laplace transform and their applications;
 - b. solve the problems of different types by applying theory; and
 - c. appreciate the important applications of mathematics in pharmacy.
3. **Course materials:**

Text books

- a. Differential calculus By Shantinakaran
- b. Text book of Mathematics for second year pre-university by Prof.B.M.Sreenivas

Reference books

- a. Integral calculus By Shanthinarayan
- b. Engineering mathematics By B.S.Grewal
- c. Trigonometry Part-I By S.L.Loney

4. Lecture wise programme :**Topics**

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Algebra: Determinants, Matrices	
2	Trigonometry: Sides and angles of a triangle, solution of triangles	
3	Analytical Geometry: Points, Straight line, circle, parabola	
4	Differential calculus: Limit of a function, Differential calculus, Differentiation of a sum, Product, Quotient Composite, Parametric, Exponential, trigonometric and Logarithmic function. Successive differentiation, Leibnitz's theorem, Partial differentiation, Euler's theorem on homogeneous functions of two variables	
5	Integral Calculus: Definite integrals, integration by substitution and by parts, Properties of definite integrals.	
6	Differential equations: Definition, order, degree, variable separable, homogeneous, Linear, heterogeneous, linear, differential equation with constant coefficient, simultaneous linear equation of second order.	
7	Laplace transform: Definition, Laplace transform of elementary functions, Properties of linearity and shifting.	

BIOLOGY:

1. Scope and objectives: This is an introductory course in Biology, which gives detailed study of natural sources such as plant and animal origin. This subject has been introduced to the pharmacy course in order to make the student aware of various naturally occurring drugs and its history, sources, classification, distribution and the characters of the plants and animals. This subject gives basic foundation to Pharmacognosy.

2. Course materials:**Text books**

- Text book of Biology by S.B.Gokhale
- A Text book of Biology by Dr.Thulajappa and Dr. Seetaram.

Reference books

- A Text book of Biology by B.V.Sreenivasa Naidu
- A Text book of Biology by Naidu and Murthy
- Botany for Degree students By A.C.Dutta.
- Outlines of Zoology by M.Ekambaranatha ayyer and T.N.Ananthakrishnan.
- A manual for pharmaceutical biology practical by S.B.Gokhale and C.K.Kokate.

3. Lecture wise programme :**Topic**

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
PART-A		
1	Introduction	
2	General organization of plants and its inclusions	
3	Plant tissues	
4	Plant kingdom and its classification	
5	Morphology of plants	
6	Root, Stem, Leaf and Its modifications	
7	Inflorescence and Pollination of flowers	
8	Morphology of fruits and seeds	
9	Plant physiology	

10	Taxonomy of Leguminosae, umbelliferae, Solanaceae, Lilliacae, Zinziberaceae, Rubiaceae	
11	Study of Fungi, Yeast, Penicillin and Bacteria	
PART-B		
1	Study of Animal cell	
2	Study animal tissues	
3	Detailed study of frog	
4	Study of Pisces, Reptiles, Aves	
5	General organization of mammals	
6	Study of poisonous animals	

1.6 BIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

Title:

1. Introduction of biology experiments
2. Study of cell wall constituents and cell inclusions
3. Study of Stem modifications
4. Study of Root modifications
5. Study of Leaf modifications
6. Identification of Fruits and seeds
7. Preparation of Permanent slides
8. T.S. of Senna, Cassia, Ephedra, Podophyllum.
9. Simple plant physiological experiments
10. Identification of animals
11. Detailed study of Frog
12. Computer based tutorials

Scheme of Practical Examination:

	Sessionals	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Second year**2.1 PATHOPHYSIOLOGY (THEORY)****Theory : 3 Hrs. /Week**

1. **Scope of the Subject:** This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic Pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge of its application in other subject of pharmacy.
2. **Objectives of the Subject:** Upon completion of the subject student shall be able to –
 - a. describe the etiology and pathogenesis of the selected disease states;
 - b. name the signs and symptoms of the diseases; and
 - c. mention the complications of the diseases.

Text books (Theory)

- a. Pathologic basis of disease by- Cotran, Kumar, Robbins
- b. Text book of Pathology- Harsh Mohan
- c. Text book of Pathology- Y.M. Bhide

Reference books (Theory)

- a. Clinical Pharmacy and Therapeutics; Second edition; Roger Walker; Churchill Livingstone publication

3. Detailed syllabus and lecture wise schedule:

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Basic principles of cell injury and Adaptation a) Causes, Pathogenesis and morphology of cell injury b) Abnormalities in lipoproteinaemia, glycogen infiltration and glycogen infiltration and glycogen storage diseases	6 Hours
2	Inflammation a) Pathogenesis of acute inflammation, Chemical mediators in inflammation, Types of chronic inflammation b) Repairs of wounds in the skin, factors influencing healing of wounds	7 Hours
3	Diseases of Immunity a) Introduction to T and B cells b) MHC proteins or transplantation antigens	15 Hours

	c) Immune tolerance - Hypersensitivity Hypersensitivity type I, II, III, IV, Biological significance, Allergy due to food, chemicals and drugs - Autoimmunity Criteria for autoimmunity, Classifications of autoimmune diseases in man, mechanism of autoimmunity, Transplantation and immunologic tolerance, allograft rejections, transplantation antigens, mechanism of rejection of allograft. - Acquired immune deficiency syndrome (AIDS) - Amyloidosis	
4	Cancer: differences between benign and malignant tumors, Histological diagnosis of malignancy, invasions and metastasis, patterns of spread, disturbances of growth of cells, classification of tumors, general biology of tumors, spread of malignant tumors, etiology and pathogenesis of cancer.	10 Hours
5	Types of shock, mechanisms, stages and management	2 Hours
6	Biological effects of radiation	1 Hour
7	Environmental and nutritional diseases a) Air pollution and smoking- SO₂, NO, NO₂, and CO b) Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation.	5 Hours
8	Pathophysiology of common diseases a) Parkinsonism b) Schizophrenia c) Depression and mania d) Hypertension, e) Stroke (ischaemic and hemorrhage) f) Angina, CCF, Atherosclerosis, Myocardial infarction g) Diabetes Mellitus h) Peptic ulcer and inflammatory bowel diseases i) Cirrhosis and Alcoholic liver diseases j) Acute and chronic renal failure k) Asthma and chronic obstructive airway diseases	19 Hours
9	Infectious diseases: Sexually transmitted diseases (HIV, Syphilis, Gonorrhea), Urinary tract infections, Pneumonia, Typhoid, Tuberculosis, Leprosy, Malaria Dysentery (bacterial and amoebic), Hepatitis- infective hepatitis.	10 Hours

4. Assignments :

Title of the Experiment

1. Chemical Mediators of inflammation
2. Drug Hypersensitivity
3. Cigarette smoking & its ill effects
4. Biological Effects of Radiation
5. Etiology and hazards of obesity
6. Complications of diabetes
7. Diagnosis of cancer
8. Disorders of vitamins
9. Methods in Pathology-Laboratory values of clinical significance
10. Pathophysiology of Dengue Hemorrhagic Fever (DHF)

Format of the assignment

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy.
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

2.2 PHARMACEUTICAL MICROBIOLOGY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** Microbiology has always been an essential component of pharmacy curriculum. This is because of the relevance of microbiology to pharmaceutical sciences and more specifically to pharmaceutical industry. Pharmaceutical biotechnology is the logical extension of pharmaceutical microbiology, which is expected to change the complete drug product scenario in the future.

This course deals with the various aspects of microorganisms, its classification, morphology, laboratory cultivation identification and maintenance. It also discusses with sterilization of pharmaceutical products, equipment, media etc. The course further discusses the immunological preparations, diseases its transmission, diagnosis, control and immunological tests.

2. **Objectives of the Subject:**

Upon completion of the subject student shall be able to –

- a. know the anatomy, identification, growth factors and sterilization of microorganisms;
- b. know the mode of transmission of disease causing microorganism, symptoms of disease, and treatment aspect;
- c. do estimation of RNA and DNA and thereby identifying the source;

- d. do cultivation and identification of the microorganisms in the laboratory ;
- e. do identification of diseases by performing the diagnostic tests; and
- f. appreciate the behavior of motility and behavioral characteristics of microorganisms.

Text books (Theory)

- a. Vanitha Kale and Kishor Bhusari – Applied Microbiology – Himalaya Publishing House, Mumbai.
- b. Mary Louis Turgeon – Immunology and Serology in Laboratory Medicines - 2nd edition, 1996 Mosby- Year book Inc, St. Louis Missouri 63146.
- c. Harsh Mohan – Text book of Pathology – 3rd edition, 1998, B-3 Ansari road, Daryaganj, New Delhi.

Reference books (Theory)

- a. Prescott L.M., Jarley G.P, Klein D.A – Microbiology – 2nd edition, Mc Graw Hill Company Inc
- b. Rawlins E.A.. Bentley's Text Book of Pharmaceutics, Bailliere Tindals, 24 -28 London 1988
- c. Forbisher — Fundamentals of Microbiology_ Philidelphia W.B. Saunders.
- d. War Roitt, Jonathan Brostoff, David male, — Immunology_3rd edition 1996, Mosby- year book Europe Ltd, London.
- e. Pharmacopoeia of India, Govt of India, 1996.

3. Detailed syllabus and lecture wise schedule:

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Introduction to the science of microbiology. Major divisions of microbial world and Relationship among them.	3 Hours
2	Different methods of classification of microbes and study of Bacteria, Fungi, virus, Rickettsiae, Spirochetes.	5 Hours
3	Nutritional requirements, growth and cultivation of bacteria and virus. Study of different important media required for the growth of aerobic and anaerobic bacteria & fungi. Differential media, enriched media and selective media, maintenance of lab cultures.	6 Hours
4	Different methods used in isolation and identification of bacteria with emphasis to different staining techniques and biochemical reactions. Counting of bacteria -Total and Viable counting techniques.	4 Hours

5	Detailed study of different methods of sterilization including their merits and demerits. Sterilization methods for all pharmaceutical products. Detailed study of sterility testing of different pharmaceutical preparations. Brief information on Validation.	12 Hours
6	Disinfectants- Study of disinfectants, antiseptics, fungicidal and virucidal agents factors affecting their activation and mechanism of action. Evaluation of bactericidal, bacteriostatic, virucidal activities, evaluation of preservatives in pharmaceutical preparations.	10 Hours
7	Immunology- Immunity, Definition, Classification, General principles of natural immunity, Phagocytosis, acquired immunity (active and passive). Antigens, chemical nature of antigens structure and formation of Antibodies, Antigen-Antibody reactions. Bacterial exotoxins and endotoxins. Significance of toxoids in active immunity, Immunization programme, and importance of booster dose.	13 Hours
8	Diagnostic tests : Schick's Test, Elisa test, Western Blot test, Southern Blot PCR Widal, QBC, Mantoux Peripheral smear. Study of malarial parasite	8 Hours
9	Microbial culture sensitivity Testing: Interpretation of results Principles and methods of different microbiological assays, microbiological assay of Penicillin, Streptomycin and vitamin B2 and B12. Standardisation of vaccines and sera.	6 Hours
10	Study of infectious diseases: Typhoid, Tuberculosis, Malaria, Cholera, Hepatitis, Meningitis, Syphilis & Gonorrhea and HIV.	8 Hours

2.2 PHARMACEUTICAL MICROBIOLOGY (PRACTICAL)

Practical: 3 Hrs./Week

Title of the Experiment:

1. Study of apparatus used in experimental microbiology*.
2. Sterilisation of glass ware's. Preparation of media and sterilisation.*
3. Staining techniques – Simple staining ; Gram's staining ; Negative staining**
4. Study of motility characters*.
5. Enumeration of micro-organisms (Total and Viable)*
6. Study of the methods of isolation of pure culture.*
7. Bio chemical testing for the identification of micro*-organisms.
8. Cultural sensitivity testing for some micro-organisms.*
9. Sterility testing for powders and liquids.*
10. Determination of minimum inhibitory concentration.*
11. Microbiological assay of antibiotics by cup plate method.*

12. Microbiological assay of vitamins by Turbidometric method**
13. Determination of RWC**
14. Diagnostic tests for some common diseases, Widal, malarial parasite**

* Indicate minor experiment & ** indicate major experiment

Assignments:

1. Visit to some pathological laboratories & study the activities and equipment/instruments used and reporting the same.
2. Visit to milk dairies (Pasturization) and microbial laboratories (other sterilization methods) & study the activities and equipment/instruments used and reporting the same.
3. Library assignments
 - a. Report of recent microbial techniques developed in diagnosing some common diseases.
 - b. Latest advancement developed in identifying, cultivating & handling of microorganisms.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

2.3 PHARMACOGNOSY & PHYTOPHARMACEUTICALS (THEORY)

Theory: 3 Hrs. /Week

- 1. Scope and objectives:** This subject has been introduced for the pharmacy course in order to make the student aware of medicinal uses of various naturally occurring drugs its history, sources, distribution, method of cultivation, active constituents, medicinal uses, identification tests, preservation methods, substitutes and adulterants.
- 2. Upon completion of the course student shall be able to:**
 - a. understand the basic principles of cultivation, collection and storage of crude drugs;
 - b. know the source, active constituents and uses of crude drugs; and
 - c. appreciate the applications of primary and secondary metabolites of the plant.

3. Course materials:**Text books**

- a. Pharmacognosy by G.E. Trease & W.C.Evans.
- b. Pharmacognosy by C.K.Kokate,Gokhale & A.C.Purohit.

Reference books

- a. Pharmacognosy by Brady &Tyler.E.
- b. Pharmacognosy by T.E.Wallis.
- c. Pharmacognosy by C.S. Shah & Qadery.
- d. Pharmacognosy by M.A. Iyengar.

4. Lecture wise programme:

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Introduction	2 Hours
2	Definition, history and scope of Pharmacognosy.	3 Hours
3	Classification of crude drugs.	5 Hours
4	Cultivation, collection, processing and storage of crude drugs.	4 Hours
5	Detailed method of cultivation of crude drugs.	13 Hours
6	Study of cell wall constituents and cell inclusions.	2 Hours
7	Microscopy and powder Microscopical study of crude drugs.	11 Hours
8	Study of natural pesticides.	3 Hours

9	Detailed study of various cell constituents.	2 Hours
10	Carbohydrates and related products.	2 Hours
11	Detailed study carbohydrates containing drugs.(11 drugs)	14 Hours
12	Definition sources, method extraction, chemistry and method of analysis of lipids.	2 Hours
13	Detailed study of oils.	3 Hours
14	Definition, classification, chemistry and method of analysis of protein.	2 Hours
15	Study of plants fibers used in surgical dressings and related products.	4 Hours
16	Different methods of adulteration of crude drugs.	3 Hours

2.3 PHARMACOGNOSY & PHYTOPHARMACEUTICALS (PRACTICAL)

Practical: 3 Hrs./Week

General Requirements: Laboratory Napkin, Observation Book 150 pages Zero brush, Needle, Blade, Match box.

List of experiments:

1. Introduction of Pharmacognosy laboratory and experiments.
2. Study of cell wall constituents and cell inclusions.
3. Macro, powder and microscopic study of Datura.
4. Macro, powder and microscopic study of Senna.
5. Macro, powder and microscopic study of Cassia.cinnamon.
6. Macro, powder and microscopic study of Cinchona.
7. Macro, powder and microscopic study of Ephedra.
8. Macro, powder and microscopic study of Quassia.
9. Macro, powder and microscopic study of Clove
10. Macro, powder and microscopic study of Fennel.
11. Macro, powder and microscopic study of Coriander.
12. Macro, powder and microscopic study of Isapgol.
13. Macro, powder and microscopic study of Nux vomica.
14. Macro, powder and microscopic study of Rauwolfia.
15. Macro, powder and microscopic study of Liquorice.

16. Macro, powder and microscopic study of Ginger.
17. Macro, powder and microscopic study of Podophyllum.
18. Determination of Iodine value.
19. Determination of Saponification value and unsaponifiable matter.
20. Determination of ester value.
21. Determination of Acid value.
22. Chemical tests for Acacia.
23. Chemical tests for Tragacanth.
24. Chemical tests for Agar.
25. Chemical tests for Starch.
26. Chemical tests for Lipids.(castor oil,sesame oil, shark liver oil,bees wax)
27. Chemical tests for Gelatin.

Scheme of Practical Examination:

	Sessionals	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

2.4 PHARMACOLOGY – I (THEORY)

Theory: 3 Hrs. /Week

1. **Scope of the Subject:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, apart from general pharmacology, drugs acting on autonomic nervous system, cardiovascular system, central nervous system, blood and blood forming agents and renal system will be taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.

2. **Objectives of the Subject** : Upon completion of the subject student shall be able to (Know, do, appreciate) -
- understand the pharmacological aspects of drugs falling under the above mentioned chapters;
 - handle and carry out the animal experiments;
 - appreciate the importance of pharmacology subject as a basis of therapeutics; and
 - correlate and apply the knowledge therapeutically.

Text books (Theory) (Author, Title, Edition, Publication Place, Publisher, Year of Publication)

- Tripathi, K. D. Essentials of medical pharmacology. 4th Ed, 1999. Publisher: Jaypee, Delhi.
- Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
- Rang, H.P. & Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory) (Author, Title, Edition, Publication Place, Publisher, Publication Year)

- Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th Ed, 1996. Publisher McGraw Hill, Pergamon press.
- Craig, C.R.&Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown.Co
- Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, Int.
- Shargel and Leon. Applied Biopharmaceutics and pharmacokinetics. Latest edition. Publisher: Prentice Hall, London.

Text books (Practical):

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallabh Prakashan, Delhi.

Reference books (Practical)

- Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.
- Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
- Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
- Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition,

Publisher: Black well Scientific.

3. Detailed syllabus and lecture wise schedule:

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	General Pharmacology - Introduction, definitions and scope of pharmacology - Routes of administration of drugs - Pharmacokinetics (absorption, distribution, metabolism and excretion) - Pharmacodynamics - Factors modifying drug effects - Drug toxicity - Acute, sub- acute and chronic toxicity. - Pre-clinical evaluations - Drug interactions <i>Note:</i> The term Pharmacology used here refers to the classification, mechanism of action, pharmacokinetics, pharmacodynamics, adverse effects, contraindications, Therapeutic uses, interactions and dose and route of administration.	18 Hours
2	Pharmacology of drugs acting on ANS - Adrenergic and antiadrenergic drugs - Cholinergic and anticholinergic drugs - Neuromuscular blockers - Mydriatics and miotics - Drugs used in myasthenia gravis - Drugs used in Parkinsonism	14 Hours
3	Pharmacology of drugs acting on cardiovascular system - Antihypertensives - Anti-anginal drugs - Anti-arrhythmic drugs - Drugs used for therapy of Congestive Heart Failure - Drugs used for hyperlipidaemias	10 Hours
4	Pharmacology of drugs acting on Central Nervous System - General anesthetics - Sedatives and hypnotics - Anticonvulsants - Analgesic and anti-inflammatory agents - Psychotropic drugs - Alcohol and methyl alcohol - CNS stimulants and cognition enhancers - Pharmacology of local anaesthetics	20 Hours

5	Pharmacology of Drugs acting on Respiratory tract a) Bronchodilators b) Mucolytics c) Expectorants d) Antitussives e) Nasal Decongestants	3 Hours
6	Pharmacology of Hormones and Hormone antagonists a) Thyroid and Antithyroid drugs b) Insulin, Insulin analogues and oral hypoglycemic agents c) Sex hormones and oral contraceptives d) Oxytocin and other stimulants and relaxants	7 Hours
7	Pharmacology of autocooids and their antagonists a) Histamines and Antihistaminics b) 5-Hydroxytryptamine and its antagonists c) Lipid derived autocooids and platelet activating factor	3 Hours

2.4 PHARMACOLOGY – I (PRACTICAL)

Practical: 3 Hrs./Week

List of Experiments:

1. Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea pigs, e. Rabbits).
2. Study of physiological salt solutions used in experimental pharmacology.
3. Study of laboratory appliances used in experimental pharmacology.
4. Study of use of anesthetics in laboratory animals.
5. To record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.
6. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.
7. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three point method.
8. To record the dose response curve of Histamine using isolated guinea -pig ileum preparation.
9. Study of agonistic and antagonistic effects of drugs using isolated guinea -pig ileum preparation.
10. To carry out bioassay of Histamine using isolated guinea -pig ileum preparation by interpolation method.

11. To carry out bioassay of Histamine using guinea -pig ileum preparation by three point method.
12. To study the routes of administration of drugs in animals (Rats, Mice, Rabbits).
13. Study of theory, principle, procedure involved and interpretation of given results for the following experiments:
 - a) Analgesic property of drug using analgesiometer.
 - b) Antiinflammatory effect of drugs using rat-paw edema method.
 - c) Anticonvulsant activity of drugs using maximal electroshock and pentylene tetrazole methods.
 - d) Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods.
 - e) Locomotor activity evaluation of drugs using actophotometer and rotorod.
 - f) Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.

Scheme of Practical Examination:

	Sessionals	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

2.5 COMMUNITY PHARMACY (THEORY)

Theory: 2 Hrs. /Week

1. **Scope:** In the changing scenario of pharmacy practice in India, Community Pharmacists are expected to offer various pharmaceutical care services. In order to meet this demand, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling, health screening services for improved patient care in the community set up.

2. Objectives: Upon completion of the course, the student shall be able to –

- a. know pharmaceutical care services;
- b. know the business and professional practice management skills in community pharmacies;
- c. do patient counselling & provide health screening services to public in community pharmacy;
- d. respond to minor ailments and provide appropriate medication;
- e. show empathy and sympathy to patients; and
- f. appreciate the concept of Rational drug therapy.

Text Books:

- a. Health Education and Community Pharmacy by N.S.Parmar.
- b. WHO consultative group report.
- c. Drug store & Business management by Mohammed Ali & Jyoti.

Reference books:

- a. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.
- a. Comprehensive Pharmacy Review – Edt. Leon Shargel. Lippincott Williams & Wilkins.

3. Special requirements:

1. Either the college is having model community pharmacy (meeting the schedule N requirement) or sign MoU with at least 4 -5 community pharmacies nearby to the college for training the students on dispensing and counselling activities.
2. Special equipments like B.P apparatus, Glucometer, Peak flow meter, and apparatus for cholesterol estimation.
3. Scheme of evaluation (80 Marks)

1. Synopsis	10
2. Major Experiment	30
(Counselling of patients with specific diseases – emphasis should be given on Counselling introduction, content, process and conclusion)	
3. Minor Experiment (Ability to measure B.P/ CBG / Lung function)	15
4. Prescription Analysis (Analyzing the prescriptions for probable drug interaction and ability to tell the management)	15
5. Viva – Voce	10

4. Lecture wise programme :

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS

1	Definition, scope, of community pharmacy Roles and responsibilities of Community pharmacist	2 Hours
2	Community Pharmacy Management a) Selection of site, Space layout, and design b) Staff, Materials- coding, stocking c) Legal requirements d) Maintenance of various registers e) Use of Computers: Business and health care soft wares	4 Hours
3	Prescriptions – parts of prescription, legality & identification of medication related problems like drug interactions.	2 Hours
4	Inventory control in community pharmacy Definition, various methods of Inventory Control ABC, VED, EOQ, Lead time, safety stock	3 Hours
5	Pharmaceutical care Definition and Principles of Pharmaceutical care.	2 Hours
6	Patient counselling Definition, outcomes, various stages, barriers, Strategies to overcome barriers Patient information leaflets- content, design, & layouts, advisory labels	4 Hours
7	Patient medication adherence Definition, Factors affecting medication adherence, role of pharmacist in improving the adherence.	2 Hours
8	Health screening services Definition, importance, methods for screening - Blood pressure/ blood sugar/ lung function and Cholesterol testing	3 Hours
9	OTC Medication- Definition, OTC medication list & Counselling	2 Hours
10	Health Education WHO Definition of health, and health promotion, care for children, pregnant & breast feeding women, and geriatric patients. Commonly occurring Communicable Diseases, causative agents, Clinical presentations and prevention of communicable diseases – Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy, Syphilis, Gonorrhea and AIDS Balance diet, and treatment & prevention of deficiency disorders Family planning – role of pharmacist	14 Hours
11	Responding to symptoms of minor ailments	9 Hours

	Relevant pathophysiology, common drug therapy to – Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Pyrexia, Ophthalmic symptoms, worms infestations.	
12	Essential Drugs concept and Rational Drug Therapy Role of community pharmacist	2 Hours
13	Code of ethics for community pharmacists	1 Hours

2.6 PHARMACOTHERAPEUTICS - I (THEORY)

Theory : 3 Hrs. /Week

- 1. Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
- 2. Objectives:** At completion of this subject it is expected that students will be able to understand –
 - a. the pathophysiology of selected disease states and the rationale for drug therapy;
 - b. the therapeutic approach to management of these diseases;
 - c. the controversies in drug therapy;
 - d. the importance of preparation of individualised therapeutic plans based on diagnosis
 - e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
 - f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
 - g. summarise the therapeutic approach to management of these diseases including reference to the latest available evidence;
 - h. discuss the controversies in drug therapy;
 - i. discuss the preparation of individualised therapeutic plans based on diagnosis; and
 - j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

- a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.
- b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange.

Reference Books

- a. Pathologic basis of disease - Robins SL, W.B.Saunders publication.
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication.
- c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication.
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda -Kimble MA
- e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature.

3. Detailed syllabus and lecture wise schedule:

Etiopathogenesis and pharmacotherapy of diseases associated with systems/ diseases following

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Cardiovascular system: Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, Hyperlipidaemias, Electrophysiology of heart and Arrhythmias	13 Hours
2	Respiratory system: Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases	6 Hours
3	Endocrine system: Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis	8 Hours
4	General prescribing guidelines for a. Paediatric patients b. Geriatric patients c. Pregnancy and breast feeding	4 Hours
5	Ophthalmology: Glaucoma, Conjunctivitis- viral & bacterial	3 Hours
6	Introduction to rational drug use Definition, Role of pharmacist Essential drug concept Rational drug formulations	2 Hours

2.6 PHARMACOTHERAPEUTICS - I (PRACTICAL)

Practical: 3 Hrs./Week

Practicals:

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Third Year

3.1 PHARMACOLOGY – II (THEORY)

Theory: 3 Hrs. /Week

- 1. Scope of the Subject:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, drugs acting on autacoids, respiratory system, GIT, immune system and hormones, and pharmacology of autocoids and hormones will be concentrated. In addition, pharmacology of chemotherapeutic agents, vitamins, essential minerals and principles of toxicology are also taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.
- 2. Objectives of the Subject:** Upon completion of the subject student shall be able to:
 - a. understand the pharmacological aspects of drugs falling under the above mentioned chapters,
 - b. carry out the animal experiments confidently,
 - c. appreciate the importance of pharmacology subject as a basis of therapeutics, and
 - d. correlate and apply the knowledge therapeutically.

Text books (Theory)

- a. Tripathi, K. D. Essentials of medical pharmacology. 4th edition, 1999. Publisher: Jaypee, Delhi.
- b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
- c. Rang, H.P. and Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Livingstone.

Reference books (Theory)

- a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th edition, 1996. Publisher: McGrawHill, Pergamon press.
- b. Craig, C.R. and Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown and company.
- c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, International.

- d. Gupta, P.K. and Salunkhe, D.K. Modern Toxicology. Volume I, II and III. Latest edition. Publisher: B.V. Gupta, Metropolitan Book Co. (p) Ltd, New Delhi.

Text books (Practical)

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallabh Prakasan, Delhi.

Reference books (Practical):

- a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.
- b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
- c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
- d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

3. Detailed syllabus and lecture wise schedule:

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Pharmacology of Drugs acting on Blood and blood forming agents a) Anticoagulants b) Thrombolytics and antiplatelet agents c) Haemopoietics and plasma expanders	6 Hours
2	Pharmacology of drugs acting on Renal System a) Diuretics b) Antidiuretics	3 Hours
3	Chemotherapy a) Introduction b) Sulfonamides and co-trimoxazole c) Penicillins and Cephalosporins d) Tetracyclins and Chloramphenicol e) Macrolides, Aminoglycosides, Polyene & Polypeptide antibiotics f) Quinolines and Fluroquinolines g) Antifungal antibiotics h) Antiviral agents i) Chemotherapy of tuberculosis and leprosy j) Chemotherapy of Malaria k) Chemotherapy of protozoal infections (amoebiasis, Giardiasis)	31 Hours

	l) Pharmacology of Anthelmintic drugs m) Chemotherapy of cancer (Neoplasms)	
4	Immunopharmacology Pharmacology of immunosuppressants and stimulants	2 Hours
5	Principles of Animal toxicology Acute, sub-acute and chronic toxicity	2 Hours
6	The dynamic cell: The structures and functions of the components of the cell a) Cell and macromolecules: Cellular classification, subcellular organelles, macromolecules, large macromolecular assemblies b) Chromosome structure: Pro and eukaryotic chromosome structures, chromatin structure, genome complexity, the flow of genetic information. c) DNA replication: General, bacterial and eukaryotic DNA replication. d) The cell cycle: Restriction point, cell cycle regulators and modifiers. e) Cell signaling: Communication between cells and their environment, ion-channels, signal transduction pathways (MAP kinase, P38 kinase, JNK, Ras and PI3 -kinase pathways, biosensors.)	14 Hours
7	The Gene: Genome structure and function: a) Gene structure: Organization and elucidation of genetic code. b) Gene expression: Expression systems (pro and eukaryotic), genetic elements that control gene expression (nucleosomes, histones, acetylation, HDACS, DNA binding protein families. c) Transcription and Transcription factors: Basic principles of transcription in pro and eukaryotes. Transcription factors that regulate transcription in pro and eukaryotes. RNA processing: rRNA, tRNA and mRNA processing. Protein synthesis: Mechanisms of protein synthesis, initiation in eukaryotes, translation control and post-translation events Altered gene functions: Mutations, deletions, amplifications, LOH, translocations, trinucleotide repeats and other genetic abnormalities. Oncogenes and tumor suppressor genes. The gene sequencing, mapping and cloning of human disease genes. Introduction to gene therapy and targeting. Recombinant DNA technology: principles. Processes (gene transfer technology) and applications	17 Hours

Books:

1. Molecular Biology of the Cell by Alberts B., Bray, D., Lewis, J., Raff M., Roberts K and Watson, JD, 3rd edition.
2. Molecular Cell Biology By Lodish, H., Baltimore, D., Berk, A et al., 5th edition.
3. Molecular Biology by Turner, PC., McLennan, AG., Bates, AD and White MRH. 2nd edition.
4. Genes VIII by Lewin, B., (2004)
5. Pharmaceutical Biotechnology, by Crommelin, DJA and Sindelar RD (1997)
6. Recombinant DNA by Watson, JD., Gilman, M., et al., (1996)
7. Biopharmaceutical: Biochemistry and Biotechnology by Walsh, G., (1998)

3.1 PHARMACOLOGY – II (PRACTICAL)**Practical : 3 Hrs./Week****List of Experiments:**

1. Study of agonistic and antagonistic effects of drugs using Guinea-pig ileum preparation.**
2. To study the effects of drugs on intestinal motility using frog's esophagus model*
3. To study the effects of drugs using rat uterus preparation.**
4. To study the anticonvulsant property of drugs (any one model).*
5. To study antihistaminic property of drug using histamine induced anaphylactic reaction in guinea pigs.
6. To study the apomorphine-induced compulsive behaviour (stereotypy) in mice.*
7. To study the muscle relaxant property of diazepam in mice using rotarod apparatus.*
8. To study the antiinflammatory property of indomethacin against carrageenan-induced paw oedema.**
9. To study the anxiolytic effect of diazepam in mice using mirrored-chamber apparatus.**
10. To demonstrate the effect of various drugs on the blood pressure and respiration of anaesthetized dog.
11. To study the effect of anthelmintics on earthworms.
12. To study the taming effect of chlorpromazine.*
13. To study the effects of drugs on vas deference of the male rat.**
14. To study the effect of drugs on pesticide toxicity using rats as model.
15. To study the effect of drugs on heavy metal toxicity.

** indicate major experiment & * indicate minor experiment

Scheme of Practical Examination:

	Sessionals	Annual
Identification	02	10
Synopsis	04	10
Major Experiment (Bioassay)	08	30
Minor Experiment (Interpretation of given Graph or simulated experiment)	04	10
Viva	02	10
Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.2 PHARMACEUTICAL ANALYSIS (THEORY)

Theory: 3 Hrs. /Week

1. Scope of the subject:**2. Objectives of the subject:****Text Books:****Reference Books:**

1. Text Book of Pharm. Analysis by Higuchi. T and Hasen. E. B., New York Inter Science Publishers.
2. Quantitative Pharma. Analysis by Jenkins, The Blakiston division, New York.
3. Quantitative Drug Analysis, by Garrot. D, Chapman & Hall Ltd., London.
4. Undergraduate Instrumental Analysis by James. E., CBS Publishers.
5. Instrumental Analysis by Willard and Merritt, EWP, East West Press Ltd., Delhi/Madras.
6. Pharm Analysis by Skoog and West, Sounders Manipal College Publishing.
7. Text Book of Chemical Analysis, by A.I.Vogel, ELBS with Macmillan press, Hampshire.
8. Textbook of Pharm. Analysis by K.A.Connors, John Wiley & Sons, New York, Brisbane, Singapore.
9. Textbook of Pharm. Analysis (Practical) by Beckett & Stenlake, CBS Publishers, Delhi.
10. Textbook of Drug Analysis by P.D. Sethi., CBS Publishers, Delhi.

11. Spectroscopy by Silverstein, John & Wiley & Sons. Inc., Canada & Singapore.
12. How to practise GMP-A Plan for total quality control by P.P. Sharma, Vandana Publications, Agra.
13. The Science & Practice of Pharmacy by Remington Vol -I & II, Mack Publishing Co. Pennsylvania.
14. TLC by Stahl, Spring Verlay.
15. Text Book of Pharm. Chemistry by Chatten, CBS Publications.
16. Spectroscopy by William Kemp, ELBS with Macmillan Press, Hampshire.
17. I.P.-1996, The Controller of Publications, New Delhi.
18. BPC- Dept. of Health, U.K. for HMSO.
19. USP - Mack Publishing Co., Easton, PA
20. The Extra Pharmacopoeia – The Pharm. Press, London.

3. Detailed syllabus and lecture wise schedule:

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Quality Assurance: a. Introduction, sources of quality variation, control of quality variation. b. Concept of statistical quality control. c. Validation methods- quality of equipment, validation of equipment and validation of analytical instruments and calibration. d. GLP, ISO 9000. e. Total quality management, quality review and documentation. f. ICH- international conference for harmonization-guidelines. g. Regulatory control.	4 Hours
2	Chromatography: Introduction, history, classification, separation techniques, choice of methods. The following techniques be discussed with relevant examples of pharmaceutical products involving principles and techniques of separation of drugs from excipients. a. Column Chromatography: Adsorption column chromatography, Operational technique, frontal analysis and elution analysis. Factors affecting column efficiency, applications and partition chromatography. b. TLC: Introduction, principle, techniques, Rf value and applications. c. PC: Introduction, principle, types of paper chromatography, preparation techniques, development techniques, applications. d. Ion-exchange chromatography: Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications.	20 Hours

	e. HPLC: Introduction, theory, instrumentation, and applications. f. HPTLC: Introduction, theory, instrumentation, and applications. g. Gas Chromatography: Introduction, theory, instrumentation-carrier gases, types of columns, stationary phases in GLC & GSC. Detectors: Flame ionization detectors, electron capture detector, thermal conductivity detector. Typical gas chromatogram, derivatisation techniques, programmed temperature gas chromatography, applications. h. Electrophoresis: Principles of separation, equipment for paper and gel electrophoresis, and application. i. Gel filtration and affinity chromatography: Introduction, technique, applications.	
3	Electrometric Methods: Theoretical aspects, instrumentation, interpretation of data/spectra and analytical applications be discussed on the following topics. a. Potentiometry: Electrical potential, electrochemical cell, reference electrodes, indicator electrodes, measurement of potential and pH, construction and working of electrodes, Potentiometric titrations, methods of detecting end point, Karl Fischer titration. b. Conductometry: Introduction, conductivity cell, conductometric titrations and applications. c. Polarography: Instrumentation, DME, residual current, diffusion current and limiting current, polarographic wave, Ilkovic's equation, Effect of oxygen on polarographic wave, Polarographic maxima and suppressors and applications. d. Amperometric Titrations: Introduction, types of electrodes used, reference and indicator electrode, instrumentation, titration procedure, advantages and disadvantages of Amperometry over potentiometry. Pharma applications.	14 Hours
4	Spectroscopy: Theoretical aspects, instrumentation, elements of interpretation of data/spectra and application of analytical techniques be discussed on: a. Absorption Spectroscopy: - Theory of electronic, atomic and molecular spectra. Fundamental laws of photometry, Beer-Lambert's Law, application and its deviation, limitation of Beer law, application of the law to single and multiple component analysis, measurement of equilibrium constant and rate constant by spectroscopy. Spectra of isolated chromophores, auxochromes, batho-chromic shift, hypsochromic shift, hyperchromic and hypochromic effect, effect of solvent on absorption spectra, molecular structure and infrared spectra.	35 Hours

	Instrumentation – Photometer, U.V.-Visible spectrophotometer-sources of U.V.-Visible radiations, collimating systems, monochromators, samples cells and following detectors-Photocell, Barrier layer cell, Phototube, Diode array, applications of U.V.-Visible spectroscopy in pharmacy and spectrophotometric titrations. - Infrared Spectroscopy: Vibrational transitions, frequency – structure correlations, Infrared absorption bands, Instrumentation–IR spectrometer – sources of IR, Collimating systems, monochromators, sample cells, sample handling in IR spectroscopy and detectors - Thermocouple, Golay Cells, Thermistor, Bolometer, Pyroelectric detector, Applications of IR in pharmacy. - Fluorimetric Analysis: Theory, luminescence, factors affecting fluorescence, quenching. Instrumentation, Applications, fluorescent indicators, study of pharmaceutically important compounds estimated by fluorimetry. b. Flame Photometry: Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceutical applications. c. Atomic Absorption Spectrometry: Introduction, Theory, types of electrodes, instrumentation and applications. d. Atomic Emission Spectroscopy: Spectroscopic sources, atomic emission spectrometers, photographic and photoelectric detection. e. NMR & ESR (introduction only): Introduction, theoretical aspects and applications. f. Mass Spectroscopy: (Introduction only) – Fragmentation, types of ions produced mass spectrum and applications. g. Polarimetry: (Introduction only) – Introduction to optical rotatory dispersion, circular dichroism, polarimeter. h. X-RAY Diffraction: (Introduction only) – Theory, reciprocal lattice concept, diffraction patterns and applications. i. Thermal Analysis: Introduction, instrumentation, applications, and DSC and DTA.	

3.2 PHARMACEUTICAL ANALYSIS (PRACTICAL)

Practical : 3 Hrs./Week**List of Experiments:**

1. Separation and identification of Amino Acids by Paper Chromatography.
2. Separation and identification of Sulpha drugs by TLC technique.
3. Effect of pH and solvent on the UV spectrum of given compound.
4. Comparison of the UV spectrum of a compound with that of its derivatives.
5. Determination of dissociation constant of Indicators using UV-Visible spectroscopy.
6. Conductometric titration of mixture of acids with a strong base.
7. Potentiometric titration of acid with a strong base.
8. Estimation of drugs by Fluorimetric technique.
9. Study of quenching effect in fluorimetry.
10. Colourimetric estimation of Supha drugs using BMR reagent.
11. Simultaneous estimation of two drugs present in given formulation.
12. Assay of Salicylic Acid by colourimetry.
13. Determination of Chlorides and Sulphates in Calcium gluconate by Nepheloturbidimetric Method.
14. Determination of Na/K by Flame Photometry.
15. Determination of pKa using pH meter.
16. Determination of specific rotation.
17. Comparison of the IR spectrum of a compound with that of its derivatives.
18. Demonstration of HPLC.
19. Demonstration of HPTLC.
20. Demonstration of GC-MS.
21. Demonstration of DSC.
22. Interpretation of NMR spectra of any one compound.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.3 PHARMACOTHERAPEUTICS – II (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives of the Subject: Upon completion of the subject student shall be able to –**
 - a. know the pathophysiology of selected disease states and the rationale for drug therapy
 - b. know the therapeutic approach to management of these diseases;
 - c. know the controversies in drug therapy;
 - d. know the importance of preparation of individualised therapeutic plans based on diagnosis; and
 - e. appreciate the needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text books (Theory)

Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication

Reference books (Theory)

- a. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange
- b. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
- c. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA

3. Detailed syllabus and lecture wise schedule:

Etiopathogenesis and pharmacotherapy of diseases associated with following systems / diseases –

SL. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Infectious disease: Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection - Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhoea and Syphilis	38 Hours
2	Musculoskeletal disorders: Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.	10 Hours
3	Renal system: Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders	11 Hours
4	Oncology: Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis	12 Hours
5	Dermatology: Psoriasis, Scabies, Eczema, Impetigo	4 Hours

3.3 PHARMACOTHERAPEUTICS – II (PRACTICAL)

Practical: 3 Hrs./Week

Practicals:

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.

The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.

A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.4 PHARMACEUTICAL JURISPRUDENCE (THEORY)

Theory: 2 Hrs. /Week

1. **Scope of the Subject:** This course exposes the student to several important legislations related to the profession of pharmacy in India. The Drugs and Cosmetics Act, along with its amendments are the core of this course. Other acts, which are covered, include the Pharmacy Act, dangerous drugs, medicinal and toilet preparation Act etc. Besides this the new drug policy, professional ethics, DPCO, patent and design Act will be discussed.
2. **Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, and appreciate) –
 - a. practice the Professional ethics;
 - b. understand the various concepts of the pharmaceutical legislation in India;
 - c. know the various parameters in the Drug and Cosmetic Act and rules;
 - d. know the Drug policy, DPCO, Patent and design act;
 - e. understand the labeling requirements and packaging guidelines for drugs and cosmetics;
 - f. be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and
 - g. other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

Text books (Theory)

Mithal B M. Textbook of Forensic Pharmacy. Calcutta: National; 1988.

Reference books (Theory)

- a. Singh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad: Law Book House; 1984.
- b. Jain, NK. A Textbook of forensic pharmacy. Delhi: Vallabh prakashan ; 1995.
- c. Reports of the Pharmaceutical enquiry Committee
- d. I.D.M.A., Mumbai. DPCO 1995
- e. Various reports of Amendments.
- f. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
- g. Eastern Book Company .The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.

3. Detailed syllabus and lecture wise schedule:

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Pharmaceutical Legislations – A brief review.	1 Hour
2	Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI.	2 Hours
3	Drugs and Cosmetics Act, 1940, and its rules 1945. Objectives, Legal definition, Study of Schedule's with reference to Schedule B, C&C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y. Sales, Import, labeling and packaging of Drugs And Cosmetics Provisions Relating to Indigenous Systems. Constitution and Functions of DTAB, DCC, CDL. Qualification and duties – Govt. analyst and Drugs Inspector.	23 Hours
4	Pharmacy Act –1948. Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER.	3 Hours
5	Medicinal and Toilet Preparation Act –1955. Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations.	3 Hours
6	Narcotic Drugs and Psychotropic substances Act-1985 and Rules. Objectives, Legal Definitions, General Study, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and regulations, Schedules to the Act.	4 Hours
7	Study of Salient Features of Drugs and magic remedies Act and its rules.	2 Hours
8	Study of essential Commodities Act Relevant to drugs price control Order.	2 Hours
9	Drug Price control Order & National Drug Policy (Current).	2 Hours
10	Prevention Of Cruelty to animals Act-1960.	3 Hours
11	Patents & design Act-1970.	3 Hours
12	Brief study of prescription and Non-prescription Products.	2 Hours

4. Assignments:**Format of the assignment**

1. Minimum & Maximum number of pages
2. It shall be a computer draft copy
3. Reference(s) shall be included at the end.
4. Name and signature of the student
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min

Case studies relating to

1. Drugs and Cosmetics Act and rules along with its amendments, Dangerous Drugs Act, Medicinal and Toilet preparation Act, New Drug Policy, Professional Ethics, Drugs (Price control) Order, Patent and Design Act.
2. Various prescription and non-prescription products.
3. Medical and surgical accessories.
4. Diagnostic aids and appliances available in the market.

3.5 MEDICINAL CHEMISTRY (THEORY)

Theory: 3 Hrs. /Week

1. Scope of the subject:**2. Objectives of the subject:****Text Books:****Reference Books:**

- a. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.
- b. William.O.Foye, Principles of Medicinal Chemistry, B.I. Waverly Pvt. Ltd., New Delhi.
- c. Burgers, Medicinal Chemistry, M.E., Welly Med.Chemistry M.E. Walffed Johnwiley and Sons, Wiley-interscience Publication, New York, Toranto.
- d. A Text Book of Medicinal Chemistry Vol. I and II by Surendra N. Pandeya, S.G. Publisher, 6, Dildayal Nagar, Varanasi -10.
- e. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi - 54.
- f. Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19.
- g. Organic Drug Synthesis-Ledniser Mitzsher Vol. I and II.
- h. Pharmaceutical Chemistry drug Synthesis Vol. I and II by H. J. Roth and A. Kleemann.
- i. The Science and Practice of Pharmacy Vol. 1 and 2, Remington, MACK Publishing Company, Easton, Pennsylvania.

3. Detailed syllabus and lecture wise schedule:

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Modern concept of rational drug design: A brief introduction to Quantitative Structure Activity Relationship (QSAR), prodrug, combinatorial chemistry and computer aided drug design (CADD) and concept of antisense molecules. A study of the development of the following classes of drugs including SAR, mechanism of action, synthesis of important compounds, chemical nomenclature, brand names of important marketed products and their side effects.	6 Hours
2	Anti-infective agents - Local anti-infective agents - Preservatives - Antifungal agents - Urinary tract anti-infectives - Antitubercular agents - Antiviral agents and Anti AIDS agents - Antiprotozoal agents - Anthelmintics - Antiscabies and Antipedicular agents	18 Hours
3	Sulphonamides and sulphones	4 Hours
4	Antimalarials	4 Hours
5	Antibiotics	12 Hours
6	Antineoplastic agents	5 Hours
7	Cardiovascular agents - Antihypertensive agents - Antianginal agents and vasodilators - Antiarrhythmic agents - Antihyperlipidemic agents - Coagulants and Anticoagulants - Endocrine	16 Hours
8	Hypoglycemic agents	2 Hours
9	Thyroid and Antithyroid agents	2 Hours
10	Diuretics	3 Hours

11	Diagnostic agents	1 Hour
12	Steroidal Hormones and Adrenocorticoids	2 Hours

3.5 MEDICINAL CHEMISTRY (PRACTICAL)

Practical: 3 Hrs./Week

1. Assays of important drugs from the course content.
2. Preparation of medicinally important compounds or intermediates required for synthesis of drugs.
3. Monograph analysis of important drugs.
4. Determination of partition coefficients, dissociation constants and molar refractivity of compounds for QSAR analysis.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.6 PHARMACEUTICAL FORMULATIONS (THEORY)

Theory: 2 Hrs. /Week

1. **Scope of the Subject:** Subject deals with the formulation and evaluation of various pharmaceutical dosage forms.
2. **Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, appreciate) –
 - a. understand the principle involved in formulation of various pharmaceutical dosage forms;
 - b. prepare various pharmaceutical formulation;
 - c. perform evaluation of pharmaceutical dosage forms; and

- d. understand and appreciate the concept of bioavailability and bioequivalence, their role in clinical situations.

Text books (Theory)

- Pharmaceutical dosage forms, Vol, I,II and III by lachman
- Rowlings Text book of Pharmaceutics
- Tutorial Pharmacy – Cooper & Gun

Reference books (Theory)

- Remington's Pharmaceutical Sciences
- USP/BP/IP

3. Detailed syllabus and lecture wise schedule:

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Pharmaceutical dosage form- concept and classification	2 Hours
2	Tablets: Formulation of different types of tablets, tablet excipients, granulation techniques quality control and evaluation of tablets. Tablet coating, Type of coating, quality control tests for coated tablet.	10 Hours
3	Capsules; Production and filling of hard gelatin capsules, Raw material for shell, finishing, quality control tests for capsules. Production and filling of soft gelatin capsules, quality control tests for soft gelatin capsules.	8 Hours
4	Liquid orals: Formulation and evaluation of suspensions, emulsions and solutions. Stability of these preparations	4 Hours
5	Parenterals: Introduction Containers used for Parenterals (including official tests) Formulation of large and small volume Parenterals Sterilization	10 Hours
6	Ophthalmic preparations (Semi-Solids): Introduction and classification Factors affecting absorption and anatomy of skin Packaging storage and labeling, Ointments. Types of Ointment Base Preparation of ointment, Jellies Types of jellies Formulation of jellies Suppositories, Method of preparation, Types Packaging	8 Hours
7	Definition and concept of Controlled and novel Drug delivery systems with available examples, viz. parenteral, trans dermal, buccal, rectal, nasal, implants, ocular	8 Hours

3.6 PHARMACEUTICAL FORMULATIONS (PRACTICAL)

Practical: 3 Hrs./Week**List of Experiments:****1. Manufacture of Tablets**

- a. Ordinary compressed tablet-wet granulation
- b. Tablets prepared by direct compression.
- c. Soluble tablet.
- d. Chewable tablet.

2. Formulation and filling of hard gelatin capsules**3. Manufacture of parenterals**

- a. Ascorbic acid injection
- b. Calcium gluconate injection
- c. Sodium chloride infusion.
- d. Dextrose and Sodium chloride injection/ infusion.

4. Evaluation of Pharmaceutical formulations (QC tests)

- a. Tablets
- b. Capsules
- c. Injections

5. Formulation of two liquid oral preparations and evaluation by assay

- a. Solution: Paracetamol Syrup
- b. Antacid suspensions- Aluminum hydroxide gel

6. Formulation of semisolids and evaluation by assay

- a. Salicylic acid and benzoic acid ointment
- b. Gel formulation Diclofenac gel

7. Cosmetic preparations

- a. Lipsticks
- b. Cold cream and vanishing cream
- c. Clear liquid shampoo
- d. Tooth paste and tooth powders.

8. Tablet coating (demonstration)**Scheme of Practical Examination:**

	Sessionals	Annual
Synopsis	05	15
Major Experiment	20	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Fourth Year

4.1 PHARMACOTHERAPEUTICS – III (THEORY)

Theory: 3 Hrs. /Week

1. **Scope:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives:** At completion of this subject it is expected that students will be able to understand –
 - a. the pathophysiology of selected disease states and the rationale for drug therapy;
 - b. the therapeutic approach to management of these diseases;
 - c. the controversies in drug therapy;
 - d. the importance of preparation of individualised therapeutic plans based on diagnosis;
 - e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
 - f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
 - g. to summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
 - h. to discuss the controversies in drug therapy;
 - i. to discuss the preparation of individualised therapeutic plans based on diagnosis; and
 - j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

- a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication
- b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange

Reference Books

- a. Pathologic basis of disease - Robins SL, W.B.Saunders publication
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication
- c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda – Kimble MA
- e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature.

3. Detailed syllabus and lecture wise schedule:

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases:

SL. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Gastrointestinal system: Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, Viral hepatitis including jaundice, and Drug induced liver disorders.	20 Hours
2	Haematological system: Anaemias, Venous thromboembolism, Drug induced blood disorders.	12 Hours
3	Nervous system: Epilepsy, Parkinsonism, Stroke, Alzheimer's disease	16 Hours
4	Psychiatry disorders: Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders	14 Hours
5	Pain management including Pain pathways, neuralgias, headaches.	8 Hours
6	Evidence Based Medicine	5 Hours

4.1 PHARMACOTHERAPEUTICS – III (PRACTICAL)

Practical: 3 Hrs./Week

Practicals:

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge.

Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.

The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.

A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

7. Minimum & Maximum number of pages.
8. Reference(s) shall be included at the end.
9. Assignment can be a combined presentation at the end of the academic year.
10. It shall be computer draft copy.
11. Name and signature of the student.
12. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	06hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

4.2 HOSPITAL PHARMACY (THEORY)

Theory: 2 Hrs. /Week

1. **Scope:** In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug dispensing, manufacturing of parenteral preparations, drug information, patient counselling, and therapeutic drug monitoring for improved patient care.
2. **Objectives:** Upon completion of the course, the student shall be able to –
 - a. know various drug distribution methods;
 - b. know the professional practice management skills in hospital pharmacies;
 - c. provide unbiased drug information to the doctors;
 - d. know the manufacturing practices of various formulations in hospital set up;
 - e. appreciate the practice based research methods; and
 - f. appreciate the stores management and inventory control.

Text books: (latest editions)

- a. Hospital pharmacy by William .E. Hassan
- b. A text book of Hospital Pharmacy by S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh

References:

- a. WHO consultative group report.
- b. R.P.S. Vol.2. Part –B; Pharmacy Practice section.
- c. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.

3. Lecture wise programme:

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Hospital - its Organisation and functions	1 Hour
2	Hospital pharmacy-Organisation and management a) Organizational structure-Staff, Infrastructure & work load statistics b) Management of materials and finance c) Roles & responsibilities of hospital pharmacist	5 Hours
3	The Budget – Preparation and implementation	1 Hour
4	Hospital drug policy	12 Hours

	a) Pharmacy and Therapeutic committee (PTC) b) Hospital formulary c) Hospital committees - Infection committee - Research and ethical committee d) developing therapeutic guidelines e) Hospital pharmacy communication – Newsletter	
5	Hospital pharmacy services a) Procurement & warehousing of drugs and Pharmaceuticals b) Inventory control Definition, various methods of Inventory Control ABC, VED, EOQ, Lead time, safety stock c) Drug distribution in the hospital i) Individual prescription method ii) Floor stock method iii) Unit dose drug distribution method d) Distribution of Narcotic and other controlled substances e) Central sterile supply services – Role of pharmacist	12 Hours
6	Manufacture of Pharmaceutical preparations a) Sterile formulations – large and small volume parenterals b) Manufacture of Ointments, Liquids, and creams c) Manufacturing of Tablets, granules, capsules, and powders d) Total parenteral nutrition	12 Hours
7	Continuing professional development programs Education and training	3 Hours
8	Radio Pharmaceuticals – Handling and packaging	2 Hours
9	Professional Relations and practices of hospital pharmacist	3 Hours

4.2 HOSPITAL PHARMACY (PRACTICAL)

Practical: 3 Hrs./Week

List of Experiments

1. Assessment of drug interactions in the given prescriptions
2. Manufacture of parenteral formulations, powders.
3. Drug information queries.
4. Inventory control

List of Assignments:

1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.
2. Pharmacy and Therapeutics committee – Organization, functions, and limitations.
3. Development of a hospital formulary for 300 bedded teaching hospital
4. Preparation of ABC analysis of drugs sold in one month from the pharmacy.
5. Different phases of clinical trials with elements to be evaluated.
6. Various sources of drug information and systematic approach to provide unbiased drug information.
7. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.

Special requirements:

8. Each college should sign MoU with nearby local hospital having minimum 150 beds for providing necessary training to the students' on hospital pharmacy activities.
9. Well equipped with various resources of drug information.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	06hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

4.3 CLINICAL PHARMACY (THEORY)

Theory: 3 Hrs. /Week

1. **Objectives of the Subject :** Upon completion of the subject student shall be able to (Know, do, appreciate) –
 - a. monitor drug therapy of patient through medication chart review and clinical review;
 - b. obtain medication history interview and counsel the patients;
 - c. identify and resolve drug related problems;
 - d. detect, assess and monitor adverse drug reaction;
 - e. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and

- f. retrieve, analyse, interpret and formulate drug or medicine information.

Text books (Theory)

- a. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
- b. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
- c. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.
- d. A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi et al, Orient Orient Langram Pvt.Ltd. ISSN8125026

References

- a. Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
- b. Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
- c. Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

2. Detailed syllabus and lecture wise schedule:

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Definitions, development and scope of clinical pharmacy	3 Hours
2	Introduction to daily activities of a clinical pharmacist a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions) b. Ward round participation c. Adverse drug reaction management d. Drug information and poisons information e. Medication history f. Patient counseling g. Drug utilisation evaluation (DUE) and review (DUR) h. Quality assurance of clinical pharmacy services	13 Hours
3	Patient data analysis The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.	3 Hours
4	Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results a. Haematological, Liver function, Renal function, thyroid function tests	15 Hours

	b. Tests associated with cardiac disorders c. Fluid and electrolyte balance d. Microbiological culture sensitivity tests e. Pulmonary Function Tests	
5	Drug & Poison information a. Introduction to drug information resources available b. Systematic approach in answering DI queries c. Critical evaluation of drug information and literature d. Preparation of written and verbal reports e. Establishing a Drug Information Centre f. Poisons information- organization & information resources	8 Hours
6	Pharmacovigilance a. Scope, definition and aims of pharmacovigilance b. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used] c. Reporting, evaluation, monitoring, preventing & management of ADRs a. d. Role of pharmacist in management of ADR.	10 Hours
7	Communication skills , including patient counselling techniques, medication history interview, presentation of cases.	10 Hours
8	Pharmaceutical care concepts	4 Hours
9	Critical evaluation of biomedical literature	6 Hours
10	Medication errors	3 Hours

4.3 CLINICAL PHARMACY (PRACTICAL)

Practical: 3 Hrs./Week

Students are expected to perform 15 practicals in the following areas covering the topics dealt in theory class.

- Answering drug information questions (4 Nos)
- Patient medication counselling (4 Nos)
- Case studies related to laboratory investigations (4 Nos)
- Patient medication history interview (3 Nos)

Assignment:

Students are expected to submit THREE written assignments (1500 – 2000 words) on the topics given to them covering the following areas dealt in theory class.

Drug information, Patient medication history interview, Patient medication counselling, Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	06hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

4.4 BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY)

Theory: 2 Hrs. /Week

1. Scope of the subject:

2. Objectives of the subject:

Text Books:

Reference Books:

- a. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton, 3rd edition, publisher Marcel Dekker Inc. NewYork.
- b. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich , 3rd edition, McGraw Hill Publications 2006

3. Detailed syllabus and lecture wise schedule:

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Research Methodology a) Types of clinical study designs: Case studies, observational studies, interventional studies, b) Designing the methodology c) Sample size determination and Power of a study - Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study d) Report writing and presentation of data	10 Hours
2.1	Biostatistics a) Introduction b) Types of data distribution c) Measures describing the central tendency distributions- average, median, mode d) Measurement of the spread of data -range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean.	10 Hours
2.2	Data graphics Construction and labeling of graphs, histogram, piecharts, scatter plots, semilogarithmic plots	2 Hours

2.3	Basics of testing hypothesis a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals. b) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way) a) Level of significance (Non-parametric data)- Sign test, Wilcoxon's signed rank test, Wilcoxon rank sum test, Mann Whitney U test, Kruskal -Wall is test (one way ANOVA) c) Linear regression and correlation- Introduction, Pearsonn's and Spearmann's correlation and correlation co-efficient. d) Introduction to statistical software: SPSS, Epi Info, SAS.	15 Hours
2.4	Statistical methods in epidemiology Incidence and prevalence, relative risk, attributable risk	5 Hours
3	Computer applications in pharmacy a) <u>Computer System in Hospital Pharmacy</u> : Patterns of Computer use in Hospital Pharmacy – Patient record database management, Medication order entry – Drug labels and list – Intravenous solution and admixture, patient medication profiles, Inventory control, Management report & Statistics. b) <u>Computer In Community Pharmacy</u> : Computerizing the Prescription Dispensing process; Use of Computers for Pharmaceutical Care in community pharmacy; Accounting and General ledger system c) <u>Drug Information Retrieval & Storage</u> : Introduction – Advantages of Computerized Literature Retrieval; Use of Computerized Retrieval	8 Hours

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

Theory: 3 Hrs. /Week

1. Scope of the subject:

2. Objectives of the subject:

Text Books:

Reference Books:

- Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
- Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania.

- c. Pharmacokinetics: By Milo Gibaldi Donald, R. Mercel Dekker Inc.
- d. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
- e. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
- f. Biopharmaceutics; By Swarbrick
- g. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
- h. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
- i. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack Publishing Company, Pennsylvania 1989.
- j. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebert F Notari Marcel Dekker Inn, New York and Basel, 1987.
- k. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

3. Detailed syllabus and lecture wise schedule:

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Biopharmaceutics - Introduction to Biopharmaceutics a. Absorption of drugs from gastrointestinal tract. b. Drug Distribution. c. Drug Elimination.	16 Hours
Pharmacokinetics		
2	Introduction to Pharmacokinetics. a. Mathematical model b. Drug levels in blood. c. Pharmacokinetic model d. Compartment models a. e. Pharmacokinetic study.	10 Hours
3	One compartment open model. a. Intravenous Injection (Bolus) b. Intravenous infusion.	8 Hours
4	Multicompartment models. a. Two compartment open model.	8 Hours

	b. IV bolus, IV infusion and oral administration	
5	Multiple – Dosage Regimens. - Repetitive Intravenous injections – One Compartment Open Model - Repetitive Extravascular dosing – One Compartment Open model - Multiple Dose Regimen – Two Compartment Open Model	10 Hours
6	Nonlinear Pharmacokinetics. - Introduction - Factors causing Non-linearity. - Michaelis-menton method of estimating parameters.	7 Hours
7	Noncompartmental Pharmacokinetics. - Statistical Moment Theory. - MRT for various compartment models. - Physiological Pharmacokinetic model.	8 Hours
8	Bioavailability and Bioequivalence. - Introduction. - Bioavailability study protocol. - Methods of Assessment of Bioavailability	8 Hours

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

Practical: 3 Hrs./Week

- Improvement of dissolution characteristics of slightly soluble drugs by some methods.
- Comparison of dissolution studies of two different marketed products of same drug.
- Influence of polymorphism on solubility and dissolution.
- Protein binding studies of a highly protein bound drug and poorly protein bound drug.
- Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.
- Bioavailability studies of some commonly used drugs on animal/human model.
- Calculation of K_a , K_e , $t_{1/2}$, C_{max} , AUC, AUMC, MRT etc. from blood profile data.
- Calculation of bioavailability from urinary excretion data for two drugs.
- Calculation of AUC and bioequivalence from the given data for two drugs.
- In vitro absorption studies.

11. Bioequivalency studies on the different drugs marketed. (eg) Tetracycline, Sulphamethoxazole, Trimethoprim, Aspirin etc., on animals and human volunteers.
12. Absorption studies in animal inverted intestine using various drugs.
13. Effect on contact time on the plasma protein binding of drugs.
14. Studying metabolic pathways for different drugs based on elimination kinetics data.
15. Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data.
16. Determination of renal clearance.

4.6 CLINICAL TOXICOLOGY (THEORY)

Theory: 2 Hrs. /Week

1. Scope of the subject:

2. Objectives of the subject:

Text Books:

Reference Books:

- a. Matthew J Ellenhorn. ELLENHORNS MEDICAL TOXICOLOGY – DIAGNOSIS AND TREATMENT OF POISONING. Second edition. Williams and Willkins publication, London
- b. V V Pillay. HANDBOOK OF FORENSIC MEDICINE AND TOXICOLOGY. Thirteenth edition 2003 Paras Publication, Hyderabad

3. Detailed syllabus and lecture wise schedule:

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	General principles involved in the management of poisoning	3 Hours
2	Antidotes and the clinical applications.	2 Hours
3	Supportive care in clinical Toxicology.	2 Hours
4	Gut Decontamination.	2 Hours
5	Elimination Enhancement	2 Hours
6	Toxicokinetics	2 Hours

7	Clinical symptoms and management of acute poisoning with the following agents – a) Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids. b) Opiates overdose. c) Antidepressants d) Barbiturates and benzodiazepines. e) Alcohol: ethanol, methanol. f) Paracetamol and salicylates. g) Non-steroidal anti-inflammatory drugs. h) Hydrocarbons: Petroleum products and PEG. i) Caustics: inorganic acids and alkali. j) Radiation poisoning	16 Hours
8	Clinical symptoms and management of chronic poisoning with the following agents – Heavy metals: Arsenic, lead, mercury, iron, copper	6 Hours
9	Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.	4 Hours
10	Plants poisoning. Mushrooms, Mycotoxins.	2 Hours
11	Food Poisonings	2 Hours
12	Envenomations – Arthropod bites and stings.	2 Hours
13	Substance abuse: Signs and symptoms of substance abuse and treatment of dependence a) CNS stimulants :amphetamine b) Opioids c) CNS depressants d) Hallucinogens: LSD e) Cannabis group f) Tobacco	3 Hours

Fifth year**5.1 CLINICAL RESEARCH (THEORY)****Theory: 3 Hrs. /Week****1. Scope of the subject:****2. Objectives of the subject:****Text Books:****Reference Books:**

- a. Central Drugs Standard Control Organization. Good Clinical Practices- Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
- b. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
- c. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
- d. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
- e. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
- f. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
- g. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

3. Detailed syllabus and lecture wise schedule:

SL. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Drug development process: - Introduction - Various Approaches to drug discovery 1. Pharmacological 2. Toxicological 3. IND Application 4. Drug characterization	6 Hours

	5. Dosage form	
2	Clinical development of drug: 1. Introduction to Clinical trials 2. Various phases of clinical trial. 3. Methods of post marketing surveillance 4. Abbreviated New Drug Application submission. 5. Good Clinical Practice – ICH, GCP, Central drug standard control organization (CDSCO) guidelines 6. Challenges in the implementation of guidelines 7. Ethical guidelines in Clinical Research 8. Composition, responsibilities, procedures of IR B / IEC 9. Overview of regulatory environment in USA, Europe and India. 10. Role and responsibilities of clinical trial personnel as per ICH GCP a. Sponsor b. Investigators c. Clinical research associate d. Auditors e. Contract research coordinators f. Regulatory authority 11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment) 12. Informed consent Process 13. Data management and its components 14. Safety monitoring in clinical trials.	44 Hours

5.2 PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS (THEORY)

Theory: 3 Hrs. /Week

1. Scope of the subject:

2. Objectives of the subject:

Text Books:

Reference Books:

a.

3. Detailed syllabus and lecture wise schedule:

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Pharmacoepidemiology :	
	Definition and scope: Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.	6 Hours
	Measurement of outcomes in pharmacoepidemiology Outcome measure and drug use measures. Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement	6 Hours
	Concept of risk in pharmacoepidemiology Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio	6 Hours
	Pharmacoepidemiological methods Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods Drug utilization review, case reports, case series, surveys of drug use, cross-sectional studies, cohort studies, case control studies, case –cohort studies, meta-analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.	22 Hours
	Sources of data for pharmacoepidemiological studies Ad Hoc data sources and automated data systems.	4 Hours
	Selected special applications of pharmacoepidemiology Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.	8 Hours
2	Pharmacoeconomics Definition, history, needs of pharmacoeconomic evaluations Role in formulary management decisions Pharmacoeconomic evaluation Outcome assessment and types of evaluation Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Cost – minimization, cost- benefit, cost – effectiveness, cost utility	20 Hours

3	Applications of Pharmacoeconomics Software and case studies	3 Hours

5.3 CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING (THEORY)

Theory: 2 Hrs. /Week

1. Scope of the subject:

2. Objectives of the subject:

Text Books:

Reference Books:

b.

3. Detailed syllabus and lecture wise schedule:

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Introduction to Clinical pharmacokinetics.	1 Hour
2	Design of dosage regimens: Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.	7 Hours
3	Pharmacokinetics of Drug Interaction: a. Pharmacokinetic drug interactions b. Inhibition and Induction of Drug metabolism c. Inhibition of Biliary Excretion.	3 Hours
4	Therapeutic Drug monitoring: a. Introduction b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight, disease, Interacting drugs). c. Indications for TDM. Protocol for TDM. d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.	20 Hours

	e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.	
5	Dosage adjustment in Renal and hepatic Disease. - Renal impairment - Pharmacokinetic considerations - General approach for dosage adjustment in Renal disease. - Measurement of Glomerular Filtration rate and creatinine clearance. - Dosage adjustment for uremic patients. - Extracorporeal removal of drugs. - Effect of Hepatic disease on pharmacokinetics.	10 Hours
6	Population Pharmacokinetics. - Introduction to Bayesian Theory. - Adaptive method or Dosing with feedback. - Analysis of Population pharmacokinetic Data.	5 Hours
7	Pharmacogenetics - Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes. - Genetic Polymorphism in Drug Transport and Drug Targets. - Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations	4 Hours

PHARM.D. (Post Baccalaureate) SYLLABUS

First Year

1.1 PHARMACOTHERAPEUTICS – I & II (THEORY)

Theory: 3 Hrs. /Week

- 4. Scope:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
- 5. Objectives:** At completion of this subject it is expected that students will be able to understand –
- the pathophysiology of selected disease states and the rationale for drug therapy;
 - the therapeutic approach to management of these diseases;
 - the controversies in drug therapy;
 - the importance of preparation of individualised therapeutic plans based on diagnosis;
 - needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
 - describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
 - summarise the therapeutic approach to management of these diseases including reference to the latest available evidence;
 - discuss the controversies in drug therapy;
 - discuss the preparation of individualised therapeutic plans based on diagnosis; and
 - identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

- Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication
- Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange

Reference Books

- a. Pathologic basis of disease - Robins SL, W.B.Saunders publication
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication
- c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda – Kimble MA
- e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature.

6. Detailed syllabus and lecture wise schedule:

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases:

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Cardiovascular system Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, Hyperlipidemia, Electrophysiology of heart and Arrhythmias.	13 Hours
2	Respiratory system Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases.	06 Hours
3	Endocrine system Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis	08 Hours
4	General prescribing guidelines for 4.1 Paediatric patients 4.2 Geriatric patients 4.3 Pregnancy and breast feeding	04 Hours
5	Ophthalmology Glaucoma, Conjunctivitis- viral & bacterial.	03 Hours
6	Introduction to rational drug use Definition, Role of pharmacist Essential drug concept Rational drug formulations.	02 Hours
7	Infectious disease Guidelines for the rational use of antibiotics and surgical prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis,	18 Hours

	Endocarditis, Septicemia, Urinary tract infections, Protozoal infection-Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhea and Syphilis.	
8	Musculoskeletal disorders Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.	06 Hours
9	Renal system Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders.	05 Hours
10	Oncology Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis.	06 Hours
11	Dermatology Psoriasis, Scabies, Eczema, Impetigo	04 Hours

1.1 PHARMACOTHERAPEUTICS – III (PRACTICAL)

Practical: 3 Hrs./Week

Practicals:

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.

The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.

A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	06hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.2 HOSPITAL & COMMUNITY PHARMACY (THEORY)**Theory: 3 Hrs. /Week**

1. **Scope:** In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug dispensing, manufacturing of parenteral preparations, drug information, patient counselling, and therapeutic drug monitoring for improved patient care.
2. **Objectives:** Upon completion of the course, the student shall be able to –
 - a. know various drug distribution methods;
 - b. know the professional practice management skills in hospital pharmacies;
 - c. provide unbiased drug information to the doctors;
 - d. know the manufacturing practices of various formulations in hospital set up;
 - e. appreciate the practice based research methods; and
 - f. appreciate the stores management and inventory control.

Text books: (latest editions)

- a. Hospital pharmacy by William .E. Hassan
- b. A text book of Hospital Pharmacy by S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh
- c. Health Education and Community Pharmacy by N.S.Parmar.
- d. WHO consultative group report.
- e. Drug store & Business management by Mohammed Ali & Jyoti.

References:

- a. WHO consultative group report.
- b. R.P.S. Vol.2. Part –B; Pharmacy Practice section.
- c. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.
- d. Comprehensive Pharmacy Review – Edt. Leon Shargel. Lippincott Williams & Wilkins.

3. Lecture wise programme:

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
A. HOSPITAL PHARMACY		
1.	Hospital - its Organization and functions	1 Hour
2.	Hospital Pharmacy - Organization and management a) Organizational Structure-Staff, Infrastructure & work load statistic b) Management of materials and finance c) Roles & responsibilities of hospital pharmacist	6 Hours
3.	Hospital drug policy a) Pharmacy and Therapeutic committee (PTC) b) Hospital formulary c) Hospital committees - Infection committee - Research and ethical committee d) Developing therapeutic guidelines e) Hospital pharmacy communication - Newsletter	15 Hours
4.	Hospital pharmacy services a) Procurement & warehousing of drugs and Pharmaceuticals b) Inventory control	15 Hours

	Definition, various methods of Inventory Control ABC, VED, EOQ, Lead time, safety stock c) Drug distribution in the hospital - Individual prescription method - Floor stock method - Unit dose drug distribution method d) Distribution of Narcotic and other controlled substances e) Central sterile supply services – Role of pharmacist	
5.	Enteral and parenteral nutrition preparations Total Parenteral Nutrition and I.V. admixtures	4 Hours
6.	Continuing professional development programs Education and training	3 Hours
7.	Radio Pharmaceuticals – Handling and packaging	2 Hours
8.	Professional Relations and practices of hospital pharmacist	3 Hours
B. COMMUNITY PHARMACY		
1.	Definition, scope, of community pharmacy Roles and responsibilities of Community pharmacist	2 Hours
2.	Community Pharmacy Management - Selection of site, Space layout, and design - Staff, Materials- coding, stocking - Legal requirements - Maintenance of various registers - Use of Computers: Business and health care softwares	5 Hours
3.	Responding to symptoms of minor ailments Relevant pathophysiology, common drug therapy to Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Pyrexia, Ophthalmic symptoms, worm's infestations.	12 Hours
4.	Code of ethics for community pharmacists	2 Hour
5.	Good Pharmacy Practice	3 Hours

4.3 HOSPITAL & COMMUNITY PHARMACY (PRACTICAL)

Practical: 3 Hrs./Week

List of Experiments

1. Assessment of drug interactions in the given prescriptions
2. Manufacture of parenteral formulations, powders.
3. Inventory control
4. Prescription Analysis (Analyzing the prescriptions for probable drug interactions and ability to tell the management)

List of Assignments:

1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.
2. Pharmacy and Therapeutics committee – Organization, functions, and limitations.
3. Development of a hospital formulary for 300 bedded teaching hospital
4. Preparation of ABC analysis of drugs sold in one month from the pharmacy.
5. Different phases of clinical trials with elements to be evaluated.
6. Various sources of drug information and systematic approach to provide unbiased drug information.
7. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.

Special requirements:

1. Each college should sign MoU with nearby local hospital having minimum 300 beds for providing necessary training to the students' on hospital pharmacy activities.
2. Well equipped with various resources of drug information.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	06hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.3 CLINICAL PHARMACY (THEORY)

Theory: 3 Hrs. /Week

- 3. Objectives of the Subject :** Upon completion of the subject student shall be able to (Know, do, appreciate) –
- g. monitor drug therapy of patient through medication chart review and clinical review;
 - h. obtain medication history interview and counsel the patients;
 - i. identify and resolve drug related problems;
 - j. detect, assess and monitor adverse drug reaction;
 - k. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and
 - l. retrieve, analyse, interpret and formulate drug or medicine information.

Text books (Theory)

- e. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
- f. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
- g. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.
- h. A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi et al, Orient Orient Langram Pvt.Ltd. ISSN8125026

References

- d. Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
- e. Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
- f. Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

4. Detailed syllabus and lecture wise schedule:

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Definitions, development and scope of clinical pharmacy	3 Hours
2	Introduction to daily activities of a clinical pharmacist i. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions) j. Ward round participation k. Adverse drug reaction management l. Drug information and poisons information m. Medication history n. Patient counseling o. Drug utilisation evaluation (DUE) and review (DUR) p. Quality assurance of clinical pharmacy services	13 Hours

3	Patient data analysis The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.	3 Hours
4	Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results f. Haematological, Liver function, Renal function, thyroid function tests g. Tests associated with cardiac disorders h. Fluid and electrolyte balance i. Microbiological culture sensitivity tests j. Pulmonary Function Tests	15 Hours
5	Drug & Poison information g. Introduction to drug information resources available h. Systematic approach in answering DI queries i. Critical evaluation of drug information and literature j. Preparation of written and verbal reports k. Establishing a Drug Information Centre l. Poisons information- organization & information resources	8 Hours
6	Pharmacovigilance d. Scope, definition and aims of pharmacovigilance e. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used] f. Reporting, evaluation, monitoring, preventing & management of ADRs b. d. Role of pharmacist in management of ADR.	10 Hours
7	Communication skills , including patient counselling techniques, medication history interview, presentation of cases.	10 Hours
8	Pharmaceutical care concepts	4 Hours
9	Critical evaluation of biomedical literature	6 Hours
10	Medication errors	3 Hours

1.3 CLINICAL PHARMACY (PRACTICAL)

Practical: 3 Hrs./Week

Students are expected to perform 15 practicals in the following areas covering the topics dealt in theory class.

- a. Answering drug information questions (4 Nos)
- b. Patient medication counselling (4 Nos)
- c. Case studies related to laboratory investigations (4 Nos)
- d. Patient medication history interview (3 Nos)

Assignment:

Students are expected to submit THREE written assignments (1500 – 2000 words) on the topics given to them covering the following areas dealt in theory class.

Drug information, Patient medication history interview, Patient medication counselling, Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

Format of the assignment:

7. Minimum & Maximum number of pages.
8. Reference(s) shall be included at the end.
9. Assignment can be a combined presentation at the end of the academic year.
10. It shall be computer draft copy.
11. Name and signature of the student.
12. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	06hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.4 BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY)

Theory: 2 Hrs. /Week

4. Scope of the subject:

5. Objectives of the subject:

Text Books:**Reference Books:**

- c. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton, 3rd edition, publisher Marcel Dekker Inc. NewYork.
- d. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich , 3rd edition, McGraw Hill Publications 2006

6. Detailed syllabus and lecture wise schedule:

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Research Methodology e) Types of clinical study designs: Case studies, observational studies, interventional studies, f) Designing the methodology g) Sample size determination and Power of a study - Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study h) Report writing and presentation of data	10 Hours
2.1	Biostatistics e) Introduction f) Types of data distribution g) Measures describing the central tendency distributions- average, median, mode h) Measurement of the spread of data -range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean.	10 Hours
2.2	Data graphics Construction and labeling of graphs, histogram, piecharts, scatter plots, semilogarithmic plots	2 Hours
2.3	Basics of testing hypothesis e) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals. f) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way)	15 Hours

	b) Level of significance (Non-parametric data)- Sign test, Wilcoxon's signed rank test, Wilcoxon rank sum test, Mann Whitney U test, Kruskal -Wall is test (one way ANOVA) g) Linear regression and correlation- Introduction, Pearson's and Spearmann's correlation and correlation co-efficient. h) Introduction to statistical software: SPSS, Epi Info, SAS.	
2.4	Statistical methods in epidemiology Incidence and prevalence, relative risk, attributable risk	5 Hours
3	Computer applications in pharmacy d) <u>Computer System in Hospital Pharmacy</u> : Patterns of Computer use in Hospital Pharmacy – Patient record database management, Medication order entry – Drug labels and list – Intravenous solution and admixture, patient medication profiles, Inventory control, Management report & Statistics. e) <u>Computer In Community Pharmacy</u> : Computerizing the Prescription Dispensing process; Use of Computers for Pharmaceutical Care in community pharmacy; Accounting and General ledger system f) <u>Drug Information Retrieval & Storage</u> : Introduction – Advantages of Computerized Literature Retrieval; Use of Computerized Retrieval	8 Hours

1.5 CLINICAL TOXICOLOGY (THEORY)

Theory: 2 Hrs. /Week

4. Scope of the subject:

5. Objectives of the subject:

Text Books:

Reference Books:

- c. Matthew J Ellenhorn. ELLENHORNS MEDICAL TOXICOLOGY – DIAGNOSIS AND TREATMENT OF POISONING. Second edition. Williams and Willkins publication, London
- d. V V Pillay. HANDBOOK OF FORENSIC MEDICINE AND TOXICOLOGY. Thirteenth edition 2003 Paras Publication, Hyderabad

6. Detailed syllabus and lecture wise schedule:

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	General principles involved in the management of poisoning	3 Hours
2	Antidotes and the clinical applications.	2 Hours
3	Supportive care in clinical Toxicology.	2 Hours
4	Gut Decontamination.	2 Hours
5	Elimination Enhancement	2 Hours
6	Toxicokinetics	2 Hours
7	Clinical symptoms and management of acute poisoning with the following agents – k) Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids. l) Opiates overdose. m) Antidepressants n) Barbiturates and benzodiazepines. o) Alcohol: ethanol, methanol. p) Paracetamol and salicylates. q) Non-steroidal anti-inflammatory drugs. r) Hydrocarbons: Petroleum products and PEG. s) Caustics: inorganic acids and alkali. t) Radiation poisoning	16 Hours
8	Clinical symptoms and management of chronic poisoning with the following agents – Heavy metals: Arsenic, lead, mercury, iron, copper	6 Hours
9	Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.	4 Hours
10	Plants poisoning. Mushrooms, Mycotoxins.	2 Hours
11	Food Poisonings	2 Hours
12	Envenomations – Arthropod bites and stings.	2 Hours
13	Substance abuse: Signs and symptoms of substance abuse and treatment of dependence	3 Hours

	g) CNS stimulants :amphetamine h) Opioids i) CNS depressants j) Hallucinogens: LSD k) Cannabis group l) Tobacco	

1.6 PHARMACOTHERAPEUTICS – III (THEORY)

Theory: 3 Hrs. /Week

7. **Scope:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
8. **Objectives:** At completion of this subject it is expected that students will be able to understand –
 - a. the pathophysiology of selected disease states and the rationale for drug therapy;
 - b. the therapeutic approach to management of these diseases;
 - c. the controversies in drug therapy;
 - d. the importance of preparation of individualised therapeutic plans based on diagnosis;
 - e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
 - f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
 - g. to summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
 - h. to discuss the controversies in drug therapy;
 - i. to discuss the preparation of individualised therapeutic plans based on diagnosis; and
 - j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

- a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication
- b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange

Reference Books

- a. Pathologic basis of disease - Robins SL, W.B.Saunders publication
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication
- c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda – Kimble MA
- e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature.

9. Detailed syllabus and lecture wise schedule:

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases:

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Gastrointestinal system: Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, Viral hepatitis including jaundice, and Drug induced liver disorders.	20 Hours
2	Haematological system: Anaemias, Venous thromboembolism, Drug induced blood disorders.	12 Hours
3	Nervous system: Epilepsy, Parkinsonism, Stroke, Alzheimer's disease	16 Hours
4	Psychiatry disorders: Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders	14 Hours
5	Pain management including Pain pathways, neuralgias, headaches.	8 Hours
6	Evidence Based Medicine	5 Hours

1.6 PHARMACOTHERAPEUTICS – III (PRACTICAL)

Practical: 3 Hrs./Week

Practicals:

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.

The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.

A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
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Max Marks	20	70
Duration	03hrs	04hrs

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.7 BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

Theory: 3 Hrs. /Week

4. Scope of the subject:

5. Objectives of the subject:

Text Books:

Reference Books:

- l. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
- m. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania.
- n. Pharmacokinetics: By Milo Gibaldi Donald, R. Mercey Dekker Inc.
- o. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
- p. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
- q. Biopharmaceutics; By Swarbrick
- r. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmanekar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
- s. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febiger, Philadelphia, 1995.
- t. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack Publishing Company, Pennsylvania 1989.
- u. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Robert F Notari Marcel Dekker Inc, New York and Basel, 1987.
- v. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

6. Detailed syllabus and lecture wise schedule:

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Biopharmaceutics - Introduction to Biopharmaceutics d. Absorption of drugs from gastrointestinal tract. e. Drug Distribution. f. Drug Elimination.	16 Hours

Pharmacokinetics		
2	Introduction to Pharmacokinetics. e. Mathematical model f. Drug levels in blood. g. Pharmacokinetic model h. Compartment models c. e. Pharmacokinetic study.	10 Hours
3	One compartment open model. b. Intravenous Injection (Bolus) d. Intravenous infusion.	8 Hours
4	Multicompartment models. c. Two compartment open model. d. IV bolus, IV infusion and oral administration	8 Hours
5	Multiple – Dosage Regimens. d. Repetitive Intravenous injections – One Compartment Open Model e. Repetitive Extravascular dosing – One Compartment Open model f. Multiple Dose Regimen – Two Compartment Open Model	10 Hours
6	Nonlinear Pharmacokinetics. d. Introduction e. Factors causing Non-linearity. f. Michaelis-menton method of estimating parameters.	7 Hours
7	Noncompartmental Pharmacokinetics. d. Statistical Moment Theory. e. MRT for various compartment models. f. Physiological Pharmacokinetic model.	8 Hours
8	Bioavailability and Bioequivalence. d. Introduction. e. Bioavailability study protocol. f. Methods of Assessment of Bioavailability	8 Hours

1.7 BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

Practical: 3 Hrs./Week

1. Improvement of dissolution characteristics of slightly soluble drugs by some methods.
2. Comparison of dissolution studies of two different marketed products of same drug.
3. Influence of polymorphism on solubility and dissolution.
4. Protein binding studies of a highly protein bound drug and poorly protein bound drug.
5. Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.
6. Bioavailability studies of some commonly used drugs on animal/human model.
7. Calculation of K_a , K_e , $t_{1/2}$, C_{max} , AUC, AUMC, MRT etc. from blood profile data.
8. Calculation of bioavailability from urinary excretion data for two drugs.
9. Calculation of AUC and bioequivalence from the given data for two drugs.
10. In vitro absorption studies.
11. Bioequivalency studies on the different drugs marketed. (eg) Tetracycline, Sulphamethoxazole, Trimethoprim, Aspirin etc., on animals and human volunteers.
12. Absorption studies in animal inverted intestine using various drugs.
13. Effect on contact time on the plasma protein binding of drugs.
14. Studying metabolic pathways for different drugs based on elimination kinetics data.
15. Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data.
16. Determination of renal clearance.

Second year**2.1 CLINICAL RESEARCH (THEORY)****Theory: 3 Hrs. /Week****1. Scope of the subject:****2. Objectives of the subject:****Text Books:****Reference Books:**

- a. Central Drugs Standard Control Organization. Good Clinical Practices- Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
- b. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
- c. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
- d. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
- e. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
- f. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
- g. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

3. Detailed syllabus and lecture wise schedule:

SL. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Drug development process: - Introduction - Various Approaches to drug discovery 1. Pharmacological 2. Toxicological 3. IND Application 4. Drug characterization	6 Hours

	5. Dosage form	
2	Clinical development of drug: 1. Introduction to Clinical trials 2. Various phases of clinical trial. 3. Methods of post marketing surveillance 4. Abbreviated New Drug Application submission. 5. Good Clinical Practice – ICH, GCP, Central drug standard control organization (CDSCO) guidelines 6. Challenges in the implementation of guidelines 7. Ethical guidelines in Clinical Research 8. Composition, responsibilities, procedures of IR B / IEC 9. Overview of regulatory environment in USA, Europe and India. 10. Role and responsibilities of clinical trial personnel as per ICH GCP a. Sponsor b. Investigators c. Clinical research associate d. Auditors e. Contract research coordinators f. Regulatory authority 11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment) 12. Informed consent Process 13. Data management and its components 14. Safety monitoring in clinical trials.	44 Hours

2.2 PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS (THEORY)

Theory: 3 Hrs. /Week

1. Scope of the subject:

2. Objectives of the subject:

Text Books:

Reference Books:

a.

3. Detailed syllabus and lecture wise schedule:

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Pharmacoepidemiology :	
	Definition and scope: Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.	6 Hours
	Measurement of outcomes in pharmacoepidemiology Outcome measure and drug use measures. Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement	6 Hours
	Concept of risk in pharmacoepidemiology Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio	6 Hours
	Pharmacoepidemiological methods Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods Drug utilization review, case reports, case series, surveys of drug use, cross-sectional studies, cohort studies, case control studies, case –cohort studies, meta-analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.	22 Hours
	Sources of data for pharmacoepidemiological studies Ad Hoc data sources and automated data systems.	4 Hours
	Selected special applications of pharmacoepidemiology Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.	8 Hours
2	Pharmacoeconomics Definition, history, needs of pharmacoeconomic evaluations Role in formulary management decisions Pharmacoeconomic evaluation Outcome assessment and types of evaluation	20 Hours

	Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Cost – minimization, cost- benefit, cost – effectiveness, cost utility	
3	Applications of Pharmacoeconomics Software and case studies	3 Hours

2.3 CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING (THEORY)

Theory: 2 Hrs. /Week

1. Scope of the subject:

2. Objectives of the subject:

Text Books:

Reference Books:

a.

3. Detailed syllabus and lecture wise schedule:

Sl. NO	TITLE OF THE TOPIC	TOTAL HOURS
1	Introduction to Clinical pharmacokinetics.	1 Hour
2	Design of dosage regimens: Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.	7 Hours
3	Pharmacokinetics of Drug Interaction: a. Pharmacokinetic drug interactions b. Inhibition and Induction of Drug metabolism c. Inhibition of Biliary Excretion.	3 Hours
4	Therapeutic Drug monitoring: a. Introduction b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight, disease, Interacting drugs).	20 Hours

	c. Indications for TDM. Protocol for TDM. d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy. e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.	
5	Dosage adjustment in Renal and hepatic Disease. a. Renal impairment b. Pharmacokinetic considerations c. General approach for dosage adjustment in Renal disease. d. Measurement of Glomerular Filtration rate and creatinine clearance. e. Dosage adjustment for uremic patients. f. Extracorporeal removal of drugs. g. Effect of Hepatic disease on pharmacokinetics.	10 Hours
6	Population Pharmacokinetics. a. Introduction to Bayesian Theory. b. Adaptive method or Dosing with feedback. c. Analysis of Population Pharmacokinetic Data.	5 Hours
7	Pharmacogenetics a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes. b. Genetic Polymorphism in Drug Transport and Drug Targets. c. Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations	4 Hours

APPENDIX-B

CONDITIONS TO BE FULFILLED BY THE ACADEMIC TRAINING INSTITUTION

1. Any authority or institution in India applying to the Pharmacy Council of India for approval of courses of study for Pharm.D. and Pharm.D. (Post Baccalaureate) under subsection (1) of section 12 of the Pharmacy Act, 1948 shall comply with the infrastructural facilities as prescribed by the Pharmacy Council of India from time to time.
2. Pharm.D. and Pharm.D. (Post Baccalaureate) programmes shall be conducted only in those institutions which -
 - a) are approved by the Pharmacy Council of India for Pharm. D course as provided under section 12 of the Pharmacy Act, 1948;
 - b) have 300 bedded hospital attached to it.

(i) Hospital Details

1. Institution with their own hospital of minimum 300 beds.
2. Teaching hospital recognised by the Medical Council of India or University, or a Government hospital not below the level of district headquarter hospital with 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
3. Corporate type hospital with minimum 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
4. The hospital may not enter into similar agreement(s) with any other Pharmacy institution/s or department/s offering or intend to offer Pharm.D programs.

(ii) Specialty

- a) Tertiary care hospitals are desirable
- b) Medicine [compulsory], and any three specializations like -
 1. Surgery
 2. Pediatrics
 3. Gynecology and obstetrics
 4. Psychiatry
 5. Skin and VD

6. Orthopedics

(iii) Location of the Hospital

Within the same limits of Corporation or Municipality or Campus with Medical Faculty involvement as adjunct faculty.

3. TEACHING STAFF REQUIREMENT

- (i) Staff Pattern: All faculty shall be full time. However, part time preceptors in hospital shall be allowed.
- (ii) Subject wise specialization of the Teaching Staff:

S.No.	Subject	Specialization required
1.	Pharmacy Practice	M.Pharm in Pharmacy Practice or Pharmacology or Pharmaceutics.
2.	Human Anatomy & Physiology	M.Pharm in Pharmacology or Pharmacy practice
3.	Pharmaceutics (Dispensing & General Pharmacy)	M.Pharm in Pharmaceutics
4.	Pharmacognosy-I	M.Pharm in Pharmacognosy
5.	Pharmaceutical Organic Chemistry-I	M.Pharm in Pharmaceutical chemistry or Pharmaceutical Analysis or Quality assurance or Bulk Drug
6.	Pharmaceutical Inorganic Chemistry	M.Pharm in Pharmaceutical chemistry or Pharmaceutical Analysis or Quality assurance or Bulk Drug
7.	Pharmaceutical microbiology	M.Pharm in Pharmaceutics or Pharmaceutical Biotechnology
8.	Pathophysiology	M.Pharm Pharmacy practice or Pharmacology
9.	Applied Biochemistry & Clinical Chemistry	M.Pharm in Pharmacology or Pharmacy practice or Pharmaceutical chemistry
10.	Pharmacology-I	M.Pharm in Pharmacology or Pharmacy practice
11.	Pharmaceutical Jurisprudence	M.Pharm in Pharmaceutics
12.	Pharmacology-II	M.Pharm in Pharmacology or Pharmacy practice
13.	Pharmaceutical Dosage Forms	M.Pharm in Pharmaceutics or Industrial Pharmacy
14.	Pharmacotherapeutics –I, II and III	M.Pharm Pharmacy practice or Pharmacology
15.	Community Pharmacy	M.Pharm in Pharmacy practice or Pharmacology or Pharmaceutics

16.	Hospital Pharmacy	M.Pharm in Pharmacy practice or Pharmacology or Pharmaceutics
17.	Clinical Pharmacy	M.Pharm in Pharmacy practice
18.	Computer Science or Computer Application in pharmacy	MCA
19.	Mathematics	M.Sc. (Maths)

iii) Teaching Staff :

Department/Division	Name of the post	No.
Department of Pharmaceutics	Professor	1
	Asst. Professor	1
	Lecturer	2
Department of Pharmaceutical Chemistry (Including Pharmaceutical Analysis)	Professor	1
	Asst. Professor	1
	Lecturer	3
Department of Pharmacology	Professor	1
	Asst. Professor	1
	Lecturer	2
Department of Pharmacognosy	Professor	1
	Asst. Professor	1
	Lecturer	1
Department of Pharmacy Practice	Professor	1
	Asst. Professor	2
	Lecturer	3

iv) Prescribed qualifications and experience for Professor, Assistant Professor, Lecturer and others :

Sl. No.	CADRE	QUALIFICATIONS	EXPERIENCE
1.	Lecturer/Assistant Professor	First Class B.Pharm with Master's degree in Pharmacy (M.Pharm) in appropriate branch of specialization in Pharmacy (Qualification must be PCI recognized).	A lecturer will be re-designated as Assistant Professor after 2 years of teaching experience in PCI approved/recognized Pharmacy College.

		A PCI recognized Pharm.D degree holder shall also be eligible for the posts of Lecturer/Assistant Professor in the subjects of pathophysiology, pharmacology and pharmacy practice.	
2.	Associate Professor	First Class B.Pharm with Master's degree in Pharmacy (M.Pharm) in appropriate branch of specialization in Pharmacy (Qualification must be PCI recognized). A PCI recognized Pharm.D degree holder shall also be eligible for the posts of Associate Professor in the subjects of pathophysiology, pharmacology sand pharmacy practice. Associate Professor shall acquire PCI recognized Ph.D in any of Pharmacy subjects within 7 years to become eligible for the post of Professor.	3 years' experience in teaching or research at the level of Assistant Professor or equivalent in PCI approved/recognized Pharmacy College.
3.	Professor	First Class B.Pharm With Master's degree in Pharmacy (M.Pharm) in appropriate branch of specialization in Pharmacy or Pharm.D (Qualifications must be PCI recognized). With Ph.D degree in any of Pharmacy subjects (Ph.D.	Essential 10 years' experience in teaching in PCI approved/recognized Pharmacy College or research experience out of which 5 years must be as Associate Professor in PCI approved/recognized Pharmacy College.

		Qualifications must be PCI recognized).	
4.	Director or Principal or Head of institute	First Class B.Pharm with Master's degree in Pharmacy (M.Pharm) in appropriate branch of specialization in Pharmacy or Pharm.D (Qualifications must be PCI recognized). With Ph.D degree in any of Pharmacy subjects (Ph.D. Qualifications must be PCI recognized).	Essential 15 years' experience in teaching or research out of which 5 years must be as Professor/HOD in a PCI approved/recognized pharmacy college. Desirable Administrative experience in a responsible position.

Note : If a class or division is not awarded at Master's level, a minimum of 60% marks in aggregate or equivalent cumulative grade point average shall be considered equivalent to first class or division, as the case may be.

v) Workload of Faculty :

Professor – 8 hrs. per week

Assistant Professor – 12 hrs. per week

Lecturers – 16 hrs. per week

vi) Training of Pharmacy Practice Faculty:

a) Teaching staff will be trained as per the module prescribed by the Central Council.

b) Duration of training – Minimum 3 months.

c) Training sites – Institutions running pharmacy practice Programmes for at least five years.

d) Trainer – Professor or Assistant Professor with minimum of five years of clinical pharmacy teaching and practice experience.

4) NON-TEACHING STAFF:

Sl.No.	Designation	Required (Minimum)	Required Qualification
1	Laboratory Technician	1 for each Dept	D. Pharm

2	Laboratory Assistants or Laboratory Attenders	1 for each Lab (minimum)	SSLC
3	Office Superintendent	1	Degree
4	Accountant	1	Degree
5	Store keeper	1	D.Pharm or a Bachelor degree recognized by a University or institution.
6	Computer Data Operator	1	BCA or Graduate with Computer Course
7	Office Staff I	1	Degree
8	Office Staff II	2	Degree
9	Peon	2	SSLC
10	Cleaning personnel	Adequate	---
11	Gardener	Adequate	---

5) ACCOMMODATION

Suitable and sufficient accommodation with adequate ventilation, lighting and other hygienic conditions should be provided to the rooms for Principal or the Head of the department, office, class rooms, library, staff, staff common room, students common room, museum, laboratories, stores, etc.

At least two lecture halls along with eight laboratories as specified below should be provided for:

1. Pharmaceutics and Pharmacokinetics Lab	- 2
2. Life Science (Pharmacology, Physiology, Pathophysiology)	- 2
3. Phytochemistry / Pharmaceutical Chemistry	- 2
4. Pharmacy Practice	- 2

	Total = 8

In addition to the laboratories, balance room, aseptic room or cabinet, animal house and a machine room shall also be provided.

Floor area of the laboratory should not be less than 30 square feet per student required to work in the laboratory at any given time subject to a minimum of 750 square feet.

Laboratories should be fitted and constructed in a manner that these can be kept reasonably clean. Gas and water fittings, shelves, fuming cupboards be provided wherever necessary.

6. EQUIPMENT AND APPARATUS:

Department wise list of minimum equipments

A. DEPARTMENT OF PHARMACOLOGY :

I. Equipment:

S.No.	Name	Minimum required Nos.
1	Microscopes	15
2	Haemocytometer with Micropipettes	20
3	Sahli's haemocytometer	20
4	Hutchinson's spirometer	01
5	Sphygmomanometer	05
6	Stethoscope	05
7	Permanent Slides for various tissues	One pair of each tissue Organs and endocrine glands One slide of each organ system
8	Models for various organs	One model of each organ system
9	Specimen for various organs and systems	One model for each organ system
10	Skeleton and bones	One set of skeleton and one spare bone
11	Different Contraceptive Devices and Models	One set of each device
12	Muscle electrodes	01
13	Lucas moist chamber	01
14	Myographic lever	01
15	Stimulator	01
16	Centrifuge	01
17	Digital Balance	01
18	Physical /Chemical Balance	01
19	Sherrington's Kymograph Machine or Polyrite	10

20	Sherrington Drum	10
21	Perspex bath assembly (single unit)	10
22	Aerators	10
23	Computer with LCD	01
24	Software packages for experiment	01
25	Standard graphs of various drugs	Adequate number
26	Actophotometer	01
27	Rotarod	01
28	Pole climbing apparatus	01
29	Analgesiometer (Eddy's hot plate and radiant heat methods)	01
30	Convulsiometer	01
31	Plethysmograph	01
32	Digital pH meter	01

II. Apparatus:

S.No	Name	Minimum required Nos.
1	Folin-Wu tubes	60
2	Dissection Tray and Boards	10
3	Haemostatic artery forceps	10
4	Hypodermic syringes and needles of size 15,24,26G	10
5	Levers, cannulae	20

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

B. DEPARTMENT OF PHARMACOGNOSY :

I. Equipment:

S.No.	Name	Minimum required Nos.
1	Microscope with stage micrometer	15
2	Digital Balance	02
3	Autoclave	02
4	Hot air oven	02
5	B.O.D.incubator	01
6	Refrigerator	01

7	Laminar air flow	01
8	Colony counter	02
9	Zone reader	01
10	Digital pH meter	01
11	Sterility testing unit	01
12	Camera Lucida	15
13	Eye piece micrometer	15
14	Incinerator	01
15	Moisture balance	01
16	Heating mantle	15
17	Flourimeter	01
18	Vacuum pump	02
19	Micropipettes (Single and multi channeled)	02
20	Micro Centrifuge	01
21	Projection Microscope	01

II. Apparatus:

S.No.	Name	Minimum required Nos.
1	Reflux flask with condenser	20
2	Water bath	20
3	Clavengers apparatus	10
4	Soxhlet apparatus	10
6	TLC chamber and sprayer	10
7	Distillation unit	01

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

C. DEPARTMENT OF PHARMACEUTICAL CHEMISTRY :

I. Equipment:

S.No.	Name	Minimum required Nos.
1	Hot plates	05
2	Oven	03
3	Refrigerator	01
4	Analytical Balances for demonstration	05
5	Digital balance 10mg sensitivity	10

6	Digital Balance (1mg sensitivity)	01
7	Suction pumps	06
8	Muffle Furnace	01
9	Mechanical Stirrers	10
10	Magnetic Stirrers with Thermostat	10
11	Vacuum Pump	01
12	Digital pH meter	01
13	Microwave Oven	02

II. Apparatus:

S.No.	Name	Minimum required Nos.
1	Distillation Unit	02
2	Reflux flask and condenser single necked	20
3	Reflux flask and condenser double/triple necked	20
4	Burettes	40
5	Arsenic Limit Test Apparatus	20
6	Nessler's Cylinders	40

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

D. DEPARTMENT OF PHARMACEUTICS:

I. Equipment:

S.No	Name	Minimum required Nos.
1	Mechanical stirrers	10
2	Homogenizer	05
3	Digital balance	05
4	Microscopes	05
5	Stage and eye piece micrometers	05
6	Brookfield's viscometer	01
7	Tray dryer	01
8	Ball mill	01
9	Sieve shaker with sieve set	01
10	Double cone blender	01
11	Propeller type mechanical agitator	05

12	Autoclave	01
13	Steam distillation still	01
14	Vacuum Pump	01
15	Standard sieves, sieve no. 8, 10, 12,22,24, 44, 66, 80	10 sets
16	Tablet punching machine	01
17	Capsule filling machine	01
18	Ampoule washing machine	01
19	Ampoule filling and sealing machine	01
20	Tablet disintegration test apparatus IP	01
21	Tablet dissolution test apparatus IP	01
22	Monsanto's hardness tester	01
23	Pfizer type hardness tester	01
24	Friability test apparatus	01
25	Clarity test apparatus	01
26	Ointment filling machine	01
27	Collapsible tube crimping machine	01
28	Tablet coating pan	01
29	Magnetic stirrer, 500ml and 1 liter capacity with speed control	05 EACH 10
30	Digital pH meter	01
31	All purpose equipment with all accessories	01
32	Aseptic Cabinet	01
33	BOD Incubator	02
34	Bottle washing Machine	01
35	Bottle Sealing Machine	01
36	Bulk Density Apparatus	02
37	Conical Percolator (glass/copper/stainless steel)	10
38	Capsule Counter	02
39	Energy meter	02
40	Hot Plate	02
41	Humidity Control Oven	01
42	Liquid Filling Machine	01
43	Mechanical stirrer with speed regulator	02
44	Precision Melting point Apparatus	01
45	Distillation Unit	01

II. Apparatus:

S.No	Name	Minimum required Nos.
1	Ostwald's viscometer	15
2	Stalagmometer	15
3	Desiccator*	05
4	Suppository moulds	20
5	Buchner Funnels (Small, medium, large)	05 each
6	Filtration assembly	01
7	Permeability Cups	05
8	Andreason's Pipette	03
9	Lipstick moulds	10

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

E. DEPARTMENT OF PHARMACEUTICAL BIOTECHNOLOGY :

S.No.	Name	Minimum required Nos.
1	Orbital shaker incubator	01
2	Lyophilizer (Desirable)	01
3	Gel Electrophoresis (Vertical and Horizontal)	01
4	Phase contrast/Trinocular Microscope	01
5	Refrigerated Centrifuge	01
6	Fermenters of different capacity (Desirable)	01
7	Tissue culture station	01
8	Laminar airflow unit	01
9	Diagnostic kits to identify infectious agents	01
10	Rheometer	01
11	Viscometer	01
12	Micropipettes (single and multi channeled)	01 each
13	Sonicator	01
14	Respinometer	01
15	BOD Incubator	01

16	Paper Electrophoresis Unit	01
17	Micro Centrifuge	01
18	Incubator water bath	01
19	Autoclave	01
20	Refrigerator	01
21	Filtration Assembly	01
22	Digital pH meter	01

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

F. DEPARTMENT OF PHARMACY PRACTICE:

Equipment:

S.No.	Name	Minimum required Nos.
1	Colorimeter	2
2	Microscope	Adequate
3	Permanent slides (skin, kidney, pancreas, smooth muscle, liver etc.,)	Adequate
4	Watch glass	Adequate
5	Centrifuge	1
6	Biochemical reagents for analysis of normal and pathological constituents in urine and blood facilities	Adequate
7	Filtration equipment	2
8	Filling Machine	1
9	Sealing Machine	1
10	Autoclave sterilizer	1
11	Membrane filter	1 Unit
12	Sintered glass funnel with complete filtering assemble	Adequate
13	Small disposable membrane filter for IV admixture filtration	Adequate
14	Laminar air flow bench	1
15	Vacuum pump	1
16	Oven	1
17	Surgical dressing	Adequate
18	Incubator	1
19	PH meter	1
20	Disintegration test apparatus	1

21	Hardness tester	1
22	Centrifuge	1
23	Magnetic stirrer	1
24	Thermostatic bath	1

NOTE:

- 1. Computers and Internet connection (Broadband), six computers for students with internet and staff computers as required.**
- 2. Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and the department.**

G. CENTRAL INSTRUMENTATION ROOM :

S.No.	Name	Minimum required Nos.
1	Colorimeter	01
2	Digital pH meter	01
3	UV- Visible Spectrophotometer	01
4	Flourimeter	01
5	Digital Balance (1mg sensitivity)	01
6	Nephelo Turbidity meter	01
7	Flame Photometer	01
8	Potentiometer	01
9	Conductivity meter	01
10	Fourier Transform Infra Red Spectrometer (Desirable)	01
11	HPLC	01
12	HPTLC (Desirable)	01
13	Atomic Absorption and Emission spectrophotometer (Desirable)	01
14	Biochemistry Analyzer (Desirable)	01
15	Carbon, Hydrogen, Nitrogen Analyzer (Desirable)	01
16	Deep Freezer (Desirable)	01
17	Ion- Exchanger	01
18	Lyophilizer (Desirable)	01

APPENDIX-C

INTERNSHIP

1) SPECIFIC OBJECTIVES:

- i) to provide patient care in cooperation with patients, prescribers, and other members of an interprofessional health care team based upon sound therapeutic principles and evidence-based data, taking into account relevant legal, ethical, social cultural, economic, and professional issues, emerging technologies, and evolving biomedical, pharmaceutical, social or behavioral or administrative, and clinical sciences that may impact therapeutic outcomes.
- ii) to manage and use resources of the health care system, in cooperation with patients, prescribers, other health care providers, and administrative and supportive personnel, to promote health; to provide, assess, and coordinate safe, accurate, and time-sensitive medication distribution; and to improve therapeutic outcomes of medication use.
- iii) to promote health improvement, wellness, and disease prevention in co-operation with patients, communities, at-risk population, and other members of an interprofessional team of health care providers.
- iv) to demonstrate skills in monitoring of the National Health Programmes and schemes, oriented to provide preventive and promotive health care services to the community.
- v) to develop leadership qualities to function effectively as a member of the health care team organised to deliver the health and family welfare services in existing socio-economic, political and cultural environment.
- vi) to communicate effectively with patients and the community.

2) OTHER DETAILS :

- i) All parts of the internship shall be done, as far as possible, in institutions in India. Internship or residency training not more than 3 months may be allowed in some other hospital / super-specialty hospital in India or abroad.
- ii) Where an intern is posted to district hospital for training, there shall be a committee consisting of representatives of the college or university, and the district hospital

administration, who shall regulate the training of such trainee. For such trainee a certificate of satisfactory completion of training shall be obtained from the relevant administrative authorities which shall be countersigned by the Principal or Dean of College.

- iii) Every candidate shall be required, after passing the final Pharm.D. or Pharm.D. (Post Baccalaureate) examination as the case may be to undergo compulsory rotational internship to the satisfaction of the College authorities and University concerned for a period of twelve months so as to be eligible for the award of the degree of Pharm.D. or Pharm.D. (Post Baccalaureate) as the case may be.

3. ASSESSMENT OF INTERNSHIP :

- i) The intern shall maintain a record of work which is to be verified and certified by the preceptor (teacher practitioner) under whom he works. Apart from scrutiny of the record of work, assessment and evaluation of training shall be undertaken by an objective approach using situation tests in knowledge, skills and attitude during and at the end of the training. Based on the record of work and date of evaluation, the Dean or Principal shall issue certificate of satisfactory completion of training, following which the university shall award the degree or declare him eligible for it.
- ii) Satisfactory completion of internship shall be determined on the basis of the following:-

- (1) Proficiency of knowledge required for each case management SCORE 0-5
- (2) The competency in skills expected for providing Clinical Pharmacy Services
SCORE 0-5
- (3) Responsibility, punctuality, work up of case, involvement in patient care
SCORE 0-5
- (4) Ability to work in a team (Behavior with other healthcare professionals including medical doctors, nursing staff and colleagues). SCORE 0-5
- (5) Initiative, participation in discussions, research aptitude. SCORE 0-5

Poor	Fair	Below Average	Average	Above Average	Excellent
0	1	2	3	4	5

A Score of less than 3 in any of above items will represent unsatisfactory completion of internship.

APPENDIX-D

CLERKSHIP

Goals:

1. To understand clinical dynamics by attending ward round on daily basis
2. To develop a sufficient, relevant, and experiential knowledge base to utilize appropriate resources necessary to provide direct patient care regarding individualized Therapeutic planning, intervention, and evaluation.
3. To master the clinical skills necessary to assume accountability and responsibility for therapeutic outcomes in the process of providing pharmaceutical care.
4. To develop professionalism and interpersonal skills as a member of team of health care providers, necessary for the provision of optimal patient care and pharmacy services

Objectives:

After successful completion of the clerkship, the student will be able to confidently do

- A. Medication Therapy management
- B. Treatment Chart Review
- C. Drug Interaction Monitoring
- D. Therapeutic Intervention
- E. Adverse Drug Reaction Monitoring
- F. Patient Counseling and Education
- G. Drug Information
- H. Prescription Audit
- I. Health/Community Outreach
- J. Journal club

Reporting format

The sufficient number of clerkship activities as per the above-mentioned objectives must be documented in a bound format and assessed in internal and final examination as per the “Pharm D student’s clerkship activity report and assessment form” annexed in the syllabus book

Textbooks / References

1. DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey LM, eds. Pharmacotherapy, a Pathophysiologic Approach, Latest Ed. McGraw-Hill, New York, NY.
2. Ruth & Karen. Pharmacy Clerkship Manual McGraw-Hill, New York, NY, 2002
3. Boh L, ed. Pharmacy Practice Clinical Manual, 2ed. Lippincott, 2002.
4. Robert J. Cipolle, Peter C. Morley: Pharmaceutical Care Practice: The Clinician Guide

Scheme of Practical examination

	Sessional	Final Examination
Major Experiment	Perform live Clinical Pharmacy Activity as per defined objectives 10 marks	Perform live Clinical Pharmacy Activity as per defined objectives 30 marks
Minor Experiment	Reviewing clerkship activities carried out by the student as per RGUHS template by presentation and evaluating their contribution 5 marks	Reviewing clerkship activities carried out by the student as per RGUHS template and evaluating their contribution 25 marks
Viva	5 marks	15 marks
Maximum Marks	20 marks	70 marks
Duration	3 hours	4 hours
	Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity& promptness)	

APPENDIX-E**RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES**4th T Block, Jayanagar, Bengaluru, Karnataka 560041**Pharm D Student's Clerkship Activity Report & Assessment Form**

Clerkship Summary Sheet

(To be filled by preceptor at the end of the clerkship)

Name of the Student:**Reg. No.:**

Activity	Total Number	Performance (On a 0 to 5 Scale)
1. Patient History Review (Medical & Medication)		
2. Treatment Chart Review		
3. Drug Interaction Monitoring (Major)		
4. Therapeutic Intervention		
5. Adverse Drug Reaction & Hemovigilance Monitoring and Reporting		
6. Patient Counseling and Education		
7. Drug Information		
8. Case Presentation		
9. Seminars and assignments		
10. Journal Club participation and presentation		
11. TDM (optional)		
12. Prescription Audit		
13. Health Outreach Programs or camps/conducted/attended/ participated		

(Above activities should be assessed in the Internals and Final examinations)

Signature of the Preceptor	Signature of Head of the Department	Signature of the Principal

STUDENT'S INTERNSHIP ROTATION REPORT & ASSESSMENT FORM
(Six Reports should be submitted to the University along with Internship completion certificate for the issue of Provisional degree certificate)

Name of the Student:

Reg.No:

Activity	Total Number	Performance (On a 0 to 5 Scale)
1. Patient History Review (Medical & Medication)		
2. Treatment Chart Review		
3. Drug Interaction Monitoring (Major)		
4. Therapeutic Intervention		
5. Adverse Drug Reaction & Hemovigilance Monitoring and Reporting		
6. Patient Counseling & Education		
7. Drug Information		
8. Responsibility, punctuality, work up of case, involvement in patient care		
9. Proficiency of knowledge required for each case management		
10. Initiative, participation in discussions, research aptitude.		
11. Journal Club Attended and Presented		
12. Prescription Audit		
13. Contribution to the newsletter (In terms of articles, news items etc)		
14. Health Outreach Programs or camps/conducted/attended/participated		
15. Conferences /CMEs Attended/ volunteered		
16. Paper/s Presented in Conferences/and published in journals		
17. Ability to work in a team (Behavior with other healthcare professionals including medical doctors, nursing staff and colleagues).		
18. The competency in skills expected for providing Clinical Pharmacy Services		
19. TDM (optional)		

Signature of the Preceptor	Signature of Head of the Department	Signature of the Principal

RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES

4th T Block, Jayanagar, Bengaluru, Karnataka 560041

Department of Pharmacy Practice

DRUG INFORMATION QUERY REPORT FORM

DIQRF No (Office use):-		QUERY RESPONSE DATE & TIME:-	
QUERY CATEGORY:			
☐ ADMINISTRATION	☐ ADR	☐ AVAILABILITY	☐ COST
☐ DOSAGE	☐ EFFICACY	☐ INTERACTIONS	☐ INDICATION
☐ LACTATION	☐ PHARMACOKINETIC	☐ PREGNANCY	☐ POISONING
☐ THERAPY	☐ OTHERS (SPECIFY):		
RESPONSE PROVIDED:			
☐ IMMEDIATELY	☐ WITHIN 2-4 HRS	☐ WITHIN A DAY	☐ WITHIN 1-2 DAYS
RESPONSE FORMAT:			
☐ ORAL	☐ WRITTEN	☐ EMAIL	☐ OTHERS (SPECIFY)
QUERY RESPONSE IN BRIEF:			
SUPPORTING DOCUMENTS (IF ANY):			
REFERENCE SOURCES:			
ENQUIRER SIGNATURE:			
NAME & SIGNATURE OF THE STUDENT:		NAME & SIGNATURE OF THE STAFF INCHARGE:	

RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES

4th T Block, Jayanagar, Bengaluru, Karnataka 560041

Department of Pharmacy Practice

DRUG INFORMATION QUERY REQUEST FORM

DIQRF No (Office use):-		DATE:-	TIME:-
WARD:-		WING:-	SPECIALITY:-
QUERY:			
QUERY TYPE:			
☐ DISEASE MANAGEMENT	☐ CLINICAL STUDIES	☐ DRUG EFFICACY	
☐ DRUG SAFETY	☐ POISON MANAGEMENT	☐ OTHERS (SPECIFY):	
PURPOSE OF THE QUERY:			
☐ UPDATING KNOWLEDGE ☐ BETTER PATIENT CARE ☐ OTHERS (SPECIFY):			
PATIENT DETAILS (If Required): Attach Patient Profile From			
MODE OF REQUEST:			
☐ DIRECT ACCESS	☐ QUERY BOX	☐ EMAIL	☐ TELEPHONE ☐ POST
RESPONSE TIME:			
☐ IMMEDIATELY	☐ WITHIN 2-4 HRS	☐ WITHIN A DAY	☐ WITHIN 1-2 DAYS
RESPONSE REQUIRED:			
☐ ORALLY	☐ WRITTEN	☐ DETAILED INFORMATION	☐ EMAIL
☐ OTHERS (SPECIFY):			
ENQUIRER PROFESSIONAL STATUS:			
☐ CONSULTANT	☐ RESIDENT	☐ PHARMACIST	☐ NURSE
☐ OTHERS (SPECIFY):			
NAME OF THE ENQUIRER:			
EXTN NO.:	MOBILE NO.:	EMAIL:	

RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES

4th T Block, Jayanagar, Bengaluru, Karnataka 560041

Department of Pharmacy Practice

DRUG INTERACTION DOCUMENTATION FORM

DICF No (Office use):-		DATE & TIME:-		IP/OP NO.:-		DOA:-	
AGE:-		SEX:-		UNIT:-		SPECIALITY:-	
PATIENT TREATMENT DETAILS : Attach Patient Profile From							
DRUG INTERACTION CHART:							
INTERACTING DRUGS				INTERACTING DRUGS			
DRUG INTERACTION CLASSIFICATION:							
PHARMACOKINETIC				PHARMACODYNAMIC			
☐ ABSORPTION		☐ DISTRIBUTION		☐ SYNERGISM		☐ ANTAGONISM	
☐ METABOLISM		☐ EXCRETION		☐ NEUTRALISATION			
DRUG INTERACTION EFFECT:							
PHARMACOLOGICAL				CLINICAL			
BRIEF DESCRIPTION OF DRUG INTERACTION:							
TYPE OF DRUG INTERACTION:							
☐ DRUG-DRUG ☐ DRUG-FOOD ☐ DRUG-HERBAL ☐ DRUG-DISEASE ☐ ANY OTHER							
DRUG INTERACTION SEVERITY:							
☐ MAJOR ☐ MODERATE ☐ MINOR							
DRUG INTERACTION ASSESSMENT:							
☐ DEFINITE ☐ PROBABLE ☐ SUSPECTED ☐ POSSIBLE ☐ UNLIKELY							
DRUG INTERACTION MANAGEMENT:							
☐ DRUG WITHDRAWN ☐ DOSE REDUCED ☐ TIME SPACING ☐ CONTINUE WITH MONITOR ☐ OTHERS (SPECIFY):							
SUGGESTIONS ACCEPTED: ☐ YES ☐ NO IF NO, GIVE REASON:							
REFERENCES:							
NAME & SIGNATURE OF THE STUDENT:				NAME & SIGNATURE OF THE STAFF INCHARGE:			

RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES

4th T Block, Jayanagar, Bengaluru, Karnataka 560041

Department of Pharmacy Practice

PATIENT COUNSELING DOCUMENTATION FORM

PCDF No (Office use):-		DATE & TIME:-		IP /OPNO.:-		DOA:-	
AGE:-		SEX:-		WARD & WING:-		SPECIALITY:-	
PATIENT AND TREATMENT DETAILS : Attach Patient Profile From							
COUNSELING PROVIDED TO: ☐ PATIENT ☐ PATIENT REPRESENTATIVE IF PATIENT REPRESENTATIVE, GIVE REASON: ☐ PATIENT IS UNCONSCIOUS ☐ LANGUAGE PROBLEM ☐ HEARING PROBLEM ☐ PEDIATRIC PATIENT ☐ OTHERS (SPECIFY):							
COUNSELED ABOUT: ☐ DRUGS ☐ DISEASE ☐ LIFE STYLE							
COUNSELING AIDS USED: ☐ PICTOGRAMS ☐ DUMMY INHALERS ☐ SPACER ☐ NONE ☐ OTHERS (SPECIFY):							
COUNSELING MATERIAL PROVIDED: ☐ PATIENT INFORMATION LEAFLETS ☐ PRODUCT INFORMATION LEAFLET ☐ PAMPHLET ☐ NONE ☐ OTHERS (SPECIFY):							
MAJOR BARRIERS INVOLVED: ☐ YES ☐ NO IF YES, ☐ PATIENT BASED ☐ PROVIDER BASED ☐ SYSTEM BASED							
COUNSLEING STEPS CASE SHEET REVIEWED ☐ SELF-INTRODUCTION ☐ PURPOSE OF COUNSELING EXPLAINED ☐ INITIAL DRUG RELATED INFORMATION OBTAINED ☐ PATIENT WAS WARNED ABOUT TAKING OTHER MEDICATION INCLUDING OTC'S, HERBAL DRUGS ETC ☐ ACTUAL COUNSELING DONE ☐ PATIENT UNDERSTANDINGS TOWARDS THERAPY WAS ASCERTAINED ☐ COUNSELING POINTS SUMMARIZED ☐				INFORMATION PROVIDED INFORMATION ON SIGNS AND SYMPTOMS/DISEASE ☐ NAME AND PURPOSE OF MEDICATION ☐ DOSAGE REGIMEN ADVICE ON MISSED DOSE ☐ POTENT SIDE EFFECTS ☐ SIGNIFICANT INTERACTIONS (DRUG-DRUG, DRUG-FOOD, DRUG-DISEASE) ☐ PRECAUTIONS TO BE TAKEN ☐ DRUG STORAGE RECOMMENDATIONS ☐ BENEFITS OF COMPLETING THE MEDICATION COURSE ☐ LIFE STYLE MODIFICATION ☐			
REMARKS:-							
NAME & SIGNATURE OF THE STUDENT:				NAME & SIGNATURE OF THE STAFF INCHARGE:			

RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES

4th T Block, Jayanagar, Bengaluru, Karnataka 560041

Department of Pharmacy Practice THERAPEUTIC INTERVENTION FORM

TIF No (Office use):-		DATE & TIME:-	IP NO.:-	DOA:-
AGE:-	SEX:-	WARD & WING:-	SPECIALITY:-	
PATIENT TREATMENT DETAILS : Attach Patient Profile From				
BRIEF DESCRIPTION OF THE INTERVENTION:-				
INTERVENTION IDENTIFIED DURING:				
☐ PRE ROUNDS ☐ WARD ROUNDS ☐ SPECIAL VISITS ☐ OTHERS (SPECIFY):				
SUGGESTIONS MADE:				
☐ DRUG WITHDRAWN ☐ DOSE TAPERED ☐ DOSE INCREASED ☐ DRUG READMINISTRATION ☐ NEW DRUG ADDED ☐ OTHERS (SPECIFY):				
SUGGESTIONS ACCEPTED: ☐ YES ☐ NO IF NO, GIVE REASON:				
DRUG THERAPY CHANGED: ☐ YES ☐ NO IF NO, GIVE REASON:				
INTERVENTION CATEGORY:				
☐ ADR ☐ CONTRA INDICATION ☐ DRUG DUPLICATION ☐ DOSAGE FORM ☐ DRUG USE WITHOUT INDICATION ☐ DOSE ADJUSTMENT IN RENAL IMPAIRMENT ☐ DOSE ADJUSTMENT IN SPECIAL POPULATION ☐ DRUG SHORTAGE ☐ DOSE ADJUSTMENT IN HEPATIC IMPAIRMENT ☐ DRUG INTERACTION ☐ EXPIRED DRUG ☐ INCOMPATIBILITY ☐ INAPPROPRIATE DRUG SELECTION ☐ MEDICATION ADHERENCE ☐ OVERDOSE ☐ SUB THERAPEUTIC DOSE ☐ UNTREATED INDICATION ☐ UNACCEPTED ABBREVIATION ☐ OTHERS				
REFERENCES:				
NAME & SIGNATURE OF THE STUDENT:			NAME & SIGNATURE OF THE STAFF INCHARGE:	

4th T Block, Jayanagar, Bengaluru, Karnataka 560041

Department of Pharmacy Practice

PATIENT PROFILE FORM

IP No:-	DOA:-	WARD/BED No:-	SPECIALITY:-
AGE:-	SEX: -	HT IN CM:-	WT IN KG:-
	ALLERGIES:-		
PRESENTING COMPLAINTS:-		HISTORY OF PRESENTING COMPLAINTS:-	
FAMILY HISTORY:-		PAST HISTORY:-	
PERSONAL HISTORY:-		OBSTETRIC HISTORY:- (WHENEVER RELEVANT) DEVELOPMENT HISTORY:- (WHENEVER RELEVANT)	
CURRENT MEDICATIONS:-		GENERAL PHYSICAL EXAMINATION:-	
BUILT:- WELL/MODERATE/POOR	BP:-	PULSE:-	RR:-
NUTRITION:- WELL/MODERATE/POOR	GCS:-	CLUBBING:-	CYANOSIS:-
LYMPHADENOPATHY:-	PALLOR:-	EDEMA:-	ICTERUS:-
CLINICAL EXAMINATION:-			

[illegible]

PRN & SOS MEDICATIONS

DATE & TIME	NAME OF MEDICATION(CAPITAL)	DOSE	ROUTE	FREQ	TIME	INDICATION

DISCHARGE MEDICATIONS**DATE OF DISCHARGE:**

DURATION OF THERAPY	NAME OF MEDICATION(CAPITAL)	DOSE	ROUTE	FREQ	TIME	INDICATION

LAB MASTER

Ha em	Hb:-				Bio che	Blood sugar			
	TC/DC:-					Creatinine			

	Plts:					Lipid Profile			
	PT/PTT					LFT			
	ESR:-					Others			
	Others								
Microbiology	Urine				Radiology	CXR			
	Faeces					Ultrasound			
	Cultures					ECG			
	Cavity fluids					Others			
Others					Others				

PHYSICIAN/NURSE NOTES		
DAY 1	DAY 2	DAY 3
DAY 4	DAY 5	DAY 6

SIGNATURE OF STUDENT:-**SIGNATURE OF IN CHARGE:-****SOAP ANALYSIS**

**RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES, KARNATAKA (RGUHS),
BANGALORE – 560 041**

Pharm D (Post Baccalaureate) Regulations 2008

1. ELIGIBILITY

1.1 Qualifying Examination

For Pharm D Post (Baccalaureate), a pass in B Pharm degree examination of Rajiv Gandhi University of Health Sciences or B Pharm examination of any other recognized Indian University established by law in India or any other degree courses in Pharmacy recognized as equivalent by RGUHS and Pharmacy Council of India.

1.2 Eligible candidates are directly joining to fourth year Pharm D course as lateral entry.

2. Duration of the course

Pharm D. (Post Baccalaureate): The duration of the course shall be for three academic years (two years of study and one year internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of three years duration is divided into two phases –

Phase I – consisting of First and Second academic year.

Phase II – consisting of Internship or residency training during third year involving posting in speciality units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services, and acquires skill under supervision so that he or she may become capable of functioning independently.

3. Medium of Instruction

Medium of Instruction and Examination Shall be English.

4. Attendance and Progress

A candidate is required to put in at least 80% attendance in theory and practical subjects separately in a recognized institution approved by Pharmacy council of India and affiliated to Rajiv Gandhi University of Health Sciences, Karnataka. The candidate shall complete prescribed course satisfactorily to be eligible to appear for the respective examination.

5. Course of study

The course of study for Pharm.D.(Post Baccalaureate) shall include the subjects as given in the Tables below. The number of hours in a week, devoted to each subject for its teaching in theory, practical and tutorial shall not be less than that noted against it in columns (3), (4) and (5) below.

T A B L E

First Year Post Baccalaureate (Fourth Year of Pharm D course)

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical / Hospital Posting	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
4.1	Pharmacotherapeutics-I	3	3	1
4.2	Pharmacotherapeutics-II	3	3	1
4.3	Clinical Pharmacy	3	3	1
4.4	Biostatistics & Research Methodology	2	-	1
4.5	Biopharmaceutics & Pharmacokinetics-	3	3	1
4.6	Clinical Toxicology	2	-	1
	Total hours	16	12	6 = 34

Second Year Post Baccalaureate: (Fifth Year of Pharm D course)

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Hospital posting*	No. of hours of Seminar
(1)	(2)	(3)	(4)	(5)
5.1	Pharmacotherapeutics-III	3	3	1
5.1	Clinical Research	3	-	1
5.2	Pharmacoepidemiology and Pharmacoeconomics	3	-	1
5.3	Clinical Pharmacokinetics & Therapeutic Drug Monitoring	2	-	1
5.4	Clerkship *	-	-	1
5.5	Project work (Six Months)	-	20	-
	Total hours	11	23	5 = 39

****Attending ward rounds on daily basis***

Third Year Post Baccalaureate (Sixth year Pharm D course)

Internship or residency training including postings in specialty units. Student should provide the clinical pharmacy services under supervision of a preceptor to the allotted wards.

- (i) Six months in General Medicine department, and
- (ii) Two months each in three other specialty departments

6. Approval of institution conducting the course of study

The regular course for Pharm D (Post Baccalaureate) I, II, and III year shall be conducted by an institution approved by Pharmacy Council of India and affiliated to Rajiv Gandhi University of Health Sciences, Karnataka. Institution running Pharm D regular courses only shall be permitted to start Pharm D (Post

Baccalaureate) course. The approval and affiliation will be granted only if adequate arrangements for teaching-infrastructure facilities, accommodation, equipments, chemicals, glassware, library, teaching and non-teaching staff are provided as prescribed by Pharmacy Council of India and as required under the norms of Rajiv Gandhi University of Health Science, Karnataka (as prescribed in Appendix B).

7. Academic Work

The teaching staff of respective subjects shall maintain a regular record of attendance in both Theory and Practical.

Internal Assessment Marks

A. Theory: Three sessional examinations evenly spread during the academic year shall be conducted by the affiliated colleges. The average marks of the best two examinations shall be computed out of a maximum 30 marks and shall constitute the sessional marks in theory. Provided further the colleges may conduct one special theory sessional examination towards the end of the academic session for those who might have missed any one of the regular sessional examination on genuine grounds.

B. Practical: Students are expected to perform the number of experiments listed in the respective syllabus. Marks shall be awarded out of a maximum of 10 to each of the practical exercise and an average of those shall be computed out of maximum of 10 each marks. In addition, three practical sessional examinations evenly spread during academic year shall be conducted. The average marks of the best two practical examinations shall be computed out of a maximum of 20 marks. A total of 30 marks shall constitute the sessional award in practical. While awarding the sessional marks of practical experiments, the following considerations should be taken into account.

1. Preparation of the candidate.
2. Manipulative skills.
3. Results of the experiment.
4. Knowledge of the experiment
5. Viva voce pertaining to the experiments only.

The College shall maintain the sessional books of the students and the record of sessional marks of the students.

A regular record of both theory and practical class work and sessional examinations conducted in an institution imparting the course shall be maintained for each student in the institution.

8. Examination for Pharm D (Post Baccalaureate)

- (1) Every year there shall be an examination to examine the students.
- (2) Each examination may be held twice every year. The first examination in a year shall be the annual examination and the second examination shall be supplementary examination.
- (3) The examinations shall be of written and practical (including oral nature) carrying maximum marks for each part of a subject as indicated in Tables below :

Scheme of Examination for Pharm D (Post Baccalaureate) Course

First Year(Fourth Year of Pharm D course):

Sl#	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
1.1	Pharmacotherapeutics- I	70	30	100	70	30	100
1.2	Pharmacotherapeutics- II	70	30	100	70	30	100
1.3	Clinical Pharmacy	70	30	100	70	30	100
1.4	Biostatistics & Research Methodology	70	30	100	-	-	-
1.5	Hospital and Community Pharmacy-	70	30	100	70	30	100
1.6	Clinical Toxicology	70	30	100	-	-	-
	Total			600			400 = 1000

Second Year (Fifth Year of Pharma D course) :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practical		
		Examination	Sessional	Total	Examination	Sessional	Total
2.1	Pharmacotherapeutics III	70	30	100	70	30	100
2.2	Clinical Research	70	30	100	-	-	-
2.3	Pharmacoepidemiology and Pharmacoeconomics	70	30	100	-	-	-
2.4	Clinical Pharmacokinetics & Therapeutic drug monitoring	70	30	100	-	-	-
2.5	Clerkship *	-	-	-	70	30	100
2.6	Project work (6 Months)	-	-	-	100**	-	100
	Total			400			300 = 700

* Attending ward rounds on daily basis.

** 30 marks – viva-voce (oral)

70 marks – Thesis work

9. Mode of examinations

(1) Theory examination shall be of three hours and practical examination shall be of four hours duration.

(2) Practical examination shall also consist of a viva –voce (Oral) examination.

(3) Clerkship examination – Oral examination shall be conducted after the completion of clerkship of students. An external and an internal examiner will evaluate the student. Students may be asked to present the allotted medical cases followed by discussion. Students' capabilities in delivering clinical pharmacy services, pharmaceutical care planning and knowledge of therapeutics shall be assessed.

10. Criteria for Pass

a) Candidates who have secured a minimum of 50% marks in the Theory (including sessional) and Practical (including sessional) separately in any subject or subjects shall be declared to have passed in that subject/ and exempted from appearing in that subject/s at subsequent examination.

b) Theory and Practical of a particular subject are considered as individual subjects for the purpose of pass criteria.

11. Eligibility for promotion to next year

All students who have appeared for all the subjects and passed the first year annual examination are eligible for promotion to the second year and, so on. However, failure in more than two subjects shall debar him or her from promotion to the next year classes.

12. Declaration of Class

Class shall be awarded at the end of I, II, III, IV, V and final year of Pharm. D examination and I, II and Final year of Pharm D (Post Baccalaureate) as shown below:

1) Distinction	75%
2) First class	60% and above and less than 75%
3) Second Class	50% and above and less than 60%

Pass class shall be awarded to such of the candidates who would have passed the examination in more than one attempt. However, this shall not be applicable to candidates who are exempted in Remedial Biology and Remedial Mathematics by the RGUHS Karnataka, Bangalore.

13. Internship

- (1) Internship is a phase of training wherein a student is expected to conduct actual practice of pharmacy and health care and acquires skills under the supervision so that he or she may become capable of functioning independently.
- (2) A student shall be permitted to start the internship only after having passed in theory and practical of all subjects of all the previous years.
- (3) Every student has to undergo one-year internship as per Appendix-C to these regulations.

14. Award of Degree

a) A candidate who has passed in all the subjects of Pharm D (Post Baccalaureate) and has successfully completed the Internship (as described in appendix C) will be eligible for the award of Pharm D (Post Baccalaureate) Degree.

15. Practical training

1. **Hospital posting** — Every student shall be posted in constituent hospital for a period of not less than seventy five hours to be covered in not less than 200 working days in each of first year course. Each student shall submit report duly certified by the preceptor and duly attested by the Head of the Department or Institution as prescribed. In the fifth year, every student shall spend half a day in the morning hours attending ward rounds on daily basis as a part of clerkship. Theory teaching may be scheduled in the afternoon.
2. **Project work** — (1) To allow the student to develop data collection and reporting skills in the area of community, hospital and clinical pharmacy, a project work shall be carried out under the supervision of a teacher. The project topic must be approved by the Head of the Department or Head of the Institution. The same shall be announced to students within one month of commencement of the fifth year classes. Project work shall be presented in a written report and as a seminar at the end of the year. External and the internal examiners shall do the assessment of the project work.
(2) Project work shall comprise of objectives of the work, methodology, results, discussions and conclusions.

3. **Objectives of project work** — The main objectives of the project work is to—
 - (i) show the evidence of having made accurate description of published work of others and of having recorded the findings in an impartial manner; and
 - (ii) develop the students in data collection, analysis and reporting and interpretation skills.

4. **Methodology** — To complete the project work following methodology shall be adopted, namely:—
 - (i) students shall work in groups of not less than *two* and not more than *four* under an authorised teacher;
 - (ii) project topic shall be approved by the Head of the Department or Head of the Institution;
 - (iii) project work chosen shall be related to the pharmacy practice in community, hospital and clinical setup. It shall be patient and treatment (Medicine) oriented, like drug utilization reviews, Pharmacoepidemiology, pharmacovigilance or pharmacoeconomics;
 - (iv) project work shall be approved by the institutional ethics committee;
 - (v) student shall present at least three seminars, one in the beginning, one at middle and one at the end of the project work; and
 - (vi) two-page write-up of the project indicating title, objectives, methodology anticipated benefits and references shall be submitted to the Head of the Department or Head of the Institution.

5. **Reporting** — (1) Student working on the project shall submit jointly to the Head of the Department or Head of the Institution a project report of about 40-50 pages. Project report should include a certificate issued by the RGUHS recognized teacher, Head of the Department as well as by the Head of the Institution
 - (2) Project report shall be computer typed in double space using Times Roman font on A4 paper. The title shall be in bold with font size 18, subtitles in bold with font size 14 and the text with font size 12. The cover page of the project report shall contain details about the name of the student and the name of the authorized teacher with font size 14.
 - (3) Submission of the project report shall be done at least one month prior to the commencement of annual or supplementary examination.

6. **Evaluation**— The following methodology shall be adopted for evaluating the project work—
 - (i) Project work shall be evaluated by internal and external examiners.
 - (ii) Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of four students).
 - (iii) Three seminars presented by students shall be evaluated for twenty marks each and the average of best two shall be forwarded to the university with marks of other subjects.
 - (iv) Evaluation shall be done on the following items:

	Marks
a) Write up of the seminar	(7.5)
b) Presentation of work	(7.5)
c) Communication skills	(7.5)
d) Question and answer skills	(7.5)
Total	(30 marks)
 - (v) Final evaluation of project work shall be done on the following items:

	Marks
a) Write up of the seminar	(17.5)
b) Presentation of work	(17.5)
c) Communication skills	(17.5)
d) Question and answer skills	(17.5)
Total	(70 marks)

Explanation.— For the purposes of differentiation in the evaluation in case of topic being the same for the group of students, the same shall be done based on item numbers b, c and d mentioned above.

17. No. of Admissions

Pharm. D. (Post Baccalaureate): 10 students

18. SYLLABUS FOR PHARM. D. Post Baccalaureate

First year (Fourth Year of Pharm D)

4.1 PHARMACOTHERAPEUTICS - I (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives:** At completion of this subject it is expected that students will be able to understand –
 - a. the pathophysiology of selected disease states and the rationale for drug therapy;
 - b. the therapeutic approach to management of these diseases;
 - c. the controversies in drug therapy;
 - d. the importance of preparation of individualised therapeutic plans based on diagnosis;
 - e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
 - f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
 - g. summarise the therapeutic approach to management of these diseases including reference to the latest available evidence;
 - h. discuss the controversies in drug therapy;
 - i. discuss the preparation of individualised therapeutic plans based on diagnosis; and
 - j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

- a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.
- b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange.

Reference Books

- a. Pathologic basis of disease - Robins SL, W.B.Saunders publication.
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication.
- c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication.
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
- e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature.

3. Detailed syllabus and lecture wise schedule :

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

Title of the topic

- 1 **Cardiovascular system:** Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, , Hyperlipidaemias , Electrophysiology of heart and Arrhythmias
- 2 **Respiratory system :** Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases

Endocrine system : Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis

3 General prescribing guidelines for

- a. Paediatric patients
- b. Geriatric patients
- c. Pregnancy and breast feeding

4 Ophthalmology: Glaucoma, Conjunctivitis- viral & bacterial

5 Introduction to rational drug use

Definition, Role of pharmacist Essential drug concept Rational drug formulations

4.1 PHARMACOTHERAPEUTICS - I (PRACTICAL)

Practical : 3 Hrs./Week

Practicals :

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

4.2 PHARMACOTHERAPEUTICS – II (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives of the Subject Upon completion of the subject student shall be able to –**
 - a. know the pathophysiology of selected disease states and the rationale for drug therapy
 - b. know the therapeutic approach to management of these diseases;
 - c. know the controversies in drug therapy;
 - d. know the importance of preparation of individualised therapeutic plans based on diagnosis; and
 - e. appreciate the needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text books (Theory)

Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication

Reference books (Theory)

- a. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange
- b. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
- c. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA]

3. **Detailed syllabus and lecture wise schedule :**

Etiopathogenesis and pharmacotherapy of diseases associated with following systems / diseases –

Title of the topic

1. **Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhoea and Syphilis
- 2 **Musculoskeletal disorders**
Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.
- 3 **Renal system**
Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders

- 4 **Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis
- 5 **Dermatology:** Psoriasis, Scabies, Eczema, Impetigo

4.2 PHARMACOTHERAPEUTICS – II (PRACTICAL)

Practical : 3 Hrs./Week

Practicals :

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.

The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.

A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment :

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination :

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

4.3 CLINICAL PHARMACY (THEORY)

Theory: 3 Hrs. /Week

1. Objectives:

Upon completion of the subject student shall be able to (Know, do, appreciate) –

- a. monitor drug therapy of patient through medication chart review and clinical review;
- b. obtain medication history interview and counsel the patients;
- c. identify and resolve drug related problems;
- d. detect, assess and monitor adverse drug reaction;
- e. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and
- f. retrieve, analyse, interpret and formulate drug or medicine information.

Text books (Theory)

- a. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
- b. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
- c. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.
- d. A textbook of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi, Karin Nyfort-Hansen and Milap Nahata Orient Langman Pvt.Ltd. ISSBN8125026

References

- a. Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
- b. Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
- c. Pharmaceutical Statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

2. Detailed syllabus and lecture wise schedule:

Title of the topic

1. **Definitions, development and scope of clinical pharmacy**
2. **Introduction to daily activities of a clinical pharmacist**
 - a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
 - b. Ward round participation
 - c. Adverse drug reaction management
 - d. Drug information and poisons information
 - e. Medication history
 - f. Patient counseling
 - g. Drug utilisation evaluation (DUE) and review (DUR)
 - h. Quality assurance of clinical pharmacy services

3. **Patient data analysis**
The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.
4. **Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results**
 - a. Haematological, Liver function, Renal function, thyroid function tests
 - b. Tests associated with cardiac disorders
 - c. Fluid and electrolyte balance
 - d. Microbiological culture sensitivity tests
 - e. Pulmonary Function Tests
5. **Drug & Poison information**
 - a. Introduction to drug information resources available
 - b. Systematic approach in answering DI queries
 - c. Critical evaluation of drug information and literature
 - d. Preparation of written and verbal reports
 - e. Establishing a Drug Information Centre
 - f. Poisons information- organization & information resources
6. **Pharmacovigilance**
 - a. Scope, definition and aims of pharmacovigilance
 - b. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used]
 - c. Reporting, evaluation, monitoring, preventing & management of ADRs
 - d. Role of pharmacist in management of ADR.
7. Communication skills, including patient counselling techniques, medication history interview, presentation of cases.
8. Pharmaceutical care concepts
9. Critical evaluation of biomedical literature
10. Medication errors

4.3 CLINICAL PHARMACY (PRACTICAL)

Practical: 3 Hrs./Week

Students are expected to perform 15 practicals in the following areas covering the topics dealt in theory class.

- a. Answering drug information questions (4 Nos)
- b. Patient medication counselling (4 Nos)
- c. Case studies related to laboratory investigations (4 Nos)
- d. Patient medication history interview (3 Nos)

Assignment:

Students are expected to submit THREE written assignments (1500 – 2000 words) on the topics given to them covering the following areas dealt in theory class.

Drug information, Patient medication history interview, Patient medication counselling, Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

4.4 BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY)

Theory: 2 Hrs. /Week

1. Detailed syllabus and lecture wise schedule

1 Research Methodology

- a) Types of clinical study designs:
Case studies, observational studies, interventional studies,
- b) Designing the methodology
- c) Sample size determination and Power of a study
Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study
- d) Report writing and presentation of data

2 Biostatistics

2.1 a) Introduction

- b) Types of data distribution
- c) Measures describing the central tendency distributions- average, median, mode
- d) Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean.

2.2 Data graphics

Construction and labeling of graphs, histogram, piecharts, scatter plots, semilogarithmic plots

2.3 Basics of testing hypothesis

- a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals.
- b) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way)
- c) Level of significance (Non-parametric data)- Sign test, Wilcoxon's signed rank test, Wilcoxon rank sum test, Mann Whitney U test, Kruskal-Wallis test (one way ANOVA)
- d) Linear regression and correlation- Introduction, Pearson's and Spearman's correlation and correlation co-efficient.
- e) Introduction to statistical software: SPSS, Epi Info, SAS.

2.4 Statistical methods in epidemiology

Incidence and prevalence, relative risk, attributable risk

3. Computer applications in pharmacy

Computer System in Hospital Pharmacy: Patterns of Computer use in Hospital Pharmacy – Patient record database management, Medication order entry – Drug labels and list – Intravenous solution and admixture, patient medication profiles, Inventory control, Management report & Statistics.

Computer In Community Pharmacy

Computerizing the Prescription Dispensing process

Use of Computers for Pharmaceutical Care in community pharmacy

Accounting and General ledger system

Drug Information Retrieval & Storage :

Introduction – Advantages of Computerized Literature Retrieval

Use of Computerized Retrieval

Reference books:

- a. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3rd edition, publisher Marcel Dekker Inc. NewYork.
- b. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich , 3rd edition, McGraw Hill Publications 2006

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

Theory: 3 Hrs. /Week

Goal: To train the students in the area of Biopharmaceutics and pharmacokinetics to work efficiently in the in clinical research and pharma industry.

Objectives: Upon completion of the course, the candidate shall have the ability to calculate Pharmacokinetic parameters from the given data, apply principles of pharmacokinetics in the design of new formulations and conduct bioavailability and bioequivalence studies.

1. Biopharmaceutics

1. Introduction to Biopharmaceutics
 - a. Absorption of drugs from gastrointestinal tract.
 - b. Drug Distribution.
 - c. Drug Elimination.

2. Pharmacokinetics

2. Introduction to Pharmacokinetics.
 - a. Mathematical model
 - b. Drug levels in blood.
 - c. Pharmacokinetic model
 - d. Compartment models
 - e. Pharmacokinetic study.
3. One compartment open model.
 - a. Intravenous Injection (Bolus)
 - b. Intravenous infusion.
4. Multicompartment models.
 - a. Two compartment open model.
 - b. IV bolus, IV infusion and oral administration
5. Multiple – Dosage Regimens.
 - a. Repetitive Intravenous injections – One Compartment Open Model
 - b. Repetitive Extravascular dosing – One Compartment Open model
 - c. Multiple Dose Regimen – Two Compartment Open Model
6. Nonlinear Pharmacokinetics.
 - a. Introduction
 - b. Factors causing Non-linearity.
 - c. Michaelis-menton method of estimating parameters.
7. Noncompartmental Pharmacokinetics.
 - a. Statistical Moment Theory.
 - b. MRT for various compartment models.
 - c. Physiological Pharmacokinetic model.
8. Bioavailability and Bioequivalence.
 - a. Introduction.
 - b. Bioavailability study protocol.
 - c. Methods of Assessment of Bioavailability

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

Practical : 3 Hrs./Week

1. Improvement of dissolution characteristics of slightly soluble drugs by some methods.
2. Comparison of dissolution studies of two different marketed products of same drug.
3. Influence of polymorphism on solubility and dissolution.
4. Protein binding studies of a highly protein bound drug and poorly protein bound drug.
5. Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.
6. Bioavailability studies of some commonly used drugs on animal/human model.
7. Calculation of K_a , K_e , $t_{1/2}$, C_{max} , AUC, AUMC, MRT etc. from blood profile data.
8. Calculation of bioavailability from urinary excretion data for two drugs.
9. Calculation of AUC and bioequivalence from the given data for two drugs.
10. In vitro absorption studies.
11. Bioequivalency studies on the different drugs marketed.(eg) Tetracycline, Sulphamethoxazole, Trimethoprim, Aspirin etc., on animals and human volunteers.
12. Absorption studies in animal inverted intestine using various drugs.
13. Effect on contact time on the plasma protein binding of drugs.
14. Studying metabolic pathways for different drugs based on elimination kinetics data.
15. Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data.
16. Determination of renal clearance.

References:

- a. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
- b. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania.
- c. Pharmacokinetics: By Milo Gibaldi Donald, R. Mercel Dekker Inc.
- d. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
- e. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
- f. Biopharmaceutics; By Swarbrick
- g. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
- h. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febiger, Philadelphia, 1995.
- i. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
- j. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Robert F Notari Marcel Dekker Inc, New York and Basel, 1987.
- k. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

4.6 CLINICAL TOXICOLOGY (THEORY)

Theory: 2 Hrs. /Week

1. General principles involved in the management of poisoning
2. Antidotes and the clinical applications.
3. Supportive care in clinical Toxicology.
4. Gut Decontamination.
5. Elimination Enhancement.
6. Toxicokinetics.
7. Clinical symptoms and management of acute poisoning with the following agents –
 - a) Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.
 - b) Opiates overdose.
 - c) Antidepressants
 - d) Barbiturates and benzodiazepines.
 - e) Alcohol: ethanol, methanol.
 - f) Paracetamol and salicylates.
 - g) Non-steroidal anti-inflammatory drugs.
 - h) Hydrocarbons: Petroleum products and PEG.
 - i) Caustics: inorganic acids and alkali.
 - j) Radiation poisoning
8. Clinical symptoms and management of chronic poisoning with the following agents –
Heavy metals: Arsenic, lead, mercury, iron, copper
9. Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.
10. Plants poisoning. Mushrooms, Mycotoxins.
11. Food poisonings
12. Envenomations – Arthropod bites and stings.

Substance abuse:

Signs and symptoms of substance abuse and treatment of dependence

- a) CNS stimulants :amphetamine
- b) Opioids
- c) CNS depressants
- d) Hallucinogens: LSD
- e) Cannabis group
- f) Tobacco

References:

- a. Matthew J Ellenhorn. ELLENHORNS MEDICAL TOXICOLOGY – DIAGNOSIS AND TREATMENT OF POISONING. Second edition. Williams and Willkins publication, London
- b. V V Pillay. HANDBOOK OF FORENSIC MEDICINE AND TOXICOLOGY. Thirteenth edition 2003 Paras Publication, Hyderabad

Second year (Fifth Year of Pharm D)

5.1 PHARMACOTHERAPEUTICS – III (THEORY)

Theory : 3 Hrs. /Week

1. **Scope :** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives:** At completion of this subject it is expected that students will be able to understand –
 - a. the pathophysiology of selected disease states and the rationale for drug therapy;
 - b. the therapeutic approach to management of these diseases;
 - c. the controversies in drug therapy;
 - d. the importance of preparation of individualised therapeutic plans based on diagnosis;
 - e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
 - f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
 - g. to summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
 - h. to discuss the controversies in drug therapy;
 - i. to discuss the preparation of individualised therapeutic plans based on diagnosis; and
 - j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

- a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication
- b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange

Reference Books

- a. Pathologic basis of disease - Robins SL, W.B.Saunders publication
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication
- c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
- e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature.

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases:

Title of the topic

- 1 **Gastrointestinal system:** Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, Viral hepatitis including jaundice, and Drug induced liver disorders.
- 2 **Haematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.
- 3 **Nervous system:** Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,
- 4 **Psychiatry disorders:** Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders
- 5 Pain management including Pain pathways, neuralgias, headaches.
- 6 Evidence Based Medicine

5.1 PHARMACOTHERAPEUTICS – III (PRACTICAL)

Practical : 3 Hrs./Week

Practicals:

Hospital postings for a period of at least 50 hours is required to understand the principles and practice involved in ward round participation and clinical discussion on selection of drug therapy. Students are required to maintain a record of 15 cases observed in the ward and the same should be submitted at the end of the course for evaluation. Each student should present at least two medical cases they have observed and followed in the wards.

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

5.2 CLINICAL RESEARCH (THEORY)

Theory : 3 Hrs. /Week

1. Drug development process:

Introduction

Various Approaches to drug discovery

1. Pharmacological
2. Toxicological
3. IND Application
4. Drug characterization
5. Dosage form

2. Clinical development of drug:

1. Introduction to Clinical trials
2. Various phases of clinical trial.
3. Methods of post marketing surveillance
4. Abbreviated New Drug Application submission.
5. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines
6. Challenges in the implementation of guidelines
7. Ethical guidelines in Clinical Research
8. Composition, responsibilities, procedures of IRB / IEC
9. Overview of regulatory environment in USA, Europe and India.
10. Role and responsibilities of clinical trial personnel as per ICH GCP
 - a. Sponsor
 - b. Investigators
 - c. Clinical research associate
 - d. Auditors
 - e. Contract research coordinators
 - f. Regulatory authority
11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)
12. Informed consent Process
13. Data management and its components
14. Safety monitoring in clinical trials.

References :

- a. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
- b. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
- c. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
- d. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
- e. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
- f. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
- g. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

5.3 PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS (THEORY)

Theory : 3 Hrs. /Week

1. Pharmacoepidemiology:

Definition and scope:

Origin and evaluation of Pharmacoepidemiology need for Pharmacoepidemiology, aims and applications.

Measurement of outcomes in Pharmacoepidemiology

Outcome measure and drug use measures

Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement

Concept of risk in pharmacoepidemiology

Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

Pharmacoepidemiological methods

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods

Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies, meta-analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

Sources of data for pharmacoepidemiological studies

Ad Hoc data sources and automated data systems.

Selected special applications of pharmacoepidemiology

Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

2. Pharmacoeconomics:

Definition, history, needs of pharmacoeconomic evaluations

Role in formulary management decisions

Pharmacoeconomic evaluation

Outcome assessment and types of evaluation

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods:

Cost – minimization, cost- benefit, cost – effectiveness, cost utility

3. Applications of Pharmacoeconomics

Software and case studies

5.4 CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING (THEORY)

Theory: 2 Hrs. /Week

- 1. Introduction to Clinical pharmacokinetics.**
- 2. Design of dosage regimens:**
Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.
- 3. Pharmacokinetics of Drug Interaction:**
 - a. Pharmacokinetic drug interactions
 - b. Inhibition and Induction of Drug metabolism
 - c. Inhibition of Biliary Excretion.
- 4. Therapeutic Drug monitoring:**
 - a. Introduction
 - b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight , disease, Interacting drugs).
 - c. Indications for TDM. Protocol for TDM.
 - d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.
 - e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.
- 5. Dosage adjustment in Renal and hepatic Disease.**
 - a. Renal impairment
 - b. Pharmacokinetic considerations
 - c. General approach for dosage adjustment in Renal disease.
 - d. Measurement of Glomerular Filtration rate and creatinine clearance.
 - e. Dosage adjustment for uremic patients.
 - f. Extracorporeal removal of drugs.
 - g. Effect of Hepatic disease on pharmacokinetics.
- 6. Population Pharmacokinetics.**
 - a. Introduction to Bayesian Theory.
 - b. Adaptive method or Dosing with feed back.
 - c. Analysis of Population pharmacokinetic Data.
- 7. Pharmacogenetics**
 - a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.
 - b. Genetic Polymorphism in Drug Transport and Drug Targets.
 - c. Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations

APPENDIX-B

CONDITIONS TO BE FULFILLED BY THE ACADEMIC TRAINING INSTITUTION

- 1) Any authority or institution in India applying to the Pharmacy Council of India for approval of courses of study for Pharm.D. and Pharm.D. (Post Baccalaureate) under sub-section (1) of section 12 of the Pharmacy Act, 1948 shall comply with the infrastructural facilities as prescribed by the Pharmacy Council of India from time to time.
- 2) Pharm.D. and Pharm.D. (Post Baccalaureate) programmes shall be conducted only in those institutions which -
 - a) are approved by the Pharmacy Council of India for Pharm. D course as provided under section 12 of the Pharmacy Act, 1948;
 - b) have 300 bedded hospital attached to it.

(i) Hospital Details

1. Institution with their own hospital of minimum 300 beds.
2. Teaching hospital recognised by the Medical Council of India or University, or a Government hospital not below the level of district headquarter hospital with 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
3. Corporate type hospital with minimum 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
4. Number of institutions which can be attached to one hospital shall be restricted by the student pharmacist to bed ratio of 1:10.

(ii) Specialty

- a) Tertiary care hospitals are desirable
- b) Medicine[compulsory], and any three specialization of the following
 1. Surgery
 2. Pediatrics
 3. Gynecology and obstetrics
 4. Psychiatry
 5. Skin and VD
 6. Orthopedics

(iii) Location of the Hospital

Within the same limits of Corporation or Municipality or Campus with Medical Faculty involvement as adjunct faculty.

3) TEACHING STAFF REQUIREMENT

- i) Staff Pattern: All faculty shall be full time. However part time perceptors in hospital shall be allowed.
- ii) Subject wise specialization of the Teaching Staff :

S.No.	Subject	Specialization required
1.	Pharmacy Practice	M.Pharm in Pharmacy Practice or Pharmacology or Pharmaceutics.
2.	Human Anatomy & Physiology	M.Pharm in Pharmacology or Pharmacy practice
3.	Pharmaceutics (Dispensing & General Pharmacy)	M.Pharm in Pharmaceutics
4.	Pharmacognosy-I	M.Pharm in Pharmacognosy
5.	Pharmaceutical Organic Chemistry-I	M.Pharm in Pharmaceutical chemistry or Pharmaceutical Analysis or Quality assurance or Bulk Drug
6.	Pharmaceutical Inorganic Chemistry	M.Pharm in Pharmaceutical chemistry or Pharmaceutical Analysis or Quality assurance or Bulk Drug
7.	Pharmaceutical microbiology	M.Pharm in Pharmaceutics or Pharmaceutical Biotechnology
8.	Pathophysiology	M.Pharm Pharmacy practice or Pharmacology
9.	Applied Biochemistry & Clinical Chemistry	M.Pharm in Pharmacology or Pharmacy practice or Pharmaceutical chemistry
10.	Pharmacology-I	M.Pharm in Pharmacology or Pharmacy practice
11.	Pharmaceutical Jurisprudence	M.Pharm in Pharmaceutics
12.	Pharmacology-II	M.Pharm in Pharmacology or Pharmacy practice
13.	Pharmaceutical Dosage Forms	M.Pharm in Pharmaceutics or Industrial Pharmacy
14.	Pharmacotherapeutics –I, II and III	M.Pharm Pharmacy practice or Pharmacology
15.	Community Pharmacy	M.Pharm in Pharmacy practice or Pharmacology or Pharmaceutics
16.	Hospital Pharmacy	M.Pharm in Pharmacy practice or Pharmacology or Pharmaceutics
17.	Clinical Pharmacy	M.Pharm in Pharmacy practice
18.	Computer Science or Computer Application in pharmacy	MCA
19.	Mathematics	M.Sc. (Maths)

iii) Teaching Staff :

Department/Division	Name of the post	No.
Department of Pharmaceutics	Professor	1
	Asst. Professor	1
	Lecturer	2
Department of Pharmaceutical Chemistry (Including Pharmaceutical Analysis)	Professor	1
	Asst. Professor	1
	Lecturer	3
Department of Pharmacology	Professor	1
	Asst. Professor	1
	Lecturer	2
Department of Pharmacognosy	Professor	1
	Asst. Professor	1
	Lecturer	1
Department of Pharmacy Practice	Professor	1
	Asst. Professor	2
	Lecturer	3

iv) Prescribed qualifications and experience for Professor, Assistant Professor, Lecturer and others :

Sl. No.	CADRE	QUALIFICATIONS	EXPERIENCE
1.	Lecturer	i) Basic degree in pharmacy (B.Pharm.). ii) Registration as a pharmacist under the Pharmacy Act. iii) First Class Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm)	No minimum requirement.
2.	Assistant Professor	i) Basic degree in pharmacy (B.Pharm) ii) Registration as a pharmacist under the Pharmacy Act. iii) Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm) iv) Ph.D. degree (with First Class degree either at Bachelor's or Master's level) in the appropriate branch of specialization in	Three years experience in Teaching or Research at the level of Lecturer or equivalent.

Pharmacy.

3.	Professor	i) Basic degree in pharmacy (B.Pharm) ii) Registration as a pharmacist under the Pharmacy Act. iii) Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm). iv) Ph.D. degree (with first Class either at Bachelor's or Master's level) in appropriate branch of specialization in Pharmacy.	i) Ten years experience in Teaching or Research. ii) Out of which five years must be as Assistant Professor.
4.	Director or Principal or Head of institute	i) Basic degree in pharmacy (B. Pharm.) ii) Registration as a pharmacist under the Pharmacy Act. iii) Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm) iv) Ph.D. degree (with first Class degree either at Bachelor's or Master's level in the appropriate branch of specialization in Pharmacy.	i) Fifteen years experience in Teaching or Research. ii) Out of which five years must be as Professor or above in Pharmacy. Desirable : Administrative experience in responsible position. The maximum age for holding the post shall be 65 years.

Note : If a class or division is not awarded at Master's level, a minimum of 60% marks in aggregate or equivalent cumulative grade point average shall be considered equivalent to first class or division, as the case may be.

v) Workload of Faculty :

Professor – 8 hrs. per week

Assistant Professor – 12 hrs. per week

Lecturers – 16 hrs. per week

vi) Training of Pharmacy Practice Faculty:

a) Teaching staff will be trained as per the module prescribed by the Central Council.

b) Duration of training – Minimum 3 months.

c) Training sites – Institutions running pharmacy practice Programmes for at least five years.

d) Trainer – Professor or Assistant Professor with minimum of five years of clinical pharmacy teaching and practice experience.

4) NON-TEACHING STAFF:

Sl.No.	Designation	Required (Minimum)	Required Qualification
1	Laboratory Technician	1 for each Dept	D. Pharm
2	Laboratory Assistants or Laboratory Attenders	1 for each Lab (minimum)	SSLC
3	Office Superintendent	1	Degree
4	Accountant	1	Degree
5	Store keeper	1	D.Pharm or a Bachelor degree recognized by a University or institution.
6	Computer Data Operator	1	BCA or Graduate with Computer Course
7	Office Staff I	1	Degree
8	Office Staff II	2	Degree
9	Peon	2	SSLC
10	Cleaning personnel	Adequate	---
11	Gardener	Adequate	---

5) ACCOMMODATION :

Suitable and sufficient accommodation with adequate ventilation, lighting and other hygienic conditions should be provided to the rooms for Principal or the Head of the department, office, class rooms, library, staff, staff common room, students common room, museum, laboratories, stores, etc.

At least two lecture halls along with eight laboratories as specified below should be provided for :—

1. Pharmaceutics and Pharmacokinetics Lab	- 2
2. Life Science (Pharmacology, Physiology, Pathophysiology)	- 2
3. Phytochemistry or Pharmaceutical Chemistry	- 2
4. Pharmacy Practice	- 2

Total = 8

In addition to the laboratories, balance room, aseptic room or cabinet, animal house and a machine room shall also be provided.

Floor area of the laboratory should not be less than 30 square feet per student required to work in the laboratory at any given time subject to a minimum of 750 square feet.

Laboratories should be fitted and constructed in a manner that these can be kept reasonably clean. Gas and water fittings, shelves, fuming cupboards be provided wherever necessary.

6. EQUIPMENT AND APPARATUS :

Department wise list of minimum equipments

A. DEPARTMENT OF PHARMACOLOGY :

I. Equipment:

S.No.	Name	Minimum required Nos.
1	Microscopes	15
2	Haemocytometer with Micropipettes	20
3	Sahli's haemocytometer	20
4	Hutchinson's spirometer	01
5	Spygmomanometer	05
6	Stethoscope	05
7	Permanent Slides for various tissues	One pair of each tissue Organs and endocrine glands One slide of each organ system
8	Models for various organs	One model of each organ system
9	Specimen for various organs and systems	One model for each organ system
10	Skeleton and bones	One set of skeleton and one spare bone

11	Different Contraceptive Devices and Models	One set of each device
12	Muscle electrodes	01
13	Lucas moist chamber	01
14	Myographic lever	01
15	Stimulator	01
16	Centrifuge	01
17	Digital Balance	01
18	Physical /Chemical Balance	01
19	Sherrington's Kymograph Machine or Polyrite	10
20	Sherrington Drum	10
21	Perspex bath assembly (single unit)	10
22	Aerators	10
23	Computer with LCD	01
24	Software packages for experiment	01
25	Standard graphs of various drugs	Adequate number
26	Actophotometer	01
27	Rotarod	01
28	Pole climbing apparatus	01
29	Analgesiometer (Eddy's hot plate and radiant heat methods)	01
30	Convulsiometer	01
31	Plethysmograph	01
32	Digital pH meter	01

II. Apparatus:

S.No	Name	Minimum required Nos.
1	Folin-Wu tubes	60
2	Dissection Tray and Boards	10
3	Haemostatic artery forceps	10
4	Hypodermic syringes and needles of size 15,24,26G	10
5	Levers, cannulae	20

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

B. DEPARTMENT OF PHARMACOGNOSY :

I. Equipment:

S.No.	Name	Minimum required Nos.
1	Microscope with stage micrometer	15
2	Digital Balance	02
3	Autoclave	02

4	Hot air oven	02
5	B.O.D.incubator	01
6	Refrigerator	01
7	Laminar air flow	01
8	Colony counter	02
9	Zone reader	01
10	Digital pH meter	01
11	Sterility testing unit	01
12	Camera Lucida	15
13	Eye piece micrometer	15
14	Incinerator	01
15	Moisture balance	01
16	Heating mantle	15
17	Flourimeter	01
18	Vacuum pump	02
19	Micropipettes (Single and multi channeled)	02
20	Micro Centrifuge	01
21	Projection Microscope	01

II. Apparatus:

S.No.	Name	Minimum required Nos.
1	Reflux flask with condenser	20
2	Water bath	20
3	Clavengers apparatus	10
4	Soxhlet apparatus	10
6	TLC chamber and sprayer	10
7	Distillation unit	01

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

C. DEPARTMENT OF PHARMACEUTICAL CHEMISTRY :

I. Equipment:

S.No.	Name	Minimum required Nos.
1	Hot plates	05
2	Oven	03
3	Refrigerator	01
4	Analytical Balances for demonstration	05
5	Digital balance 10mg sensitivity	10
6	Digital Balance (1mg sensitivity)	01
7	Suction pumps	06
8	Muffle Furnace	01

9	Mechanical Stirrers	10
10	Magnetic Stirrers with Thermostat	10
11	Vacuum Pump	01
12	Digital pH meter	01
13	Microwave Oven	02

II. Apparatus:

S.No.	Name	Minimum required Nos.
1	Distillation Unit	02
2	Reflux flask and condenser single necked	20
3	Reflux flask and condenser double/triple necked	20
4	Burettes	40
5	Arsenic Limit Test Apparatus	20
6	Nessler's Cylinders	40

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

D. DEPARTMENT OF PHARMACEUTICS:

I. Equipment:

S.No	Name	Minimum required Nos.
1	Mechanical stirrers	10
2	Homogenizer	05
3	Digital balance	05
4	Microscopes	05
5	Stage and eye piece micrometers	05
6	Brookfield's viscometer	01
7	Tray dryer	01
8	Ball mill	01
9	Sieve shaker with sieve set	01
10	Double cone blender	01
11	Propeller type mechanical agitator	05
12	Autoclave	01
13	Steam distillation still	01
14	Vacuum Pump	01
15	Standard sieves, sieve no. 8, 10, 12, 22, 24, 44, 66, 80	10 sets
16	Tablet punching machine	01
17	Capsule filling machine	01
18	Ampoule washing machine	01
19	Ampoule filling and sealing machine	01

20	Tablet disintegration test apparatus IP	01
21	Tablet dissolution test apparatus IP	01
22	Monsanto's hardness tester	01
23	Pfizer type hardness tester	01
24	Friability test apparatus	01
25	Clarity test apparatus	01
26	Ointment filling machine	01
27	Collapsible tube crimping machine	01
28	Tablet coating pan	01
29	Magnetic stirrer, 500ml and 1 liter capacity with speed control	05 EACH 10
30	Digital pH meter	01
31	All purpose equipment with all accessories	01
32	Aseptic Cabinet	01
33	BOD Incubator	02
34	Bottle washing Machine	01
35	Bottle Sealing Machine	01
36	Bulk Density Apparatus	02
37	Conical Percolator (glass/copper/stainless steel)	10
38	Capsule Counter	02
39	Energy meter	02
40	Hot Plate	02
41	Humidity Control Oven	01
42	Liquid Filling Machine	01
43	Mechanical stirrer with speed regulator	02
44	Precision Melting point Apparatus	01
45	Distillation Unit	01

II. Apparatus:

S.No	Name	Minimum required Nos.
1	Ostwald's viscometer	15
2	Stalagmometer	15
3	Desiccator*	05
4	Suppository moulds	20
5	Buchner Funnels (Small, medium, large)	05 each
6	Filtration assembly	01
7	Permeability Cups	05
8	Andreason's Pipette	03
9	Lipstick moulds	10

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

E. DEPARTMENT OF PHARMACEUTICAL BIOTECHNOLOGY :

S.No.	Name	Minimum required Nos.
1	Orbital shaker incubator	01
2	Lyophilizer (Desirable)	01
3	Gel Electrophoresis (Vertical and Horizontal)	01
4	Phase contrast/Trinocular Microscope	01
5	Refrigerated Centrifuge	01
6	Fermenters of different capacity (Desirable)	01
7	Tissue culture station	01
8	Laminar airflow unit	01
9	Diagnostic kits to identify infectious agents	01
10	Rheometer	01
11	Viscometer	01
12	Micropipettes (single and multi channeled)	01 each
13	Sonicator	01
14	Respinometer	01
15	BOD Incubator	01
16	Paper Electrophoresis Unit	01
17	Micro Centrifuge	01
18	Incubator water bath	01
19	Autoclave	01
20	Refrigerator	01
21	Filtration Assembly	01
22	Digital pH meter	01

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

F. DEPARTMENT OF PHARMACY PRACTICE:**Equipment:**

S.No.	Name	Minimum required Nos.
1	Colorimeter	2
2	Microscope	Adequate
3	Permanent slides (skin, kidney, pancreas, smooth muscle, liver etc.,)	Adequate
4	Watch glass	Adequate
5	Centrifuge	1
6	Biochemical reagents for analysis of normal and pathological constituents in urine and blood facilities	Adequate
7	Filtration equipment	2
8	Filling Machine	1
9	Sealing Machine	1
10	Autoclave sterilizer	1
11	Membrane filter	1 Unit

12	Sintered glass funnel with complete filtering assemble	Adequate
13	Small disposable membrane filter for IV admixture filtration	Adequate
14	Laminar air flow bench	1
15	Vacuum pump	1
16	Oven	1
17	Surgical dressing	Adequate
18	Incubator	1
19	PH meter	1
20	Disintegration test apparatus	1
21	Hardness tester	1
22	Centrifuge	1
23	Magnetic stirrer	1
24	Thermostatic bath	1

NOTE:

1. **Computers and Internet connection (Broadband), six computers for students with internet and staff computers as required.**
2. **Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and the department.**

G. CENTRAL INSTRUMENTATION ROOM :

S.No.	Name	Minimum required Nos.
1	Colorimeter	01
2	Digital pH meter	01
3	UV- Visible Spectrophotometer	01
4	Fluorimeter	01
5	Digital Balance (1mg sensitivity)	01
6	Nephelo Turbidity meter	01
7	Flame Photometer	01
8	Potentiometer	01
9	Conductivity meter	01
10	Fourier Transform Infra Red Spectrometer (Desirable)	01
11	HPLC	01
12	HPTLC (Desirable)	01
13	Atomic Absorption and Emission spectrophotometer (Desirable)	01
14	Biochemistry Analyzer (Desirable)	01
15	Carbon, Hydrogen, Nitrogen Analyzer (Desirable)	01
16	Deep Freezer (Desirable)	01
17	Ion- Exchanger	01
18	Lyophilizer (Desirable)	01

APPENDIX-C

INTERNSHIP

1) SPECIFIC OBJECTIVES:

- i) to provide patient care in cooperation with patients, prescribers, and other members of an interprofessional health care team based upon sound therapeutic principles and evidence-based data, taking into account relevant legal, ethical, social cultural, economic, and professional issues, emerging technologies, and evolving biomedical, pharmaceutical, social or behavioral or administrative, and clinical sciences that may impact therapeutic outcomes.
- ii) to manage and use resources of the health care system, in cooperation with patients, prescribers, other health care providers, and administrative and supportive personnel, to promote health; to provide, assess, and coordinate safe, accurate, and time-sensitive medication distribution; and to improve therapeutic outcomes of medication use.
- iii) to promote health improvement, wellness, and disease prevention in co-operation with patients, communities, at-risk population, and other members of an interprofessional team of health care providers.
- iv) to demonstrate skills in monitoring of the National Health Programmes and schemes, oriented to provide preventive and promotive health care services to the community.
- v) to develop leadership qualities to function effectively as a member of the health care team organised to deliver the health and family welfare services in existing socio-economic, political and cultural environment.
- vi) to communicate effectively with patients and the community.

2) **OTHER DETAILS :**

- i) All parts of the internship shall be done, as far as possible, in institutions in India. In case of any difficulties, the matter may be referred to the Pharmacy Council of India to be considered on merits.
- ii) Where an intern is posted to district hospital for training, there shall be a committee consisting of representatives of the college or university, and the district hospital administration, who shall regulate the training of such trainee. For such trainee a certificate of satisfactory completion of training shall be obtained from the relevant administrative authorities which shall be countersigned by the Principal or Dean of College.

- iii) Every candidate shall be required, after passing the final Pharm.D. or Pharm.D. (Post Baccalaureate) examination as the case may be to undergo compulsory rotational internship to the satisfaction of the College authorities and University concerned for a period of twelve months so as to be eligible for the award of the degree of Pharm.D. or Pharm.D. (Post Baccalaureate) as the case may be.

3. ASSESSMENT OF INTERNSHIP :

- i) The intern shall maintain a record of work which is to be verified and certified by the preceptor (teacher practioner) under whom he works. Apart from scrutiny of the record of work, assessment and evaluation of training shall be undertaken by an objective approach using situation tests in knowledge, skills and attitude during and at the end of the training. Based on the record of work and date of evaluation, the Dean or Principal shall issue certificate of satisfactory completion of training, following which the university shall award the degree or declare him eligible for it.
- ii) Satisfactory completion of internship shall be determined on the basis of the following:-
- (1) Proficiency of knowledge required for each case management SCORE 0-5
 - (2) The competency in skills expected for providing Clinical Pharmacy Services SCORE 0-5
 - (3) Responsibility, punctuality, work up of case, involvement in patient care SCORE 0-5
 - (4) Ability to work in a team (Behavior with other healthcare professionals including medical doctors, nursing staff and colleagues). SCORE 0-5
 - (5) Initiative, participation in discussions, research aptitude. SCORE 0-5

Poor	Fair	Below Average	Average	Above Average	Excellent
0	1	2	3	4	5

A Score of less than 3 in any of above items will represent unsatisfactory completion of internship.



ರಾಜೀವ್ ಗಾಂಧಿ ಆರೋಗ್ಯ ವಿಜ್ಞಾನಗಳ ವಿಶ್ವವಿದ್ಯಾಲಯ, ಕರ್ನಾಟಕ, ಬೆಂಗಳೂರು

RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES, KARNATAKA, BENGALURU
4th T Block, Jayanagar, Bengaluru - 560 041

RGU/AUTH/MPHARM/147/2017-18

10.05.2017

NOTIFICATION

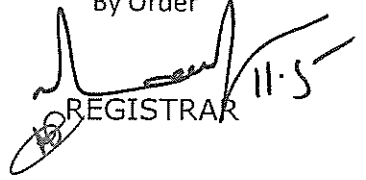
Sub: Revised ordinance relating to Master of Pharmacy (M.Pharm) course (Semester System)

Ref: (1) PCI Notification ref.No.14-136-2016-PCI,14-154/2015-PCI (53095-55431) dated 21.12.2016
(2) Proceedings of meeting of BOS in Pharmacy (PG) held on 05.12.2016
(3) Proceedings of meeting of Faculty of Pharmacy held on 05.12.2016
(4) Proceedings of meeting of Academic Council held on 22.12.2016
(5) Approval of Syndicate in its 125th meeting held on 06.01.2017.

In exercise of the powers conferred under section 35 of RGUHS Act, 1994, Syndicate is pleased to notify the revised ordinance relating to Master of Pharmacy (M.Pharm) course (Semester System) as shown in annexure appended herewith.

The revised ordinance shall come into force from the academic year 2017-18 and onwards.

By Order


REGISTRAR

To

1. All the Principals of Pharmacy Colleges affiliated to RGUHS
2. The Registrar (Evaluation), RGUHS
3. The Director, Dept. of Curriculum Development, RGUHS

Copy to:

1. The Secretary to Governor, Governor's Secretariat, Raj Bhavan, Bangalore-560 001.
2. The Secretary to Government, Health & Family Welfare Department (Medical Education), Vikasa Soudha, Bangalore-560 001.
3. The PA to Vice-Chancellor/Registrar/Registrar(Evaluation), RGUHS, Bangalore
4. The System Analyst, RGUHS to host the notification on RGUHS website.
5. Guard File/Office Copy

**Revised Regulations for the
Master of Pharmacy Degree Program
(w.e.f. June 2016)**

Credit Based Semester System

Pharmacy Council of India
Combined Council's Building, Kotla Road,
Aiwan-E-Ghalib Marg,
New Delhi-110 002

CHAPTER – I: REGULATIONS

1. Short Title and Commencement

These regulations shall be called as “The Revised Regulations for the Master of Pharmacy (M. Pharm.) Degree Program - Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi”. They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by the authorities of the university.

2. Minimum qualification for admission

A Pass in the following examinations

- a) B. Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B.Pharm.)
- b) Every student, selected for admission to post graduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

Note: It is mandatory to submit a migration certificate obtained from the respective university where the candidate had passed his/her qualifying degree (B.Pharm.)

3. Duration of the program

The program of study for M.Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Pharmacy Council of India, New Delhi.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

Each semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from the month of December/January to May/June in every calendar year.

6. Attendance and progress

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly the credit associated with any of the other academic, co/extra-curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

7.1. Credit assignment

7.1.1. Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

7.2. Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits are distributed semester-wise as shown in Table V. Courses generally progress in sequence, building competencies and their positioning indicates certain academic

maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

8. Academic work

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective courses.

9. Course of study

The specializations in M.Pharm program is given in Table I.

Table – 1: List of M.Pharm. Specializations and their Code

S. No.	Specialization	Code
1.	Cosmeceutics	MCC
2.	Industrial Pharmacy	MIP
3.	Pharmaceutical Analysis	MPA
4.	Pharmaceutical Biotechnology	MPB
5.	Pharmaceutical Chemistry	MPC
6.	Pharmaceutics	MPH
7.	Pharmacognosy	MPG
8.	Pharmacology	MPL
9.	Pharmacy Practice	MPP
10.	Pharmaceutical Quality Assurance	MQA
11.	Pharmaceutical Regulatory Affairs	MRA

The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Table – II to XIII. The number of hours to be devoted to each theory and practical course in any semester shall not be less than that shown in Table – II to XIII.

Table – 2: Course of study for M. Pharm. (Cosmeceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MCC101T	Cosmeceuticals – Biology	4	4	4	100
MCC102T	Cosmetics - Formulation Science	4	4	4	100
MCC103T	Quality Assurance	4	4	4	100
MCC104T	Cellular and Molecular Pharmacology	4	4	4	100
MCC105P	Cosmeceutics Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MCC201T	Cosmeceuticals	4	4	4	100
MCC202T	Cosmetic Analysis and Evaluation	4	4	4	100
MCC203T	Cosmetics- Industry and Regulatory	4	4	4	100
MCC204T	Computer Aided Drug Delivery System	4	4	4	100
MCC205P	Cosmeceutics Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 3: Course of study for M. Pharm. (Industrial Pharmacy)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MIP101T	Pharmaceutical Formulation Development	4	4	4	100
MIP102T	Customized drug Delivery System	4	4	4	100
MIP103T	Drug Regulations and Intellectual Property Rights	4	4	4	100
MIP104P	Industrial Pharmacy Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MIP201T	Advanced Biopharmaceutics and Pharmacokinetics	4	4	4	100
MIP202T	Scale up and Technology Transfer	4	4	4	100
MIP203T	Pharmaceutical Production Technology	4	4	4	100
MIP204T	Entrepreneurship Management	4	4	4	100
MIP205P	Industrial Pharmacy Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 4: Course of study for M. Pharm. (Pharmaceutical Analysis)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPA102T	Advanced Pharmaceutical Analysis	4	4	4	100
MPA103T	Pharmaceutical Validation	4	4	4	100
MPA104T	Food Analysis	4	4	4	100
MPA105P	Pharmaceutical Analysis Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPA201T	Advanced Instrumental Analysis	4	4	4	100
MPA202T	Modern Bio-Analytical Techniques	4	4	4	100
MPA203T	Quality Control and Quality Assurance	4	4	4	100
MPA204T	Cosmetic Analysis and Evaluation	4	4	4	100
MPA205P	Pharmaceutical Analysis Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 5: Course of study for M. Pharm. (Pharmaceutical Biotechnology)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPB101T	Microbial And Cellular Biology	4	4	4	100
MPB102T	Bioprocess Engineering and Technology	4	4	4	100
MPB103T	Advanced Pharmaceutical Biotechnology	4	4	4	100
MPB104P	Pharmaceutical Biotechnology Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPB201T	Proteins and protein Formulation	4	4	4	100
MPB202T	Immunotechnology	4	4	4	100
MPB203T	Bioinformatics and Computer Technology	4	4	4	100
MPB204T	Biological Evaluation of Drug Therapy	4	4	4	100
MPB205P	Pharmaceutical Biotechnology Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 6: Course of study for M. Pharm. (Pharmaceutical Chemistry)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPC101T	Advanced Organic Chemistry -I	4	4	4	100
MPC102T	Advanced Medicinal chemistry	4	4	4	100
MPC103T	Chemistry of Natural Products	4	4	4	100
MPC104P	Pharmaceutical Chemistry Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPC201T	Advanced Spectral Analysis	4	4	4	100
MPC202T	Advanced Organic Chemistry -II	4	4	4	100
MPC203T	Computer Aided Drug Design	4	4	4	100
MPC204T	Pharmaceutical Process Chemistry	4	4	4	100
MPC205P	Pharmaceutical Chemistry Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 7: Course of study for M. Pharm. (Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH101T	Modified Release Drug Delivery System	4	4	4	100
MPH102T	Modern Pharmaceutics	4	4	4	100
MPH103T	Pharmaceutical Regulatory Affair	4	4	4	100
MPH104P	Pharmaceutics Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPH201T	Molecular Pharmaceutics(Nano Tech and Targeted DDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH203T	Computer Aided Drug Delivery System	4	4	4	100
MPH204T	Cosmetic and Cosmeceuticals	4	4	4	100
MPH205P	Pharmaceutics Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 8: Course of study for M. Pharm. (Pharmacognosy)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPG101T	Advanced Pharmacognosy-I	4	4	4	100
MPG102T	Phytochemistry	4	4	4	100
MPG103T	Industrial Herbal drug technology	4	4	4	100
MPG104P	Pharmacognosy Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPG201T	Medicinal Plant biotechnology	4	4	4	100
MPG102T	Advanced Pharmacognosy-II	4	4	4	100
MPG203T	Indian system of medicine	4	4	4	100
MPG204T	Herbal cosmetics	4	4	4	100
MPG205P	Pharmacognosy Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 9: Course of study for (Pharmacology)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPL101T	Advanced Pharmacology-I	4	4	4	100
MPL102T	Pharmacological and Toxicological Screening Methods-I	4	4	4	100
MPL103T	Cellular and Molecular Pharmacology	4	4	4	100
MPL104P	Pharmacology Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPL201T	Advanced Pharmacology II	4	4	4	100
MPL102T	Pharmacological and Toxicological Screening Methods-II	4	4	4	100
MPL203T	Principles of Drug Discovery	4	4	4	100
MPL204T	Experimental Pharmacology practical- II	4	4	4	100
MPL205P	Pharmacology Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 10: Course of study for M. Pharm. (Pharmacy Practice)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPP101T	Clinical Pharmacy Practice	4	4	4	100
MPP102T	Pharmacotherapeutics-I	4	4	4	100
MPP103T	Hospital & Community Pharmacy	4	4	4	100
MPP104T	Clinical Research	4	4	4	100
MPP105P	Pharmacy Practice Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPP201T	Principles of Quality Use of Medicines	4	4	4	100
MPP102T	Pharmacotherapeutics II	4	4	4	100
MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	4	4	100
MPP204T	Pharmacoepidemiology & Pharmacoeconomics	4	4	4	100
MPP205P	Pharmacy Practice Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 11: Course of study for M. Pharm. (Pharmaceutical Quality Assurance)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MQA101T	Quality Management System	4	4	4	100
MQA102T	Quality Control and Quality Assurance	4	4	4	100
MQA103T	Product Development and Technology Transfer	4	4	4	100
MQA104P	Pharmaceutical Quality Assurance Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MQA201T	Hazards and Safety Management	4	4	4	100
MQA202T	Pharmaceutical Validation	4	4	4	100
MQA203T	Audits and Regulatory Compliance	4	4	4	100
MQA204T	Pharmaceutical Manufacturing Technology	4	4	4	100
MQA205P	Pharmaceutical Quality Assurance Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 12: Course of study for M. Pharm. (Pharmaceutical Regulatory Affairs)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MRA101T	Good Pharmaceutical Practices	4	4	4	100
MRA102T	Pharmaceutical Regulations in India	4	4	4	100
MRA103T	International Pharmaceutical Regulations I	4	4	4	100
MRA104T	Clinical Research Regulations	4	4	4	100
MRA105T	Pharmaceutical Regulatory Affairs Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MRA201T	Documentation and Regulatory Writing	4	4	4	100
MRA202T	Biologicals Regulations	4	4	4	100
MRA203T	International Pharmaceutical Regulations II	4	4	4	100
MRA204T	Medical Device Regulations	4	4	4	100
MRA205P	Pharmaceutical Regulatory Affairs Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table – 13: Course of study for M. Pharm. III Semester
(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
MRM101T	Research Methodology and Biostatistics*	4	4
-	Journal club	1	1
-	Discussion / Presentation (Proposal Presentation)	2	2
-	Research Work	28	14
Total		35	21

* Non University Exam

Table – 14: Course of study for M. Pharm. IV Semester
(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
-	Journal Club	1	1
-	Research Work	31	16
-	Discussion/Final Presentation	3	3
Total		35	20

Table – 15: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	Minimum=02 Maximum=07*
Total Credit Points	Minimum=95 Maximum=100*

*Credit Points for Co-curricular Activities

Table – 16: Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	Maximum Credit Points Eligible / Activity
Participation in National Level Seminar/Conference/Workshop/Symposium/Training Programs (related to the specialization of the student)	01
Participation in international Level Seminar/Conference/Workshop/Symposium/Training Programs (related to the specialization of the student)	02
Academic Award/Research Award from State Level/National Agencies	01
Academic Award/Research Award from International Agencies	02
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	01
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)	02

Note: International Conference: Held Outside India

International Journal: The Editorial Board Outside India

* The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

10. Program Committee

1. The M. Pharm. programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.
2. The composition of the Programme Committee shall be as follows:

A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M.Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.

3. Duties of the Programme Committee:
 - i. Periodically reviewing the progress of the classes.
 - ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
 - iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
 - iv. Communicating its recommendation to the Head of the institution on academic matters.

- v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessionalexam and before the end semester exam.

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table – XVII.

11.1. End semester examinations

The End Semester Examinations for each theory and practical coursethrough semesters I to IVshall beconducted by the respective university except for the subject with asterix symbol (*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Tables – 17: Schemes for internal assessments and end semester examinations (Cosmeceutics)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MCC101T	Cosmeceuticals – Biology	10	15	1 Hr	25	75	3 Hrs	100
MCC102T	Cosmetics - Formulation Science	10	15	1 Hr	25	75	3 Hrs	100
MCC103T	Quality Assurance	10	15	1 Hr	25	75	3 Hrs	100
MCC104T	Cellular and Molecular Pharmacology	10	15	1 Hr	25	75	3 Hrs	100
MCC105P	Cosmeceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MCC201T	Cosmeceuticals	10	15	1 Hr	25	75	3 Hrs	100
MCC202T	Cosmetic Analysis and Evaluation	10	15	1 Hr	25	75	3 Hrs	100
MCC203T	Cosmectics- Industry and Regulatory	10	15	1 Hr	25	75	3 Hrs	100
MCC204T	Computer Aided Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MCC201T	Cosmeceuticals	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 18: Schemes for internal assessments and end semester examinations (Industrial Pharmacy)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MIP101T	Pharmaceutical Formulation Development	10	15	1 Hr	25	75	3 Hrs	100
MIP102T	Customized drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MIP103T	Drug Regulations and Intellectual Property Rights	10	15	1 Hr	25	75	3 Hrs	100
MIP104P	Industrial Pharmacy Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MIP201T	Advanced Biopharmaceutics and Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100
MIP202T	Scale up and Technology Transfer	10	15	1 Hr	25	75	3 Hrs	100
MIP203T	Pharmaceutical Production Technology	10	15	1 Hr	25	75	3 Hrs	100
MIP204T	Entrepreneurship Management	10	15	1 Hr	25	75	3 Hrs	100
MIP205P	Industrial Pharmacy Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 19: Schemes for internal assessments and end semester examinations (Pharmaceutical Analysis)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA102T	Advanced Pharmaceutical Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA103T	Pharmaceutical Validation	10	15	1 Hr	25	75	3 Hrs	100
MPA104T	Food Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA105P	Pharmaceutical Analysis-I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPA201T	Advanced Instrumental Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA202T	Modern Bio-Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPA203T	Quality Control and Quality Assurance	10	15	1 Hr	25	75	3 Hrs	100
MPA204T	Cosmetic Analysis and Evaluation	10	15	1 Hr	25	75	3 Hrs	100
MPA205P	Pharmaceutical Analysis-II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 20: Schemes for internal assessments and end semester examinations (Pharmaceutical Biotechnology)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPB101T	Microbial And Cellular Biology	10	15	1 Hr	25	75	3 Hrs	100
MPB102T	Bioprocess Engineering and Technology	10	15	1 Hr	25	75	3 Hrs	100
MPB103T	Advanced Pharmaceutical Biotechnology	10	15	1 Hr	25	75	3 Hrs	100
MPB104P	Pharmaceutical Biotechnology Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPB201T	Proteins and protein Formulation	10	15	1 Hr	25	75	3 Hrs	100
MPB202T	Immunotechnology	10	15	1 Hr	25	75	3 Hrs	100
MPB203T	Bioinformatics and Computer Technology	10	15	1 Hr	25	75	3 Hrs	100
MPB204T	Biological Evaluation of Drug Therapy	10	15	1 Hr	25	75	3 Hrs	100
MPB205P	Pharmaceutical Biotechnology Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 21: Schemes for internal assessments and end semester examinations (Pharmaceutical Chemistry)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPC101T	Advanced Organic Chemistry -I	10	15	1 Hr	25	75	3 Hrs	100
MPC102T	Advanced Medicinal chemistry	10	15	1 Hr	25	75	3 Hrs	100
MPC103T	Chemistry of Natural Products	10	15	1 Hr	25	75	3 Hrs	100
MPC104P	Pharmaceutical Chemistry Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPC201T	Advanced Spectral Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPC202T	Advanced Organic Chemistry -II	10	15	1 Hr	25	75	3 Hrs	100
MPC203T	Computer Aided Drug Design	10	15	1 Hr	25	75	3 Hrs	100
MPC204T	Pharmaceutical Process Chemistry	10	15	1 Hr	25	75	3 Hrs	100
MPC205P	Pharmaceutical Chemistry Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 22: Schemes for internal assessments and end semester examinations (Pharmaceutics)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPH101T	Modified Release Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH102T	Modern Pharmaceutics	10	15	1 Hr	25	75	3 Hrs	100
MPH103T	Pharmaceutical Regulatory Affair	10	15	1 Hr	25	75	3 Hrs	100
MPH104P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPH201T	Molecular Pharmaceutics(Nano Tech and Targeted DDS)	10	15	1 Hr	25	75	3 Hrs	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100
MPH203T	Computer Aided Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH204T	Cosmetic and Cosmeceuticals	10	15	1 Hr	25	75	3 Hrs	100
MPH205P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 23: Schemes for internal assessments and end semester examinations (Pharmacognosy)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPG101T	Advanced Pharmacognosy-1	10	15	1 Hr	25	75	3 Hrs	100
MPG102T	Phytochemistry	10	15	1 Hr	25	75	3 Hrs	100
MPG103T	Industrial Herbal drug technology	10	15	1 Hr	25	75	3 Hrs	100
MPG104P	Pharmacognosy Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPG201T	Medicinal Plant biotechnology	10	15	1 Hr	25	75	3 Hrs	100
MPG102T	Advanced Pharmacognosy-II	10	15	1 Hr	25	75	3 Hrs	100
MPG203T	Indian system of medicine	10	15	1 Hr	25	75	3 Hrs	100
MPG204T	Herbal cosmetics	10	15	1 Hr	25	75	3 Hrs	100
MPG205P	Pharmacognosy Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 24: Schemes for internal assessments and end semester examinations (Pharmacology)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPL101T	Advanced Pharmacology-I	10	15	1 Hr	25	75	3 Hrs	100
MPL102T	Pharmacological and Toxicological Screening Methods-I	10	15	1 Hr	25	75	3 Hrs	100
MPL103T	Cellular and Molecular Pharmacology	10	15	1 Hr	25	75	3 Hrs	100
MPL104P	Pharmacology Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPL201T	Advanced Pharmacology II	10	15	1 Hr	25	75	3 Hrs	100
MPL102T	Pharmacological and Toxicological Screening Methods-II	10	15	1 Hr	25	75	3 Hrs	100
MPL203T	Principles of Drug Discovery	10	15	1 Hr	25	75	3 Hrs	100
MPL204T	Experimental Pharmacology practical- II	10	15	1 Hr	25	75	3 Hrs	100
MPL205P	Pharmacology Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 25: Schemes for internal assessments and end semester examinations (Pharmacy Practice)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPP101T	Clinical Pharmacy Practice	10	15	1 Hr	25	75	3 Hrs	100
MPP102T	Pharmacotherapeutics-I	10	15	1 Hr	25	75	3 Hrs	100
MPP103T	Hospital & Community Pharmacy	10	15	1 Hr	25	75	3 Hrs	100
MPP104T	Clinical Research	10	15	1 Hr	25	75	3 Hrs	100
MPP105P	Pharmacy Practice Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPP201T	Principles of Quality Use of Medicines	10	15	1 Hr	25	75	3 Hrs	100
MPP102T	Pharmacotherapeutics II	10	15	1 Hr	25	75	3 Hrs	100
MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	10	15	1 Hr	25	75	3 Hrs	100
MPP204T	Pharmacoepidemiology & Pharmacoeconomics	10	15	1 Hr	25	75	3 Hrs	100
MPP205P	Pharmacy Practice Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 26: Schemes for internal assessments and end semester examinations (Pharmaceutical Quality Assurance)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MQA101T	Quality Management System	10	15	1 Hr	25	75	3 Hrs	100
MQA102T	Quality Control and Quality Assurance	10	15	1 Hr	25	75	3 Hrs	100
MQA103T	Product Development and Technology Transfer	10	15	1 Hr	25	75	3 Hrs	100
MQA104P	Pharmaceutical Quality Assurance Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MQA201T	Hazards and Safety Management	10	15	1 Hr	25	75	3 Hrs	100
MQA202T	Pharmaceutical Validation	10	15	1 Hr	25	75	3 Hrs	100
MQA203T	Audits and Regulatory Compliance	10	15	1 Hr	25	75	3 Hrs	100
MQA204T	Pharmaceutical Manufacturing Technology	10	15	1 Hr	25	75	3 Hrs	100
MQA205P	Pharmaceutical Quality Assurance Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 27: Schemes for internal assessments and end semester examinations (Pharmaceutical Regulatory Affairs)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MRA101T	Good Pharmaceutical Practices	10	15	1 Hr	25	75	3 Hrs	100
MRA102T	Pharmaceutical Regulations in India	10	15	1 Hr	25	75	3 Hrs	100
MRA103T	International Pharmaceutical Regulations I	10	15	1 Hr	25	75	3 Hrs	100
MRA104T	Clinical Research Regulations	10	15	1 Hr	25	75	3 Hrs	100
MRA105T	Pharmaceutical Regulatory Affairs Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MRA201T	Documentation and Regulatory Writing	10	15	1 Hr	25	75	3 Hrs	100
MRA202T	Biologicals Regulations	10	15	1 Hr	25	75	3 Hrs	100
MRA203T	International Pharmaceutical Regulations II	10	15	1 Hr	25	75	3 Hrs	100
MRA204T	Medical Device Regulations	10	15	1 Hr	25	75	3 Hrs	100
MRA205P	Pharmaceutical Regulatory Affairs Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 28: Schemes for internal assessments and end semester examinations (Semester III& IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
MRM101T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
-	Research work*	-	-	-	-	350	1 Hr	350
Total								525
SEMESTER IV								
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75
-	Research work and Colloquium	-	-	-	-	400	1 Hr	400
Total								500

***Non University Examination**

11.2. Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table – 29: Scheme for awarding internal assessment: Continuous mode

Theory	
Criteria	Maximum Marks
Attendance (Refer Table – 30)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – 30)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

Table – 30: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95 – 100	8	10
90 – 94	6	7.5
85 – 89	4	5
80 – 84	2	2.5
Less than 80	0	0

11.2.1. Sessional Exams

Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical sessional examinations is given below. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables – X.

12. Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of M.Pharm. programme if he/she secures at least 50% marks in that particular course including internal assessment.

13. Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 12, then he/she shall reappear for the end semester examination of that course. However his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

14. Improvement of internal assessment

A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end semester theory examinations.

15. Reexamination of end semester examinations

Reexamination of end semester examination shall be conducted as per the schedule given in table XIII. The exact dates of examinations shall be notified from time to time.

Table – 31: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I and III	November / December	May / June
II and IV	May / June	November / December

16. Allowed to keep terms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in 6. ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I and II semesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

17. Grading of performances

17.1. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in **Table – 32:**

**Table – 32: Letter grades and grade points equivalent to
Percentage of marks and performances**

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

18. The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called ‘Semester Grade Point Average’ (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C₁, C₂, C₃ and C₄ and the student’s grade points in these courses are G₁, G₂, G₃ and G₄, respectively, and then students’ SGPA is equal to:

$$\text{SGPA} = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4}{C_1 + C_2 + C_3 + C_4}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and ABS grade awarded in that semester. For example if a learner has a F or ABS grade in course 4, the SGPA shall then be computed as:

$$\text{SGPA} = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4 * \text{ZERO}}{C_1 + C_2 + C_3 + C_4}$$

19. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed by obtaining a pass grade

on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier. The CGPA is calculated as:

$$\text{CGPA} = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4}{C_1 + C_2 + C_3 + C_4}$$

where $C_1, C_2, C_3, \dots$ is the total number of credits for semester I, II, III, ... and $S_1, S_2, S_3, \dots$ is the SGPA of semester I, II, III, ...

20. Declaration of class

The class shall be awarded on the basis of CGPA as follows:

First Class with Distinction	= CGPA of 7.50 and above
First Class	= CGPA of 6.00 to 7.49
Second Class	= CGPA of 5.00 to 5.99

21. Project work

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

Objective(s) of the work done	50 Marks
Methodology adopted	150 Marks
Results and Discussions	250 Marks
Conclusions and Outcomes	50 Marks

Total	500 Marks

Evaluation of Presentation:

Presentation of work	100 Marks
Communication skills	50 Marks
Question and answer skills	100 Marks

Total	250 Marks

22. Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the M.Pharm program shall not be eligible for award of ranks. Moreover, the candidates should have completed the M. Pharm program in minimum prescribed number of years, (two years) for the award of Ranks.

23. Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

24. Duration for completion of the program of study

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

25. Revaluation / Retotaling of answer papers

There is no provision for revaluation of the answer papers in any examination. However, the candidates can apply for retotaling by paying prescribed fee.

26. Re-admission after break of study

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying a condonation fee.

M. PHARM. PHARMACEUTICS (MPH)

MODERN PHARMACEUTICAL ANALYSIS (MPA101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know,

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY

60 HOURS

- 1. UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation **11 Hrs**
associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.
IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy
Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.
- 2 NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, **11 Hrs**
Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy.
- 3 Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass **11 Hrs**
Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

- 4 Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: **11 Hrs**
a) Paper chromatography b) Thin Layer chromatography
c) Ion exchange chromatography d) Column chromatography
e) Gas chromatography f) High Performance Liquid chromatography
g) Affinity chromatography
- 5 Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: **11 Hrs**
a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.
- 6 Immunological assays :** RIA (Radio immuno assay), ELISA, Bioluminescence assays. **5 Hrs**

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

DRUG DELIVERY SYSTEM (MPH101T)

SCOPE

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

OBJECTIVES

Upon completion of the course, student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of
- The formulation and evaluation of Novel drug delivery systems..

THEORY

60 Hrs

10 Hrs

1. **SR/CR formulation:** Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers :introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems,Bioelectronic Medicines,3D printing of pharmaceuticals, Telepharmacy.

10 Hrs

2. **Rate Controlled Drug Delivery Systems:** Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems;Mechanically activated, PH activated , Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals

3. **Gastro-Retentive Drug Delivery Systems:** Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation,Methods of formulation and its evaluations.

10 Hrs

4. **Ocular Drug Delivery Systems:** Barriers of drug permeation, Methods to overcome barriers.

6 Hrs

5. **Trans Dermal Drug Delivery Systems:** Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation

10 Hrs

6. **Protein and Peptide Delivery:** Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.

8 Hrs

- 7. Vaccine delivery systems:** Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

6 Hrs

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

JOURNALS

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

MODERN PHARMACEUTICS (MPH102T)

Scope

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

Objectives

Upon completion of the course, student shall be able to understand

- To understand the elements of preformulation studies.
- To understand the Active Pharmaceutical Ingredients and Generic drug Product development
- To learn Industrial Management and GMP Considerations.
- To understand Optimization Techniques & Pilot Plant Scale Up Techniques
- To study Stability Testing, sterilization process & packaging of dosage forms.

THEORY

60 HRS

10 hrs

1. **Preformation Concepts** – Drug Excipient interactions - different methods, kinetics of stability, Stability testing.
Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability
Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation

10 Hrs

2. **Optimization techniques in Pharmaceutical Formulation:** Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation.

10 Hrs

3. **Validation :** Introduction to Pharmaceutical Validation, Scope & merits of Validation, , Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities

10 Hrs

4. **cGMP & Industrial Management:** Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials

management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management

10 Hrs

- 5. Compression and compaction:** Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility enhancement techniques.

10 Hrs

- 6. Study of consolidation parameters;** Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckal plots, Similarity factors – f_2 and f_1 , Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation, chi square test, student T-test, Anova test.

REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred Martin
9. Bentley's Textbook of Pharmaceutics – Rawbins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H. Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P. Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.

REGULATORY AFFAIRS (MPH103T)

Scope

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents filing process of IND, NDA and ANDA

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance and

Objectives:

Upon completion of the course, it is expected that the students will be able to understand

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilance and process of monitoring in clinical trials.

THEORY

60 Hr

1. **Documentation in pharmaceutical industry:** Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch- Waxman act and amendments , CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro ,ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO

1
2 hrs
2. **Regulatory requirement for product approval:** API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs

12 hrs

3. CMC, post approval regulatory affairs.Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison.
ICH - Guidelines of ICH-Q,S E,M.
Regulatory requirements of EU, MHRA, TGA and ROW countries.

12

hrs

4. **Non clinical drug development:** Global submission of IND,NDA,ANDA.Investigation medicinal products dossier, dossier (IMPD) and investigator brochure (IB)

12 hrs

5. **Clinical trials:** Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.

12 hrs

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. <https://www.tga.gov.au/tga-basics>

PRACTICALS (MPH104P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. To perform *In-vitro* dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Muco adhesive tablets.
12. Formulation and evaluation of trans dermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)(MPH201T)

Scope

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Objectives

Upon completion of the course student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of NTDS
- The formulation and evaluation of novel drug delivery systems.

THEORY

60 Hrs

12 hrs

1. **Targeted Drug Delivery Systems:** Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.

12hrs

2. **Targeting Methods:** introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation

12hrs

3. **Micro Capsules / Micro Spheres:** Types, preparation and evaluation , Monoclonal Antibodies ; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.

12hrs

4. **Pulmonary Drug Delivery Systems :** Aerosols, propellents, ContainersTypes, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation

12hrs

5. **Veterinary Drug Delivery Systems:** Tablets and bolus, Feed additives, Drinking water medication, Oral paste and gels, Drenchers and Tubing product

REFERENCES:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel

- Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, VallabhPrakashan, New Delhi, First edition 2002.
 3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 2001).

Journals

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH202T)

Scope

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

Objectives

At completion of this course it is expected that students will be able understand –

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- The design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and apply basic pharmacokinetic
- The principles to solve them

THEORY

60 Hrs

12hrs

1. **Drug Absorption From The Gastrointestinal Tract:** Gastrointestinal tract, Mechanism of drug absorption, Factors affecting passive drug absorption, pH-partition theory of drug absorption. Factors affecting drug absorption: physicochemical factors:Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data.Transport model:

Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex, Structure of Octanol, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

12Hrs

- 2. Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance:** Introduction, Biopharmaceutic Factors Affecting Drug Bioavailability, Rate-Limiting Steps in Drug Absorption, Physicochemical Nature of the Drug Formulation Factors Affecting Drug Product Performance, Drug Product Performance, *In Vitro*: Dissolution and Drug Release Testing, Compendial Methods of Dissolution, Alternative Methods of Dissolution Testing, Meeting Dissolution Requirements, Problems of Variable Control in Dissolution Testing Performance of Drug Products. *In Vitro–In Vivo* Correlation, Dissolution Profile Comparisons, Drug Product Stability, Considerations in the Design of a Drug Product, Drug Product Considerations.

12Hrs

- 3. Pharmacokinetics:** Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model- IV bolus, IV infusion, Extravascular. Multi Compartment model: Two compartment - model in brief, Non-Linear Pharmacokinetics: Cause of non-linearity, Michaelis – Menten equation, Estimation K_{max} and V_{max} . Drug interactions: Introduction, The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters.

12Hrs

- 4. Drug Product Performance, In Vivo: Bioavailability and Bioequivalence:** Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Evaluation of the Data, Bioequivalence Example, Study Submission and Drug Review Process. Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution.

12Hrs

- 5. Application of Pharmacokinetics:** Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. pharmacokinetic and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.

REFERENCES:

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991

2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmarkar and Sunil B.J aiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
- 12.Basic Pharmacokinetics,1 st edition,Sunil S JambhekarandPhilip J Breen,pharmaceutical press,RPS Publishing,2009.
- 13.Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

COMPUTER AIDED DRUG DEVELOPMENT (MPH203T)

Scope

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students' to clarify the concepts.

Objectives

At completion of this course it is expected that students will be able to understand-

- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition
- Computers in Preclinical Development
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics(CFD)

THEORY

60Hrs

1. **Computers in Pharmaceutical Research and Development:** A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameter Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling

Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application

12Hrs

2. **Computational Modeling Of Drug Disposition:** Introduction ,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.

12Hrs

3. **Computer-aided formulation development:** Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis

12Hrs

4. **Computer-aided biopharmaceutical characterization:** Gastrointestinal absorption simulation
Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and *in vitro-in vivo* correlation, Biowaiver considerations

Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.

Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems

12Hrs

5. **Artificial Intelligence (AI), Robotics and Computational fluid dynamics:** General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

12Hrs

REFERENCES:

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

COSMETICS AND COSMECEUTICALS (MPH204T)

Scope

This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.

Objectives: Upon completion of the course, the students will be able to understand

- The key ingredients used in cosmetics and cosmeceuticals.
- The key building blocks for various formulations.
- The current technologies in the market
- The various key ingredients and basic science to develop cosmetics and cosmeceuticals
- The scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, sensory, stability, and efficacy.

THEORY

60Hrs

12Hrs

1. Formulations approaches and Requirements

Definition of cosmetic products as per EU guidelines .Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arms. Formulation requirements for ethnic needs.

12Hrs

2.Plant Lay out, factory requirements and commonly used cosmetics raw materials

Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants- Classification and application. Emollients rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a cream, shampoo and toothpaste.

Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.

Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

12Hrs

3.Design of special purpose cosmeceutical products

Sun protection, sunscreens classification and regulatory aspects. addressing dry skin, acne,

sun-protection, pigmentation, prickly heat, wrinkles, body odor. Dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth.

12Hrs

3. Herbal Cosmetics

Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

12Hrs

4. Formulation of Lip care products and Cosmetic Safety .

Chemistry and formulation of paraphenylenediamine based hair colorants. Soaps and syndet bars Labelling requirements for cosmetics Study of salient features of cosmetic safety data base developed by private body, and International Nomenclature of Cosmetic Ingredients (INCI). Review of the list of ingredients on the labels of cosmetics, cosmeceuticals, baby care and men's range of the products in the market and conduct comparative study of the formulations.

RECOMMENDED BOOKS:

1. Harry's Cosmeticology. 8th edition
2. Poucher's perfume cosmetics and Soaps, 10th edition
3. Cosmetics - Formulation, manufacture and quality control PP.Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I.Maibach. 3rd edition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.

PRACTICAL (MPH205P)

1. To study the effect of temperature change , non solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes
5. Formulation and evaluation of niosomes
6. Formulation and evaluation of spheruls
7. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
8. Comparison of dissolution of two different marketed products /brands
9. Protein binding studies of a highly protein bound drug & poorly protein bound drug
10. Bioavailability studies of Paracetamol.
11. Pharmacokinetic and IVIVC data analysis by Winnoline^R software
12. *In vitro* cell studies for permeability and metabolism
13. DoE Using Design Expert[®] Software
14. Formulation data analysis Using Design Expert[®] Software
15. Quality-by-Design in Pharmaceutical Development
16. Computer Simulations in Pharmacokinetics
17. Computer Simulations Pharmacodynamics
18. Computational Modeling Of Drug Disposition
19. To develop Clinical Data Collection manual
20. To carry out Sensitivity Analysis, and Population Modeling.
21. Development and evaluation of Creams
22. Development and evaluation of Shampoo and Toothpaste base
23. To Incorporate herbal and chemical actives to develop products
24. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

**M. PHARM. PHARMACEUTICAL CHEMISTRY
(MPC)**

MODERN PHARMACEUTICAL ANALYSIS (MPA101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know,

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY HOURS

60

- 1. UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. **12 Hrs**
IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy
Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.
- 2 NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy. **12 Hrs**
- 3 Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy **12 Hrs**

- 4 Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: **12 Hrs**
a) Paper chromatography b) Thin Layer chromatography
c) Ion exchange chromatography d) Column chromatography
e) Gas chromatography f) High Performance Liquid chromatography
g) Affinity chromatography
- 5 Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: **12 Hrs**
a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.
- 6 Medical device and applications:** Introduction, Historical and current prospectus (specific division to be included)

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

ADVANCED ORGANIC CHEMISTRY-1 (MPC101T)

Scope

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Objectives

Upon completion of course, the student shall be to understand-

- The principles and applications of retrosynthesis
- The mechanism & applications of various named reactions
- The concept of disconnection to develop synthetic routes for small target molecule.
- The various catalysts used in organic reactions
- The chemistry of heterocyclic compounds

THEORY

60 Hrs

1. Basic Aspects of Organic Chemistry

- a. Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications.
- b. Types of reaction mechanisms and methods of determining them,
- c. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations.
 - i. Aliphatic and aromatic compounds,
 - ii. Nucleophilic uni- and bimolecular reactions (SN1 and SN2)
 - iii. Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule)
 - iv. Rearrangement reaction

12Hrs

2. Study of mechanism synthetic applications of following named Reactions:

Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner-Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeier-Haack Reaction, Sharpless asymmetric epoxidation, Baeyer-Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction

12 Hrs

3. Synthetic Reagents & Applications

Aluminiumisopropoxide, N-bromosuccinamide, diazomethane, dicyclohexylcarbodiimide, Wilkinson reagent, Witting reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, Triphenylphosphine, Benzotriazol-1-yloxy) tris (dimethylamino) phosphonium hexafluoro-phosphate (BOP).

Protecting groups

- a. Role of protection in organic synthesis
- b. Protection for the hydroxyl group, including 1,2-and 1,3-diols: ethers, esters, carbonates, cyclic acetals & ketals
- c. Protection for the Carbonyl Group: Acetals and Ketals
- d. Protection for the Carboxyl Group: amides and hydrazides, esters
- e. Protection for the Amino Group and Amino acids: carbamates and amides

12Hrs

4. Heterocyclic Chemistry

General methods of synthesis and applications of drugs of five, six membered and fused heterocycles such as imidazole, pyrazole, triazole, pyrimidine, quinoline, acridine, phenothiazine and purine. Synthesis of few representative drugs containing these heterocyclic nucleus

12Hrs

5. Synthon approach and retrosynthesis applications

- i. Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconversion and addition (FGI and FGA)
- ii. C-X disconnections; C-C disconnections – alcohols and carbonyl compounds; 1,2-, 1,3-, 1,4-, 1,5-, 1,6-difunctionalized compounds
- iii. Strategies for synthesis of three, four, five and six-membered ring

12Hrs

REFERENCES

1. “Advanced Organic chemistry, Reaction, mechanisms and structure”, J March, John Wiley and sons, New York.
2. “Mechanism and structure in organic chemistry”, ES Gould, Hold Rinchart and Winston, New York.
3. “Organic Chemistry” Clayden, Greeves, Warren and Wothers., Oxford University Press 2001.
4. “Organic Chemistry” Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5. A guide to mechanisms in Organic Chemistry – Peter Skyes (Orient Longman, New Delhi).
6. Reactive intermediates in organic chemistry – Tandon and Gowell.

7. Combinational Chemistry – Synthesis and applications – Stephen R Wilson & Anthony W Czarnik.
8. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
9. Organic synthesis-The disconnection approach, S. Warren, Wiley India
10. Principles of organic synthesis, R.C. Norman and J.M. Coxon, Nelson Thornes
11. Organic synthesis- Special techniques VK Ahluwalia and R Agarwal, Narosa Publishers
12. Organic reaction mechanisms IV edn, VK Ahluwalia and RK Parashar, Narosa Publishers

ADVANCED MEDICINAL CHEMISTRY (MPC102T)

Scope

The subject is designed to impart knowledge about recent advances in the field of medicinal chemistry at the molecular level including different techniques for the rational drug design.

Objectives

At completion of this course it is expected that students will be able to understand-

- Different stages of drug discovery
- Role of medicinal chemistry in drug research
- Different techniques for drug discovery
- Various strategies to design and develop new drug like molecules for biological targets
- Peptidomimetics

THEORY

60 Hrs

1. **Drug discovery:** Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets. Chemistry of prostaglandins, leukotrienes and thromboxones.

Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs antagonists, artificial enzymes.

12

Hrs

2. **Prodrug Design and Analog design:**

- **Prodrug design:** Basic concept, Carrier linked prodrugs/ Bioprecursors, Prodrugs of functional group, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.
- **Combating drug resistance:** Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance.

Hrs

- **Analog Design:** Introduction, Classical & Non classical, Bioisosteric replacement strategies, rigid analogs, alteration of chain branching, changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.

3 Chemistry of Synthetic drugs: Systematic study, SAR, Mechanism of action and synthesis of

new generation molecules of following class of drugs: Anti-hypertensive drugs, Psychoactive

drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors,

Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents.

Stereochemistry and Drug action: Realization that stereo selectivity is a pre-requisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug adsorption, metabolism, distribution and elimination.

12 Hrs

4. Rational Design of Enzyme Inhibitors: Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.

12 Hrs

5. Peptidomimetics: Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally.

Combinatorial chemistry and High throughput screening: Different techniques, Solid phase synthesis, Solution phase synthesis, Parallel synthesis, applications of combinatorial chemistry. High Throughput Screening- general outline, importance and application.

12

Hrs

REFERENCES:

1. Medicinal Chemistry by Burger.
2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry.
3. Comprehensive Medicinal Chemistry – Corwin and Hansch.
4. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

5. Introduction to Quantitative Drug Design by Y.C. Martin.
6. Principles of Medicinal Chemistry by William Foye.
7. Drug Design Volumes by Arienes.
8. Principles of Drug Design by Smith.
9. The Organic Chemistry of the Drug Design and Drug action by Richard B.Silverman.
10. An Introduction to Medicinal Chemistry –Graham L.Patrick, (III Edition.)
11. Biopharmaceutics and pharmacokinetics by DM.Brahmankar, Sunil B .Jaiswal.
12. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, First edition, Wiley publishers.

CHEMISTRY OF NATURAL PRODUCTS (MPC103T)

Scope

The subject is designed to provide detail knowledge about chemistry of medicinal compounds from natural origin and general methods of structural elucidation of such compounds. It also emphasizes on isolation, purification and characterization of medicinal compounds from natural origin.

Objectives

At completion of this course it is expected that students will be able to understand-

- Different types of natural compounds and their chemistry and medicinal importance
- The importance of natural compounds as lead molecules for new drug discovery
- The concept of rDNA technology tool for new drug discovery
- General methods of structural elucidation of compounds of natural origin
- Isolation, purification and characterization of simple chemical constituents from natural source

THEORY

60 Hrs

1. Study of Natural products as leads for new pharmaceuticals for the following class of drugs:

- a. Drugs Affecting the Central Nervous System: Morphine Alkaloids
- b. Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide
- c. Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol
- d. Neuromuscular Blocking Drugs: Curare alkaloids
- e. Chemistry of macrolid antibiotics: Erythromycine, Azithromycine, Cephalosporins(New generation)

12Hrs

2. Alkaloids- General introduction, classification, isolation, purification, stereochemistry, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation of ephedrine, morphine, ergot, emetine and reserpine.

Flavonoids. Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin.

12Hrs

3. Steroids- General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, Structure elucidation of

male & female sex hormones(testosterone, Estradial, progesterone), Adrenocortcoids (carsisone) and contraceptive agents.

Terpenoids – Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono, di and tri terpenoids, carotinoids.

12Hrs

4. Recombinant DNA technology and drug discovery:

rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation

Active constituent of certain crude drugs used in Indigenous system.

Diabetic therapy – *Gymnema sylvestre*, *Salacia reticulate*, *Pterocarpus marsupiam*, *Swertia chirata*, *Trigonella foenum graccum*; Liver dysfunction – *Phyllanthus niruri*; Antitumor – *Curcuma longa* Linn.

12Hrs

5. Structural Characterization of natural Products

Structural characterization of natural compounds using IR, ¹HNMR, ¹³CNMR and MS Spectroscopy

12Hrs

REFERENCES

1. Modern methods of plant analysis – Peech and M.V.Tracey.
2. Phytochemistry Vol. I and II by Miller, Jan Nostrant Rein Hld.
3. Recent advances in Phytochemistry Vol. I to IV – Scikel Runeckles.
4. Chemistry of natural products Vol I onwards IWPAC.
5. Natural Product Chemistry Nakanishi Gggolo.
6. Natural Product Chemistry “A laboratory guide” – Rapheal Khan.
7. The Alkaloid Chemistry and Physiology by THF Manske.
8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmannstall.
9. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall.
10. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal.
11. Organic Chemistry Vol I and II by I.L. Finar
12. Elements of Biotechnology by P.K. Gupta.
13. Pharmaceutical Biotechnology by S.P.Vyas and V.K.Dixit.
14. Biotechnology by Purohit and Mathoor.
15. Phytochemical methods of Harborne.
16. Burger’s Medicinal Chemistry.

PRACTICALS (MPC104P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer, RNA & DNA estimation
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

To perform the following reactions of synthetic importance

7. Purification of organic solvents, column chromatography
8. Claisen-schmidt reaction.
9. Benzylic acid rearrangement.
10. Beckmann rearrangement.
11. Hoffmann rearrangement
12. Mannich reaction
13. Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4 experiments)
14. Estimation of elements and functional groups in organic natural compounds
15. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, co-chromatographic technique for identification of isolated compounds and interpretation of UV and IR data.
16. Some typical degradation reactions to be carried on selected plant constituents

ADVANCED SPECTRAL ANALYSIS (MPC201T)

Scope

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, ATR-IR, DSC etc.

Objectives

At completion of this course it is expected that students will be able to understand-

- Interpretation of the NMR, Mass and IR spectra of various organic compounds
- Theoretical and practical skills of the hyphenated instruments
- Identification of organic compounds

THEORY

60Hrs

1. **UV and IR spectroscopy:** Woodward – Fieser rule for 1,3-butadienes, cyclic dienes and α , β -carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds.

1

2Hrs

2. **NMR spectroscopy:** 1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds.

12Hrs

3. **Mass Spectroscopy:** Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, McLafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds.

12Hrs

4. **Chromatography:** Principle, Instrumentation and Applications of the following:
a) GC-MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CE-MS g) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I-EC (Ion-Exclusion Chromatography)

k)

Flash

chromatography.

12Hrs

5. **Thermal methods of analysis** – Introduction, principle, instrumentation and application of DSC, DTA and TGA.

Raman Spectroscopy: Introduction, Principle, Instrumentation and Applications.

Radio immuno assay: Biological standardization , bioassay, ELISA,
Radioimmuno assay of digitalis and insulin

12Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

ADVANCED ORGANIC CHEMISTRY -II(MPC202T)

Scope

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Objectives

Upon completion of course, the student shall be able to understand

- The principles and applications of Green chemistry
- The concept of peptide chemistry.
- The various catalysts used in organic reactions
- The concept of stereochemistry and asymmetric synthesis.

THEORY

60 Hrs

1. Green Chemistry

- a. Introduction, principles of green chemistry
- b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis
- c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications
- d. Continuous flow reactors: Working principle, advantages and synthetic applications.

12Hrs

2. Chemistry of peptides

- a. Coupling reactions in peptide synthesis
- b. Principles of solid phase peptide synthesis, t-BOC and Fmoc protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides
- c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies
- d. Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, over-activation and side reactions of individual amino acids.

12Hrs

3. Photochemical Reactions

Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation

Pericyclic reactions

Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatropic rearrangement reactions with examples

12Hrs

4. Catalysis

- Types of catalysis, heterogeneous and homogeneous catalysis, advantages and disadvantages
- Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.
- Homogeneous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogeneous catalysis used in synthesis of drugs
- Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions
- Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.
- Phase transfer catalysis - theory and applications

12Hrs

5. Stereochemistry & Asymmetric Synthesis

- Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis-trans isomerism, E and Z notation.
- Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.

12Hrs

REFERENCES

- “Advanced Organic chemistry, Reaction, mechanisms and structure”, J March, John Wiley and sons, New York.
- “Mechanism and structure in organic chemistry”, ES Gould, Hold Rinchart and Winston, New York.

3. "Organic Chemistry" Clayden, Greeves, Warren and Wothers., Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
6. Organic synthesis-the disconnection approach, S. Warren, Wiley India
7. Principles of organic synthesis, R.C. Norman and J.M. Coxon, Nelson Thornes
8. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal, Narosa Publishers
9. Organic reaction mechanisms IV edn, VK Ahluwalia and RK Parashar, Narosa Publishers

COMPUTER AIDED DRUG DESIGN (MPC203T)

Scope

The subject is designed to impart knowledge on the current state of the art techniques involved in computer assisted drug design.

Objectives

At completion of this course it is expected that students will be able to understand-

- Role of CADD in drug discovery
- Different CADD techniques and their applications
- Various strategies to design and develop new drug like molecules.
- Working with molecular modeling softwares to design new drug molecules
- The *in silico* virtual screening protocols

Theory

60 Hrs

1. **Introduction to Computer Aided Drug Design (CADD):** History, different techniques and applications.

Quantitative Structure Activity Relationships: Basics

History and development of QSAR: Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equation and electronic parameters (sigma), lipophilicity effects and parameters (log P, pi-substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters.

12 Hrs

2. **Quantitative Structure Activity Relationships: Applications**

Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations.

3D-QSAR approaches and contour map analysis.

Statistical methods used in QSAR analysis and importance of statistical parameters.

12 Hrs

3. **Molecular Modeling and Docking**

a. Molecular and Quantum Mechanics in drug design

b. Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation

Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, choline esterase (AChE & BChE)

12 Hrs

4. **Molecular Properties and Drug Design**

a. Prediction and analysis of ADMET properties of new molecules and its importance in drug design.

- b. *De novo* drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design.
- c. Homology modeling and generation of 3D-structure of protein.

12 Hrs

5. Pharmacophore Mapping and Virtual Screening

Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping.

In Silico Drug Design and Virtual Screening Techniques

Similarity based methods and Pharmacophore based screening, structure based *in silico* virtual screening protocols.

12 Hrs

REFERENCES:

1. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore
2. Introduction to Quantitative Drug Design by Y.C. Martin.
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975.
4. Principles of Drug Design by Smith and Williams.
5. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman.
6. Medicinal Chemistry by Burger.
7. An Introduction to Medicinal Chemistry –Graham L. Patrick, (III Edition.)
8. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry.
9. Comprehensive Medicinal Chemistry – Corwin and Hansch.
10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

PHARMACEUTICAL PROCESS CHEMISTRY (MPC204T)

Scope

Process chemistry is often described as scale up reactions, taking them from small quantities created in the research lab to the larger quantities that are needed for further testing and then to even larger quantities required for commercial production. The goal of a process chemist is to develop synthetic routes that are safe, cost-effective, environmentally friendly, and efficient. The subject is designed to impart knowledge on the development and optimization of a synthetic route/s and the pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients (APIs) and new chemical entities (NCEs) for the drug development phase.

Objectives

At completion of this course it is expected that students will be able to understand-

- The strategies of scale up process of APIs and intermediates
- The various unit operations and various reactions in process chemistry

THEORY

60 Hrs

1. Process chemistry

- a. Introduction, Synthetic strategy
- b. Stages of scale up process: Bench, pilot and large scale process.
- c. In-process control and validation of large scale process.
- d. Case studies of some scale up process of APIs.
- e. Impurities in API, types and their sources including genotoxic impurities

12 Hrs

2. Unit operations

- a. *Extraction*: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.
- b. *Filtration*: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,
- c. *Distillation*: azeotropic and steam distillation
- d. *Evaporation*: Types of evaporators, factors affecting evaporation.
- e. *Crystallization*: Crystallization from aqueous, non-aqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.

12 Hrs

3. Unit Processes

- a. **Nitration:** Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration,
- b. **Halogenation:** Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process.
- c. **Oxidation:** Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H_2O_2 , sodium hypochlorite, Oxygen gas, ozonolysis.

12 Hrs

4. Unit Processes

- a. **Reduction:** Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.
- b. **Fermentation:** Aerobic and anaerobic fermentation. Production of
 - i. Antibiotics; Penicillin and Streptomycin,
 - ii. Vitamins: B2 and B12
 - iii. Statins: lovastatin, simvastatin

Reaction progress kinetic analysis

- a. Streamlining reaction steps, route selection,
- b. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.

12 Hrs

5. Industrial Safety

- a. MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE)
- b. Fire hazards, types of fire & fire extinguishers
- c. Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001 (Environmental Management System), Effluents and its management

12 Hrs

REFERENCES:

1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever-Changing Climate-An Overview; K. Gadamasetti
2. Pharmaceutical Manufacturing Encyclopedia, 3rd edition, Volume 2.
3. Medicinal Chemistry by Burger, 6th edition, Volume 1-8.

4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7th edition, McGraw Hill
5. Polymorphism in Pharmaceutical Solids .Dekker Series Volume 95 Ed: H G Brittain (1999)
6. Regina M. Murphy: Introduction to Chemical Processes: Principles, Analysis, Synthesis
7. Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up
8. P.H.Groggins: Unit processes in organic synthesis (MGH)
9. F.A.Henglein: Chemical Technology (Pergamon)
10. M.Gopal: Dryden's Outlines of Chemical Technology
11. Clausen,Mattson: Principle of Industrial Chemistry
12. Lowenheim & M.K. Moran: Industrial Chemicals
13. S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II
14. J.K. Stille: Industrial Organic Chemistry (PH)
15. Srreva: Chemical Proccess
16. B.K.Sharma: Industrial Chemistry
17. ICH Guidelines
18. United States Food and Drug Administration official website www.fda.gov

PRACTICALS (MPC205P)

1. Synthesis of organic compounds by adapting different approaches involving (3 experiments)
 - a. Oxidation
 - b. Reduction/hydrogenation
 - c. Nitration
2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)
3. Assignments on regulatory requirements in API (2 experiments)
4. Comparison of absorption spectra by UV and Woodward – Fieser rule
5. Interpretation of organic compounds by FT-IR
6. Interpretation of organic compounds by NMR
7. Interpretation of organic compounds by MS
8. Determination of purity by DSC in pharmaceuticals
9. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
10. To carry out the preparation of following organic compounds
11. Preparation of 4-chlorobenzhydrylpiperazine. (an intermediate for cetirizine HCl).
12. Preparation of 4-iodotoluene from p-toluidine.
13. NaBH₄ reduction of vanillin to vanillyl alcohol
14. Preparation of umbelliferone by Pechmann reaction
15. Preparation of triphenyl imidazole
16. To perform the Microwave irradiated reactions of synthetic importance (Any two)
17. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using softwares
18. Calculation of ADMET properties of drug molecules and its analysis using softwares
Pharmacophore modeling
19. 2D-QSAR based experiments
20. 3D-QSAR based experiments
- 21. Docking study**
- 22. Virtual screening based experiment**

PHARMACOLOGY

(MPC)

SEMISTER I

1. MODERN PHARMACEUTICAL ANALYSIS
2. ADVANCED PHARMACOLOGY-I
3. PHARMACOLOGICAL AND TOXICOLOGICAL
SCREENING METHODS-I
4. CELLULAR AND MOLECULAR PHARMACOLOGY

Practicals

SEMISTER I

1. ADVANCED PHARMACOLOGY-II
2. TOXICOLOGICAL SCREENING METHODS
3. PRINCIPLES OF DRUG DISCOVERY
4. CLINICAL RESEARCH AND PHARMACOVIGILANCE
5. EXPERIMENTAL PHARMACOLOGY-II

Practicals

*Soft skills should be added in research methodology and biostatistics paper in semester III

*Practical in Modern pharmaceutical with emphasis on analysis case study

MODERN PHARMACEUTICAL ANALYSIS (MPA101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know,

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills

THEORY HOURS

60

1. **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. **12 Hrs**
IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy
Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.
2. **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy. **12 Hrs**
3. **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy **12 Hrs**

- 4 Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: **12 Hrs**
a) Paper chromatography b) Thin Layer chromatography
c) Ion exchange chromatography d) Column chromatography
e) Gas chromatography f) High Performance Liquid chromatography
g) Affinity chromatography
- 5 Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: **12 Hrs**
a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
- X ray Crystallography:** Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

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ADVANCED PHARMACOLOGY-I (MPL101T)

Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved

Objectives

Upon completion of the course the student shall be able to:

- Discuss the pathophysiology and pharmacotherapy of certain diseases
- Explain the mechanism of drug actions at cellular and molecular level
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

THEORY

60

HOURS

UNIT-I

General Pharmacology

12 Hrs

- a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding. 06 hrs
- b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects. 06 hrs

UNIT-II

12 Hrs

Neurotransmission

06 Hrs

- a. General aspects and steps involved in neurotransmission.
- b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline).
- c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine).
- d. Non adrenergic non cholinergic transmission (NANC). Co-transmission

Systemic Pharmacology

06 Hrs

A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems

a. Autonomic Pharmacology

Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

UNIT-III**12 Hrs****Central nervous system Pharmacology**

General and local anesthetics	02 hrs
Sedatives and hypnotics, drugs used to treat anxiety.	02 hrs
Depression, psychosis, mania, epilepsy, neurodegenerative diseases.	05 hrs
Narcotic and non-narcotic analgesics.	03 hrs

UNIT-IV**Cardiovascular Pharmacology****12 Hrs**

Diuretics, antihypertensives, antiischemics, anti-arrhythmics, drugs for heart failure and hyperlipidemia.	07 hrs
Hematinics, coagulants, anticoagulants, fibrinolytics and anti-platelet drugs	05 hrs

UNIT- V**Autocoid Pharmacology****12 Hrs**

The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids.	08 hrs
Pharmacology of antihistamines, 5HT antagonists.	04 hrs

REFEERENCES

1. The Pharmacological basis of therapeutics- Goodman and Gill man's
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G -Katzung
4. Pharmacology by H.P. Rang and M.M. Dale.
6. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-I (MPL102T)

Scope

This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various *in-vitro* and *in-vivo* preclinical evaluation processes

Objectives

Upon completion of the course the student shall be able to,

- Appraise the regulations and ethical requirement for the usage of experimental animals.
- Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
- Describe the various newer screening methods involved in the drug discovery process
- Appreciate and correlate the preclinical data to humans

THEORY HOURS

60

Unit-I

12 Hrs

Laboratory Animals

Common lab animals: Description, handling and applications of different species and strains of animals.

02 hrs

Transgenic animals: Production, maintenance and applications

02 hrs

Anaesthesia and euthanasia of experimental animals.

03 hrs

Maintenance and breeding of laboratory animals.

02 hrs

CPCSEA guidelines to conduct experiments on animals

02 hrs

Good laboratory practice.

01 hrs

Unit-II

12 Hrs

Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models.

General principles of preclinical screening. CNS Pharmacology: behavioral and muscle coordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics

and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.

Unit-III

12 Hrs

Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models.

Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergies.

Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti -emetic, anti-diarrheal and laxatives.

Unit-IV

12 hrs

Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models.

Cardiovascular Pharmacology: antihypertensives, antiarrhythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antihyperlipidemic, and agents. Anti cancer agents

Unit V

12 hrs

Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models.

Immunosuppressants and immunomodulators 02 hrs

General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin

08 hrs

Limitations of animal experimentation and alternate animal experiments. 01 hr

Extrapolation of *in vitro* data to preclinical and preclinical to humans. 01 hr

REFERENCES

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Indian Pharmacopeia and other Pharmacopeias
3. Screening methods in Pharmacology by Robert Turner. A
4. Evaluation of drugs activities by Laurence and Bachrach

5. Methods in Pharmacology by Arnold Schwartz.
6. Fundamentals of experimental Pharmacology by M.N.Ghosh
7. Pharmacological experiment on intact preparations by Churchill Livingstone
8. Drug discovery and Evaluation by Vogel H.G.
9. Experimental Pharmacology by R.K.Goyal.
10. Preclinical evaluation of new drugs by S.K. Gupta

CELLULAR AND MOLECULAR PHARMACOLOGY (MPL103T)

Scope:

The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process

Objectives:

Upon completion of the course, the student shall be able to,

- Explain the receptor signal transduction processes.
- Explain the molecular pathways affected by drugs.
- Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
- Demonstrate molecular biology techniques as applicable for pharmacology

Unit I

12 Hrs

Cell biology

Structure and functions of cell and its organelles

Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing

Cell cycles and its regulation.

Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis.

Necrosis and autophagy.

Unit II

12Hrs

Cell signaling

Intercellular and intracellular signaling pathways.

Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors.

Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol.

Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

Unit III

12Hrs

Principles and applications of genomic and proteomic tools

06 hrs

DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting,

Recombinant DNA technology and gene therapy **06 hrs**

Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology.

Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy

Unit IV

12Hrs

Pharmacogenomics

08 hrs

Gene mapping and cloning of disease gene.

Genetic variation and its role in health/ pharmacology

Polymorphisms affecting drug metabolism

Genetic variation in drug transporters

Genetic variation in G protein coupled receptors

Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics

Immunotherapeutics

04 hrs

Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice

Unit V

12Hrs

Cell culture techniques

Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application.

Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays

Principles and applications of flow cytometry

Unit VI

Biosimilars

References:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong

3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et la.

Experimental Pharmacology- I (MPL104P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

Handling of laboratory animals.

1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Bradford/Lowry's in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based *in-vitro* assays (MPO, AChEs, α amylase, α glucosidase).
16. Cell viability assays (MTT/Trypan blue/SRB).
17. DNA fragmentation assay by agarose gel electrophoresis.

18. DNA damage study by Comet assay.
19. Apoptosis determination by fluorescent imaging studies.
20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
21. Enzyme inhibition and induction activity
22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

References

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds - Robert M Silverstein,
6. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman,
7. Vogel's Text book of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney,
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille
9. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)

ADVANCED PHARMACOLOGY-II (MPL201T)

Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, the subject helps the student to understand the concepts of drug action and mechanism involved

Objectives

Upon completion of the course the student shall be able to:

- Explain the mechanism of drug actions at cellular and molecular level
- Discuss the Pathophysiology and pharmacotherapy of certain diseases
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

UNIT-I

Endocrine Pharmacology

12 Hrs

Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones

Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation

UNIT-II

Chemotherapy

12 Hrs

Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as β -lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.

UNIT-III

12 Hrs

Chemotherapy

06 Hrs

Drugs used in Protozoal Infections

Drugs used in the treatment of Helminthiasis

Chemotherapy of cancer

Immunopharmacology

06 Hrs

Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD.

Immunosuppressants and Immunostimulants

UNIT-IV

GIT Pharmacology

08 Hrs

Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome.

Chronopharmacology

04 Hrs

Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer

UNIT-V

Free radicals Pharmacology

04 Hrs

Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer.

Protective activity of certain important antioxidant

Recent Advances in Treatment:

08 Hrs

Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus

References

1. The Pharmacological basis of therapeutics- Goodman and Gilman's
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G -Katzung
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists

TOXICOLOGICAL SCREENING METHODS (MPL202T)

Scope:

The subject imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

Objectives:

Upon completion of the course, the student shall be able to,

- Explain the various types of toxicity studies.
- Appreciate the importance of ethical and regulatory requirements for toxicity studies.
- Demonstrate the practical skills required to conduct the preclinical toxicity studies.

Unit I

12 Hrs

Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive)
Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y
OECD principles of Good laboratory practice (GLP)
History, concept and its importance in drug development

Unit II

12 Hrs

Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines.
Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.
Test item characterization- importance and methods in regulatory toxicology studies

Unit III

12 Hrs

Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenicity studies (segment II)
Genotoxicity studies (Ames Test, *in vitro* and *in vivo* Micronucleus and Chromosomal aberrations studies)
In vivo carcinogenicity studies

Unit IV

12 Hrs

IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission.
Safety pharmacology studies- origin, concepts and importance of safety pharmacology.
Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies

Unit V**12 Hrs**

Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics
Importance and applications of toxicokinetic studies.
Alternative methods to animal toxicity testing.

REFERENCES

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (<http://www.who.int/tdr/publications/documents/glp-handbook.pdf>).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan
5. OECD test guidelines.
6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf>)

PRINCIPLES OF DRUG DISCOVERY (MPL203T)

Scope:

The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

Objectives:

Upon completion of the course, the student shall be able to,

- Explain the various stages of drug discovery.
- Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery
- Explain various targets for drug discovery.
- Explain various lead seeking method and lead optimization
- Appreciate the importance of the role of computer aided drug design in drug discovery

Unit-I

12 Hrs

An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery.

Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

Unit-II

12 Hrs

Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification.

Protein structure

Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction

Unit-III

12 Hrs

Rational Drug Design

Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches

Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

Unit-IV**12 Hrs**

Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design.

Quantitative analysis of Structure Activity Relationship

History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.

Unit-V**12 Hrs**

QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA

Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design

References

1. MouldySioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott MarkellIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., Hoboken, New Jeney.

CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL204T)

Scope:

This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials.

This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

Objectives:

Upon completion of the course, the student shall be able to,

- Explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance

UNIT-I hours

12

Regulatory Perspectives of Clinical Trials:

Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines

Ethical Committee- Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR

Informed Consent Process: Structure and content of an Informed Consent Process
Ethical principles governing informed consent process

UNIT- II hours

12

Clinical Trials: Types and Design

Experimental Study- RCT and Non RCT,

Observation Study: Cohort, Case Control, Cross sectional

Clinical Trial Study Team

Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management

UNIT- III
hours**12**

Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT

Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.

UNIT-IV
hours**12****Basic aspects, terminologies and establishment of pharmacovigilance**

History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance

UNIT-V**12 hours****Methods, ADR reporting and tools used in Pharmacovigilance**

International classification of diseases, International Non-proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, Vigiflow, Statistical methods for evaluating medication safety data.

UNIT-VI

Pharmacoeconomics, Dermatology, pharmacoeconomics, safety pharmacology

References:

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

Experimental Pharmacology-II (MPL205P)

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of PA_2 values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial.
17. Protocol design for clinical trial.
18. Protocol design for clinical trial.
19. Design of ADR monitoring protocol.

20. In silico docking studies.
21. In silico pharmacophore based screening.
22. In silico QSAR studies.
23. ADR reporting
24. In silico docking studies.

References

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. Text book of *in-vitro* practical Pharmacology by Ian Kitchen
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and William Thomsen
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

M. PHARM. PHARMACOGNOSY (MPG)

ADVANCED PHARMACOGNOSY-1 (MPG101 T)

SCOPE:

To learn and understand the advances in the field of cultivation and isolation of drugs of natural origin, various phytopharmaceuticals, nutraceuticals and their medicinal use and health benefits.

OBJECTIVES:

Upon completion of the course, the student shall be able to

1. Know the advances in the cultivation and production of drugs
2. Know the various phyto-pharmaceuticals and their source & utilization and medicinal value.
3. Know the various nutraceuticals/herbs and their health benefits

Course Description

THEORY

60

Hours

1. Plant drug cultivation: General introduction to the importance of Pharmacognosy in herbal drug industry, Indian Council of Agricultural Research, Current good agricultural practices, Current good cultivation practices, Current good collection practices, Conservation of medicinal plants- *Ex-situ* and *In-situ* conservation of medicinal plants.

12 Hrs

2. Marine natural products: General methods of isolation and purification, Study of Marine toxins, Recent advances in research in marine drugs, Problems faced in research on marine drugs such as taxonomical identification, chemical screening and their solution.

12 Hrs

3. Nutraceuticals: Current trends and future scope, Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibres, Cereals and grains, Health drinks from natural origin, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods, Formulation and standardization of nutraceuticals, Regulatory aspects, FSSAI guidelines, Sources, name of marker compounds and their chemical nature, medicinal uses and health benefits of following

i) Spirulina ii) Soya bean iii) Ginseng iv) Garlic v) Broccoli vi) Green and Herbal Tea vii) Flax seeds viii) Black cohosh ix) Turmeric.

12 Hrs

4. Phytopharmaceuticals: Occurrence, isolation and characteristic features (Chemical nature, uses in pharmacy, medicinal and health benefits) of following.

- a) Carotenoids – i) α and β - Carotene ii) Xanthophyll (Lutein)
- b) Limonoids – i) d-Limonene ii) α – Terpineol
- c) Saponins – i) Shatavarins
- d) Flavonoids – i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin
- e) Phenolic acids- Ellagic acid
- f) Tocotrienols and Tocopherols
- g) Andrographolide, glycolipids, guggulipids, withanolides, vascine, taxol **12 Hrs**

5. Pharmacovigilance of drugs of natural origin: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for biodrug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. **12 Hrs**

REFERENCES:

- 1) Cultivation of medicinal and aromatic crops, 1st edition, by AA Farooqui and B.S. Sreeramu. University Press, 2001.
- 2) Medicinal natural products (a biosynthetic approach), 1st edition, by Paul M. Dewick, John Wiley & Sons Ltd., England, 1998.
- 3) Natural Products from Plants, 1st edition, by Peter B. Kaufman, CRC Press, New York, 1998
- 4) Glimpses of Indian Ethano Pharmacology by P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute, 1995.
- 5) Natural products: A lab guide by Raphael Ikan , 2nd Edition, Academic Press 1991.
- 6) Pharmacognosy - G. E. Trease and W.C. Evans. 15th Edition W.B. Saunders Edinburgh, New York.
- 7) Pharmacognosy-Tyler, Brady, Robbers
- 8) Modern Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
- 9) Recent Advances in Phytochemistry- Vol. 1&4: Scikel Runeckles- Appleton Century crofts.
- 10) Chemistry of Marine Natural Products- Paul J. Schewer 1973.
- 11) Marine Natural Products-Vol.I to IV.
- 12) Cultivation of Medicinal Plants by C.K. Atal & B.M. Kapoor.
- 13) Cultivation and Utilization of Aromatic Plants By C.K. Atal & B.M. Kapoor

- 14) Herbal Drug Industry by RD. Choudhary, 1st edition, Eastern Publisher, New Delhi, 1996.
- 15) Text book of Pharmacognosy by C.K.Kokate, Purohit, Ghokhale, 4th edition, Nirali Prakasshan, 1996.
- 16) Pharmacognosy and Pharmacobiotechnology by Ashutoshkar, New Age Publications, New Delhi.
- 17) Text Book of Pharmacognosy by T.E. Wallis

PHYTOCHEMISTRY (MPG102T)

Scope:

Students shall be equipped with the knowledge of natural product drug discovery and will be able to isolate, identify the extract and phyto-constituents

Objectives:

Upon completion of the course, the student shall be able to

1. know the different classes of phytoconstituents and their properties and general process of natural product drug discovery
2. know the process isolation, purification and identification of phytoconstituents

THEORY

60 Hrs

1. **Biosynthetic pathways and Radio tracing techniques:** Constituents & their Biosynthesis, Isolation, Characterization and purification with a special reference to their importance in herbal industries of following phyto-pharmaceuticals containing drugs:

- a) Alkaloids: Ephedrine, Quinine, Strychnine, Piperine, Berberine, Taxol, Vincaalkaloids.
- b) Glycosides: Digitoxin, Glycyrrhizin, Sennosides, Bacosides, Ginsenosides, Quercetin, Rutin.
- c) Steroids: Hecogenin, guggulosterone and withanolides
- d) Coumarin: Umbelliferone.
- e) Terpenoids: Cucurbitacins
- f) Carotenoids: Lycopene, β -carotene.
- g) Camphor, Menthol, Eugenol.

12 Hrs

2. **Drug discovery and development:** History of herbs as source of drugs and drug discovery, the lead structure selection process, structure development, product discovery process and drug registration, Selection and optimization of lead compounds with suitable examples from anticancer, CNS cardiovascular drugs, antitubercular drugs and immunomodulators, Clinical studies emphasis on phase of clinical trials, protocol design for lead molecules.

12 Hrs

- 3. Extraction and Phytochemical studies:** Recent advances in extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used like microwave assisted extraction, and method of fractionation. Detection of different classes of phytoconstituents by latest CCCET, SCFE techniques including preparative HPLC and Flash column chromatography, AAS.

12 Hrs

- 4. Phytochemical finger printing:** HPTLC and LCMS/GCMS characterization of extracts containing alkaloids, saponins, glycosides and flavanoids.

12 Hrs

- 5. Pharmacological screening:** In vitro, In vivo screening techniques with reference to antiglycomerate, analgesics, antidiabetic, antilipidemic, anticancer, antiulcer, antiviral, antipsychotic, antilithiatic, Toxicity studies as per OECD guidelines, acute, chronic and clinical toxicity.

12 Hrs

REFERENCES:

- 1) Organic chemistry by I.L. Finar Vol.II
- 2) Pharmacognosy by Trease and Evans, ELBS.
- 3) Pharmacognosy by Tylor and Brady.
- 4) Text book of Pharmacognosy by Wallis.
- 5) Clark's isolation and Identification of drugs by A.C. Mottal.
- 6) Plant Drug Analysis by Wagner & Bladt.
- 7) Wilson and Gisvolds text book of Organic Medicinnal and Pharmaceutical Chemistry by Deorge. R.F.
- 8) The Chemistry of Natural Products, Edited by R.H. Thomson, Springer International Edn. 1994.
- 9) Natural Products Chemistry Practical Manual by Anees A Siddiqui and SeemiSiddiqui
- 10) Organic Chemistry of Natural Products, Vol. 1&2. Gurdeep R Chatwal.
- 11) Chemistry of Natural Products- Vol. 1 onwards IWPAC.
- 12) Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II

INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY (MPG103T)

Scope:

To understand the Industrial and commercial potential of herbal drugs and drugs of natural origin, integrate traditional medicines and systems of India with modern medicine and also to know regulatory and quality policy for the trade of herbals and drugs of natural origin.

Objective:

By the end of the course the student shall be able to:-

1. Know the requirements for setting up the herbal/natural drug industry.
2. To know and understand the guidelines for quality of herbal/natural medicines and regulatory issues.
3. To know patenting/IPR of herbals/natural drugs and trade of raw and finished materials.

THEORY

60Hrs

1. **Herbal drug industry:** Infrastructure of herbal drug industry involved in production of standardized extracts and various dosage forms. Current challenges in upgrading and modernization of herbal formulations. Entrepreneurship Development, Project selection, project report, technical knowledge, Capital venture, plant design, layout and construction. Pilot plant scale –up techniques, case studies of herbal extracts. Formulation production management.

12 Hrs

2. **Regulatory requirements for setting herbal drug industry:** Global marketing management. Indian and international patent law as applicable herbal drugs and natural products.
Export –import (EXIM) policy, TRIPS, IPR.
Quality assurance in herbal/natural drug products.
Concepts of TDM, GMP, GLP, ISO-9000.

12Hrs

3. **Monographs of herbal drugs:** Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic pharmacopoeia, American herbal pharmacopoeia, British herbal pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

12 Hrs

4. **Testing of natural products and drugs:** Effect of herbal medicines on clinical laboratory testing. Regulation and dispensing of herbal drugs. Stability testing of

natural
12 Hrs

products,

protocols.

- 5. Patents:** Indian and international patent laws, proposed amendments as applicable to herbal/natural products and process. Geographical indication, Copyright, Patentable subject matters, novelty, non obviousness, utility, enablement and best mode, procedure for Indian patent filing, patent processing, grant of patents, rights of patents, cases of patents, opposition and revocation of patents, patent search and literature, Controllers of patents.

12 Hrs

REFERENCES:

1. Herbal drug industry by R.D. Choudhary (1996), 1st Edn, Eastern Publisher, New Delhi.
2. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee (2003), 1st Edition, Business horizons Robert Verpoorte, New Delhi.
3. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.
4. The complete technology book on herbal perfumes and cosmetics, by H.Pande, National Institute of Industrial Research, Delhi.
5. Quality control of herbal drugs by Pulok K Mukarjee (2002), 1st Edition, Business Horizons Pharmaceutical Publisher, New Delhi.
6. PDR for Herbal Medicines (2000), 2nd Edition, Medicinal Economic Company, New Jersey.
7. Indian Herbal Pharmacopoeia (2002), Revised Edition, 1DMA, Mumbai.
8. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (1996), 4th Edition, Nirali Prakashan, New Delhi.
9. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI (2002), Part I & II, Career Publication, Nasik, India.
10. Plant drug analysis by H.Wagner and S.Bladt, 2nd edition, Springer, Berlin.
11. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern Publisher, New Delhi.
12. Phytochemical Dictionary. Handbook of Bioactive Compounds from Plants by J.B.Harborne, (1999), IInd Edition, Taylor and Francis Ltd, UK.
13. Herbal Medicine. Expanded Commission E Monographs by M.Blumenthal, (2004), 1ST Edition,
14. Drug Formulation Manual by D.P.S.Kohli and D.H.Shah (1998), II Edition, Eastern Publisher, New Delhi.

PRACTICALS (MPGI04P)

1. Analysis of pharmacopoeial compounds of natural origin and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Analysis of recorded spectra of simple phytoconstituents
4. Experiments based on Gas Chromatography
5. Estimation of sodium/potassium by flame photometry
6. Development of fingerprint of selected medicinal plant extracts commonly used in herbal drug industry viz. ashwagandha, tulsi, bael, amla, ginger, aloe, vidang, senna, lawsonia by HPTLC method
7. Method of extraction
8. Phytochemical screening
9. Thin layer chromatography
10. Demonstration of HPLC- estimation of glycyrrhizin
11. Monograph analysis of clove oil
12. Monograph analysis of castor oil.
13. Identification of bioactive constituents from plant extracts
14. Formulation using qualitative and quantitative methods.

MEDICINAL PLANT BIOTECHNOLOGY (MPG201T)

Scope

To explore the knowledge of Biotechnology and its application in the improvement of quality of medicinal plants

Objectives

Upon completion of the course, the student shall be able to

- Know the process like genetic engineering in medicinal plants for higher yield of Phytopharmaceuticals.
- Use the biotechnological techniques for obtaining and improving the quality of natural products/medicinal plants

THEORY

60Hrs

1. **Introduction to Plant biotechnology:** Historical perspectives, prospects for development of plant biotechnology as a source of medicinal agents. Applications in pharmacy and allied fields. Genetic and molecular biology as applied to pharmacognosy, study of DNA, RNA and protein replication, genetic code, regulation of gene expression, structure and complicity of genome, cell signaling, DNA recombinant technology.

1

2 Hrs

2. **Different tissue culture techniques:** Organogenesis and embryogenesis, synthetic seed and monoclonal variation, Protoplast fusion, Hairy root multiple shoot cultures and their applications. Micro propagation of medicinal and aromatic plants. Sterilization methods involved in tissue culture, gene transfer in plants and their applications.

12 Hrs

3. **Immobilisation techniques & Secondary Metabolite Production:** Immobilization techniques of plant cell and its application on secondary metabolite Production. Cloning of plant cell: Different methods of cloning and its applications. Advantages and disadvantages of plant cell cloning. Secondary metabolism in tissue cultures with emphasis on production of medicinal agents. Precursors and elicitors on production of secondary metabolites.

12 Hrs

4. **Biotransformation and Transgenesis:** Biotransformation, bioreactors for pilot and large scale cultures of plant cells and retention of biosynthetic potential in cell

culture. Transgenic plants, methods used in gene identification, localization and sequencing of genes. Application of PCR in plant genome analysis.

12 Hrs

- 5. Fermentation technology:** Application of Fermentation technology, Production of ergot alkaloids, single cell proteins, enzymes of pharmaceutical interest.

12 Hrs

REFERENCES:

1. Plant tissue culture – Bhagwani, Vol 5. (Elsevier)
2. Plant cell and Tissue Culture (Lab. Manual) – J.R.M.M. Yeoman.
3. Elements in biotechnology by P. K. Gupta.
4. An introduction to plant tissue culture by M. K. Razdan.
5. Experiments in plant tissue culture by John H. D and Lorin W. R.
6. Pharmaceutical biotechnology by S. P. Vyas and V. K. Dixit.
7. Plant cell and tissue culture by Jeffrey W. Pollard and John M Walker.
8. Plant tissue culture by Dixon, Oxford Washington DC, 1985
9. Plant tissue culture by Street.
10. Pharmacognosy by G. E. Trease and W. C. Evans.
11. Biotechnology by Purohit and Mathur.
12. Biotechnological applications to tissue culture by Shargool.
13. Pharmacognosy by Virroo E. Tyler, Lynn R. Brady and James E. Robberrt.

ADVANCED PHARMACOGNOSY-II (MPG202T)

Scope:

To know and understand the Adulteration and Deterioration that occurs in herbal/natural drugs and methods of detection of the same. Study of herbal remedies and their validations, including methods of screening

Objectives

Upon completion of the course, the student shall be able to

- Know the validation of herbal remedies
- Know the methods of detection of adulteration and evaluation techniques for the herbal drugs
- To know the methods of screening of herbals for various biological properties

THEORY

60Hrs

1. **Herbal remedies – Toxicity and Regulations:** Herbals vs Conventional drugs, Efficacy of Herbal medicine products, Validation of herbal therapies, Pharmacodynamic and Pharmacokinetic issues.

12 Hrs

2. **Adulteration and Deterioration:** Introduction, Types of Adulteration/ Substitution of Herbal drugs, Causes and Measures of Adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phytotoxin, microbial contamination in herbs fruital formulation.

12 Hrs

3. **Ethnobotany and Ethnopharmacology:** Ethnobotany in herbal drug evaluation, Impact of Ethnobotany in traditional medicine, New development in herbals, Bio-prospecting tools for drug discovery, Role of Ethnopharmacology in drug evaluation, Reverse Pharmacology.

12 Hrs

4. **Analytical Profiles of herbal drugs:** *Andrographis paniculata*, *Boswellia serata*, *Coleus forskholii*, *Curcuma longa*, *Embelica officinalis*, *Psoralea corylifolia*.

12 Hrs

5. **Biological screening of herbal drugs:** Introduction and Need for Phyto-Pharmacological Screening, New Strategies for evaluating Natural Products, *In vitro* evaluation techniques for Antioxidants, Antimicrobial and Anticancer drugs. *In vivo* evaluation techniques for Anti-inflammatory, Antiulcer, Anticancer,

Wound healing, Antidiabetic, Hepatoprotective, Cardio protective, Diuretics and Antifertility.
12 Hrs

REFERENCES:

1. Glimpses of Indian Ethano Pharmacology by P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute, 1995.
2. Natural products: A lab guide by Raphael Ikan , 2nd Edition, Academic Press 1991.
3. Pharmacognosy - G. E. Trease and W.C. Evans. 15th Edition W.B. Saunders Edinburgh, New York.
4. Pharmacognosy-Tyler, Brady, Robbers
5. Modern Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
6. Herbal Drug Industry by RD. Choudhary, 1st edition, Eastern Publisher, New Delhi, 1996.
7. Text book of Pharmacognosy by C.K.Kokate, Purohit, Ghokhale, 4th edition, Nirali Prakasshan, 1996.
8. Text Book of Pharmacognosy by T.E. Wallis
9. Quality control of herbal drugs by Pulok K Mukarjee (2002), 1st Edition, Business Horizons Pharmaceutical Publisher, New Delhi.
10. Indian Herbal Pharmacopoeia (2002), Revised Edition, IDMA, Mumbai.
11. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI (2002), Part I & II, Career Publication, Nasik, India.
12. Plant drug analysis by H.Wagner and S.Bladt, 2nd edition, Springer, Berlin.
13. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern Publisher, New Delhi.
14. Herbal Medicine. Expanded Commission E Monographs by M.Blumenthal, (2004), IST Edition,

INDIAN SYSTEMS OF MEDICINE (MPG203T)

Scope

To make the students understand thoroughly on principles, preparations of medicines of various Indian systems of medicine like Ayurveda, Siddha, Homeopathy and Unani. Also focusing on clinical research of traditional medicines, quality assurance and challenges in monitoring the safety of herbal medicines.

Objective

After completion of the course, student is able to

- To understand the basic principles of various Indian systems of medicine
- To know the clinical research of traditional medicines, Current Good Manufacturing Practice of Indian systems of medicine and formulation.

THEORY

60Hrs

1. Fundamental concepts of Ayurveda, Siddha, Unani, and Homoeopathy systems of medicine:

Different dosage forms of the ISM-

Ayurveda: Chronological development of Charak Samhita, Sushrut Samhita and Kashyapa Samhita. Ayurvedic Pharmacopoeia Analysis of Ayurvedic Formulations and crude drugs with references to: Identity, purity and quality of crude drugs.

Siddha: Gunapadam (Siddha Pharmacology), raw drugs/Dhatu/Jeevam in siddha system of medicine, Purification process (Suddhi).

12Hrs

2. Naturopathy, Yoga and Aromatherapy practices:

a) Naturopathy - Introduction, basic principles and treatment modalities.

b) Yoga - Introduction and Streams of Yoga. Asanas, Pranayama, Meditations and Relaxation techniques.

c) Aromatherapy – Introduction, aroma oils for common problems, carrier oils.

12 Hrs

3. Formulation development of various systems of medicine: Salient features of the techniques of preparation of some of the important class of Formulations as per Ayurveda, Siddha, Homeopathy and Unani Pharmacopoeia and texts. Standardization,

Shelf life and Stability studies of ISM formulations.

12 Hrs

4. Schedule T – Good Manufacturing Practice of Indian systems of medicine:

Components of GMP (Schedule – T) and its objectives, Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.

Quality assurance in herbal drug industry of GAP, GMP and GLP in traditional system of medicine. Preparation of documents for new drug application and export registration.

Challenges in monitoring the safety of herbal medicines: Regulation, quality assurance and control, National/regional pharmacopoeias.

12 Hrs

5. TKDL, Geographical indication skill, Government skills in AYUSH, ISM, CCRAS, CCRS, CCRH, CCRU.

12 Hrs

REFERENCES:

1. Ayurvedic Pharmacopoeia (2004), The Controller of Publications, Civil Lines, Govt. of India, New Delhi.
2. Hand Book on Ayurvedic Medicines by H.Panda National Institute of Industrial Research, New Delhi.
3. Ayurvedic System of Medicine by Kaviraj Nagendranath Sengupata (1998), 2nd Revised Edition, Sri Satguru Publications, New Delhi.
4. Ayurvedic Pharmacopoeia. Formulary of Ayurvedic Medicines (2000), IMCOPS, Chennai.
5. Homeopathic Pharmacopoeia. Formulary of Homeopathic Medicines (2004), IMCOPS, Chennai.
6. Homeopathic Pharmacy An introduction & Hand book by Steven B. Kayne (1997), Churchill Livingstone, New York.
7. Indian Herbal Pharmacopoeia (2002), Revised Edition, IDMA, Mumbai.
8. British Herbal Pharmacopoeia British (1990), Herbal Medicine Association, UK.
9. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee (2003), First edition, Business Horizons, New Delhi.
10. Indian System of Medicine and Homeopathy in India (2001), Planning and Evaluation Cell, Govt.of India, New Delhi.
11. Essential of Food and Nutrition by Swaminathan (1999), Bappco, Bangalore.
12. Clinical Dietitics and Nutrition by F.P. Antia (1997), 4th Edi, Oxford Universith Press, Delhi.
13. Yoga- The Science of Holistic Living by V.K.Yoga (2005), Vivekananda Yoga Prakashna Publishing, Bangalore.

HERBAL COSMETICS (MPG204T)

Scope

This subject deals with the study of preparation and standardization of herbal/natural cosmetics. This subject gives emphasis to various national and international standards prescribed regarding Drug and cosmetic act.

Objective

After completion of the course, student is able to

- Understand the basic principles of various herbal/natural cosmetic preparations
- Current Good Manufacturing Practices of herbal/natural cosmetics as per the regulatory authorities

THEORY

60Hrs

1. **Introduction:** Herbal/natural cosmetics, Classification & Economic aspects.
Regulatory Provisions relation to manufacture of cosmetics: - License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics.

12 Hrs

2. **Herbal Cosmetics for the skin:** Physiology and chemistry of skin and pigmentation, hairs, scalp, oral and nail, Cleansing cream, Lotions, Vanishing and Foundation creams, Anti- sun burn preparations, Moisturizing cream, deodorants, Face powders, Face packs, Lipsticks, Bath products, soaps and baby product, Preparation and standardisation of the following :
Shampoos, Conditioners, Tonic, Bleaches, Colorants, Depilatories and Hair oils, Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails.

12 Hrs

3. **Cosmeceuticals of herbal and natural origin:** Hair growth formulations, Fairness formulations.

12 Hrs

4. Commonly used herbal cosmetics, raw materials, preservatives, surfactants, humectants, oils, colours, and some functional herbs, preformulation studies, compatibility studies, possible interactions between chemicals and herbs, design of herbal cosmetic formulation.

12 Hrs

5. **Analysis of Cosmetics, Toxicity screening and test methods:** Quality control and toxicity studies as per Drug and Cosmetics acts.
12 Hrs

REFERENCES:

- ❖ Panda H. 2007. Herbal Cosmetics (Hand book), Edition I, Asia Pacific Business Press Inc, New Delhi.
- ❖ Thomson EG. 2006. Modern Cosmetics, Edition I, Universal Publishing Corporation, Mumbai.
- ❖ P.P.Sharma. 2008. Cosmetics- Formulation, Manufacturing & Quality Control, Edition 4, Vandana Publications, New Delhi.
- ❖ Supriya K B. 2005. Handbook of Aromatic Plants, Edition II(Revised and Enlarged), Pointer Publishers, Jaipur.
- ❖ Skaria P. 2007. Aromatic Plants (Horticulture Science Series Vol. 1) , Edition I, New India Publishing Agency, New Delhi.
- ❖ Kathi Keville and Mindy Green.1995. Aromatherapy (A Complete Guide to the Healing Art), Edition I, Sri Satguru Publications, New Delhi.
- ❖ Chattopadhyay PK. 2000. Herbal Cosmetics & Ayurvedic Medicines (EOU), Edition I, National Institute of Industrial Research, Delhi.
- ❖ Balsam MS & Edward Sagarin. 2008. Cosmetics Science and Technology, Edition II (Vol-II), Wiley Interscience, New York.

PRACTICALS (MPG205P)

1. Isolation of nucleic acid from cauliflower heads
2. Isolation of RNA from yeast
3. Quantitative estimation of DNA
4. Immobilization of whole cell
5. Establishment of callus culture
6. Establishment of suspension culture
7. Estimation of aldehyde
8. Estimation of phenolic content in herbal raw materials
9. Estimation of alkaloid content in herbal raw materials
10. Estimation of flavonoid content in herbal raw materials
11. Preparation and standardization of various simple dosage forms from Ayurvedic, siddha, homoeopathy and Unani formulary
12. Preparation of certain Aromatherapy formulations
13. Herbal cosmetic formulation such as lip balm, lipstick, facial cream, herbal hair and nail care products
14. Evaluation of herbal tablets and capsules
15. Dermatological preparation like sunscreen, UV protection cream, skin care formulations for fungal and dermato reaction
16. Formulation of cough syrup

M. PHARM. COSMECEUTICS (MCC)

COSMECEUTICALS-BIOLOGY (MCC101T)

Scope:

- To impart knowledge on the biological aspects of – skin and hair, nails, eyes.
- To understand basic problems associated with skin and hair.
- To understand the mechanism of Skin irritation, allergy and allergic reactions that are major causes for skin problems.

Objectives:

- To have stronger scientific basis in developing cosmeceutical products.

Theory

60 Hours

1. Skin

Structure and functions of skin, baby's skin and problems unique to baby's skin, Age-associated morphological and histological changes in human skin. Difference between baby's skin and adult skin, Ethnic and gender differences in skin properties. Etiology and current treatment for psoriasis and wound healing process.

1

2Hrs

2. Immunology

Types of skin allergic reaction, immunological mechanism of skin allergy.

Terminologies used: Contact dermatitis, Irritant Contact Dermatitis, allergic Contact dermatitis, photo-irritant contact dermatitis, phototoxicity, contact urticaria syndrome

General concepts of skin irritancy: Principles and molecular mechanisms of skin irritation,

evaluation, factors predisposing to cutaneous irritation. Cosmetic and occupational Irritants.

12Hrs

3. Irritation study models

Artificial skin modeling – Human reconstituted epidermis and skin, Skin organ culture models and other new types of skin equivalents

Cosmetic safety testing as per BIS (Bureau of Indian Standards), alternate safety testing methods: Cell line techniques for safety studies (including mutagenicity studies) and toxicity studies, toxicity studies models.

12Hrs

4. Nail :

Anatomy of nail. Common problems associated with nail- Brittleness striations, splitting, pitting and fungal infections.

12Hrs

5. Hair:

The Structure and Properties of Hair, hair growth cycle. Hair-fall aetiology and current treatment. Racial differences in hair structure.

Microbiology:

Pharmacopeial methods of evaluation of preservative efficacy.

12Hrs

REFERENCES

1. Harry's Cosmeticology. 8th edition
2. Poucher's perfume cosmetics and Soaps, 10th edition
3. Cosmetics - Formulation, manufacture and quality control PP.Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I.Maibach. 3rd edition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.
7. British Pharmacopoeia

COSMETICS – FORMULATION SCIENCE (MCC102T)

SCOPE:

- To impart knowledge on the fundamental principles of cosmetic product development.
- To understand key ingredients used in cosmetics and cosmeceuticals
- To understand the building blocks in the formulation of cosmetic products.

OBJECTIVES:

- Upon completion of the course, the students will be able to:
- Know various key ingredients used to develop cosmetics.
- Combine the ingredients together to develop cosmetics with desired sensory.

THEORY

60 HOURS

1. Formulation Principles:

- a. Definition of Cosmetics as per EU and Indian Guidelines
- b. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and underarms. Examples of marketed product.
- c. Formulation requirements for ethnic needs.
- d. Cosmetic product development process

12 Hrs

2. Formulation Building blocks:

Building blocks for different product formulations of cosmetics/cosmeceuticals:

- e. Surfactants- Classification and application.
- f. Emollients and rheological additives: classification and application.
- g. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy.
- h. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens.
- i. Application of various product forms in cosmetics: Solution, creams, lotion, ointment, paste, gels, stick, tablets, capsules, powders and aerosol. Examples from marketed product.

12 Hrs

3. Skin cleansing and care

Dry skin, skin moisturisation,

Skin Cleansing: Building blocks and formulation of Soap, syndet bars, face wash, body wash, face mask. Their relative advantages and disadvantages

Skin Care: Classification, requirement of an Ideal skin cream.

Building blocks and formulation of cold cream, vanishing cream, moisturizing cream, moisturizing gel, body lotion, petroleum Jelly.

12 Hrs

4. Hair

Hair Care: Ideal requirements of a shampoo.

Formulation of shampoos, Hair conditioners, Hair oil, hair cream.
and hair styling gels

Chemistry and formulation of Paraphenylene diamine based Hair dyes.

12

Hrs

5. Oral care, color cosmetics, deodorants and baby care

Oral Care: Ideal requirement of a toothpaste. Building blocks and formulation of tooth paste and mouth wash.

Color Cosmetics: Building blocks and formulation of Lipstick, Mascara, nail polish and Face Powder.

Deodorants and antiperspirants: Ingredients and mechanism of action

Baby Care: Approach to baby care formulations.

12 Hrs

REFERENCES:

1. Harry's Cosmeticology. 8th edition
2. Poucher's perfume cosmetics and Soaps, 10th edition
3. Cosmetics - Formulation, manufacture and quality control PP.Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I.Maibach. 3rd edition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.

PRODUCTION TECHNOLOGY & QUALITY ASSURANCE (MCC103T)

SCOPE:

This course deals with the various quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, documentation, to understand about validation types, methodology application and how it can be applied to industry and thus to improve the quality of the products. Impart fundamental knowledge about quality management System. This knowledge can be applied in QA of cosmetics.

Objectives:

At the completion of this subject it is expected that the student will be able to know:

- The cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation.
- Explain the aspect of validation
- Apply the knowledge of validation to manufacturing, instruments and equipments
- To understand the quality evaluation of products
- Need of Quality management system in Industry
- This knowledge can be used to evolve stringent QA systems for cosmeceuticals

THEORY

60 HOURS

1. Introduction to Quality

Definition - Quality assurance and Quality control, concept of TQM, GMP, ICH, Brief study of ICH common technical documents – Q1-Q11, Quality by design, six sigma concept, ISO 9000 & 14000.

Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, Quality audit reports and documents, quality reports, distribution records, Common Technical Document and Drug Master Files, Medical Devices, Electronic Common Technical Documentation, complaints and evaluation of complaints, Handling of return goods, recalling and waste disposal.

12Hrs

2. cGMP of Pharmaceutical manufacturing:

Evolution and Principles of cGMP, Schedule-M, WHO-GMP requirements, European Union (EU) and United States Food and Drug Administration (USFDA) guidelines on Pharmaceutical manufacturing. URS, FAT, DQ, SAT, IQ, OQ, PQ of machines and equipment. Clean room standards for different countries and names.

12Hrs

3. Introduction to Pharmaceutical Validation:

Definition, Manufacturing Process Model, scope of Validation, Advantage of Validation, Organization for Validation, Validation Master plan, Types of validation, Design Qualification, Installation Qualification, Operational Qualification & Performance Qualification of facilities. A Review of Prospective, Concurrent, Retrospective Validation & Revalidation including the use of Statistical Process Control (SPC).

12Hrs

4. Quality Management System :

Quality risk management: Introduction, risk assessment, risk control, risk review, risk Management tools, HACCP, risk ranking and filtering. Change Control, Deviation-(planned and unplanned), Corrective Action and Preventive Action (CAPA), Handling of nonconformance, Vendor evaluation process, Out of specification (OOS), Annual Product Review, batch reconciliation and finished goods release, Market recalls & Market complaints.

12Hrs

5. Quality Control Process

In process quality control and finished products quality control for following formulation in pharma industry: Liquids – Suspension, Emulsion, solutions, Ointments, creams, Jelly's, Parenterals , ophthalmic. Quality control test for containers, closures and secondary packing materials.

12Hrs

REFERENCES

1. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
2. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
3. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
4. ICH guidelines
5. ISO 9000 and total quality management
6. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.

7. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
8. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
9. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
10. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
11. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
12. Lachman L Liberman Theory and practice of industrial pharmacy by 3 rd edition
13. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.

CELLULAR AND MOLECULAR PHARMACOLOGY (MCC104T)

SCOPE:

The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process.

This subject is important since animal experimentation is restricted and cell biology knowledge is critical for alternate preclinical studies on safety and efficacy.

OBJECTIVES:

Upon completion of the course, the student shall be able to,

- Explain the receptor signal transduction processes.
- Explain the molecular pathways affected by drugs.
- Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
- Demonstrate molecular biology techniques as applicable for pharmacology
- Apply the knowledge in developing cell line safety studies.

THEORY

60 HOURS

1. Cell biology

Structure and functions of cell and its organelles

Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing. Cell cycles and its regulation. Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis. Necrosis and autophagy.

12 rs

2. Cell signaling

Intercellular and intracellular signaling pathways.

Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors. Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol.

Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

12 Hrs

3. Principles and applications of genomic and proteomic tools

DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting,

12Hrs

4. Cell culture techniques

Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application.

Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays .

Principles and applications of flow cytometry

5. Chapter to be identified

12Hrs

REFERENCES:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current protocols in molecular biology Vol I to VI edited by Frederick M.Ausuvel et la.

PRACTICALS (MCC105P)

- A) Visit to dermatology and dental wards. Submitting case report on common skin and oral cavity problems observed.
- B) Analysis in detail selecting a specific skin or oral cavity problem.

Lab Practicals

- 1) Cytotoxicity studies using cell lines,
- 2) Preservative efficacy test
- 3) *In vitro* assay for antibacterial efficacy.

Design and Development of following products:

- 4) Moisturizing cream
- 5) Tooth Paste
- 6) Shampoo
- 7) Hair oil
- 8) Lip Balm
- 9) Petroleum jelly
- 10) Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
- 11) Isolation of RNA from yeast
- 12) Estimation of RNA/DNA by UV Spectroscopy
- 13) Gene amplification by PCR.
- 14) Enzyme based *in-vitro* assays (MPO, AChEs, α amylase, α glucosidase).
- 15) Cell viability assays (MTT/Trypan blue/SRB).
- 16) DNA damage study by Comet assay.

COSMECEUTICALS (MCC201T)

SCOPE:

- To impart knowledge on the fundamental principles of cosmeceuticals product development.
- To understand the building blocks in the formulation of cosmeceutical products.
- To develop knowledge in design and development of cosmeceuticals- focusing on safety, stability, sensory and delivery of actives.

OBJECTIVES:

Upon completion of the course, the students will be able to Know

- Various key ingredients used to develop cosmeceuticals.
- Combine the ingredients together to develop cosmeceuticals with desired sensory and efficacy.

THEORY

60 HOURS

1. Sun protection, pigmentation and wrinkles

Sun Protection: Solar spectrum, UV A and UV B rays of the sun. Skin damages caused by over exposure to sunlight, organic and in-organic sunscreens, SPF and Tan protection. Challenges in developing sunscreen formulations. Global regulatory aspects of sunscreen products. Case study on sunscreen products in the market.

Skin Pigmentation and Wrinkles: Melanogenesis and ethnic differences. Ways to control skin pigmentation. Actives and mechanism of action. Building blocks and formulation of a skin anti-blemish cream. Skin bleaches and skin lightening. Case study on skin lightening products in the market.

Skin wrinkles: Factors that leads to skin wrinkles. Role of anti-oxidants in reducing skin wrinkles. Building block and formulation of an anti-wrinkle product. Case study on anti-aging/antiwrinkle product in the market.

12Hrs

2. Acne, Prickly heat, Dandruff and oral care

Causes for acne, prickly heat and dandruff and current treatment.

Building blocks and formulation of products for treatment of acne, prickly heat and dandruff.

Case study of marketed products.

Oral care:

Basic understating of the cause of Bleeding gums, sensitive teeth, plague, halitosis.

Role of antimicrobial agents, anti oxidants and astringents for oral care.

Denture cleansers. Building blocks and formulation of anti-cavity, tooth sensitivity relief and teeth-whitening tooth paste. Case study on the marketed products

12Hrs

3. Herbal Cosmetics

Herbal ingredients used in Hair care, skin care and oral care and nail.

Guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers.

Formulation and development of herbal cosmetics.

12Hrs

4. Dermal Drug Delivery

Factors affecting dermal drug delivery. Role of penetration enhancers in dermal delivery.

Dermal drug delivery systems: Nano particles, Liposomes, patches, Ionotophoresis, sonophoresis, electroporation, micro-needles.

12Hrs

5. To be identified

REFERNECES

1. Harry's Cosmeticology. 8th edition.
2. Poucher's perfume cosmetics and Soaps, 10th edition
3. Cosmetics - Formulation, manufacture and quality control PP.Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I.Maibach. 3rd edition
5. S.P.Vyas and Roop K.Khar Controlled Drug Delivery system, Concepts and Advances
6. Cosmetic and Toiletries recent suppliers catalogue.
7. CTFA directory.

COSMETIC ANALYSIS & EVALUATION (MCC202T)

SCOPE

This course is designed to impart knowledge on analysis of cosmetic raw materials and finished products. Performance evaluation of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.

OBJECTIVES

At completion of this course student shall be able to understand

- Determination of physical constants of cosmetic raw materials
- Cosmetic raw materials, additives and their analysis
- Analysis of finished cosmetic products
- Principles of performance evaluation of cosmetic products.

THEORY

60Hrs

1. Determination of acid value, ester value, Saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powders, density, viscosity of cosmetics raw materials.

12 hrs
2. Study on the quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.

12 hrs
3. Indian standard specifications laid down for sampling and testing of various cosmetics in finished forms such as baby care powders, skin care products, dental products, personal hygiene preparations, lips sticks, hair products and skin creams by the Bureau Indian Standards.

12 hrs
4. Principles of equipment used to measure product performance of skin and hair care products - Sebumeter, corneometer, trans-epidermal water loss, Skin color, hair tensile properties, hair combing properties.
Performance evaluation of shampoos, antiperspirants, deodorants, sunscreens, foam baths and abrasiveness of dentifrices.

12 hrs
5. Study of specialized additives- quality parameters and analysis of rheology modifiers, preservatives, emollients, hair conditioners and fragrances

12 hrs

REFERENCES:

1. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi
2. Indian Standard specification, for raw materials, BIS, New Delhi.
3. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
4. Harry's Cosmeticology 8th edition
5. Suppliers catalogue on specialized cosmetic excipients
6. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
7. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition,
8. Dry skin syndrome: Taylor and Francis.

COSMETICS- INDUSTRY AND REGULATORY (MCC203T)

SCOPE:

- To impart knowledge on the basic regulatory aspects relating to cosmetics
- To understand the manufacturing equipments and GMP as per regulatory guidelines
- To understand the aspects of technology transfer from R&D to manufacturing.

Objectives: Upon completion of the course, the students will be able to:

- Effectively design products and documentation that meets regulatory requirements
- Implement smooth transfer of technology from design stage to factory production.

**Theory
Hours**

60

1. Indian Regulations

Indian Regulation for cosmetics:

Regulatory provisions relating to import and manufacturing of cosmetics – conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

Misbranded and spurious cosmetics.

Indian regulatory requirement for factory premises, location and surrounding, designing of plant layout, building, light, ventilation, water supply, disposal of waste, first aid, packaging facilities, sanitation in manufacturing premises and health clothing and sanitary requirement of staff.

12Hrs

2. Manufacturing & ASEAN standards

Equipments used in the manufacturing of creams, shampoo and toothpaste. GMP guidelines as per ASEAN standards for cosmetics

12Hrs

3. European Union Guidelines

Summary of features of EU guidelines for cosmetics: Ingredients, safety assessment, labeling, the product information package, GMP, animal testing and efficacy testing. Cosmeceuticals as OTC and quasi drugs.

12Hrs

4. Technology transfer

Significance of pilot plant scale up studies.

Stability studies: Change in parameter to be observed, Photostability, accelerated stability testing- Temperature humidity, freeze thaw and stress test. Aerosol product stability studies. Technology transfer of formulations from R&D to factory- Documentations.

1

2Hrs

5. Private Regulatory bodies:

a) Environmental and safety concerns of certain cosmetic ingredients that are debated and discussed. – Nano sized sunscreens, triclosan, formaldehyde liberators, Polythene beads, Sodium and ammonium lauryl sulfates, phthalates.

b) Study of salient features of cosmetic safety data base developed by private body, and International Nomenclature of Cosmetic Ingredients (INCI).

c) Principles of cosmetovigilance.

d) Product claim development and advertisement; Role of ASCI.

12Hrs

REFERENCES

7. Harry's Cosmeticology. 8th edition
8. Cosmetics - Formulation, manufacture and quality control PP.Sharma, 4th edition
9. ASEAN definition of Cosmetics and illustrative list by category of Cosmetic products.
10. EU regulation (EC) no. 1223/2009 of the European parliament and of the council of 30th November 2009, on cosmetic products.
11. Theory and Practice of Industrial Pharmacy by Lachmann and Libermann

COMPUTER AIDED DRUG DELIVERY SYSTEM (MCC204T) **(This should be an Elective)**

Scope

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students' to clarify the concepts.

Objectives

At completion of this course it is expected that students will be able to understand-

- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition
- Computers in Preclinical Development
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics(CFD)

THEORY

60Hrs

6. **Computers in Pharmaceutical Research and Development:** A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameter Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling
Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application

12Hrs

7. **Computational Modeling Of Drug Disposition:** Introduction ,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution

,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.

12 Hrs

8. **Computer-aided formulation development::** Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis

12 Hrs

9. **Computer-aided biopharmaceutical characterization:** Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and *in vitro-in vivo* correlation, Biowaiver considerations
Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.
Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems

12 Hrs

10. **To be identified**

REFERENCES

4. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
5. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
6. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

PRACTICALS (MCC205P):

1. Design and formulate unique Cream, shampoo, toothpaste, moisturizing gel, and lip balm.
Study private body guidelines for green/premium cosmetics of Ecocert/Cosmos, and suggest changes in the formulations.
2. Design and Development of cosmeceutical product for the treatment of dry skin, wrinkles, acne, blemishes, dandruff, and bleeding gums.
3. Case study report of products in the market- Sun-protection, aging, acne, pigmentation, prickly heat, dandruff, hair-fall, teeth cavities, bleeding gums, teeth whitening, Comparing labeled formulation ingredients.
4. Quantitative analysis of rancidity in hair oils and Lipsticks
5. Determination of aryl amine content and Developer in hair dye
6. Determination of foam height and SLS content of Shampoo.
7. Determination of total fatty matter in creams (Soap, Skin and hair Creams)
9. Comparative Study of marketed cosmetic product claims
10. DoE Using Design Expert[®] Software
10. Formulation data analysis Using Design Expert[®] Software
11. Quality-by-Design in Pharmaceutical Development

**M. PHARM. INDUSTRIAL PHARMACY
(MIP)**

MODERN PHARMACEUTICAL ANALYSIS (MPA101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know,

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY

60 HOURS

- 1. UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation **11 Hrs**
associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.
IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy
Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.
- 2 NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, **11 Hrs**
Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy.

- 3 **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy **11 Hrs**
- 4 **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: **11 Hrs**
 - a) Paper chromatography b) Thin Layer chromatography
 - c) Ion exchange chromatography d) Column chromatography
 - e) Gas chromatography f) High Performance Liquid chromatography
 - g) Affinity chromatography
- 5 **Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: **11 Hrs**
 - a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis
 - d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.
6. **Immunological Assays:** Radioimmunity assay (RIA), ELISA (Theory & practical) and knowledge on Bioluminescence assays. **5 Hrs**

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

PHARMACEUTICAL FORMULATION DEVELOPMENT (MIP101T)

Scope

This course is designed to impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D

Objectives

At completion of this course it is expected that students will be able to understand-

- The scheduled activities in a Pharmaceutical firm.
- The pre formulation studies of pilot batches of pharmaceutical industry.
- The significance of dissolution and product stability

THEORY

60Hrs

12 Hrs

1. **Preformulation Studies:** Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.

12 Hrs

2. **Formulation Additives:** Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science, determination methods, drug excipient interactions. Design of experiments – factorial design for product and process development.

12 Hrs

3. **Solubility:** Importance, experimental determination, phase-solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy.

12 Hrs

4. **Dissolution:** Theories, mechanisms of dissolution, *in-vitro* dissolution testing models – sink and non-sink. Factors influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Biorelevant media, *in-vitro* and *in-vivo* correlations, levels of correlations.

- 5. Product Stability:** Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf life assignment. Stability protocols, reports and ICH guidelines.

REFERENCES:

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Connors KA. A Text book of pharmaceutical analysis Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
5. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. Marcel Dekker Inc., New York, 1981
6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi, 2005.
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3rd ed., CBS publications, New Delhi, 2008.
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3rd ed., CBS Publishers & distributors, New Delhi, 2005.
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
11. W. Grimm - Stability testing of drug products.
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999.
13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I & II., 4th ed., CBS Publishers & distributors, New Delhi, 2004.
14. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
15. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
16. United States Pharmacopoeia. United States Pharmacopoeial Convention, Inc, USA, 2003.

CUSTOMIZED DRUG DELIVERY SYSTEMS (MIP102T)

Scope

This course is designed to impart knowledge and skills necessary to train the students in the area of customized drug delivery systems.

Objective

At completion of this course it is expected that students will be able to understand-

- The need, concept, design and evaluation of various customized, sustained and controlled release dosage forms.
- To formulate and evaluate various customized/novel drug delivery systems

THEORY

60Hrs

12 Hrs

1. **Concept & Models for NDDS:** Classification of rate controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release.

Carriers for Drug Delivery: Polymers / co-polymers-introduction, classification, characterization, polymerization techniques, application in CDDS / NDDS, biodegradable & natural polymers.

12 Hrs

2. **Study of Various DDS:** Concepts, design, formulation & evaluation of controlled release oral DDS, Mucoadhesive DDS (buccal, nasal, pulmonary) Pulsatile, colon specific, liquid sustained release systems.

12 Hrs

3. **Transdermal Drug Delivery Systems:** Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems.

Sub Micron Cosmeceuticals: Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, oral cavity, eye etc and it's regulatory aspects.

12 Hrs

4. **Targeted Drug Delivery Systems:** Importance, concept, biological process and events involved in drug targeting, design, formulation & evaluation, methods in drug targeting – nanoparticles, liposomes, niosomes, pharmacosomes, resealed erythrocytes, microspheres, magnetic microspheres. Specialized pharmaceutical

emulsions – multiple emulsions, micro-emulsions.

Protein / Peptide Drug Delivery Systems: Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stability and destabilization.

Biotechnology in Drug Delivery Systems: Brief review of major areas-recombinant DNA technology, monoclonal antibodies, gene therapy.

12 Hrs

- 5. Dosage Forms for Personalized Medicine:** Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.

REFERENCES:

1. Novel Drug Delivery System, Y.W. Chein, Vol 50, Marcel Dekker, NY.
2. Controlled Drug Delivery Systems, Robinson, Vol 29, Marcel Dekker, NY.
3. Transdermal Controlled Systemic Medications, YW Chein, Vol 31, Marcel Dekker, NY.
4. Bioadhesive DDS, E. Mathiowitz, Vol 98, Marcel Dekker, NY.
5. Nasal System Drug Delivery, K.S.E. Su, Vol 39, Marcel Dekker, NY.
6. Drug Delivery Devices, Vol 32, P Tyle Marcel Dekker, NY.
7. Polymers for Controlled Drug Delivery, P.J. Tarcha, CRC Press.
8. Pharmaceutical Biotechnology, Vyas, CBS, Delhi.
9. Biotechnology of Industrial Antibiotics, E.J. Vandamme, Marcel Dekker, NY.
10. Protein Formulation & Delivery, E.J. McNally, Vol 99, Marcel Dekker, NY.
11. Drug Targeting, M.H. Rubinstein, John Wiley, NY.

INTELLECTUAL PROPERTY RIGHTS (MIP103T)

Scope

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in drug regulatory affairs

Objectives

At completion of this course it is expected that students will be able to understand-

- Assist in Regulatory Audit process.
- Establish regulatory guidelines for drug and drug products
- The Regulatory requirements for contract research organization

THEORY

60Hrs

12 Hrs

1. Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filling of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in Patent.

12 Hrs

2. Role of GATT, TRIPS, and WIPO.

12 Hrs

3. Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating Indian Pharmaceutical sector,

12 Hrs

4. Brief introduction to CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA

12 Hrs

5. Regulatory requirements for contract research organization. Regulations for Biosimilars.

REFERENCES:

1. Pharmaceutical Process Validation: By Fra R. Berry and Robert A. Nash, Vol 57, 2nd Edition
2. Applied Production and Operation Management By Evans, Anderson and Williams
3. GMP for pharmaceuticals Material Management by K.K. Ahuja Published by CBS publishers
4. ISO 9000-Norms and explanations

PRACTICALS

SEMESTER-1(MIP104P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Effect of surfactants on the solubility of drugs.
8. Effect of pH on the solubility of drugs.
9. Dissolution methods of transdermal drug delivery systems.
10. Stability testing of solution and solid dosage forms for photo degradation..
11. Stability studies of drugs in dosage forms at 25 °C, 60% RH and 40 °C, 75% RH.
12. Compatibility evaluation of drugs and excipients.
13. Preparation and evaluation of different polymeric membranes.
14. Formulation and evaluation of sustained release oral matrix tablet.
15. Formulation and evaluation of sustained release oral reservoir system.
16. Formulation and evaluation of microspheres / microcapsules.
17. Formulation and evaluation of transdermal films.
18. Design and evaluation of face wash, body- wash, creams, lotions, shampoo, toothpaste, lipstick.

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MIP201T)

Scope

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply Biopharmaceutics theories in practical problem solving.

Objectives

At completion of this course it is expected that students will be able to understand–

- The basic concepts in Biopharmaceutics and pharmacokinetics.
- The use of raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- To critically evaluate Biopharmaceutics studies involving drug product equivalency.
- To design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

THEORY

60Hrs

12Hrs

- 1. Drug Absorption From The Gastrointestinal Tract:** Gastrointestinal tract, Mechanism of drug absorption, Factors affecting passive drug absorption, pH-partition theory of drug absorption. Factors affecting drug absorption: physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex, Structure of Octanol, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

12Hrs

- 2. Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance:** Introduction, Biopharmaceutic Factors Affecting Drug Bioavailability, Rate-Limiting Steps in Drug Absorption, Physicochemical Nature of the Drug Formulation Factors Affecting Drug Product Performance, Drug Product Performance, *In Vitro*: Dissolution and Drug Release Testing, Compendial Methods of Dissolution, Alternative Methods of Dissolution Testing, Meeting Dissolution Requirements, Problems of Variable Control in Dissolution Testing Performance of Drug Products: *In Vitro–In Vivo* Correlation, Dissolution Profile Comparisons, Drug Product Stability, Considerations in the Design of a Drug Product, Drug Product Considerations.

12Hrs

- 3. Pharmacokinetics:** Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model- IV bolus, IV infusion, Extra-vascular; Multi Compartment model: Two compartment - model in brief, Non-Linear Pharmacokinetics: Cause of non-linearity, Michaelis – Menten equation, Estimation K_{max} and V_{max} . Drug interactions: Introduction, The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters.

12Hrs

- 4. Drug Product Performance, In Vivo: Bioavailability and Bioequivalence:** Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability, , Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Evaluation of the Data, Bioequivalence Example, Study Submission and Drug Review Process, The Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution.

12Hrs

- 5. Application of Pharmacokinetics:** Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Relationship between Pharmacokinetics and Pharmacodynamics: Generation of a pharmacokinetic–pharmacodynamic (PKPD) equation, Pharmacokinetic and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology

drugs: Introduction, Proteins and peptides ,Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy),Gene therapies.

REFERENCES:

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmanekar and Sunil B.J. Aiswal., Vallab Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thomas N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pamarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics, 1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.

SCALE UP AND TECHNOLOGY TRANSFER (MIP202T)

Scope

This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

Objectives:

At completion of this course it is expected that students will be able to understand-

- Manage the scale up process in pharmaceutical industry.
- Assist in technology transfer.
- To establish safety guidelines, which prevent industrial hazards.

THEORY

60Hrs

12Hrs

- 1. Pilot plant design:** Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parenterals and semisolid preparations.

Scale up: Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parenterals, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology.

12Hrs

- 2. Validation:** General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vendor qualification.

12Hrs

- 3. Equipment Qualification:** Importance, IQ, OQ, PQ for equipments – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine.

12Hrs

- 4. Process validation:** importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.

12Hrs

- 6. Industrial safety:** Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution.

REFERENCES:

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T.Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L.Lachman, H.A.Lieberman, Varghese Publ. Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parenteral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan, Dehli.

PHARMACEUTICAL PRODUCTION TECHNOLOGY (MIP203T)

Scope

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in Production

Objectives

At completion of this course it is expected that students will be able to understand–

- Handle the scheduled activities in a Pharmaceutical firm.
- Manage the production of large batches of pharmaceutical formulations.

THEORY

60Hrs

12Hrs

- 1. Improved Tablet Production:** Tablet production process, unit operation improvements, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, speronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.
Coating Technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

12Hrs

- 2. Parenteral Production:** Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.

12Hrs

- 3. Lyophilization Technology:** Principles, process, freeze-drying equipments.

12Hrs

- 4. Capsule Production:** Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered.
Disperse Systems Production: Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion, problems encountered.

Packaging Technology: Types of packaging materials, machinery, labeling, package printin for different dosage forms.

12Hrs

- 5. Air Handling Systems:** Study of AHUs, humidity & temperature control, air filtration systems, dust collectors. **Water Treatment Process:** Techniques and maintenance – RO, DM, ultra – filtration, WFI.

REFERENCES:

1. The theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publ, Bombay.
2. Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.
3. Pharmaceutical Dosage Forms, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
4. Pharmaceutical Dosage Forms, Parental medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
5. Pharmaceutical Production Facilities, design and applications, by G.C. Cole, Taylor and Francis.
6. Dispersed System Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Product design and testing of polymeric materials by N.P. Chezerisionoff.
8. Pharmaceutical Project Management, T.Kennedy, Vol 86, Marcel Dekker, NY.
9. Packaging Pharmaceutical and Health Care, H.Lockhard.
10. Quality Control of Packaging Materials in Pharmaceutical Industy, .Kharburn, Marcel Dekker, NY.
11. Freeze drying / Lyophilization of Pharmaceuticals & Biological Products, L. Ray, Vol 96, Marcel Dekker, NY.
12. Tablet Machine instrumentation in pharmaceuticals, PR Watt, Ellis Horwoods, UK.

ENTREPRENEURSHIP MANAGEMENT (MIP204T)

Scope

This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

Objectives:

At completion of this course it is expected that students will be able to understand-

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies And Networking

THEORY

60Hrs

12Hrs

1. Conceptual Frame Work

Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management

12Hrs

2. Entrepreneur

Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts.

Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

12Hrs

3. Launching And Organising An Enterprise

Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilisation - finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

12Hrs

4. Growth Strategies And Networking

Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of

expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study.

12Hrs

5. Preparing Project Proposal To Start On New Enterprise

Project work – Feasibility report; Planning, resource mobilisation and implementation.

REFERENCES:

1. Akhauri, M.M.P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R.D & Brush, C.G.(1996) The Women Entrepreneurs, D.C. Heath & Co., Toronto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C.(1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.

PRACTICALS

SEMESTER-2(MIP205P)

1. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
2. Comparison of dissolution of two different marketed products /brands
3. Protein binding studies of a highly protein bound drug & poorly protein bound drug
4. Bioavailability studies of Paracetamol.
5. Pharmacokinetic and IVIVC data analysis by Winnoline^R software
6. *In vitro* cell studies for permeability and metabolism
7. Formulation and evaluation of tablets
8. Formulation and evaluation of capsules
9. Formulation and evaluation of injections
10. Formulation and evaluation of emulsion
11. Formulation and evaluation of suspension.
12. Formulation and evaluation of enteric coating tablets.

M. PHARM. PHARMACEUTICAL ANALYSIS (MPA)

MODERN PHARMACEUTICAL ANALYSIS (MPA101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know,

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY

60 HOURS

- 1. UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation **11 Hrs**
associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.
IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy
Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.
- 2 NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy. **11 Hrs**
- 3 Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, **11 Hrs**

Isotopic peaks and Applications of Mass spectroscopy.

- 4 Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: **11 Hrs**
a) Paper chromatography b) Thin Layer chromatography
c) Ion exchange chromatography d) Column chromatography
e) Gas chromatography f) High Performance Liquid chromatography
g) Affinity chromatography
- 5 Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: **11 Hrs**
a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis
d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.
- 6. Immunological Assays:** Radioimmunity assay (RIA), ELISA (Theory & practical) and knowledge on Bioluminescence assays. **5 Hrs**

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

ADVANCED PHARMACEUTICAL ANALYSIS (MPA102T)

Scope

This subject deals with the various aspects of reagents, quantitative analysis of functional group used in the analytical method development. It also covers the biological testing of various vaccines and impurities

Objectives

After the completion of the course, it is expected that the student shall be able to know

- Appropriate analytical skills required for the analytical method development.
- Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.
- Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products.

THEORY

60 HOURS

- 1. Analytical principle and procedure involved in the assay of following methods 12 Hrs with special emphasize on official drugs in IP:**
 - a) Complexometric titration b) Non aqueous titration c) Redox titration d) Diazotization titration e) UV – Visible method f) HPLC g) Potentiometric titrations h) pKa and log p determination
- 2 Analytical principle, procedure and applications of the following reagents: 12 Hrs**
 - a) Ninhydrin b) 3-Methyl-2- benzthiazolinone hydrazone [MBTH] c) Folin – Ciocaltau [FC] d) Para-dimethyl-amino benzaldehyde [PDAB] e) Para-dimethyl- amino cinnamaldehyde [PDAC] f) 2, 6- Dichloroquinone chlorimide g) 1,2- napthaquinone-4-sulfonate h) 2,3,5-Triphenyltetrazolium i) 2,4-Dinitro Phenyl hydrazine [DNPH] j) Bratton – Marshall reagent k) 3,5- Dinitro salicylic acid [DNSA]
- 3. Principles and procedure involved in quantitative estimation of following functional groups in drugs and elements: 12 Hrs**
 - a) Hydroxyl b) Amine c) Carboxyl d) Carbonyl f) Ester g) Methoxyl

a) Sodium b) Potassium c) Calcium d) Halogens e) Phosphorus e) Sulphur

4. Biological tests and assays of the following: 12 Hrs

a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine
c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin
f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom.
PCR, PCR studies for gene regulation, instrumentation (Principles and procedures).

5. Impurities and stability studies 12 Hrs

Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines

Impurities In New Drug Products

Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products

Impurities in residual solvents

General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, Reporting levels of residual solvents

Elemental Impurities

Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N, S analysis.

Method development, Stability studies and concepts of validation

Accelerated stability testing & shelf life calculation, WHO and ICH stability testing guideline, Stability zones, Photostability testing guidelines, ICH stability guidelines for biological products

REFERENCES

1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th Edition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, John Wiley & Sons, 1982.
4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers New Delhi, 1997.

6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, NewDelhi, 1964.
8. Indian Pharmacopoeia Vol I , II & III 2006, 2010.
9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005
12. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.
13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London.

PHARMACEUTICAL VALIDATION (MPA103T)

Scope

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Objectives

Upon completion of the subject student shall be able to

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments
- Validate the manufacturing facilities

THEORY

60 HOURS

1. **Introduction** -Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.

Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status- Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments.

12 Hrs

2. **Qualification of analytical instruments:** Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC, Disintegration and Dissolution

Qualification of Glassware: Volumetric flask, pipette, beakers and burette

12 Hrs

3. Validation of Utility systems - Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen.

Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).

12 Hrs

4. History of various phases of drug development and drug approval, IND, NDA (Phase I - IV), Content and Formal ANDA

Analytical method validation: General principles, Validation of analytical method as per ICH guidelines

12 Hrs

5. Regulatory scenario in India:

Regulatory aspects of pharmaceutical and bulk drug manufacture and drug analysis, loan license (contract manufacture) auditing, recent amendments to drugs and cosmetics act, provisions of consumer protection act, environment protection act.

12 Hrs

REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up||, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.

FOOD ANALYSIS (MPA104T)

Scope

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products.

Objectives

At completion of this course student shall be able to understand various analytical techniques in the determination of

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- Student shall have the knowledge on food regulations and legislations.

THEORY

60Hrs

1. a. Carbohydrates – Chemistry & classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, crude fibre and application of food carbohydrates

b. Proteins - Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins

12Hrs

2. a. Lipids – Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fats and fatty foods.

b. Vitamins – classification of vitamins, methods of analysis of vitamins, Principles of microbial assay and physiological significance of vitamins of B-series.

12Hrs

3. a. Food additives – Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents

b. Pigments and synthetic dyes - Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes

12Hrs

4. a. General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk.

b. Analysis of fermentation products like wine, spirits, beer and vinegar.

12Hrs

5. a. Pesticide analysis - Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorous and organo chlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products.

b. Legislation regulations of food products with special emphasis on BIS, Agmark and US-FDA.

12Hrs

REFERENCES

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Analysis of Food constituents – Multon, Wiley VCH.

5. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005.

PRACTICAL (MPL101P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Assay of official compounds by different titrations
8. Assay of official compounds by instrumental techniques.
9. Quantitative determination of hydroxyl group.
10. Quantitative determination of amino group
11. Colorimetric determination of drugs by using different reagents
12. Impurity profiling of drugs
13. Calibration of glasswares
14. Calibration of pH meter
15. Calibration of UV-Visible spectrophotometer
16. Calibration of FTIR spectrophotometer
17. Calibration of GC instrument
18. Calibration of HPLC instrument
19. Cleaning validation of one equipment

20. Determination of total reducing sugar
21. Determination of proteins
22. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
23. Determination of fat content and rancidity in food products
24. Analysis of natural and synthetic colors in food
25. Determination of preservatives in food
26. Determination of pesticide residue in food products
27. Analysis of vitamin content in food products
28. Determination of density and specific gravity of foods
29. Determination of food additives

ADVANCED INSTRUMENTAL ANALYSIS (MPA201T)

Scope

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, ATR-IR, DSC etc.

Objectives

After completion of course student is able to know,

- Interpretation of the NMR, Mass and IR spectra of various organic compounds
- Theoretical and practical skills of the hyphenated instruments
- Identification of organic compounds

Theory

60 Hrs

- 1. UV and IR spectroscopy:** Wood ward – Fiesure rule for 1,3- butadienes, cyclic dienes and α , β -carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds **12Hrs**
- 2. NMR spectroscopy:** 1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds **12 Hrs**
- 3. Mass Spectroscopy:** Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds **12 Hrs**
- 4. Hyphenated analytical techniques :** Principle, Instrumentation and Applications of the following: **12 Hrs**
a) GC-MS b) LC-MS c) ICP-MS d) LC-NMR e) EC-MS f) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I-EC (Ion-Exclusion Chromatography) k) Flash chromatography
- 5. Thermal methods of analysis –** Introduction, principle, instrumentation and application of DSC, DTA and TGA. **12 Hrs**

Radio Immuno Assay: Importance, various components, Principle, Different methods, Limitation & Applications of RIA.

Optical Rotatory Dispersion: Principle, Plain curves, Cotton effect, Circular Dichroism, Measurement of rotation angle in ORD and applications

References

8. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
9. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
10. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
11. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
12. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
13. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
14. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

MODERN BIO-ANALYTICAL TECHNIQUES (MPA202T)

Scope

This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

Objectives

Upon completion of the course, the student shall be able to understand

- Extraction of drugs from biological samples
- Separation of drugs from biological samples using different techniques
- Bioanalytical method validation
- Guidelines for BA/BE studies.
- GCP

THEORY

60 HOURS

1. Analysis of drugs in biological matrices:

Analysis of drugs in use and drugs in Research and Development

Biological matrix and Problems with analysis of biological matrices:

Properties of the biological media, small organic molecules, peptides and protein drugs, prodrugs, formulations, drug metabolites, other drugs, safety considerations.

2. Good Clinical Practice (GCP):

12 Hrs

Origin of GCP, Requirements of GCP compliance, Guidelines for GCP, guidelines of ICH, guidelines of ICMR, Ensuring GCP, Documentation of GCP practice, Audit of GCP compliance

3. USFDA & UDSCO Guidelines for BA/BE studies for orally administered drug products:

12 Hrs

Introduction, Design and conduct of studies, Facilities to conduct BA/BE studies, SPE sorbents, Retention of BA/BE samples, Maintenance of records of BA/BE studies

4.Extraction of drugs and metabolites from biological matrices: 12 Hrs

General principle and procedure involved in the bio-analytical methods such as Protein precipitation, Liquid - Liquid extraction and Solid phase extraction and membrane filtration.

5.Separation techniques 12 Hrs

Bio molecules separation by HPLC, LC MS/MS and Gel electrophoresis

REFERENCES:

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition. CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercey. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, Newyork, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercey, USA. 2007.
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
10. ICH guidelines

QUALITY CONTROL AND QUALITY ASSURANCE (MPA203T)

Scope

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Objectives

At the completion of this subject it is expected that the student will be able to know the cGMP aspects in a pharmaceutical industry

- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable to Pharmaceutical industries
- To understand the responsibilities of QA & QC departments

THEORY

60 HOURS

1. Concept and evolution of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines. **12 Hrs**
Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation.
2. **cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering:** Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guidelines. **12 Hrs**
3. **Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3)** Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures **12 Hrs**

and secondary packing materials.

- 4. Documentation in pharmaceutical industry:** Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data. **12 Hrs**
- 5. Manufacturing operations and controls:** Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging. **12 Hrs**
- b. NABL certification & accreditation procedure c. Patent Regime and IPR

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines

8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.

COSMETIC ANALYSIS & EVALUATION (MPA204T)

Scope

This course is designed to impart knowledge on analysis of cosmetic raw materials and finished products. Performance analysis of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.

Objectives

At completion of this course student shall be able to understand Food constituents

- Determination of physical constants of cosmetic raw materials
- Cosmetic raw materials, additives and their analysis
- Analysis of finished cosmetic products
- Principles of performance evaluation of cosmetic products.

THEORY

60Hrs

1. Determination of acid value, ester value, Saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powders, density, viscosity of cosmetics raw materials and finished products
12 Hrs
2. Study on the quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.
12 Hrs
3. Indian standard specifications laid down for sampling and testing of various cosmetics in finished forms such as baby care powders, skin care products, dental products, personal hygiene preparations, lips sticks, hair products and skin creams by the Bureau Indian Standards.
12 Hrs
4. Principles of equipment used to measure product performance of skin and hair care products - Sebumeter, corneometer, trans-epidermal water loss, Skin color, hair tensile properties, hair combing properties.
Performance evaluation of shampoos, antiperspirants, deodorants, sunscreens, foam baths and abrasiveness of dentifrices.
12 Hrs
5. Study of specialized additives- quality parameters and analysis of rheology modifiers, preservatives, emollients, hair conditioners and fragrances
12 Hrs

References

1. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi
2. Indian Standard specification, for raw materials, BIS, New Delhi.
3. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
4. Harry's Cosmeticology
5. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
6. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition,

PRACTICAL (MPL205P):

1. Comparison of absorption spectra by UV and Wood ward – Fiesure rule
2. Interpretation of organic compounds by FT-IR
3. Interpretation of organic compounds by NMR
4. Interpretation of organic compounds by MS
5. Determination of purity by DSC in pharmaceuticals
6. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
7. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis.
8. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques.
9. Isolation of analgesics from biological fluids (Blood serum and urine).
10. Protocol preparation and performance of analytical/Bioanalytical method validation.
11. Protocol preparation for the conduct of BA/BE studies according to guidelines.
12. In process and finished product quality control tests for tablets, capsules, parenterals and creams
13. Quality control tests for Primary and secondary packing materials
14. Assay of raw materials as per official monographs
15. Testing of related and foreign substances in drugs and raw materials
17. Preparation of Master Formula Record.
18. Preparation of Batch Manufacturing Record.
19. Quantitative analysis of rancidity in lipsticks and hair oil
20. Determination of aryl amine content and Developer in hair dye
21. Determination of foam height and SLS content of Shampoo.
22. Determination of total fatty matter in creams (Soap, skin and hair creams)
23. Determination of acid value and saponification value.
24. Determination of calcium thioglycolate in depilatories

**M. PHARM. PHARMACEUTICAL QUALITY
ASSURANCE (MQA)**

MODERN PHARMACEUTICAL ANALYSIS (MPA101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know about chemicals and excipients

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY HOURS

60

- 1. UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. **14 Hrs**
IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.
Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.
- 2 NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy. **10 Hrs**
- 3 Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy **10 Hrs**

- 4 Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: **12 Hrs**
- Thin Layer chromatography
 - High Performance Thin Layer Chromatography
 - Ion exchange chromatography
 - Column chromatography
 - Gas chromatography
 - High Performance Liquid chromatography
 - Ultra High Performance Liquid chromatography
 - Affinity chromatography
 - Gel Chromatography
- 5 Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: **8 Hrs**
- Paper electrophoresis
 - Gel electrophoresis
 - Capillary electrophoresis
 - Zone electrophoresis
 - Moving boundary electrophoresis
 - Iso electric focusing
- X ray Crystallography:** Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.
- 6 Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry. **4 Hrs**
- Thermal Analysis:** Polymer behavior, factors affecting and instrumentation, and working, application of TGA

REFERENCES (Latest edition to be recommended)

- Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
- Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
- Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
- Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
- Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
- Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
- Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
- James Connors

QUALITY MANAGEMENT SYSTEMS (MQA101T)

Scope

This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.

Objectives

At completion of this course it is expected that students will be able to understand-

- The importance of quality
- ISO management systems
- Tools for quality improvement
- Analysis of issues in quality
- Quality evaluation of pharmaceuticals
- Stability testing of drug and drug substances
- Statistical approaches for quality

THEORY

60 Hrs

1. **Introduction to Quality:** Evolution of Quality, Definition of Quality, Dimensions of Quality

Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality

Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behavior, concept of internal and external customers. Case studies.

Cost of Quality: Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, Preventing cost of quality

12 Hrs

2. **Pharmaceutical quality Management:** Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.

12 Hrs

3. **Six System Inspection model:** Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system. Concept of self inspection.

Quality systems: Change Management/ Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.

12 Hrs

4. **Drug Stability:** ICH guidelines for stability testing of drug substances and drug products.

Study of ICH Q8, Quality by Design and Process development report

Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines

12 Hrs

5. **Statistical Process control (SPC):** Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.

8Hrs

6. **Regulatory Compliance through Quality Management and development of Quality Culture**

Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking

4 Hrs

REFERENCES:

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
3. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
4. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001
5. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
6. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
7. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
8. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications

QUALITY CONTROL AND QUALITY ASSURANCE (MQA102T)

Scope:

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Objectives:

Upon completion of this course the student should be able to

- Understand the cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable to Pharmaceutical industries
- To understand the responsibilities of QA & QC departments.

THEORY

60 Hrs

1. **Introduction:** Concept and evolution and scopes of Quality Control and Quality Assurance,

Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines.

Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.

12 Hrs

2. **cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering:** Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.

12 Hrs

- 3. Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3),** purchase specifications and maintenance of stores for raw materials.

In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).

10 Hrs

- 4. Documentation in pharmaceutical industry:** Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non regulated markets.

12 Hrs

- 5. Manufacturing operations and controls:** Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal. Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.

12 Hrs

REFERENCES

- 1 Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
- 2 Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
- 3 Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
- 4 How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.

- 5 The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
- 6 Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
- 7 ICH guidelines
- 8 ISO 9000 and total quality management
- 9 The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
- 10 QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
- 11 Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
- 12 Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
- 13 Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
- 14 Packaging of Pharmaceuticals.
- 15 Schedule M and Schedule N.

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (MQA103T)

Scope

This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and analytical tests and methods, required following candidate drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in manufacturing places.

Objectives:

Upon completion of this course the student should be able to

- To understand the new product development process
- To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D
- To elucidate necessary information to transfer technology of existing products between various manufacturing places

THEORY

60 Hrs

- 1. Principles of Drug discovery and development:** Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA.

12 Hrs

- 2. Preformulation studies:** Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Preformulation protocol, Stability testing during product development.

12 Hrs

- 3. Pilot plant scale up:** Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges.

12 Hrs

- 4. Pharmaceutical packaging:** Pharmaceutical dosage form and their packaging requirements, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing

modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials.

Quality control test: Containers, closures and secondary packing materials.

12 Hrs

- 5. Technology transfer:** Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models.

Documentation in technology transfer: Development report, technology transfer plan and Exhibit.

12 Hrs

REFERENCES

1. The process of new drug discovery and development. I and II Edition (2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis.
2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
4. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.
5. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rd Edn, Lea & Febriger, Philadelphia.
6. Pharmaceutical product development. Vandana V. Patreval. John I. Disouza. Maharukh T.Rustomji. CRC Press, Group of Taylor and Francis.
7. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania.
8. Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19th Edn.(1995)OO2C Lippincott;Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
9. The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt. Ltd.
10. Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1st Edition(Reprint 2006). Taylor and Francis. London and New York.

QUALITY ASSURANCE PRACTICAL-I (MQA104P)

PRACTICALS

1. Analysis of pharmacopoeial compounds in bulk and in their formulations (tablet/capsules/ semisolids) by UV Vis spectrophotometer
2. Simultaneous estimation of multi-drug component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry or AAS
7. **Case studies on**
 - Total Quality Management
 - Six Sigma
 - Change Management/ Change control. Deviations,
 - Out of Specifications (OOS)
 - Out of Trend (OOT)
 - Corrective & Preventive Actions (CAPA)
 - Deviations
- 8 Development of Stability study protocol
9. Estimation of process capability
11. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
12. Assay of raw materials as per official monographs
13. Testing of related and foreign substances in drugs and raw materials
14. To carry out pre formulation study for tablets, parenterals (2 experiment).
15. To study the effect of pH on the solubility of drugs, (1 experiment)
16. Quality control tests for Primary and secondary packaging materials
17. Accelerated stability studies (1 experiment)
18. Improved solubility of drugs using surfactant systems (1 experiment)
19. Improved solubility of drugs using co-solvency method (1 experiment)
20. Determination of Pka and Log p of drugs.

HAZARDS AND SAFETY MANAGEMENT (MPA201T)

Scope

This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle based approach to solve the complex tribulations.

Objectives

At completion of this course it is expected that students will be able to

- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an ideas to clear mechanism and management in different kinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

THEORY

60Hrs

1. **Multidisciplinary nature of environmental studies:** Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources

Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem.
Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.

12 Hrs

2. **Air based hazards:** Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non sterile area, Preliminary Hazard Analysis (PHA)
Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.

12 Hrs

- 3. Chemical based hazards:** Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards, Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.

12 Hrs

- 4. Fire and Explosion:** Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion- electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers.

12 Hrs

- 5. Hazard and risk management:** Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools
Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services

12 Hrs

REFERENCES:

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. "Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

PHARMACEUTICAL VALIDATION (MQA202T)

Scope

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Objectives

At completion of this course, it is expected that students will be able to understand-

- The concepts of calibration, qualification and validation
- The qualification of various equipments and instruments
- Process validation of different dosage forms
- Validation of analytical method for estimation of drugs
- Cleaning validation of equipments employed in the manufacture of pharmaceuticals

THEORY

60 Hrs

1. **Introduction to validation:** Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan.

Qualification: User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status- Calibration Preventive Maintenance, Change management).

12 Hrs

2. **Qualification of manufacturing equipment:** Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine.

Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.

12 Hrs

3. **Qualification of laboratory equipments:** Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus

Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.

12 Hrs

4. **Process Validation:** Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach.

Analytical method validation: General principles, Validation of analytical method as per ICH guidelines (Q2) and USP.

12 Hrs

5. **Cleaning Validation:** Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).

Validation of facilities in sterile and non-sterile plant.

Computerized system validation: Electronic records and digital signature - 21 CFR Part 11 and GAMP 5.

12 Hrs

REFERENCES:

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol.

157,2nd Ed., Marcel Dekker Inc., N.Y.

6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.
10. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
11. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press
12. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press

AUDITS AND REGULATORY COMPLIANCE (MPA203T)

Scope:

This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Objectives:

Upon completion of this course the student should be able to

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

THEORY

60 Hrs

1. **Introduction:** Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies

12 Hrs

2. **Role of quality systems and audits in pharmaceutical manufacturing environment:** cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.

1

2

Hrs

3. **Auditing of vendors and production department:** Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.

1

2

Hrs

4. **Auditing of Microbiological laboratory:** Auditing the manufacturing process,

Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.

12 Hrs

5. **Auditing of Quality Assurance and engineering department:** Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.

12 Hrs

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).

PHARMACEUTICAL MANUFACTURING TECHNOLOGY (MPA204T)

Scope

This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.

Objectives

At completion of this course it is expected that students will be able to understand-

- The common practice in the pharmaceutical industry developments, plant layout and production planning
- Will be familiar with the principles and practices of aseptic process technology, non sterile manufacturing technology and packaging technology.
- Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing

THEORY

60Hrs

1. **Pharmaceutical industry developments:** Legal requirements and Licenses for API and formulation industry, Plant location-Factors influencing.

Plant layout: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout.

Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.

1

2H

rs

2. **Aseptic process technology:** Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume).

Advanced sterile product manufacturing technology : Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.

Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS).

Lyophilization technology: Principles, process, equipment.

12Hrs

3. **Non sterile manufacturing process technology:** Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft).

Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.

Coating technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

12Hrs

4. **Containers and closures for pharmaceuticals:** Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit

worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material.

1

2H

rs

5. **Quality by design (QbD) and process analytical technology (PAT):** Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.

REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
6. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
8. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA,

2003.

9. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor & Francis, 1st Edition. UK.
10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA Inc. New york.
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey, 2008.

QUALITY ASSURANCE PRACTICAL-II(MQA204P)

PRACTICALS

1. Organic contaminants residue analysis by HPLC
2. Estimation of Metallic contaminants by Flame photometer
3. Identification of antibiotic residue by TLC
4. Estimation of Hydrogen Sulphide in Air.
5. Estimation of Chlorine in Work Environment.
6. Sampling and analysis of SO₂ using Colorimetric method
7. Qualification of following Pharma equipment
 - a. Autoclave
 - b. Hot air oven
 - c. Powder Mixer (Dry)
 - d. Tablet Compression Machine
8. Validation of an analytical method for a drug
9. Validation of a processing area
10. Qualification of at least two analytical instruments
11. Cleaning validation of one equipment
12. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
13. Check list for Bulk Pharmaceutical Chemicals vendors
14. Check list for tableting production.
15. Check list for sterile production area
16. Check list for Water for injection.
17. Design of plant layout: Sterile and non-sterile
18. Case study on application of QbD
19. Case study on application of PAT

**M.PHARM. PHARMACEUTICAL REGULATORY AFFAIRS
(MRA)**

GOOD REGULATORY PRACTICES (MRA 101T)

Scope

This course is designed to impart fundamental knowledge biological and medical devices on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP pharmaceutical industries and understand the rationale behind these requirements and will propose ways and means of complying them.

Objectives

At completion of this course it is expected that students will be able to understand-

- The key elements of current Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices, Good Documentation Practices
- The check lists for various Good Regulatory Practices and
- Prepare SOPs for Good Pharmaceutical Practices
- Implement Good Regulatory Practices in the Health care Industries and
- Prepare for the Audit of the Pharmaceutical Industries.
- Prepare for the rediness and conduct of the audit/inspections

THEORY

60Hrs

1. **Current Good Manufacturing Practices:** Introduction, US cGMP Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical devices, GHTF guidance docts

12Hrs

2. **Good Laboratory Practices:** Introduction,USFDA GLP Regulations (Subpart A to Subpart K),Controlling the GLP inspection process,GLP Documentation,Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, ISO

12Hrs

3. **Good Automated Laboratory Practices:** Introduction to GALP, Principles of GALP, GALP Requirements, SOPs of GALP, Training Documentation,21 CFR Part 11,General check list of 21CFR Part 11, Software Evaluation checklist, ISO.

12Hrs

4. **Good Distribution Practices:** Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP(Supply chain integrity), GHTF guidance/IMDRF/CDSCO

12Hrs

5. **Quality management systems:** Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)]and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and

products, ISO 13485, Schedule M III

12Hrs

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REFERENCES

1. Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth Edition, Drugs and the Pharmaceutical Sciences, Vol.168
2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press
3. Establishing a cGMP Laboratory Audit System, A practical Guide by David M.Bleisner, Wiley Publication.
4. How to practice GLP by PP Sharma, Vandana Publications.
5. Laboratory Auditing for Quality and Regulatory compliance bu Donald C.Singer, Drugs and the Pharmaceutical Sciences, Vol.150.

REGULATIONS LEGISLATIONS FOR FOOD PMBC IN INDIA (MRA 102T)

Scope:

This course is designed to impart fundamental knowledge on regulations and legislations in India with respect to PMBC. It prepares the students for basic regulatory requirements in India of PMB for manufacture, import, registration, export, sale, marketing authorization, clinical trials and intellectual property rights.

Objectives:

Upon the completion of the course the student shall be able to:

- Know different Acts and guidelines that regulate PMBC industry in India.
- Understand the approval process and regulatory requirements for drugs and medical devices

THEORY

60 HOURS

UNIT I

➤ **Study of Relevant provisions of FPMBC**

➤ **Acts and Rules (with latest amendments):**

- Drugs and Cosmetics Act 1940 and other Relevant provisions (Rules, Schedules and Guidelines) for approval of FPMBC , Rules 1945: DPCO and NPPA
- Legal definitions of schedules to the Act and Rules, Import of drugs, Manufacture of drugs, Sale of Drugs& Packing of drugs & other related Acts-Narcotic etc

Central Drug Standard Control Organization and State Licensing Authority:

1. Rules, Regulations, Guidelines For Regulatory filling of FPMB to Relevant Regulations
2. Fomat and contents of Regulatory dossier filling
3. Clinical trials /Investigations
 - Clinical Trials
 - New Drugs
 - Medical Devices
 - Fixed Dose Combinations

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12 Hrs

UNIT II

Regulatory requirements FNPCMB and approval procedures for:

12 Hrs

UNIT III

Indian Pharmacopoeial standards

- **BIS Standards & ISO and other relevant standards**

UNIT IV

BA/ BE: Bioavailability and Bioequivalence data, BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study

Stability requirements: ICH and WHO

Guidelines for drug testing in animals/Preclinical studies

- Animal testing: Rationale for conducting studies, CPCSEA Guidelines
- ethical guidelines for human participants
- ICMR-DBT Guidelines for Stem Cell Research

12 Hrs

UNIT V

Intellectual Property Rights: Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. IPR vs Regulatory Affairs

12 Hrs

REFERENCES

1. Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Office of India
2. Patent Failure How Judges, Bureaucrats, and Lawyers put innovators at risk by James Bessen and Michael J. Meurer
3. Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee
4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New delhi 2006.
5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA)
6. ICH E6 Guideline — Good Clinical Practice|| by ICH Harmonised Tripartite
7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation)
8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO
9. Guidelines for Import and Manufacture of Medical Devices by CDSCO
10. Guidelines from official website of CDSCO

INTERNATIONAL REGULATORY ASPECTS OF FNPCMB (MRA103T)

Scope:

This course is designed to impart the fundamental knowledge on the drug development general regulatory requirements for approval of FNPCMB Japan. It prepares the students to have elementary knowledge on the regulatory requirements, documentation requirements, and registration procedures for marketing the products in above countries.

Objectives: Upon completion of the course, the student shall be able to understand the Regulatory registration and landscape

THEORY

60 Hours

Unit-I

12 Hours

USA and CANADA: Organization structure and functions of FDA. Federal register and Code of Federal Regulations (CFR), History and evolution of United States Federal, Food, Drug and Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, Drug Master Files (DMF) system in US, Regulatory Approval Process for Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA); Regulatory requirements for Orphan drugs and Combination Products, Changes to an approved NDA / ANDA. Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in USA

Unit-II

12 Hours

EUROPEAN UNION and AUSTRALIA: Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files (ASMF) system in EU, Content and approval process of IMPD, Marketing Authorization procedures in EU (Centralized procedure, Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU

Unit-III

12

Hours

Japan: Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, Regulatory considerations

for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in Japan

UNIT IV

BRAZIL and CHINA

UNIT V

ASEAN and SOUTH ASIA

REFERENCES:

Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series, Vol.144

1. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185
Informa Health care Publishers.
2. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
3. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
4. Drugs: From Discovery to Approval, Second Edition By Rick Ng
5. New Drug Development: A Regulatory Overview, Eighth Edition By Mark Mathieu
6. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
7. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema
8. Country Specific Guidelines from official websites.

CLINICAL RESEARCH REGULATIONS (MRA 104T)

Scope:

This course is designed to impart the fundamental knowledge on the clinical development process of FNPMB, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in INDIA. It prepares the students to learn in detail on various laws, legislations and guidance related to safety, efficacy, ethical conduct and regulatory approval of clinical trials and investigations

Objectives: Upon completion of the course, the student shall be able to (know, do and appreciate)

- Clinical drug development process and different phases of clinical trials, investigations
- History, origin and ethics of clinical research
- regulatory requirements for conducting clinical trials investigations and research
- regulations and guidance governing the conduct of clinical research,

THEORY

60 Hours

Unit-I

12 Hours

Basics for Clinical trials for drug development process

- Phases of clinical trials, Clinical Trial protocol
- Phase 0 studies
- Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points)
- Phase II studies (proof of concept or principle studies to establish efficacy)
- Phase III studies (Multi ethnicity, global clinical trial, registration studies)
- Phase IV studies (Post marketing authorization studies; pits and practices)
- Ethical principles governing informed consent process
- Patient Information Sheet and Informed Consent Form
- The informed consent process and documentation

Unit-II

12 Hours

Basic CT for MD Ethics in Clinical Research:

- Historical Perspectives: Nuremberg Code, Thalidomide study , Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki
- Origin of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines.
- The ethics of randomized clinical trials
- The role of placebo in clinical trials
- Ethics of clinical research in special population
- Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data

- Data safety monitoring boards.
- Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research

Unit-III

12 Hours

Regulations governing Clinical Trials

USA: Regulations to conduct drug studies in USA (FDA)

- NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug)
- NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant)
- ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product)
- FDA Guidance for Industry - Acceptance of Foreign Clinical Studies
- FDA Clinical Trials Guidance Document: Good Clinical Practice

EU: Clinical Research regulations in European Union (EMA)

India: Clinical Research regulations in India – Schedule Y

Unit-IV

Clinical Research Related Guidelines

12 Hours

- Good Clinical Practice Guidelines (ICH GCP E6)
- Indian GCP Guidelines
- ICMR Ethical Guidelines for Biomedical Research
- CDSCO guidelines

Regulatory Guidance on Efficacy and Safety

ICH Guidance's

- E4 – Dose Response Information to support Drug Registration
- E7 – Studies in support of General Population: Geriatrics
- E8 – General Considerations of Clinical Trials
- E10 – Choice of Control Groups and Related Issues in Clinical Trials,
- E 11 – Clinical Investigation of Medicinal Products in the Pediatric Population

Unit-V

12 Hours

USA & EU Guidance

USA: FDA Guidance

- CFR 21Part 50: Protection of Human Subjects
- CFR 21Part 54: Financial Disclosure by Clinical Investigators
- CFR 21Part 312: IND Application
- CFR 21Part 314: Application for FDA Approval to Market a New Drug
- CFR 21Part 320: Bioavailability and bioequivalence requirements
- CFR 21Part 812: Investigational Device Exemptions

- CFR 21Part 822: Post-market surveillance
- FDA Safety Reporting Requirements for INDs and BA/BE Studies
- FDA Med Watch
- Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment

European Union: EMA Guidance

- EU Directives 2001
- EudraLex (EMA) Volume 3 – Scientific guidelines for medicinal products for human use
- EU Annual Safety Report (ASR)
- Volume 9A – Pharmacovigilance for Medicinal Products for Human Use

REFERENCES:

1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
2. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LL.M and Jennifer Kulynych, JD, PhD
3. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
4. Reviewing Clinical Trials: A Guide for the Ethics Committee; Johan PE Karlberg and Marjorie A Speers; Karlberg, Johan Petter Einar, Hong Kong.
5. International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy; Anthony C. Cartwright; Taylor & Francis Inc., USA.
6. New Drug Approval Process: The Global Challenge; Guarino, Richard A; Marcel Dekker Inc., NY.
7. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics; Douglas J. Pisano, David Mantus; CRC Press, USA
8. Country Specific Guidelines from official websites.

RECOMMENDED WEBSITES:

1. 1. EU Clinical Research Directive 2001: <http://www.eortc.be/services/doc/clinical-eudirective-04-april-01.pdf>
2. Code of Federal Regulations,
FDA:<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>
3. Guidelines of International Conference on Harmonization:
<http://www.ich.org/products/guidelines.html>
4. Eudralex Guidelines: <http://www.gmpcompliance.info/euguide.htm>
5. FDA New Drug Application:
<http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/ucm108125.htm>
6. Medicines and Healthcare products Regulatory Agency: <http://www.mhra.gov.uk>

7. Central Drugs Standard Control Organization Guidance for Industry: <http://cdsco.nic.in/CDSCO-GuidanceForIndustry.pdf>
8. ICMR Ethical Guidelines for Biomedical Research: http://icmr.nic.in/ethical_guidelines.pdf

PRACTICALS (MRA105P)

1. Case studies (4 Nos.) of each of Good Pharmaceutical Practices.
2. Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.
3. Preparation of SOPs, Analytical reports (Stability and validation)
4. Protocol preparation for documentation of various types of records (BMR, MFR, DR)
5. Labeling comparison between brand & generics.
6. Preparation of clinical trial protocol for registering trial in India
7. Registration for conducting BA/ BE studies in India
8. Import of drugs for research and developmental activities
9. Preparation of regulatory dossier as per Indian CTD format
10. Registering for different Intellectual Property Rights in India
11. GMP Audit Requirements as per CDSCO
12. Preparation and documentation for Indian Patent application.
13. Preparation of checklist for registration of IND as per ICH CTD format.
14. Preparation of checklist for registration of NDA as per ICH CTD format.
15. Preparation of checklist for registration of ANDA as per ICH CTD format.
16. Case studies on response with scientific rationale to USFDA Warning Letter
17. Preparation of submission checklist of IMPD for EU submission.
18. Comparison study of marketing authorization procedures in EU.
19. Comparative study of DMF system in US, EU and Japan
20. Preparation of regulatory submission using eCTD software
21. Preparation of Clinical Trial Application (CTA) for US submission
22. Preparation of Clinical Trial Application (CTA) for EU submission
23. Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form.
24. Regulatory requirements checklist for conducting clinical trials in India.
25. Regulatory requirements checklist for conducting clinical trials in Europe.
26. Regulatory requirements checklist for conducting clinical trials in USA

DOCUMENTATION AND REGULATORY WRITING (MRA 201T)

Scope

This course is designed to impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.

Objectives

Upon completion of the course the student shall be able to:

1. Know the various documents pertaining to drugs in pharmaceutical industry
 2. Understand the basics of regulatory compilation
 3. Create and assemble the regulation submission as per the requirements of agencies
 4. Follow up the submissions and post approval document requirements
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1. **Documentation in pharmaceutical industry:** Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF).
 2. **Dossier preparation and submission:** Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions
Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non eCTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission
 3. **Audits:** Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection
 4. **Inspections:** Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA)
 5. **Product life cycle management:** Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Effectuated in 30 Days (CBE-30), Annual Report, Post marketing

Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
5. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
6. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
7. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
8. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001
9. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
10. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
11. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
12. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications

BIOLOGICS REGULATIONS (MRA 203T)

Scope

This course is designed to impart fundamental knowledge on Regulatory Requirements, Licensing and Registration, Regulation on Labelling of Biologics in India, USA and Europe

It prepares the students to learn in detail on Regulatory Requirements for biologics, Vaccines and Blood Products

Objectives

Upon the completion of the course the student shall be able to:

- Know the regulatory Requirements for Biologics and Vaccines
- Understand the regulation for newly developed biologics and biosimilars
- Know the pre-clinical and clinical development considerations of biologics
- Understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements

Theory

60 Hrs

Unit I

1.India : Introduction, Applicable Regulations and Guidelines , Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance. GMP and GDP.

12 Hrs

Unit II

2.USA: Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics

12 Hrs

Unit III

3. European Union: Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ biosimilarity assessment, Plasma master file, TSE/ BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars), pre-clinical and clinical development considerations; stability, safety, advertising, labelling and packing of biologics in EU

12 Hrs

Unit IV

4. **Vaccine regulations in India, US and European Union:** Clinical evaluation, Marketing authorisation, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements

12 Hrs

Unit V

5. **Blood and Blood Products Regulations in India, US and European Union:** Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilance Network)

12 Hrs

REFERENCES

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano , David S. Mantus ; Informa ,2008
2. Biological Drug Products: Development and Strategies; Wei Wang , Manmohan Singh ; wiley ,2013
3. Development of Vaccines: From Discovery to Clinical Testing; Manmohan Singh , Indresh K. Srivastava ;Wiley, 2011
4. www.who.int/biologicals/en
5. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/
6. www.ihn-org.com
7. www.isbtweb.org
8. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India
9. www.cdsco.nic.in
10. www.ema.europa.eu › scientific guidelines › Biologicals
11. www.fda.gov/biologicsbloodVaccines/GuidanceComplianceRegulatoryInformation (Biologics)

INTERNATIONAL PHARMACEUTICAL REGULATIONS – II (MRA 203T)

Scope

This course is designed to impart fundamental knowledge on Regulatory Requirements for registration of drugs, medical devices and post approval requirements in WHO and emerging market (rest of world countries) like CIS, GCC, LATAM, ASIAN and African region.

Objectives

At completion of this course it is expected that students will be able to understand-

- Know the regulatory Requirements for drug and medical device registration in emerging market;
- Understand the registration requirements of emerging market by comparison; and
- Prepare dossiers for the registration of the products in emerging market.

THEORY

60 HOURS

1. **Emerging Market:** Introduction, Countries covered, Study of the world map, study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC)
12Hrs
2. **WHO:** WHO GMP, Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product (CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana)
12Hrs
3. **ASIAN Countries:** Introduction to ACTD, Regulatory Requirements for registration of drugs and post approval requirements in **China and South Korea & Association of Southeast Asian Nations (ASEAN) Region** i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand.
12Hrs
4. **CIS (Commonwealth Independent States):** Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine
12Hrs
5. **GCC (Gulf Cooperation Council) for Arab states:** Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE
12Hrs

REFERENCES

1. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ListMRAWebsites.pdf
2. Roadmap to an ASEAN economic community Edited by Denis Hew. ISEAS Publications, Singapore 2005, ISBN 981-230-347-2
3. ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978-981-230-750-7
4. Building a Future With Brics: The Next Decade for Offshoring, Mark Kobayashi-Hillary, Springer
5. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer
6. Trade performance and Regional Integration of the CIS Countries, Lev Freinkman, The world Bank, Washington, DC, ISBN: 0-8212-5896-0
7. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World By Frederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes 139
8. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low and Lorraine Carlos Salazar (Nov 22, 2010)
9. Doing Business in the Asean Countries, Balbir Bhasin, Business Expert Press ISBN: 13:978-1-60649-108-9
10. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Institute of South east asian studies, Singapore

INDIA MEDICAL DEVICE REGULATIONS (MRA 204T)

Scope:

This course is designed to impart the fundamental knowledge on the medical devices and *in vitro* diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU and ASEAN countries along with WHO regulations. It prepares the students to learn in detail on the harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketing medical devices in regulated countries.

Objectives:

Upon completion of the course, the student shall be able to know

- basics of medical devices, process of development, ethical and quality considerations
- harmonization initiatives for approval and marketing medical devices
- regulatory approval process for medical devices in US, EU and Asia
- clinical aspects of medical devices

THEORY

60 Hours

Unit-I

12 Hours

Medical Devices: Introduction, differentiating medical devices from IVDs and Combination Products, History of Medical Device Regulation, Product Lifecycle of Medical Devices, Classification of Medical Devices.

IMDRF/GHTF: Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN).

Unit-II

12 Hours

Ethics: Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011)

Quality: Quality System Regulations of Medical Devices: ISO 13485, Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device

Unit-III

12 Hours

USA: Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and *In vitro* Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements

21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI).
Basics of *In vitro* diagnostics, classification and approval process.

Unit-IV

12 Hours

European Union: Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and *In vitro* Diagnostics (*In Vitro* Diagnostics Directive), CE certification process.
Basics of *In vitro* diagnostics, classification and approval process.

Unit-V

12 Hours

Medical Device Regulations in World Health Organization (WHO): Registration Procedures, Quality System requirements and Regulatory requirements
Asia: Clinical Trial Regulations specific for Medical Devices, Registration Procedures, Quality System requirements and Regulatory requirements for Japan, India and China

REFERENCES:

1. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics by Douglas J. Pisano, David Mantus.
2. Medical Device Development: A Regulatory Overview by Jonathan S. Kahan
3. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh
4. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics by Carmen Medina
5. Country Specific Guidelines from official websites.

PRACTICAL (MRA205P)

1. Case studies on
 - Change Management/ Change control. Deviations
 - Corrective & Preventive Actions (CAPA)
2. Documentation of raw materials analysis as per official monographs
3. Preparation of audit checklist for various agencies
4. Preparation of submission to FDA using eCTD software
5. Preparation of submission to EMA using eCTD software
6. Preparation of submission to MHRA using eCTD software
7. Preparation of Biologics License Applications (BLA)
8. Preparation of documents required for Vaccine Product Approval
9. Comparison of clinical trial application requirements of US, EU and India of Biologics
10. Preparation of Checklist for Registration of Blood and Blood Products
11. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization
12. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization
13. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization
14. Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization
15. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization
16. Checklists for 510k and PMA for US market
17. Checklist for CE marking for various classes of devices for EU
18. STED Application for Class III Devices
19. Audit Checklist for Medical Device Facility
20. Clinical Investigation Plan for Medical Devices

**M. PHARM. PHARMACEUTICAL
BIOTECHNOLOGY (MPB)**

MODERN PHARMACEUTICAL ANALYSIS (MPA101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know,

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY

60 HOURS

- 1. UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation **12 Hrs**
associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.
IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy
Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.
- 2 NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy. **12 Hrs**

- 3 Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy **12 Hrs**
- 4 Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: **12 Hrs**
a) Paper chromatography b) Thin Layer chromatography
c) Ion exchange chromatography d) Column chromatography
e) Gas chromatography f) High Performance Liquid chromatography
g) Affinity chromatography
- 5 Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: **12 Hrs**
a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis
d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

MICROBIAL AND CELLULAR BIOLOGY (MPB101T)

Scope

This subject is designed to provide the advanced knowledge to the biotechnology students in invaluable areas of advanced microbiology which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry.

Objective

At the completion of this course it is expected that the students will get an understanding about the following aspects;

- Importance of Microorganisms in Industry
- Central dogma of molecular biology
- Structure and function of cell and cell communication
- Cell culture technology and its applications in pharmaceutical industries.
- Microbial pathogenesis

THEORY

60Hrs

UNIT I

12Hrs

Microbiology

Introduction – Prokaryotes and Eukaryotes. Bacteria, fungi, actionomyocytes and virus - structure, chemistry and morphology, cultural, physiological and reproductive features. Methods of isolation, cultivation and maintenance of pure cultures. Industrially important microorganisms - examples and applications

UNIT II

12 Hrs

Molecular Biology

05 Hrs

Structure of nucleus and chromosome, Nucleic acids and composition, structure and types of DNA and RNA. Central dogma of molecular biology: Replication, Transcription and transcription.

Gene regulation

02 Hrs

Gene copy number, transcriptional control and translational control.

RNA processing

05 Hrs

Modification and Maturation, RNA splicing, RNA editing, RNA amplification. Mutagenesis and repair mechanisms, types of mutants, application of mutagenesis in stain

improvement, gene mapping of plasmids- types purification and application. Phage genetics, genetic organization, phage mutation and lysogeny.

UNIT III

12 Hrs

Cell structure and function

05 Hrs

Cell organelles, cytoskeleton & cell movements, basic aspects of cell regulation, bioenergetics and fuelling reactions of aerobics and anaerobics, secondary metabolism & its applications. Cell communication, cell cycle and apoptosis, mechanism of cell division. Cell junctions/adhesion and extra cellular matrix, germ cells and fertilization, histology – the life and death of cells in tissues.

Cell Cycle and Cytoskeleton

03 Hrs

Cell Division and its Regulation, G-Protein Coupled Receptors, Kinases, Nuclear receptors, Cytoskeleton & cell movements, Intermediate Filaments.

Apoptosis and Oncogenes

02 Hrs

Programmed Cell Death, Tumor cells, carcinogens & repair.

Differentiation and Developmental Biology

02 Hrs

Fertilization, Events of Fertilization, *In vitro* Fertilization, Embryonic Germ Cells, Stem Cells and its Application.

UNIT IV

12 Hrs

Principles of microbial nutrition

05 Hrs

Physical and chemical environment for microbial growth, Stability and degeneration of microbial cultures.

Growth of animal cells in culture

07 Hrs

General procedure for cell culture, Nutrient composition, Primary, established and transformed cell cultures, applications of cell cultures in pharmaceutical industry and research. Growth of viruses in cell culture propagation and enumeration. *In vitro* screening techniques- cytotoxicity, anti-tumor, anti-viral assays.

UNIT V

12 Hrs

Microbial pathology

Identifying the features of pathogenic bacteria, fungi and viruses. Mechanism of microbial pathogenicity, etiology and pathology of common microbial diseases and currently recommended therapies for common bacterial, fungal & viral infections. Mechanism of action of antimicrobial agents and possible sites of chemotherapy.

REFERENCES

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn, Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. David Freifelder, Molecular Biology, 2nd edition, Narosa Publishing House.
5. R. Ian Freshney, Culture of animal cells – A manual of Basic techniques, 6th edition, Wileys publication house.
6. David Baltimore, Molecular cell biology, W H Freeman & Co publishers.
7. Cell biology vol-I,II,III by Julio E.Cells
8. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company.

BIOPROCESS ENGINEERING AND TECHNOLOGY (MPB102T)

Scope

This paper has been designed to provide the knowledge to the biotechnology students in invaluable areas of bioprocess technology to develop skills to modify, design and operate different types of fermenters, to understand and implement various fermentation procedures, to train students in scale up fermentation operations.

Objective

At the completion of this subject it is expected that students will be able to,

- Understand basics and design of fermentation technology
- Scale up and scale down processing of fermentation technology
- Bioprocessing of the industrially important microbial metabolites for the growth of microorganisms in industries and R & D organizations.
- Regulation governing the manufacturing of biological products
- Understand and conduct fermentation process kinetics.

THEORY **60 Hrs**

UNIT I **12 Hrs**

Introduction to fermentation technology

Basic principles of fermentation **02 Hrs**

Study of the design and operation of bioreactor **04 Hrs**

Ancillary parts and function, impeller design and agitation, power requirements on measurements and control of dissolved oxygen, carbon dioxide, temperature, pH and foam.

Types of bioreactor **04 Hrs**

CSTR, tower, airlift, bubble column, packed glass bead, hollow fiber, configuration and application

Computer control of fermentation process **02 Hrs**

System configuration and application

UNIT II **12 Hrs**

Mass transfer and Rheology

Mass transfer **07 Hrs**

Theory, diffusional resistance to oxygen requirements of microorganisms, measurements of mass transfer co- efficient and factor affecting them, effects of aeration and agitation on

mass transfer, supply of air, air compressing, cleaning and sterilization of air and plenumventilation, air sampling and testing standards for air purity.

Rheology **05 Hrs**

Rheological properties of fermentation system and their importance in bioprocessing.

UNIT III **12 Hrs**

Scale up of fermentation process **04 Hrs**

Principles, theoretical considerations, techniques used, media for fermentation, HTST sterilization, advantage and disadvantage, liquid sterilization.

Cultivation and immobilized culture system **04 Hrs**

Cultivation system - batch culture, continuous culture, synchronous cultures, fed batch culture. Graphical plot representing the above systems.

Introduction to immobilization **04 Hrs**

Techniques, immobilization of whole cell, immobilized culture system to prepare fine chemicals. Immobilization of enzymes and their applications in the industry. Reactors for immobilized systems and perspective of enzyme engineering.

UNIT IV **12 Hrs**

Scale down of fermentation process **08 Hrs**

Theory, equipment design and operation, methods of filtration, solvent extraction, chromatographic separation, crystallization turbidity analysis and cell yield determination, metabolic response assay, enzymatic assay, bioautographic techniques and disruption of cells for product recovery.

Isolation, screening **04 Hrs**

Primary and secondary, maintenance of stock culture, strain improvement for increased yield.

UNIT V **12 Hrs**

Bioprocessing of the industrially important microbial metabolites **08 Hrs**

- a. Organic solvents – Alcohol and Glycerol
- b. Organic acids - Citric acids, Lactic acids,
- c. Antibiotics - Penicillin, Streptomycin, Griseofulvin,
- d. Vitamins - B12, Riboflavin and Vitamin C
- e. Amino acids - Glutamic acids, Lysine, Cyclic AMP and GMP

Biosynthetic pathways for some secondary metabolites, microbial transformation of steroids and alkaloids

02 Hrs

REFERENCES

1. Peter Stanbury, Allan Whitaker, Stephen Hall, Principles of Fermentation technology, 3rd edition, Elsevier stores.
2. L.E. Casida, Industrial Microbiology, 3rd edition, John Wiley & sons Inc.
3. F.M. Asubel, Current protocols in molecular biology, volume I and II, John Wiley Publishers.
4. Biotol Board, Bioreactor design and product yield, Butterworth and Helhemann publishers.
5. A. H. Patel, Industrial microbiology, 2nd edition, Macmillan India Limited; Second edition

ADVANCED PHARMACEUTICAL BIOTECHNOLOGY (MPB103T)

Scope

This paper has been designed to provide the knowledge to the students to develop skills of advanced techniques of isolation and purification of enzymes, to enrich students with current status of development of vaccines and economic importance of biotechnology products.

Objective

At the completion of this subject it is expected that students will be able to –

- Understand about the latest technology development in biotechnology technique, tools and their uses in drug and vaccine development.
- Identify appropriate sources of enzymes.
- Understand and perform genetic engineering techniques in gene manipulation, r-DNA technology and gene amplification.
- Understand the overview of pharmacogenomics.
- Learn the regulatory approval process and key regulatory agencies for new drugs, biologics, devices, and drug-device combinations.

THEORY

60 Hrs

UNIT I

12 Hrs

Enzyme Technology

Classification, general properties of enzymes, dynamics of enzymatic activity, sources of enzymes, extraction and purification, Applications pharmaceutical, therapeutic and clinical. Production of amyloglucosidase, glucose isomerase, amylase and trypsin.

UNIT II

12 Hrs

Genetic Engineering

06 Hrs

Techniques of gene manipulation, cloning strategies, procedures, cloning vectors expression vectors, recombinant selection and screening, expression in E.coli and yeast.

Site directed mutagenesis, polymerase chain reaction, and analysis of DNA sequences .

02 Hrs

Gene library and cDNA

01 Hrs

Applications of the above technique in the production of,

03 Hrs

- Regulatory proteins - Interferon, Interleukins
- Blood products -Erythropoietin
- Vaccines - Hepatitis-B
- Hormones -Insulin

UNIT III

12 Hrs

Therapeutic peptides

05 Hrs

Study on controlled and site specified delivery of therapeutic peptides and proteins through various routes of administration.

Transgenic animals

02 Hrs

Production of useful proteins in transgenic animals and gene therapy.

Human Genome

05 Hrs

The human genome project-a brief study, Human chromosome – Structure and classification, chromosomal abnormalities – Syndromes

UNIT IV

12Hrs

Signal transduction

08 Hrs

Introduction, cell signaling pathways, Ion channels, Sensors and effectors, ON and OFF mechanisms, Spatial and temporal aspects of signaling, cellular process, development, cell cycle and proliferation, neuronal signaling, cell stress, inflammatory responses and cell death, signaling defects and diseases.

Oncogenes

04 Hrs

Introduction, definition, various oncogenes and their proteins.

UNIT V

12 Hrs

Microbial Biotransformation

04 Hrs

Biotransformation for the synthesis of chiral drugs and steroids.

Microbial Biodegradation

04 Hrs

Biodegradation of xenobiotics, chemical and industrial wastes,

Production of single-cell protein,

Applications of microbes in environmental monitoring.

Biosensors

04 Hrs

Definition, characteristics of ideal biosensors, types of biosensors, biological recognition elements, transducers, application of biosensors.

REFERENCES

1. Biotechnology-The biological principles: MD Trevan, S Boffey, KH Goulding and P.F. Stanbury.
2. Immobilization of cells and enzymes: HosevearKennadycabral& Bicker staff
3. Principles of Gene Manipulating: RW Old and S.B.Primrose.
4. Molecular Cell Biology: Harvey Lodish, David Baltimore, Arnold Berk, S LawenceZipursky, Paul Matsudaira, James Darnell.
5. Modern Biotechnology: S.B Primrose
6. Gene transfer and expression protocols-methods in Molecular Biology, vol. VII, Edit E.T. Murray
7. Current protocols in Molecular Biology, Vo1.I & II:F.M. Asubel, John wiley Publishers
8. Current protocols in cellular biology, Vo1.1 & II John wiley publishers.
9. Principles of human genetics; by Curt Stern, published by W.H. Freeman, 1960.

SEMESTER – I

PRACTICALS (MPB104P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Isolation and Purification of microorganism from the soil
8. Microbial contamination of Water and biochemical parameters.
9. Determination of Minimum Inhibitory concentration by gradient plate technique and serial dilution method.
10. UV- survival curve and Dark repair
11. Sterility test for pharmaceutical preparations
12. Sub culturing of cells and cytotoxicity assays.
13. Construction of growth curve and determination of specific growth rate and doubling time
14. Fermentation process of alcohol and wine production
15. Fermentation of vitamins and antibiotics
16. Whole cell immobilization engineering
17. Thermal death kinetics of bacteria
18. Replica plating
19. Bio-autography.
20. Isolation and estimation of DNA
21. Isolation and estimation of RNA
22. Isolation of plasmids
23. Agarose gel electrophoresis.
24. Transformation techniques
25. SDS – polyacrylamide gel electrophoresis for proteins
26. Polymerase chain reaction technique.

PROTEINS AND PROTEIN FORMULATIONS (MPB201T)

Scope

This course is designed to impart knowledge and skills necessary for knowing fundamental aspects of proteins and their formulations is a part of drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of information for protein formulation and design are provided to help the students to clarify the various biological concepts of protein.

Objective

At the completion of this course it is expected that students will be able to understand,

- Various methods of purification of proteins
- Peptides in drug development
- Protein identification and characterization
- Protein based formulations
- Sequencing proteins

THEORY

60 Hrs

UNIT I

12 Hrs

Protein engineering

Concepts for protein engineering. Isolation and purification of proteins, Stability and activity based approaches of protein engineering, Chemical and Physical Considerations in Protein and Peptide Stability, Different methods for protein engineering, gene shuffling, and direct evolution

UNIT II

12 Hrs

Peptidomimetics

Introduction, classification; Conformationally restricted peptides, design, pseudopeptides, peptidomimetics and transition state analogs; Biologically active template; Amino acid replacements; Peptidomimetics and rational drug design; CADD techniques in peptidomimetics; Development of non peptide peptidomimetics.

UNIT III

12 Hrs

Proteomics

08 Hrs

Protein identification and characterization: Methods/strategies, protein identification, de novo protein characterization, Isotope labelling, N- and C-terminal tags.

2-Dimensional gel electrophoresis

04 Hrs

Methods (including IPGs), resolution, reproducibility and image analysis, future developments

UNIT IV

12 Hrs

Protein formulation

Different strategies used in the formulation of DNA and proteins, Analytical and biophysical parameters of proteins and DNA in pre-formulation, Liposomes, Neon-spears, Neon-particulate system, Pegilation, Biological Activity, Biophysical Characterization Techniques, Forced degradation studies of protein.

UNIT V

12 Hrs

Methods of protein sequencing

Various methods of protein sequencing, characterisation, Edman degradation, Tryptic and/or Chymotryptic Peptide Mapping.

REFERENCE

1. H. Lodish et al. Molecular Cell Biology, W. H. Freeman and Company
2. Protein Purification – Hand Book – 1998 Amersham pharmacia biotech
3. Engelbert Buxbaum, Fundamentals of Protein Structure and Function (2007), Springer Science
4. Sheldon J. Park, Jennifer R. Cochran, Protein Engineering and Design (2009), CRC press.
5. Robert K. Skopes. Protein purification, principle and practice (1993), springer link.
6. David Whitford, Proteins-Structure and Function (2005), John Wiley & Sons Ltd.

7. James Swarbrick, Protein Formulation and Delivery (2008) Informa Healthcare USA, Inc.
8. Rodney Pearlman, Y. John Wang Formulation, Characterization, and Stability of Protein Drugs (2002), Kluwer Academic Publishers.

IMMUNOTECHNOLOGY (MPB202T)

Scope

This course is designed to impart knowledge on production and engineering of antibodies, the application of antigens, the design of (recombinant) vaccines, strategies for immune intervention, etc. The Immunotechnology - based techniques will be used in the medicine for therapeutics and diagnostics, industries in the production, quality control and quality assurance, and in R&D.

Objective

After this course, the students will be able to:-

- Understand the techniques like immunodiagnostic tests,
- Characterization of lymphocytes, purification of antigens and antibody, etc.
- Access health problems with immunological background;
- Develop approaches for the immune intervention of diseases

THEORY

60 Hrs

UNIT I

12 Hrs

Fundamental aspects of immunology

06 Hrs

Introduction, cells and organs of the immune system, cellular basis of Immune response, primary and secondary lymphoid organs, antigen antibody and their structure.

Types of immune responses, anatomy of immune response.

Overview of innate and adaptive Immunity.

Humoral Immunity

03 Hrs

B – Lymphocytes and their activation. Structure and function of immunoglobulins, idiotypes and anti idiotypic antibodies.

Cell mediated Immunity

03 Hrs

Thymus derived lymphocytes (T cells) – their ontogeny and types, MHC complex, antigen presenting cells (APC), mechanisms of T cell activation, macrophages, dendritic cells, langerhans cells, mechanism of phagocytosis

UNIT II

12 Hrs

Immune Regulation and Tolerance

08 Hrs

Complement activation and types and their biological functions, cytokines and their role in immune response.

Hypersensitivity

02 Hrs

Hypersensitivity Types I-IV, Hypersensitivity reactions and treatment

Autoimmune diseases

02 Hrs

UNIT III

12 Hrs

Vaccine technology

06 Hrs Vaccine and their types, conventional vaccines, novel methods for vaccine production, antiidiotypic vaccine, DNA vaccine, genetically engineered vaccine, iscoms, synthetic peptides, and immunodiagnostics.

Stem cell technology

06 Hrs

Stem cell technology and applications to immunology

UNIT IV

12 Hrs

Hybridoma Technology

Hybridoma techniques – fusion methods for myeloma cells and B-Lymphocytes, selection and screening techniques. Production and purification of monoclonal antibodies and their applications in Pharmaceutical industry.

UNIT V

12 Hrs

Immunological Disorder

06 Hrs

Autoimmune disorders and types, pathogenic mechanisms, treatment, experimental models of auto immune diseases, primary and secondary immunodeficiency disorders.

Immunodiagnosis

06 Hrs

Antigen antibody interaction – Precipitation reaction, Agglutination reactions, Principles and applications of ELISA, Radio Immuno Assay, Western blot analysis, immune-

electrophoresis, immunofluorescence, chemiluminescence assay.

References

1. J. Kubey, Immunology – an Introduction, 2004.
2. S.C. Rastogi, Immunodiagnosics, New Age International, 1996.
3. Ashim Chakravarty, Immunology and Immunotechnology, Oxford University Press, 2006.
4. E. Benjamini, Molecular Immunology, 2002.

BIOINFORMATICS AND COMPUTATIONAL BIOTECHNOLOGY (MPB203T)

Scope

This paper has been designed to provide the advanced knowledge to the biotechnology students in invaluable areas of advanced bioinformatics which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry.

Objectives

At completion of this course it is expected that the students will be able to understand,

- Usage of computers in developing a new drugs
- Biological concepts for bioinformatics
- Proteins and their diversity
- Various gene finding methods
- Searching the biological databases
- Target searching
- Various methods of drug designing

THEORY

60 Hrs

UNIT I

12Hrs

Introduction to Bioinformatics

04 Hrs

Definition and History of Bioinformatics, Internet and Bioinformatics, Introduction to Data Mining, Applications of Data Mining to Bioinformatics,

Biological Database

08 Hrs

Protein and nucleic acid databases. Structural data bases. Collecting and storing the sequence and Applications of Bioinformatics.

UNIT II

12 Hrs

Sequence analysis

Sequence alignment, pair wise alignment techniques, multiple sequence analysis, multiple sequence alignment; Flexible sequence similarity searching with the FAST3 program package, the use of CLUSTAL W and CLUSTAL X for the multiple sequence alignment. Tools used for sequence analysis.

UNIT III

12 Hrs

Protein informatics

05 Hrs

Introduction; Force field methods; Energ, buried and exposed residues, side chains and neighbours; Fixed regions, hydrogen bonds, mapping properties onto surfaces; Fitting monomers, rms fit of conformers, assigning secondary structures; Sequence alignment-methods, evaluation, scoring; Protein completion, backbone construction and side chain addition; Small peptide methodology, software accessibility, building peptides; Protein displays; Substructure manipulations, annealing.

Protein structure prediction

05 Hrs

Protein folding and model generation; Secondary structure prediction, analyzing secondary structures; Protein loop searching, loop generating methods, loop analysis; Homology modeling, concepts of homology modeling, potential applications, description, methodology, homologous sequence identification; Align structures, align model sequence; Construction of variable and conserved regions, threading techniques, Topology fingerprint approach for prediction, evaluation of alternate models; Structure prediction on a mystery sequence, structure aided sequence techniques of structure prediction, structural profiles, alignment algorithms, mutation tables, prediction, validation, sequence based methods of structure prediction, prediction using inverse folding, fold prediction; Significance analysis, scoring techniques, sequence- sequence scoring.

Docking

02 Hrs

Docking problems, methods for protein- ligand docking, validation studies and applications; Screening small molecule databases, docking of combinatorial libraries, input data, analyzing docking results.

UNIT IV

12Hrs

Diversity of Genomes

04Hrs

Prokaryotic and Eukaryotic Gene Families. Genome Analysis: Introduction, Gene prediction methods, Gene mapping and applications- Genetic and Physical Mapping, Integrated map, Sequence assembly and gene expression.

Completed Genomes

02 Hrs

Bacterium, Nematode, Plant and Human

Evolution of Genomes

04 Hrs

Lateral or Horizontal Transfer among Genomes, Transcriptome and Proteome-General Account

Phylogenetic analysis

02 Hrs

Evolutionary Change in Nucleotide Sequences, Rates and Patterns of Nucleotide Substitution, Models for Nucleotide Substitution, Construction of Phylogenetic Tree, Genome Annotation technique.

UNIT V

12Hrs

Target searching and Drug Designing

Target and lead, timeline for drug development, target discovery, target modulators, *insilico* gene expression, microarray, and lead discovery, libraries of ligands, active site analysis, and prediction of drug quality.

REFERENCE

1. David W. Mount, Bioinformatics Sequence and Genome Analysis, Second Edition – 2005, CBS Publishers and Distributors
2. S. C. Rastogi et al. Bioinformatics- Concepts Skill and Applications, First Edition –2003, CBS Publishers and Distributors
3. T. E. Creighton, Protein Structure and Molecular Properties, Second Edition-1993 W. H. Freeman and Company
4. Andreas D. Baxevanis, B. F. Francis Ouellette, Bioinformatics; A Practical Guide to the Analysis of Genes and Proteins, 2nd Edition. 2001 John Wiley & Sons, Inc.
5. Arthur M. Lesk, Introduction to Bioinformatics (2002), Oxford University Press.

6. Shui Qing Ye. Bioinformatics: A Practical Approach (2008), Chapman & Hall/CRC.
7. David Posada, Bioinformatics for DNA Sequence Analysis (2008), Humana press.
8. Lesk, A.M. 2002 Introduction to Bioinformatics. Oxford University Press.
9. Letovsky, S.I. 1999 Bioinformatics. Kluwer Academic Publishers.
10. Baldi, P. and Brunak, S. 1998 Bioinformatics. The MIT Press.

BIOLOGICAL EVALUATION OF DRUG THERAPY (MPB204T)

Scope

This paper has been designed to provide the knowledge to the biotechnology students to understand the importance of biological and evaluation of drug therapy of biological medicines.

Objective

At the completion of this subject it is expected that students will be able to –

- Understand about the general concept of standardization of biological.
- Understand the importance of transgenic animals and knockout animals.
- Understand the biological medicines in development of various diseases.
- Learn the biological evaluation of drugs *in vitro* and *in vivo*

THEORY

60 Hrs

UNIT I

12 Hrs

Biological Standardization

04 Hrs

General principles, Scope and limitation of bio-assay, bioassay of some official drugs.

Preclinical drug evaluation

06 Hrs

Preclinical drug evaluation of its biological activity, potency and toxicity-Toxicity test in animals including acute, sub-acute and chronic toxicity, ED50 and LD50 determination, special toxicity test like teratogenicity and mutagenicity.

Guidelines for toxicity studies

02 Hrs

Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials.

UNIT II

12 Hrs

Pyrogens

04 Hrs

Pyrogens: Sources, Chemistry and properties of bacterial pyrogens and endotoxins, Official pyrogen tests.

Microbiological assay

04 Hrs

Assay of antibiotics and vitamins.

Biological evaluation of drugs

04 Hrs

Screening and evaluation (including principles of screening, development of models for diseases: *In vivo* models / *In vitro* models / cell line study).

UNIT III

12 Hrs

Biologic Medicines in Development for various diseases —

06 Hrs

By Therapeutic Category

- Genetic Disorders
- Eye Conditions
- Digestive Disorders
- Diabetes/Related Conditions
- Cardiovascular Disease
- Cancer/Related Conditions
- Blood Disorders
- Autoimmune Disorders
- Infectious Diseases
- Neurologic Disorders
- Skin Diseases
- Transplantation

Biologic Medicines in Development for various diseases —

06 Hrs

by Product Category

- Antisense
- Vaccines
- Recombinant Hormones/Proteins
- Monoclonal Antibodies (mAb)
- Interferons
- Growth Factors
- Gene Therapy

- RNA Interference

UNIT IV

12 Hrs

Regulatory aspects : drugs, biologics and medical devices

04 Hrs

An introduction to the regulations and documents necessary for approval of a medical product.

Regulatory consideration

04 Hrs

Regulatory consideration for pre-clinical testing and clinical testing of drugs, biologics and medical devices.

New Drug Applications for Global Pharmaceutical Product Approvals

04 Hrs

UNIT V

12 Hrs

Bioavailability

06 Hrs

Objectives and consideration in bio-availability studies, Concept of equivalents, Measurements of bio-availability.

Determination of the rate of absorption, Bioequivalence and its importance, Regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems.

Pharmacokinetics

06 Hrs

Pharmacokinetics:- Basic consideration, Pharmacokinetic models, Application of Pharmacokinetics in new drug development and designing of dosage forms and Novel drug delivery systems.

References:

1. Perkins F.T., Hennessen W. Standardization and Control of Biologicals Produced by Recombinant DNA Technology, International Association of Biological Standardization
2. J.H. Burn., Biological Standardization, Oxford University Press
3. Drug Discovery and Evaluation in Pharmacology assay: Vogel

4. Chow, Shein, Ching, Design and analysis of animal studies in pharmaceutical development,
5. Nodine and Siegler, Animal and Clinical pharmacologic Techniques in Drug Evaluation-
6. Screening methods in pharmacology (vol I & II)–R.A. Turner

SEMESTER – II

PRACTICALS (MPB205P)

1. Protein identification
2. Protein characterization
3. Protein biochemistry
4. Recombinant DNA Technology
5. Protein expression
6. Protein formulations
7. Database searching
8. Sequence analysis methods
9. Protein structure prediction
10. Gene annotation methods
11. Phylogenetic analysis
12. Protein, DNA binding studies
13. Preparation of DNA for PCR applications – Isolation, Purity and Quantification
14. Introduction to PCR – working of PCR, Programming.
15. Introduction to RT-PCR – working, programming.
16. Primer design using softwares.
17. Gene DNA amplification by random / specific primers.
18. Southern Hybridization
19. Western Blotting
20. Gene transformation

PHARMACY PRACTICE
(MPP)

CLINICAL PHARMACY PRACTICE (MPP101T)

Scope

This course is designed to impart the basic knowledge and skills that are required to practice pharmacy including the provision of pharmaceutical care services to both healthcare professionals and patients in clinical settings.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Understand the elements of pharmaceutical care and provide comprehensive patient care services
- Interpret the laboratory results to aid the clinical diagnosis of various disorders
- Provide integrated, critically analyzed medicine and poison information to enable healthcare professionals in the efficient patient management

THEORY

60 Hrs

1. **Introduction to Clinical Pharmacy:** Definition, evolution and scope of clinical pharmacy, International and national scenario of clinical pharmacy practice, Pharmaceutical care

Clinical Pharmacy Services: Ward round participation, Drug therapy review (Drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions)

12 Hrs

2. **Clinical Pharmacy Services:** Patient medication history interview, Basic concept of medicine and poison information services, Basic concept of pharmacovigilance, Hemovigilance, Materiovigilance and AEFI, Patient medication counselling, Drug utilisation evaluation, Documentation of clinical pharmacy services, Quality assurance of clinical pharmacy services

1

2 Hrs

3. **Patient Data Analysis:**

Patient Data & Practice Skills: Patient's case history - its structure and significances in drug therapy management, Common medical abbreviations and terminologies used in clinical practice, Communication skills: verbal and non-verbal communications, its applications in patient care services.

Lab Data Interpretation: Haematological tests, Renal function tests, Liver function tests

12 Hrs

4. **Lab Data Interpretation:** Tests associated with cardiac disorders, Pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, Microbiological culture sensitivity tests

1

2 Hrs

5. Medicines & Poison Information Services

Medicine Information Service: Definition and need for medicine information service, Medicine information resources, Systematic approach in answering medicine information queries, Preparation of verbal and written response, Establishing a drug information centre

Poison Information Service: Definition, need, organization and functions of poison information centre

12 Hrs

REFERENCES

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata (latest edition)
2. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia (latest edition)
3. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc (latest edition)
4. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS-I (MPP102T)

Scope

This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualising the treatment plan through evidence-based medicines.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence based medicine
- Prepare individualized therapeutic plans based on diagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time- course of clinical and laboratory indices of therapeutic response and adverse effect/s)

THEORY

60 Hrs

Etiopathogenesis and pharmacotherapy of diseases associated with following systems

1. **Cardiovascular system:** Hypertension, Congestive cardiac failure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias

12 Hrs

2. **Respiratory system:** Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases

Endocrine system: Diabetes, Thyroid diseases

12 Hrs

3. **Gastrointestinal system:** Peptic ulcer diseases, Reflux esophagitis, Inflammatory bowel diseases, Jaundice & hepatitis

12 Hrs

4. **Gastrointestinal system:** Cirrhosis, Diarrhea and Constipation, Drug-induced liver disease

Hematological diseases: Anemia, Deep vein thrombosis, Drug induced hematological disorders

12 Hrs

- 5. Bone and joint disorders:** Rheumatoid arthritis, Osteoarthritis, Gout, Osteoporosis

Dermatological Diseases: Psoriasis, Eczema and scabies, impetigo, drug induced skin disorders

Ophthalmology: Conjunctivitis, Glaucoma

12 Hrs

REFERENCES

1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice— McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

HOSPITAL & COMMUNITY PHARMACY (MPP103T)

Scope

This course is designed to impart basic knowledge and skills that are required to practice pharmacy in both hospital and community settings.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Understand the organizational structure of hospital pharmacy
- Understand drug policy and drug committees
- Know about procurement & drug distribution practices
- Know the admixtures of radiopharmaceuticals
- Understand the community pharmacy management
- Know about value added services in community pharmacies

THEORY

60

Hrs

1. **Introduction to Hospitals** – Definition, classification, organizational structure
Hospital Pharmacy: Definition, Relationship of hospital pharmacy department with other departments, Organizational structure, legal requirements, work load statistics, Infrastructural requirements, Hospital Pharmacy Budget and Hospital Pharmacy management
Hospital Drug Policy: Pharmacy & Therapeutics Committee, Infection Control committee, Research & Ethics Committee
12 Hrs
2. Hospital Formulary Guidelines and its development, Developing Therapeutic guidelines, Drug procurement process, and methods of Inventory control, Methods of Drug distribution, Intravenous admixtures, Hospital Waste Management
12 Hrs
3. **Education and training:** Training of technical staff, Training and continuing education for pharmacists, Pharmacy students, Medical staff and students, Nursing staff and students, Formal and informal meetings and lectures, Drug and therapeutics newsletter.

Community Pharmacy Practice: Definition, roles & responsibilities of community pharmacists, relationship of community pharmacists with other health care providers

Community Pharmacy management: Legal requirements to start community pharmacy, site selection, lay out & design, drug display, super drug store model, accounts

12 Hrs

4. **Prescription** – Legal requirements & interpretation, prescription related problems

Responding to symptoms of minor ailments: Head ache, pyrexia, menstrual pains, food and drug allergy,

OTC medication: Rational use of over the counter medications

Medication adherence and Patient referrals to the doctors

ADR monitoring in community pharmacies

12 Hrs

5. **Health Promotion** – Definition and health promotion activities, family planning, Health screening services, first aid, prevention of communicable and non-communicable diseases, smoking cessation, Child & mother care

Home Medicines review program – Definition, objectives, Guidelines, method and outcomes

Research in community pharmacy

12 Hrs

REFERENCES

1. Hospital Pharmacy - Hassan WE. Lec and Febiger publication.
2. Textbook of hospital pharmacy - Allwood MC and Blackwell.
3. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
4. Remington Pharmaceutical Sciences.
5. Relevant review articles from recent medical and pharmaceutical literature

CLINICAL RESEARCH (MPP104T)

Scope

This course aims to provide the students an opportunity to learn drug development process especially the phases of clinical trials and also the ethical issues involved in the conduct of clinical research. Also, it aims to impart knowledge and develop skills on conceptualizing, designing, conducting and managing clinical trials.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Know the new drug development process.
- Understand the regulatory and ethical requirements.
- Appreciate and conduct the clinical trials activities
- Know safety monitoring and reporting in clinical trials
- Manage the trial coordination process

THEORY

60 Hrs

1. **Drug development process:** Introduction, various approaches to drug discovery, Investigational new drug application submission
Ethics in Biomedical Research: Ethical Issues in Biomedical Research – Principles of ethics in biomedical research, Ethical committee [institutional review board] - its constitution and functions, Challenges in implementation of ethical guidelines

12 Hrs

2. **Types and Designs used in Clinical Research:** Planning and execution of clinical trials, Various Phases of clinical trials, Bioavailability and Bioequivalence studies, Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification), Types of research designs based on Controlling Method (Experimental, Quasi experimental, and Observational methods) Time Sequences (Prospective and Retrospective), Sampling methods (Cohort study, case Control study and cross sectional study), Health outcome measures (Clinical & Physiological, Humanistic and economic)
Clinical Trial Study team: Roles and responsibilities of: Investigator, Study Coordinator, Sponsor, Monitor, Contract Research Organization.

12 Hrs

3. **Clinical trial Documents:** Guidelines to the preparation of following documents: Protocols, Investigator's Brochure, Informed Consent Form, Case report forms, Contracts and agreements, Dairy Cards
Clinical Trial Start up activities: Site Feasibility Studies, Site/Investigator selection, Pre-study visit, Investigator meeting, Clinical trial agreement execution, Ethics committee document preparation and submission

12 Hrs

4. **Investigational Product:** Procurement and Storage of investigation product
Filing procedures: Essential documents for clinical trial, Trial Master File preparation and maintenance, Investigator Site File, Pharmacy File, Site initiation visit, Conduct, Report and Follow up

Clinical Trial Monitoring and Close out:

Preparation and conduct of monitoring visit: Review of source documents, CRF, ICF, IP storage, accountability and reconciliation, Study Procedure, EC communications, Safety reporting, Monitoring visit reporting and follow-up

Close-Out visit: Study related documents collection, Archival requirement, Investigational Product reconciliation and destruction, Close-Out visit report

12 Hrs

5. **Quality Assurance and Quality Control in Clinical Trials:** Types of audits, Audit criteria, Audit process, Responsibilities of stakeholders in audit process, Audit follow-up and documentation, Audit resolution and Preparing for FDA inspections, Fraud and misconduct management

Data Management

Infrastructure and System Requirement for Data Management: Electronic data capture systems, Selection and implementation of new systems, System validation and test procedures, Coding dictionaries, Data migration and archival

Clinical Trial Data Management: Standard Operating Procedures, Data management plan, CRF & Data base design considerations, Study set-up, Data entry, CRF tracking and corrections, Data cleaning, Managing laboratory and ADR data, Data transfer and database lock, Quality Control and Quality Assurance in CDM, Data mining and warehousing

12 Hrs

REFERENCES

1. Principles and practice of pharmaceutical medicine, Second edition.
Authors: Lionel. D. Edward, Andrew J. Flether, Anthony W. Fos, Peter D. Sloaier
Publisher: Wiley;
2. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone
3. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
4. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
5. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice. E6; May 1996.
6. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
7. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
8. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
9. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
10. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.
11. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACY PRACTICE PRACTICAL – I (MPP105P)

Pharmacy Practice practical component includes experiments covering important topics of the courses Clinical Pharmacy Practice, Pharmacotherapeutics-I, Hospital & Community Pharmacy and Clinical Research.

List of Experiments (24)

1. Treatment Chart Review (one)
2. Medication History Interview (one)
3. Patient Medication Counseling (two)
4. Drug Information Query (two)
5. Poison Information Query (one)
6. Lab Data Interpretation (two)
7. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
8. ABC Analysis of a given list of medications (one)
9. Preparation of content of a medicine, with proper justification, for the inclusion in the hospital formulary (one)
10. Formulation and dispensing of a given IV admixtures (one)
11. Preparation of a patient information leaflet (two)
12. Preparation of Study Protocol (one)
13. Preparation of Informed Consent Form (one)

PRINCIPLES OF QUALITY USE OF MEDICINES (MPP201T)

Scope:

This course is designed to impart basic knowledge and skills that are required to practice quality use of medicines (QUM) in different healthcare settings and also to promote quality use of medicines, in clinical practice, through evidence-based medicine approach.

Objectives:

Upon completion of this course it is expected that students shall be able to:

- Understand the principles of quality use of medicines
- Know the benefits and risks associated with use of medicines
- Understand regulatory aspects of quality use of medicines
- Identify and resolve medication related problems
- Promote quality use of medicines
- Practice evidence-based medicines

THEORY

60 Hrs

1. Introduction to Quality use of medicines (QUM): Definition and Principles of QUM, Key partners and responsibilities of the partners, Building blocks in QMC, Evaluation process in QMC, Communication in QUM, Cost effective prescribing

12 Hrs

2. Concepts in QUM

Evidence based medicine: Definition, concept of evidence based medicine, Approach and practice of evidence based medicine in clinical settings

Essential drugs: Definition, need, concept of essential drug, National essential drug policy and list

Rational drug use: Definition, concept and need for rational drug use, Rational drug prescribing, Role of pharmacist in rational drug use

12 Hrs

- 3. QUM in various settings:** Hospital settings, Ambulatory care/Residential care, Role of health care professionals in promoting the QUM, Strategies to promote the QUM, Impact of QUM on E-health, integrative medicine and multidisciplinary care.

QUM in special population: Pediatric prescribing, Geriatric prescribing, Prescribing in pregnancy and lactation, Prescribing in immune compromised and organ failure patients

12 Hrs

- 4. Regulatory aspects of QUM in India:** Regulation including scheduling, Regulation of complementary medicines, Regulation of OTC medicines, Professional responsibility of pharmacist, Role of industry in QUM in medicine development

12 Hrs

- 5. Medication errors:** Definition, categorization and causes of medication errors, Detection and prevention of medication errors, Role of pharmacist in monitoring and management of medication errors

Pharmacovigilance: Definition, aims and need for pharmacovigilance, Types, predisposing factors and mechanism of adverse drug reactions (ADRs), Detection, reporting and monitoring of ADRs, Causality assessment of ADRs, Management of ADRs, Role of pharmacist in pharmacovigilance

12 Hrs

REFERENCES:

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata (Latest edition)
2. Andrews EB, Moore N. Mann's Pharmacovigilance (Latest Edition)
3. Dipiro JT, Talbert RL, Yee GC. Pharmacotherapy: A Pathophysiologic Approach (Latest Edition)
4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teach it (Latest Edition)
5. Cohen MR. Medication Errors (Latest Edition)
6. Online:

- http://medicinesaustralia.com.au/files/2012/05/MA_QUM_External_Reduced.pdf
- <http://curriculum.racgp.org.au/statements/quality-use-of-medicines/>
- http://www.rug.nl/research/portal/files/14051541/Chapter_2.pdf

7. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS II (MPP202T)

Scope

This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualising the treatment plan through evidence-based medicines.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence based medicine
- Prepare individualized therapeutic plans based on diagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time- course of clinical and laboratory indices of therapeutic response and adverse effect/s)

THEORY

60 Hrs

1. **Nervous system:** Epilepsy, Parkinson's disease, Stroke, Headache, Alzheimer's disease, Neuralgias and Pain pathways and Pain management

12 Hrs

2. **Psychiatric disorders:** Schizophrenia, Depression, Anxiety disorders, Sleep disorders, Drug induced psychiatric disorders

Renal system: Acute renal failure, Chronic renal failure, Renal dialysis, Drug induced renal disease

12 Hrs

3. **Infectious diseases:** General guidelines for the rational use of antibiotics and surgical prophylaxis, Urinary tract infections, Respiratory tract infections, Gastroenteritis, Tuberculosis, Malaria, Bacterial endocarditis, Septicemia

1

2 Hrs

- 4. Infectious diseases:** Meningitis, HIV and opportunistic infections, Rheumatic fever, Dengue fever, H1N1, Helmenthiasis, Fungal infections

Gynecological disorders: Dysmenorrhea, Hormone replacement therapy
12 Hrs

- 5. Oncology:** General principles of cancer chemotherapy, pharmacotherapy of breast cancer, lung cancer, head & neck cancer, hematological malignancies, Management of nausea and vomiting, Palliative care

1

2 Hrs

REFERENCES

1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice— McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING (MPP203T)

Scope

This course is designed to enable students to understand the basic principles and applications of pharmacokinetics in designing the individualized dosage regimen, to interpret the plasma drug concentration profile in altered pharmacokinetics, drug interactions and in therapeutic drug monitoring processes to optimize the drug dosage regimen. Also, it enables students to understand the basic concepts of pharmacogenetics, pharmacometrics for modeling and simulation of pharmacokinetic data.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Design the drug dosage regimen for individual patients
- Interpret and correlate the plasma drug concentrations with patients' therapeutic outcomes
- Recommend dosage adjustment for patients with renal/ hepatic impairment
- Recommend dosage adjustment for paediatrics and geriatrics
- Manage pharmacokinetic drug interactions
- Apply pharmacokinetic parameters in clinical settings
- Interpret the impact of genetic polymorphisms of individuals on pharmacokinetics and or pharmacodynamics of drugs
- Do pharmacokinetic modeling for the given data using the principles of pharmacometrics

THEORY

60 Hrs

1. Introduction to Clinical pharmacokinetics: Compartmental and Non compartmental models, Renal and non-renal clearance, Organ extraction and models of hepatic clearance, Estimation and determinants of bioavailability, Multiple dosing, Calculation of loading and maintenance doses

Designing of dosage regimens: Determination of dose and dosing intervals, Conversion from intravenous to oral dosing, Nomograms and Tabulations in designing dosage regimen

12 Hrs

2. Pharmacokinetics of Drug Interaction: Pharmacokinetic drug interactions, Inhibition and Induction of Drug metabolism, Inhibition of Biliary Excretion

Pharmacogenetics: Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes, Genetic Polymorphism in Drug Transport and Drug Targets, Pharmacogenetics and Pharmacokinetic / Pharmacodynamic considerations

Introduction to Pharmacometrics: Introduction to Bayesian Theory, Adaptive method or Dosing with feedback, Analysis of Population pharmacokinetic Data

12 Hrs

- 3. Non Linier Mixed Effects Modelling:** The Structural or Base Model, Modeling Random Effects, Modeling Covariate Relationships, Mixture Model, Estimation Methods, Model Building Techniques, Covariate Screening Methods, Testing the model assumptions, Precision of the parameter estimates and confidence intervals, Model misspecification and violation of the model assumptions, Model Validation, Simulation of dosing regimens and dosing recommendations, Pharmacometrics software

12 Hrs

- 4. Altered Pharmacokinetics:** Drug dosing in the elderly, Drug dosing in the paediatrics, Drug dosing in the obese patients, Drug dosing in the pregnancy and lactation, Drug dosing in the renal failure and extracorporeal removal of drugs, Drug dosing in the in hepatic failure

12 Hrs

- 5. Therapeutic Drug monitoring:** Introduction, Individualization of drug dosage regimen (Variability – Genetic, age, weight, disease and Interacting drugs), Indications for TDM, Protocol for TDM, Pharmacokinetic/Pharmacodynamic Correlation in drug therapy, TDM of drugs used in the following conditions: Cardiovascular disease: Digoxin, Lidocaine, Amiodarone; Seizure disorders: Phenytoin, Carbamazepine, Sodium Valproate; Psychiatric conditions: Lithium, Fluoxetine, Amitriptyline; Organ transplantations: Cyclosporine; Cytotoxic Agents: Methotrexate, 5-FU, Cisplatin; Antibiotics: Vancomycin, Gentamicin, Meropenem

12 Hrs

REFERENCES

1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics. 6th edition. New York: Mc Graw Hill;2012.
2. Peter L. Bonate. Pharmacokinetic - Pharmacodynamic Modeling and Simulation. 2nd edition. USA: Springer;2011.

3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E. Evans. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring. 4th edition. US: Ippincott Williams & Wilkins; 2005.
4. Steven How-Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. 1st edition. USA: CRC Press; 1996.
5. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press; 2006.
6. Joseph T. Dipiro, William J. Spruill, William E. Wade, Robert A. Blouin and Jane M. Pruemer. Concepts in Clinical Pharmacokinetics. 4th edition. US: American Society of Health-System Pharmacists; 2005.
7. Malcolm Rowland, Thomas N. Tozer. Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. 4th edition. US: Ippincott Williams & Wilkins; 2010.
8. Evans, Schentag, Jusko. Applied pharmacokinetics. 2nd edition. US: American Society of Health system Pharmacists; 2006.
9. Michael E. Winter. Basic Clinical Pharmacokinetics. 5th edition. US: Ippincott Williams & Wilkins; 2012.
10. Milo Gibaldi. Biopharmaceutics and Clinical Pharmacokinetics. 4th edition. India: Pharma Book Syndicate; 2005.
11. Dhillon and Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press; 2006.
12. John E. Murphy. Clinical Pharmacokinetics. 5th edition. US: American Society of Health- System Pharmacist; 2004.
13. Relevant review articles from recent medical and pharmaceutical literature

PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (MPP204T)

Scope

This course enable students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with pharmacoeconomics and health related outcomes, and when should be appropriate pharmacoeconomic model should be applied for a health care regimen.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Understand the various epidemiological methods and their applications
- Understand the fundamental principles of pharmacoeconomics.
- Identify and determine relevant cost and consequences associated with pharmacy products and services.
- Perform the key pharmacoeconomics analysis methods
- Understand the pharmacoeconomic decision analysis methods and its applications.
- Describe current pharmacoeconomic methods and issues.
- Understand the applications of pharmacoeconomics to various pharmacy settings.

THEORY

60 Hrs

1. **Introduction to Pharmacoepidemiology:** Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements.

Concept of risk: Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio

12 Hrs

2. **Pharmacoepidemiological Methods:** Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds ratio, Meta analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of pharmacoepidemiology

12 Hrs

3. **Introduction to Pharmacoeconomics:** Definition, history of pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system.

Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs.

Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost Effective Ratio, Average Cost Effective Ratio. Person Time, Willingness To Pay, Time Trade Off and Discounting.

12 Hrs

- 4. Pharmacoeconomic evaluations:** Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).

12 Hrs

- 5. Definition, Steps involved, Applications, Advantages and disadvantages of the following:**

Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, Common HRQOL measures.

Definition, Steps involved, Applications of the following: Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in pharmacoeconomic analysis, Applications of Pharmacoeconomics

12 Hrs

REFERENCES

1. Rascati K L. Essentials of Pharmacoeconomics, 2nd ed. Philadelphia: Woulters Kluwer Lippincott Williams & Wilkins, 2013.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. 1997, 2003. John Wiley & Sons, second edition.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health Economic Evaluation, Published by the Oxford University Press 2006.
4. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press (Third Edition) – 2005.
5. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics, 2013.
6. Graker, Dennis. Pharmacoeconomics and outcomes, 2nd edition.
7. Walley, Pharmacoeconomics, 1st edition.
8. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan 2009.

9. Relevant review articles from recent medical and pharmaceutical literature

PHARMACY PRACTICE PRACTICAL - II (MPP205T)

Pharmacy Practice practical component includes experiments covering important topics of the courses Principles of Quality Use of Medicines, Pharmacotherapeutics-II, Clinical Pharmacokinetics & Therapeutic Drug Monitoring and Pharmacoepidemiology and Pharmacoeconomics.

List of Experiments (24)

1. Causality assessment of adverse drug reactions (three)
2. Detection and management of medication errors (three)
3. Rational use of medicines in special population (three)
4. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
5. Calculation of Bioavailability and Bioequivalence from the given data (two)
6. Interpretation of Therapeutic Drug Monitoring reports of a given patient (three)
7. Calculation of various Pharmacoeconomic outcome analysis for the given data (two)



ರಾಜೀವ್ ಗಾಂಧಿ ಆರೋಗ್ಯ ವಿಜ್ಞಾನಗಳ ವಿಶ್ವವಿದ್ಯಾಲಯ, ಕರ್ನಾಟಕ, ಬೆಂಗಳೂರು

RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES, KARNATAKA, BENGALURU
4th T Block, Jayanagar, Bengaluru - 560 041

RGU/AUTH/BPHARM/146/2017-18

10.05.2017

NOTIFICATION

Sub: Revised ordinance relating to Bachelor of Pharmacy (B.Pharm) Degree course (Semester System)

Ref: (1) PCI Notification ref.No.14-136-2016-PCI,14-154/2015-PCI (53095-55431) dated 21.12.2016
(2) Proceedings of meeting of BOS in Pharmacy (UG) held on 03.12.2016
(3) Proceedings of meeting of Faculty of Pharmacy held on 05.12.2016
(4) Proceedings of meeting of Academic Council held on 22.12.2016
(5) Approval of Syndicate in its 125th meeting held on 06.01.2017.

In exercise of the powers conferred under section 35 of RGUHS Act, 1994, Syndicate is pleased to notify the revised ordinance relating to Bachelor of Pharmacy (B.Pharm) Degree course (Semester System) as shown in annexure appended herewith.

This revised ordinance shall come into force from the academic year 2017-18 and onwards. However, for the students taking admission directly to 2nd year of B.Pharm Degree course through lateral entry, the said ordinance shall come into force from the academic year 2018-19 and onwards.

By Order


REGISTRAR

To

1. All the Principals of Pharmacy Colleges affiliated to RGUHS
2. The Registrar (Evaluation), RGUHS
3. The Director, Dept. of Curriculum Development, RGUHS

Copy to:

1. The Secretary to Governor, Governor's Secretariat, Raj Bhavan, Bangalore-560 001.
2. The Secretary to Government, Health & Family Welfare Department (Medical Education).Vikasa Soudha, Bangalore-560 001.
3. The PA to Vice-Chancellor/Registrar/Registrar(Evaluation), RGUHS, Bangalore
4. The System Analyst, RGUHS to host the notification on RGUHS website.
5. Guard File/Office Copy

**Rajiv Gandhi University of Health
Sciences, Karnataka, Bengaluru**

**Revised Syllabus of Bachelor of
Pharmacy (B. Pharm) Degree Course**

**For the Academic Year 2017-18 and
onwards**

**REVISED ORDINANCE GOVERNING
BACHELOR OF PHARMACY (B. PHARM.)
DEGREE COURSE**

2017



Rajiv Gandhi University of Health Sciences, Karnataka

4th 'T' Block, Jayanagar, Bangalore – 560 041

**Revised Ordinance Governing
Bachelor of Pharmacy (B. Pharm.)
Degree Course**

This book can be had from:

Director

Prasaranga

**Rajiv Gandhi University of Health Sciences,
Karnataka**

4th 'T' Block, Jayanagar, Bangalore – 560 041

Web:www.rguhs.ac.in

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SECTION I

GOALS OF EDUCATION AND TRAINING IN PHARMACEUTICAL SCIENCES OF RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES, KARNATAKA

The pharmacy curriculum shall be oriented towards educating students of B.Pharm course to:

1. Imbibe the concept of better patient health care at every face of Health related activities.
2. Should be capable of functioning independently in both rural and urban environment.
3. Appraise fellow professionals in Hospitals, Community and Industry of newer developments in pharmacy.
4. Be a part of all National & International sponsored health education programmes.
5. Educate the community about disease prevention measures, community hygiene and better health.
6. Inculcate critical thinking, clarity of expression, independent thinking and scientific temperament.
7. Encourage active learning methods like group discussions, Seminars, peer interactions etc., which would enable students to develop discipline, personality, communicating skills, and other qualities, which are necessary.
8. Be able to produce and market dosage forms and be responsible in minimizing the pollution hazards, by using proper scientific and logical techniques.

Regular periodic assessment shall be done throughout the course. Examinations shall be designed with a view to assess not merely the knowledge but also practical skills, habits and values which are necessary for a pharmacy graduate to carry out the professional obligations competently.

Towards achieving these goals every pharmacy College should:

- Evolve institutional objectives, which would be in consonance with the national goals and health policies.
- Shift the role of pharmacy teachers from merely imparting knowledge to that of facilitator and motivator of student learning.
- Establish an institution for faculty development, preparation of learning resource materials and for improving evaluation methods.
- Encourage and facilitate for industry-Academic interaction.

SECTION II

AIMS AND OBJECTIVES OF B.PHARM COURSE

Aims:

Pharmacy graduates are required to learn and acquire adequate knowledge, necessary skills to practice the profession of pharmacy including thorough and exhaustive knowledge of synthesis and assay of Medicinal agents including mode of action, drug interactions and Patient counseling and professional information exchange with Physicians and other paramedicos. The graduates are required to acquire an in-depth knowledge of formulation, storage and analysis of various pharmaceutical dosage forms including herbal medicines required for both large scale commercial production & research. The graduates should understand the concept of Community Pharmacy and be able to participate in rural and urban health care projects of State and Central government. The graduate is also required to detail the physicians and community' and market the medicinal agents for diagnosis, prevention and therapeutic purposes. The pharmacist should act as bridge between Physicians and Patients and strive for better healthcare.

Objectives:

The objectives are covered under three headings namely:

- (a) Knowledge and understanding
- (b) Skills and
- (c) Attitude

(a) KNOWLEDGE & UNDERSTANDING

The graduate should acquire the following during their four year B Pharm course

1. Adequate knowledge and scientific information regarding basic principles of Pharmaceutical chemistry, Pharmaceutics including cosmetics, Pharmacology/ and Pharmacognosy including Herbal drugs
2. Adequate knowledge of practical aspects of synthesis, formulation and analysis of various pharmaceutical and Herbal medicinal agents

3. Adequate knowledge of practical aspects of delivering a quality assured product as per pharmacopoeia, WHO and ISO standards
4. Adequate knowledge of practical aspects of pharmacological screening, biological standardization and *in-vivo* drug interactions.
5. Adequate knowledge of clinical studies for patient counseling leading to physical and social well being of patients.
6. Adequate knowledge of practical aspects of product detailing and marketing of Pharmaceutical products.

(b) SKILLS

A graduate should be able to demonstrate the following skills necessary for practice of a pharmacy.

1. Able to synthesize, purify, identify and analyze medicinal agents.
2. Able to formulate, store, dispense, analyze the prescriptions and / or manufacture the medicinal agents at commercial level.
3. Able to learn and apply the quality assurance principles including legal and ethical aspects involving drugs.
4. Able to extract, purify, identify and know the therapeutic value of herbal / crude / natural products.
5. Able to screen various medicinal agents using animal models for pharmacological activity.

(C) ATTITUDES

The graduate should develop the following attitudes during their four year B.Pharm course.

1. Willing to apply the current knowledge of pharmacy in the best interest of patients and the community.
2. Maintain a high standard of professional ethics in discharging professional obligations.
3. Continuously upgrade professional information and be conversant with latest advances in Pharmacy field to serve the community better.
4. Willing to participate in continuing education programmes of PCI and AICTE to upgrade knowledge and professional skills.
5. To help and to participate in the implementation of National Health programs.

SECTION III:

REGULATIONS

1. Short Title and Commencement

These regulations shall be called as “The Revised Regulations for the B. Pharm. Degree Program of Rajiv Gandhi University of Health sciences, Bengaluru, Karnataka”. They shall come into effect from the Academic Year 2017-18. The regulations framed are subject to modifications from time to time by Pharmacy Council of India.

2. Minimum qualification for admission

2.1 First year B. Pharm:

Candidate shall have passed 10+2 examination conducted by the respective state/central government authorities recognized as equivalent to 10+2 examination by the Association of Indian Universities (AIU) with English as one of the subjects and Physics, Chemistry, Mathematics (P.C.M) and or Biology (P.C.B / P.C.M.B.) as optional subjects individually. Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examinations.

Note: Provided that a student should have completed 17 years of age on the date of admission or should complete the age of 17 years on or before 31st December of the year of admission to the program.

2.2. B. Pharm lateral entry (to third semester):

A pass in D. Pharm. course from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act.

3. Duration of the program

The course of study for B.Pharm shall extend over a period of eight semesters (four academic years) and six semesters (three academic years) for lateral entry students. The curricula and syllabi for the program shall be prescribed from time to time by RGUHS, Bengaluru.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

Each semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of July/August to December/ January and the even semesters shall be conducted from January to June/July in every calendar year.

6. Attendance and progress

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, tutorial hours, practical classes, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly, the credit associated with any of the other academic, co/extra-curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week.

7.1. Credit assignment

7.1.1. Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and /or tutorial (T) hours, and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and tutorial hours, and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having three lectures and one tutorial per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

7.2. Minimum credit requirements

The minimum credit points required for award of a B. Pharm. degree is 208. These credits are divided into Theory courses, Tutorials, Practical, Practice School and Project work over the duration of eight semesters. The credits are distributed semester-wise as shown in Table IX. Courses generally progress in sequences, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

The lateral entry students shall get 52 credit points transferred from their D. Pharm program. Such students shall take up additional remedial courses of 'Communication Skills' (Theory and Practical) and 'Computer Applications in Pharmacy' (Theory and Practical) equivalent to 3 and 4 credit points respectively, a total of 7 credit points to attain 59 credit points, the maximum of I and II semesters.

8. Academic work

A regular record of attendance both in Theory and Practical shall be maintained by the teaching staff of respective courses.

9. Course of study

The course of study for B. Pharm shall include Semester Wise Theory & Practical as given in Table – I to VIII. The number of hours to be devoted to each theory, tutorial and practical course in any semester shall not be less than that shown in Table – I to VIII.

Table-I: Course of study for semester I

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP101T	Human Anatomy and Physiology I– Theory	3	1	4
BP102T	Pharmaceutical Analysis I – Theory	3	1	4
BP103T	Pharmaceutics I – Theory	3	1	4
BP104T	Pharmaceutical Inorganic Chemistry – Theory	3	1	4
BP105T	Communication skills – Theory *	2	-	2
BP106RBT BP106RMT	Remedial Biology/ Remedial Mathematics – Theory*	2	-	2
BP107P	Human Anatomy and Physiology – Practical	4	-	2
BP108P	Pharmaceutical Analysis I – Practical	4	-	2
BP109P	Pharmaceutics I – Practical	4	-	2
BP110P	Pharmaceutical Inorganic Chemistry – Practical	4	-	2
BP111P	Communication skills – Practical*	2	-	1
BP112RBP	Remedial Biology – Practical*	2	-	1
Total		32/34^{\$}/36[#]	4	27/29^{\$}/30[#]

[#] Applicable ONLY for the students who have studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB) course.

^{\$} Applicable ONLY for the students who have studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM) course.

* Non University Examination (NUE)

Table-II: Course of study for semester II

Course Code	Name of the course	No. of hours	Tutorial	Credit points
BP201T	Human Anatomy and Physiology II – Theory	3	1	4
BP202T	Pharmaceutical Organic Chemistry I – Theory	3	1	4
BP203T	Biochemistry – Theory	3	1	4
BP204T	Pathophysiology – Theory	3	1	4
BP205T	Computer Applications in Pharmacy – Theory *	3	-	3
BP206T	Environmental sciences – Theory *	3	-	3
BP207P	Human Anatomy and Physiology II –Practical	4	-	2
BP208P	Pharmaceutical Organic Chemistry I– Practical	4	-	2
BP209P	Biochemistry – Practical	4	-	2
BP210P	Computer Applications in Pharmacy – Practical*	2	-	1
Total		32	4	29

*Non University Examination (NUE)

Table-III: Course of study for semester III

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP301T	Pharmaceutical Organic Chemistry II – Theory	3	1	4
BP302T	Physical Pharmaceutics I – Theory	3	1	4
BP303T	Pharmaceutical Microbiology – Theory	3	1	4
BP304T	Pharmaceutical Engineering – Theory	3	1	4
BP305P	Pharmaceutical Organic Chemistry II – Practical	4	-	2
BP306P	Physical Pharmaceutics I – Practical	4	-	2
BP307P	Pharmaceutical Microbiology – Practical	4	-	2
BP 308P	Pharmaceutical Engineering –Practical	4	-	2
Total		28	4	24

Table-IV: Course of study for semester IV

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP401T	Pharmaceutical Organic Chemistry III– Theory	3	1	4
BP402T	Medicinal Chemistry I – Theory	3	1	4
BP403T	Physical Pharmaceutics II – Theory	3	1	4
BP404T	Pharmacology I – Theory	3	1	4
BP405T	Pharmacognosy and Phytochemistry I– Theory	3	1	4
BP406P	Medicinal Chemistry I – Practical	4	-	2
BP407P	Physical Pharmaceutics II – Practical	4		2
BP408P	Pharmacology I – Practical	4	-	2
BP409P	Pharmacognosy and Phytochemistry I – Practical	4	-	2
Total		31	5	28

Table-V: Course of study for semester V

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP501T	Medicinal Chemistry II – Theory	3	1	4
BP502T	Formulative Pharmacy– Theory	3	1	4
BP503T	Pharmacology II – Theory	3	1	4
BP504T	Pharmacognosy and Phytochemistry II– Theory	3	1	4
BP505T	Pharmaceutical Jurisprudence – Theory	3	1	4
BP506P	Formulative Pharmacy – Practical	4	-	2
BP507P	Pharmacology II – Practical	4	-	2
BP508P	Pharmacognosy and Phytochemistry II – Practical	4	-	2
Total		27	5	26

Table-VI: Course of study for semester VI

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP601T	Medicinal Chemistry III – Theory	3	1	4
BP602T	Pharmacology III – Theory	3	1	4
BP603T	Herbal Drug Technology – Theory	3	1	4
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	3	1	4
BP605T	Pharmaceutical Biotechnology – Theory	3	1	4
BP606T	Quality Assurance –Theory	3	1	4
BP607P	Medicinal chemistry III – Practical	4	-	2
BP608P	Pharmacology III – Practical	4	-	2
BP609P	Herbal Drug Technology – Practical	4	-	2
Total		30	6	30

Table-VII: Course of study for semester VII

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP701T	Instrumental Methods of Analysis – Theory	3	1	4
BP702T	Industrial Pharmacy – Theory	3	1	4
BP703T	Pharmacy Practice – Theory	3	1	4
BP704T	Novel Drug Delivery System – Theory	3	1	4
BP705P	Instrumental Methods of Analysis – Practical	4	-	2
BP706PS	Practice School*	12	-	6
Total		28	5	24

* Non University Examination (NUE)

Table-VIII: Course of study for semester VIII

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP801T	Biostatistics and Research Methodology	3	1	4
BP802T	Social and Preventive Pharmacy	3	1	4
BP803ET	Pharmaceutical Marketing	3 + 3 = 6	1 + 1 = 2	4 + 4 = 8
BP804ET	Pharmaceutical Regulatory Science			
BP805ET	Pharmacovigilance			
BP806ET	Quality Control and Standardizations of Herbals			
BP807ET	Computer Aided Drug Design			
BP808ET	Cell and Molecular Biology			
BP809ET	Cosmetic Science			
BP810ET	Experimental Pharmacology			
BP811ET	Advanced Instrumentation Techniques	12	-	6
BP812PW	Project Work			
Total		24	4	22

Table-IX: Semester wise credits distribution

Semester	Credit Points
I	27/29 ^{\$} /30 [#]
II	29
III	26
IV	28
V	26
VI	26
VII	24
VIII	22
Extracurricular/ Co curricular activities	01*
Total credit points for the program	209/211^{\$}/212[#]

* The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.

^{\$} Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics course.

[#] Applicable ONLY for the students studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology course.

10. Program Committee

1. The B. Pharm. program shall have a Program Committee constituted by the Head of the institution in consultation with all the Heads of the departments.
2. The composition of the Program Committee shall be as follows:

A senior teacher shall be the Chairperson; One Teacher from each department handling B.Pharm courses; and four student representatives of the program (one from each academic year), nominated by the Head of the institution.

3. Duties of the Program Committee:
 - i. Periodically reviewing the progress of the classes.
 - ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
 - iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
 - iv. Communicating its recommendation to the Head of the institution on academic matters.
 - v. The Program Committee shall meet at least thrice in a semester preferably at the end of each Sessional exam (Internal Assessment) and before the end semester exam.

11. Examinations/Assessments

The scheme for internal assessment and end semester examinations is given in Table – X.

11.1. End semester examinations

The End Semester Examinations for each theory and practical course through semesters I to VIII shall be conducted by the university except for the subjects with asterix symbol (*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Tables-X: Schemes for internal assessments and end semester examinations semester wise

Semester I

Course	Name of the course	Internal Assessment				End Semester Exams		Total
code		Continuous Mode	Sessional Exams		Total	Marks	Duration	Marks
			Marks	Duration				
BP101T	Human Anatomy and Physiology I– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP102T	Pharmaceutical Analysis I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP103T	Pharmaceutics I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP104T	Pharmaceutical Inorganic Chemistry – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP105T	Communication skills – Theory *	5	10	1 Hr	15	35	1.5 Hrs	50
BP106RBT BP106RMT	Remedial Biology/ Mathematics – Theory*	5	10	1 Hr	15	35	1.5 Hrs	50
BP107P	Human Anatomy and Physiology – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP108P	Pharmaceutical Analysis I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP109P	Pharmaceutics I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP110P	Pharmaceutical Inorganic Chemistry – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP111P	Communication skills – Practical*	5	5	2 Hrs	10	15	2 Hrs	25
BP112RBP	Remedial Biology – Practical*	5	5	2 Hrs	10	15	2 Hrs	25
Total		70/75 [§] /80 [#]	115/125 [§] /130 [#]	23/24 [§] /26 [#] Hrs	185/200 [§] /210 [#]	490/525 [§] / 540 [#]	31.5/33 [§] / 35 [#] Hrs	675/725 [§] / 750 [#]

[#] Applicable ONLY for the students studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB)course.

^{\$} Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM)course. * Non University Examination (NUE)

Semester II

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP201T	Human Anatomy and Physiology II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP202T	Pharmaceutical Organic Chemistry I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP203T	Biochemistry – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP204T	Pathophysiology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP205T	Computer Applications in Pharmacy – Theory*	10	15	1 Hr	25	50	2 Hrs	75
BP206T	Environmental sciences – Theory*	10	15	1 Hr	25	50	2 Hrs	75
BP207P	Human Anatomy and Physiology II –Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP208P	Pharmaceutical Organic Chemistry I– Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP209P	Biochemistry – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP210P	Computer Applications in Pharmacy – Practical*	5	5	2 Hrs	10	15	2 Hrs	25
Total		80	125	20 Hrs	205	520	30 Hrs	725

* The subject experts at college level shall conduct examinations

Semester III

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP301T	Pharmaceutical Organic Chemistry II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP302T	Physical Pharmaceutics I –Theory	10	15	1 Hr	25	75	3 Hrs	100
BP303T	Pharmaceutical Microbiology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP304T	Pharmaceutical Engineering – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP305P	Pharmaceutical Organic Chemistry II – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP306P	Physical Pharmaceutics I – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP307P	Pharmaceutical Microbiology – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP308P	Pharmaceutical Engineering – Practical	5	10	4 Hr	15	35	4 Hrs	50
Total		60	100	20	160	440	28Hrs	600

Semester IV

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP401T	Pharmaceutical Organic Chemistry III– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP402T	Medicinal Chemistry I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP403T	Physical Pharmaceutics II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP404T	Pharmacology I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP405T	Pharmacognosy I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP406P	Medicinal Chemistry I – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP407P	Physical Pharmaceutics II – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP408P	Pharmacology I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP409P	Pharmacognosy I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
Total		70	115	21 Hrs	185	515	31 Hrs	700

Semester V

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP501T	Medicinal Chemistry II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP502T	Formulative Pharmacy– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP503T	Pharmacology II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP504T	Pharmacognosy II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP505T	Pharmaceutical Jurisprudence – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP506P	Formulative Pharmacy – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP507P	Pharmacology II – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP508P	Pharmacognosy II – Practical	5	10	4 Hr	15	35	4 Hrs	50
Total		65	105	17 Hr	170	480	27 Hrs	650

Semester VI

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP601T	Medicinal Chemistry III – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP602T	Pharmacology III – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP603T	Herbal Drug Technology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP605T	Pharmaceutical Biotechnology– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP606T	Quality Assurance– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP607P	Medicinal chemistry III – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP608P	Pharmacology III – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP609P	Herbal Drug Technology – Practical	5	10	4 Hrs	15	35	4 Hrs	50
Total		75	120	18 Hrs	195	555	30 Hrs	750

Semester VII

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP701T	Instrumental Methods of Analysis – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP702T	Industrial Pharmacy – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP703T	Pharmacy Practice – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP704T	Novel Drug Delivery System – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP705 P	Instrumental Methods of Analysis – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP706 PS	Practice School*	25	-	-	25	125	5 Hrs	150
Total		70	70	8Hrs	140	460	21 Hrs	600

* The subject experts at college level shall conduct examinations

Semester VIII

Course code	Name of the course	Internal Assessment				End Semester Exams		Total
		Continuous Mode	Sessional Exams		Total	Marks	Duration	Marks
			Marks	Duration				
BP801T	Biostatistics and Research Methodology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP802T	Social and Preventive Pharmacy – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP803ET	Pharmaceutical Marketing – Theory	10 + 10 = 20	15 + 15 = 30	1 + 1 = 2 Hrs	25 + 25 = 50	75 + 75 = 150	3 + 3 = 6 Hrs	100 + 100 = 200
BP804ET	Pharmaceutical Regulatory Science – Theory							
BP805ET	Pharmacovigilance – Theory							
BP806ET	Quality Control and Standardizations of Herbals – Theory							
BP807ET	Computer Aided Drug Design – Theory							
BP808ET	Cell and Molecular Biology – Theory							
BP809ET	Cosmetic Science – Theory							
BP810ET	Experimental Pharmacology – Theory							
BP811ET	Advanced Instrumentation Techniques – Theory							
BP812PW	Project Work	-	-	-	-	150	4 Hrs	150

Total	40	60	4 Hrs	100	450	16 Hrs	550

11.2. Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table-XI: Scheme for awarding internal assessment: Continuous mode

Theory		
Criteria	Maximum Marks	
Attendance (Refer Table – XII)	4	2
Academic activities (Average of any 3 activities e.g. quiz, assignment, open book test, field work, group discussion and seminar)	3	1.5
Student – Teacher interaction	3	1.5
Total	10	5
Practical		
Attendance (Refer Table – XII)	2	
Based on Practical Records, Regular viva voce, etc.	3	
Total	5	

Table- XII: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95 – 100	4	2
90 – 94	3	1.5
85 – 89	2	1
80 – 84	1	0.5
Less than 80	0	0

11.2.1. Sessional Exams

Two Sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical Sessional examinations is given below. The average marks of two Sessional exams shall be computed for internal assessment as per the requirements given in tables – X.

Sessional exam shall be conducted for 30 marks for theory and shall be computed for 15 marks. Similarly Sessional exam for practical shall be conducted for 40 marks and shall be computed for 10 marks.

Question paper pattern for theory Sessional examinations

For subjects having University examination

I. Short answers (Answer all questions)	=	5x2	=10
I. Long essay (Answer 1 out of 2)	=	1 x 10	= 10
II. Short essays (Answer 2 out of 3)	=	2 x 5	= 10

Total	=		30 marks

For subjects having Non University Examination

I. Long Essays (Answer 1 out of 2)	=	1 x 10 = 10
II. Short Essays (Answer 4 out of 6)	=	4 x 5 = 20

Total	=	30 marks

Question paper pattern for practical sessional examinations

I. Synopsis	=	10
II. Experiments	=	25
III. Viva voce	=	05

Total	=	40 marks

12. Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of B.Pharm program if he/she secures at least 50% marks including internal assessment marks in that particular course provided a minimum of 40% marks in each Theory subject in the end semester university examinations for passing of that subject. For example, to be declared as PASS and to get grade, the student has to secure a minimum of 50 marks for the total of 100 including continuous mode of assessment and end semester theory examination and has to secure a minimum of 25 marks for the total 50 including internal assessment and end semester practical examination.

13. Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 12, then he/she shall reappear for the end semester examination of that course. However his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

14. Improvement of internal assessment

A student shall have the opportunity to improve his/her performance only once in the Sessional exam component of the internal assessment. The re-conduct of the Sessional exam shall be completed before the commencement of next end semester theory examinations.

15. Re-examination of end semester examinations

Re-examination of end semester examination shall be conducted as per the schedule given in table XIII. The exact dates of examinations shall be notified from time to time.

Table-XIII: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I, III, V and VII	December/ January	June/July
II, IV, VI and VIII	June/July	December/ January

Question paper pattern for end semester theory examinations**For 75 marks paper**

I. Short Answers

(Answer all the questions) = 10 x 2 = 20

I. Long Essays (Answer 2 out of 3) = 2 x 10 = 20

II. Short Essays (Answer 7 out of 9) = 7 x 5 = 35

Total = 75 marks

For 50 marks paper

I. Long Essays (Answer 2 out of 3) = 2 x 10 = 20

II. Short Essays (Answer 6 out of 8) = 6 x 5 = 30

Total = 50 marks

For 35 marks paper

I. Long Essays (Answer 1 out of 2) = 1 x 10 = 10

II. Short Essays (Answer 5 out of 7) = 5 x 5 = 25

Total = 35 marks

Question paper pattern for end semester practical examinations

I. Synopsis = 5

II. Experiments = 25

III. Viva voce = 5

Total = 35 marks

16. Academic Progression:

No student shall be admitted to any examination unless he/she fulfills the norms given in 6. Academic progression rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I, II and III semesters till the IV semester examinations. However, he/she shall not be eligible to attend the courses of V semester until all the courses of I and II semesters are successfully completed.

A student shall be eligible to carry forward all the courses of III, IV and V semesters till the VI semester examinations. However, he/she shall not be eligible to attend the courses of VII semester until all the courses of I, II, III and IV semesters are successfully completed.

A student shall be eligible to carry forward all the courses of V, VI and VII semesters till the VIII semester examinations. However, he/she shall not be eligible to get the course completion certificate until all the courses of I, II, III, IV, V and VI semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to VIII semesters within the stipulated time period as per the norms specified in 26.

A lateral entry student shall be eligible to carry forward all the courses of III, IV and V semesters till the VI semester examinations. However, he/she shall not be eligible to attend the courses of VII semester until all the courses of III and IV semesters are successfully completed.

A lateral entry student shall be eligible to carry forward all the courses of V, VI and VII semesters till the VIII semester examinations. However, he/she shall not be eligible to get the course completion certificate until all the courses of III, IV, V and VI semesters are successfully completed.

A lateral entry student shall be eligible to get his/her CGPA upon successful completion of the courses of III to VIII semesters within the stipulated time period as per the norms specified in 26.

Any student who has given more than 4 chances for successful completion of I / III semester courses and more than 3 chances for successful completion of II / IV semester courses shall be permitted to attend V / VII semester classes ONLY during the subsequent academic year as the case may be. In simpler terms there shall NOT be any ODD - BATCH for any semester.

Note: Grade AB should be considered as failed and treated as one head for deciding academic progression. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

17. Grading of performances

17.1. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – XII.

Table – XII: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

18. The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called ‘Semester Grade Point Average’ (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C₁, C₂, C₃, C₄ and C₅ and the student’s grade points in these courses are G₁, G₂, G₃, G₄ and G₅, respectively, and then students’ SGPA is equal to:

$$\text{SGPA} = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4 + C_5G_5}{C_1 + C_2 + C_3 + C_4 + C_5}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and AB grade awarded in that semester. For example if a learner has a F or AB grade in course 4, the SGPA shall then be computed as:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4* ZERO + C_5G_5}{C_1 + C_2 + C_3 + C_4 + C_5}$$

19. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the VIII semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all VIII semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier. The CGPA is calculated as:

$$CGPA = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4 + C_5S_5 + C_6S_6 + C_7S_7 + C_8S_8}{C_1 + C_2 + C_3 + C_4 + C_5 + C_6 + C_7 + C_8}$$

where $C_1, C_2, C_3, \dots$ is the total number of credits for semester I, II, III, ... and $S_1, S_2, S_3, \dots$ is the SGPA of semester I, II, III, ...

20. Declaration of class

The class shall be awarded on the basis of CGPA as follows:

First Class with Distinction	= CGPA of 7.50 and above
First Class	= CGPA of 6.00 to 7.49
Second Class	= CGPA of 5.00 to 5.99

21. Project work

All the students shall undertake a project under the supervision of a teacher and submit a report. The area of the project shall directly relate any one of the elective subject opted by the student in semester VIII. The project shall be carried out in group not exceeding 5 in number. The project report shall be submitted in triplicate (typed & bound copy not less than 25 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of five students). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

Objective(s) of the work done	15 Marks
Methodology adopted	20 Marks
Results and Discussions	20 Marks
Conclusions and Outcomes	20 Marks

Total	75 Marks

Evaluation of Presentation:

Presentation of work	25 Marks
Communication skills	20 Marks
Question and answer skills	30 Marks

Total	75 Marks

Explanation: The 75 marks assigned to the dissertation book shall be same for all the students in a group. However, the 75 marks assigned for presentation shall be awarded based on the performance of individual students in the given criteria.

22. Industrial training (Desirable)

Every candidate shall be required to work for at least 150 hours spread over four weeks in a Pharmaceutical Industry/Hospital. It includes Production unit, Quality Control department, Quality Assurance department, Analytical laboratory, Chemical manufacturing unit, Pharmaceutical R&D, Hospital (Clinical Pharmacy), Clinical Research Organization, Community Pharmacy, etc. After the Semester – VI and before the commencement of Semester – VII, and shall submit satisfactory report of such work and certificate duly signed by the authority of training organization to the head of the institute.

23. Practice School

In the VII semester, every candidate shall undergo practice school for a period of 150 hours evenly distributed throughout the semester. The student shall opt any one of the domains for practice school declared by the program committee from time to time.

At the end of the practice school, every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages). Along with the exams of semester VII, the report submitted by the student, knowledge and skills acquired by the student through practice school shall be evaluated by the subject experts at college level and grade point shall be awarded.

24. Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the B.Pharm program shall not be eligible for award of ranks. Moreover, the candidates should have completed the B. Pharm program in minimum prescribed number of years, (four years) for the award of Ranks.

25. Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

26. Duration for completion of the program of study

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

27. Re-admission after break of study

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying a condonation fee.

No condonation is allowed for the candidate who has more than 2 years of break up period and he/she has to rejoin the program by paying the required fees.

CHAPTER - II: SYLLABUS

Semester I

BP101T. HUMAN ANATOMY AND PHYSIOLOGY-I (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

Objectives: Upon completion of this course the student should be able to

1. Explain the gross morphology, structure and functions of various organs of the human body.
2. Describe the various homeostatic mechanisms and their imbalances.
3. Identify the various tissues and organs of different systems of human body.
4. Perform the various experiments related to special senses and nervous system.
5. Appreciate coordinated working pattern of different organs of each system

Course Content:

Unit I

10 hours

☐ **Introduction to human body**

Definition and scope of anatomy and physiology, levels of structural organization and body systems, basic life processes, homeostasis, basic anatomical terminology.

☐ **Cellular level of organization**

Structure and functions of cell, transport across cell membrane, cell division, cell junctions. General principles of cell communication, intracellular signaling pathway activation by extracellular signal molecule, Forms of intracellular signaling: a) Contact-dependent b) Paracrine c) Synaptic d) Endocrine

☐ **Tissue level of organization**

Classification of tissues, structure, location and functions of epithelial, muscular and nervous and connective tissues.

Unit II

10 hours

☐ **Integumentary system**

Structure and functions of skin

☐ **Skeletal system**

Divisions of skeletal system, types of bone, salient features and functions of bones of axial and appendicular skeletal system

Organization of skeletal muscle, physiology of muscle contraction, neuromuscular junction

□ **Joints**

Structural and functional classification, types of joints movements and its articulation

Unit III

10 hours

□ **Nervous system**

Organization of nervous system, neuron, neuroglia, classification and properties of nerve fibre, electrophysiology, action potential, nerve impulse, receptors, synapse, neurotransmitters.

Central nervous system: Meninges, ventricles of brain and cerebrospinal fluid, structure and functions of brain (cerebrum, brain stem, cerebellum), spinal cord (gross structure, functions of afferent and efferent nerve tracts, reflex activity)

Unit IV

08 hours

Peripheral nervous system:

Classification of peripheral nervous system: Structure and functions of sympathetic and parasympathetic nervous system.

Origin and functions of spinal and cranial nerves.

□ **Special senses**

Structure and functions of eye, ear, nose and tongue and their disorders.

Unit V

07 hours

□ **Endocrine system**

Classification of hormones, mechanism of hormone action, structure and functions of pituitary gland, thyroid gland, parathyroid gland, adrenal gland, pancreas, pineal gland, thymus and their disorders.

BP107P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject.

1. Study of compound microscope.
2. Microscopic study of epithelial and connective tissue
3. Microscopic study of muscular and nervous tissue
4. Identification of axial bones
5. Identification of appendicular bones
6. To study the integumentary and special senses using specimen, models, etc.,
7. To study the nervous system using specimen, models, etc.,
8. To study the endocrine system using specimen, models, etc
9. To demonstrate the general neurological examination
 10. To demonstrate the function of olfactory nerve
 11. To examine the different types of taste.
 12. To demonstrate the visual acuity
 13. To demonstrate the reflex activity
 14. Recording of body temperature
 15. To demonstrate positive and negative feedback mechanism.

Recommended Books (Latest Editions)

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,Riverview,MI USA
4. Text book of Medical Physiology- Arthur C,Guyton andJohn.E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.

6. Textbook of Human Histology by Inderbir Singh, Jaypee brother's medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother's medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

Reference Books (Latest Editions)

1. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje ,Academic Publishers Kolkata

BP102T. PHARMACEUTICAL ANALYSIS (Theory)

45 Hours

Scope: This course deals with the fundamentals of analytical chemistry and principles of electrochemical analysis of drugs

Objectives: Upon completion of the course student shall be able to

- ☐ understand the principles of volumetric and electro chemical analysis
- ☐ carryout various volumetric and electrochemical titrations
- ☐ develop analytical skills

Course Content:

UNIT-I

10 Hours

(a) Pharmaceutical analysis- Definition and scope

- i) Different techniques of analysis
- ii) Methods of expressing concentration
- iii) Primary and secondary standards.
- iv) Preparation and standardization of various molar and normal solutions- Oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulphate, sulphuric acid, potassium permanganate and ceric ammonium sulphate

(b)Errors: Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures

UNIT-II

10 Hours

- ☐ **Acid base titration:** Theories of acid base indicators, classification of acid base titrations and theory involved in titrations of strong, weak, and very weak acids and bases, neutralization curves
- ☐ **Non aqueous titration:** Solvents, acidimetry and alkalimetry titration and estimation of Sodium benzoate and Ephedrine HCl

UNIT-III

10 Hours

- ☐ **Precipitation titrations:** Mohr's method, Volhard's, Modified Volhard's, Fajans method, estimation of sodium chloride.
- ☐ **Complexometric titration:** Classification, metal ion indicators, masking and demasking reagents, estimation of Magnesium sulphate, and calcium gluconate.
- ☐ **Gravimetry:** Principle and steps involved in gravimetric analysis. Purity of the precipitate: co-precipitation and post precipitation, Estimation of barium sulphate.

UNIT-IV

08 Hours

Redox titrations

- (a) Concepts of oxidation and reduction
- (b) Types of redox titrations (Principles and applications)

Cerimetry, Iodimetry, Iodometry, Bromatometry, Dichrometry, Titration with potassium iodate

UNIT-V

07 Hours

- **Electrochemical methods of analysis**
 - **Conductometry**- Introduction, Conductivity cell, Conductometric titrations, applications.
 - **Potentiometry** - Electrochemical cell, construction and working of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine end point of potentiometric titration and applications.
 - **Polarography** - Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications

BP108P. PHARMACEUTICAL ANALYSIS (Practical)

4 Hours / Week

I Preparation and standardization of

- (1) Sodium hydroxide
- (2) Sulphuric acid
- (3) Sodium thiosulfate
- (4) Potassium permanganate
- (5) Ceric ammonium sulphate

II Assay of the following compounds along with Standardization of Titrant

- (1) Ammonium chloride by acid base titration
- (2) Ferrous sulphate by Cerimetry
- (3) Copper sulphate by Iodometry
- (4) Calcium gluconate by complexometry
- (5) Hydrogen peroxide by Permanganometry
- (6) Sodium benzoate by non-aqueous titration
- (7) Sodium Chloride by precipitation titration

III Determination of Normality by electro-analytical methods

- (1) Conductometric titration of strong acid against strong base
- (2) Conductometric titration of strong acid and weak acid against strong base
- (3) Potentiometric titration of strong acid against strong base

Recommended Books: (Latest Editions)

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry
4. Bentley and Driver's Textbook of Pharmaceutical Chemistry
5. John H. Kennedy, Analytical chemistry principles
6. Indian Pharmacopoeia.

BP103T. PHARMACEUTICS- I (Theory)

45 Hours

Scope: This course is designed to impart a fundamental knowledge on the preparatory pharmacy with arts and science of preparing the different conventional dosage forms.

Objectives: Upon completion of this course the student should be able to:

- ☐ Know the history of profession of pharmacy
- ☐ Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations
- ☐ Understand the professional way of handling the prescription
- ☐ Preparation of various conventional dosage forms

Course Content:

UNIT – I

10 Hours

- ☐ **Historical background and development of profession of pharmacy:** History of profession of Pharmacy in India in relation to pharmacy education, industry and organization, Pharmacy as a career, Pharmacopoeias: Introduction to IP, BP, USP and Extra Pharmacopoeia.
- ☐ **Dosage forms:** Introduction to dosage forms, classification and definitions
- ☐ **Prescription:** Definition, Parts of prescription, handling of Prescription and Errors in prescription.
- ☐ **Posology:** Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area.

UNIT – II

10 Hours

- ☐ **Pharmaceutical calculations:** Weights and measures – Imperial & Metric system, Calculations involving percentage solutions, alligation, proof spirit and isotonic solutions based on freezing point and molecular weight.
- ☐ **Powders:** Definition, classification, advantages and disadvantages, Simple & compound powders – official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.
- ☐ **Liquid dosage forms:** Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques

UNIT – III

08 Hours

- ☐ **Monophasic liquids:** Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions.
- ☐ **Biphasic liquids:**
- ☐ **Suspensions:** Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome.
- ☐ **Emulsions:** Definition, classification, emulsifying agent, test for the identification of type of Emulsion, Methods of preparation & stability problems and methods to overcome.

UNIT – IV

08 Hours

- ☐ **Suppositories:** Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories.
- ☐ **Pharmaceutical incompatibilities:** Definition, classification, physical, chemical and therapeutic incompatibilities with examples.

UNIT – V

07 Hours

- ☐ **Semisolid dosage forms:** Definitions, classification, mechanisms and factors influencing dermal penetration of drugs. Preparation of ointments, pastes, creams and gels. Excipients used in semi solid dosage forms. Evaluation of semi solid dosage forms

BP109P. PHARMACEUTICS I (Practical)

3 Hours / week

- 1. Syrups**
 - a) Syrup IP
 - b) Paracetamol pediatric syrup
- 2. Elixirs**
 - a) Piperazine citrate elixir
 - b) Paracetamol pediatric elixir
- 3. Linctus**
 - a) Simple Linctus BPC
- 4. Solutions**
 - a) Strong solution of ammonium acetate
 - b) Cresol with soap solution
- 5. Suspensions**
 - a) Calamine lotion
 - b) Magnesium Hydroxide mixture
- 5. Emulsions**
 - a) Turpentine Liniment
 - b) Liquid paraffin emulsion
- 6. Powders and Granules**
 - a) ORS powder (WHO)
 - b) Effervescent granules
 - c) Dusting powder
- 7. Suppositories**
 - a) Glycero gelatin suppository
 - b) Soap glycerin suppository
- 8. Semisolids**
 - a) Sulphur ointment
 - b) Non staining iodine ointment with methyl salicylate
 - c) Bentonite gel
- 9. Gargles and Mouthwashes**
 - a) Potassium chlorate gargle
 - b) Chlorhexidine mouthwash

Recommended Books: (Latest Editions)

1. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and Walkins, New Delhi.
2. Carter S.J., Cooper and Gunn's-Dispensing for Pharmaceutical Students, CBS publishers, New Delhi.
3. M.E. Aulton, Pharmaceutics, The Science& Dosage Form Design, Churchill Livingstone, Edinburgh.
4. Indian pharmacopoeia.
5. British pharmacopoeia.
6. Lachmann. Theory and Practice of Industrial Pharmacy, Lea& Febiger Publisher, The University of Michigan.
7. Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott Williams, New Delhi.
8. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, CBS Publications, New Delhi.
9. E.A. Rawlins, Bentley's Text Book of Pharmaceutics, English Language Book Society, Elsevier Health Sciences, USA.
10. Isaac Ghebre Sellassie: Pharmaceutical Pelletization Technology, Marcel Dekker, INC, New York.
11. Dilip M. Parikh: Handbook of Pharmaceutical Granulation Technology, Marcel Dekker, INC, New York.
12. Francoise Nieloud and Gilberte Marti-Mestres: Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC, New York.

BP104T. PHARMACEUTICAL INORGANIC CHEMISTRY (Theory)

45 Hours

Scope: This subject deals with the monographs of inorganic drugs and pharmaceuticals.

Objectives: Upon completion of course student shall be able to

- ☐ know the sources of impurities and methods to determine the impurities in inorganic drugs and pharmaceuticals
- ☐ understand the medicinal and pharmaceutical importance of inorganic compounds

Course Content:

UNIT I

10 Hours

- ☐ **Impurities in pharmaceutical substances:** History of Pharmacopoeia, Sources and types of impurities, principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals, modified limit test for Chloride and Sulphate

General methods of preparation, assay for the compounds superscripted with **asterisk (*)**, properties and medicinal uses of inorganic compounds belonging to the following classes

UNIT II

10 Hours

- ☐ **Acids, Bases and Buffers:** Buffer equations and buffer capacity in general, buffers in pharmaceutical systems, preparation, stability, buffered isotonic solutions, measurements of tonicity, calculations and methods of adjusting isotonicity.
- ☐ **Major extra and intracellular electrolytes:** Functions of major physiological ions, Electrolytes used in the replacement therapy: Sodium chloride*, Potassium chloride, Calcium gluconate* and Oral Rehydration Salt (ORS), Physiological acid base balance.
- ☐ **Dental products:** Dentifrices, role of fluoride in the treatment of dental caries, Desensitizing agents, Calcium carbonate, Sodium fluoride, and Zinc eugenol cement.

UNIT III

10 Hours

- ☐ **Gastrointestinal agents**

Acidifiers: Ammonium chloride* and Dil. HCl

Antacid: Ideal properties of antacids, combinations of antacids, Sodium

Bicarbonate*, Aluminum hydroxide gel, Magnesium hydroxide mixture

Cathartics: Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite

Antimicrobials: Mechanism, classification, Potassium permanganate, Boric acid, Hydrogen peroxide*, Chlorinated lime*, Iodine and its preparations

UNIT IV

08 Hours

□ **Miscellaneous compounds**

Expectorants: Potassium iodide, Ammonium chloride*.

Emetics: Copper sulphate*, Sodium potassium tartarate

Haematinics: Ferrous sulphate*, Ferrous gluconate

Poison and Antidote: Sodium thiosulphate*, Activated charcoal, Sodium nitrite³³³

Astringents: Zinc Sulphate, Potash Alum

UNIT V

07 Hours

- **Radiopharmaceuticals:** Radio activity, Measurement of radioactivity, Properties of α , β , γ radiations, Half life, radio isotopes and study of radio isotopes - Sodium iodide I^{131} , Storage conditions, precautions & pharmaceutical application of radioactive substances.

BP110P. PHARMACEUTICAL INORGANIC CHEMISTRY (Practical)

4 Hours / Week

I Limit tests for following ions

Limit test for Chlorides and Sulphates
Modified limit test for Chlorides and Sulphates
Limit test for Iron
Limit test for Heavy metals
Limit test for Lead
Limit test for Arsenic

II Identification test

Magnesium hydroxide
Ferrous sulphate
Sodium bicarbonate
Calcium gluconate
Copper sulphate

III Test for purity

Swelling power of Bentonite
Neutralizing capacity of aluminum hydroxide gel
Determination of potassium iodate and iodine in potassium Iodide

IV Preparation of inorganic pharmaceuticals

Boric acid
Potash alum
Ferrous sulphate

Recommended Books (Latest Editions)

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London, 4th edition.
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry, 3rd Edition
4. M.L Schroff, Inorganic Pharmaceutical Chemistry
5. Bentley and Driver's Textbook of Pharmaceutical Chemistry
6. Anand & Chatwal, Inorganic Pharmaceutical Chemistry
7. Indian

Pharmacopoeia

BP105T.COMMUNICATION SKILLS (Theory)

30 Hours

Scope: This course will prepare the young pharmacy student to interact effectively with doctors, nurses, dentists, physiotherapists and other health workers. At the end of this course the student will get the soft skills set to work cohesively with the team as a team player and will add value to the pharmaceutical business.

Objectives:

Upon completion of the course the student shall be able to

1. Understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation
2. Communicate effectively (Verbal and Non Verbal)
3. Effectively manage the team as a team player
4. Develop interview skills
5. Develop Leadership qualities and essentials

Course content:

UNIT – I

07 Hours

- **Communication Skills:** Introduction, Definition, The Importance of Communication, The Communication Process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context
- **Barriers to communication:** Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers
- **Perspectives in Communication:** Introduction, Visual Perception, Language, Other factors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment

UNIT – II

07 Hours

- **Elements of Communication:** Introduction, Face to Face Communication - Tone of Voice, Body Language (Non-verbal communication), Verbal Communication, Physical Communication
- **Communication Styles:** Introduction, The Communication Styles Matrix with example for each -Direct Communication Style, Spirited Communication Style, Systematic Communication Style, Considerate Communication Style

UNIT – III

07 Hours

- ☐ **Basic Listening Skills:** Introduction, Self-Awareness, Active Listening, Becoming an Active Listener, Listening in Difficult Situations
- ☐ **Effective Written Communication:** Introduction, When and When Not to Use Written Communication - Complexity of the Topic, Amount of Discussion' Required, Shades of Meaning, Formal Communication
- ☐ **Writing Effectively:** Subject Lines, Put the Main Point First, Know Your Audience, Organization of the Message

UNIT – IV

05 Hours

- ☐ **Interview Skills:** Purpose of an interview, Do's and Dont's of an interview
- ☐ **Giving Presentations:** Dealing with Fears, Planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery

UNIT – V

04 Hours

- ☐ **Group Discussion:** Introduction, Communication skills in group discussion, Do's and Dont's of group discussion

BP111P.COMMUNICATION SKILLS (Practical)

2 Hours / week

The following learning modules are to be conducted using wordsworth[®] English language lab software

Basic communication covering the following topics

Meeting People

Asking Questions

Making Friends

What did you do?

Do's and Dont's

Pronunciations covering the following topics

Pronunciation (Consonant Sounds)

Pronunciation and Nouns

Pronunciation (Vowel Sounds)

Advanced Learning

Listening Comprehension / Direct and Indirect Speech

Figures of Speech

Effective Communication

Writing Skills

Effective Writing

Interview Handling Skills

E-Mail etiquette

Presentation Skills

Recommended Books: (Latest Edition)

1. Basic communication skills for Technology, Andreja. J. Ruther Ford, 2nd Edition, Pearson Education, 2011
2. Communication skills, Sanjay Kumar, Pushpalata, 1st Edition, Oxford Press, 2011
3. Organizational Behaviour, Stephen .P. Robbins, 1st Edition, Pearson, 2013
4. Brilliant- Communication skills, Gill Hasson, 1st Edition, Pearson Life, 2011
5. The Ace of Soft Skills: Attitude, Communication and Etiquette for success, Gopala Swamy Ramesh, 5th Edition, Pearson, 2013
6. Developing your influencing skills, Deborah Dalley, Lois Burton, Margaret, Green hall, 1st Edition Universe of Learning LTD, 2010
7. Communication skills for professionals, Konar nira, 2nd Edition, New arrivals – PHI, 2011
8. Personality development and soft skills, Barun K Mitra, 1st Edition, Oxford Press, 2011
9. Soft skill for everyone, Butter Field, 1st Edition, Cengage Learning india pvt.ltd, 2011
10. Soft skills and professional communication, Francis Peters SJ, 1st Edition, Mc Graw Hill Education, 2011
11. Effective communication, John Adair, 4th Edition, Pan Mac Millan, 2009
12. Bringing out the best in people, Aubrey Daniels, 2nd Edition, Mc Graw Hill, 1999

BP 106RBT.REMEDIAL BIOLOGY (Theory)

30 Hours

Scope: To learn and understand the components of living world, structure and functional system of plant and animal kingdom.

Objectives: Upon completion of the course, the student shall be able to

- ☐ know the classification and salient features of five kingdoms of life
- ☐ understand the basic components of anatomy & physiology of plant
- ☐ know understand the basic components of anatomy & physiology animal with special reference to human

UNIT I

07 Hours

Living world:

- ☐ Definition and characters of living organisms
- ☐ Diversity in the living world
- ☐ Binomial nomenclature
- ☐ Five kingdoms of life and basis of classification. Salient features of Monera, Protista, Fungi, Animalia and Plantae, Virus,

Morphology of Flowering plants

- ☐ Morphology of different parts of flowering plants – Root, stem, inflorescence, flower, leaf, fruit, seed.
- ☐ General Anatomy of Root, stem, leaf of monocotyledons & Dicotyledones.

UNIT II

07 Hours

Body fluids and circulation

- ☐ Composition of blood, blood groups, coagulation of blood
- ☐ Composition and functions of lymph
- ☐ Human circulatory system
- ☐ Structure of human heart and blood vessels
- ☐ Cardiac cycle, cardiac output and ECG

Digestion and Absorption

- ☐ Human alimentary canal and digestive glands
- ☐ Role of digestive enzymes
- ☐ Digestion, absorption and assimilation of digested food

Breathing and respiration

- ☐ Human respiratory system
- ☐ Mechanism of breathing and its regulation
- ☐ Exchange of gases, transport of gases and regulation of respiration
- ☐ Respiratory volumes

UNIT III

07 Hours

Excretory products and their elimination

- ☐ Modes of excretion
- ☐ Human excretory system- structure and function
- ☐ Urine formation
- ☐ Rennin angiotensin system

Neural control and coordination

- ☐ Definition and classification of nervous system
- ☐ Structure of a neuron
- ☐ Generation and conduction of nerve impulse
- ☐ Structure of brain and spinal cord
- ☐ Functions of cerebrum, cerebellum, hypothalamus and medulla oblongata

Chemical coordination and regulation

- ☐ Endocrine glands and their secretions
- ☐ Functions of hormones secreted by endocrine glands

Human reproduction

- ☐ Parts of female reproductive system
- ☐ Parts of male reproductive system
- ☐ Spermatogenesis and Oogenesis
- ☐ Menstrual cycle

UNIT IV

05 Hours

Plants and mineral nutrition:

- ☐ Essential mineral, macro and micronutrients
- ☐ Nitrogen metabolism, Nitrogen cycle, biological nitrogen fixation

Photosynthesis

- ☐ Autotrophic nutrition, photosynthesis, Photosynthetic pigments, Factors affecting photosynthesis.

UNIT V

04 Hours

Plant respiration:Respiration, glycolysis, fermentation (anaerobic).

Plant growth and development

- ☐ Phases and rate of plant growth, Condition of growth,Introduction to plant growth regulators

Cell - The unit of life

- ☐ Structure and functions of cell and cell organelles.Cell division

Tissues

- ☐ Definition, types of tissues, location and functions.

Text Books

- a. Text book of Biology by S. B. Gokhale
- b. A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.

Reference Books

- a. A Text book of Biology by B.V. Sreenivasa Naidu
- b. A Text book of Biology by Naidu and Murthy
- c. Botany for Degree students By A.C.Dutta.
- d.Outlines of Zoology by M. Ekambaranatha ayyer and T. N. Ananthakrishnan.
- e. A manual for pharmaceutical biology practical by S.B. Gokhale and C. K. Kokate

BP112RBP.REMEDIAL BIOLOGY (Practical)

30 Hours

1. Introduction to experiments in biology
 - a) Study of Microscope
 - b) Section cutting techniques
 - c) Mounting and staining
 - d) Permanent slide preparation
2. Study of cell and its inclusions
3. Study of Stem, Root, Leaf and its modifications
4. Detailed study of frog by using computer models
5. Microscopic study and identification of tissues
6. Identification of bones
7. Determination of blood group
8. Determination of blood pressure
9. Determination of tidal volume

Reference Books

1. Practical human anatomy and physiology. by S.R.Kale and R.R.Kale.
2. A Manual of pharmaceutical biology practical by S.B.Gokhale, C.K.Kokate and S.P.Shriwastava.
3. Biology practical manual according to National core curriculum .Biology forum of Karnataka. Prof .M.J.H.Shafi

BP 106RMT.REMEDIAL MATHEMATICS (Theory)

30 Hours

Scope: This is an introductory course in mathematics. This subject deals with the introduction to Partial fraction, Logarithm, matrices and Determinant, Analytical geometry, Calculus, differential equation and Laplace transform.

Objectives: Upon completion of the course the student shall be able to:-

1. Know the theory and their application in Pharmacy
2. Solve the different types of problems by applying theory
3. Appreciate the important application of mathematics in Pharmacy

Course Content:

UNIT – I

06 Hours

□ Partial fraction

Introduction, Polynomial, Rational fractions, Proper and Improper fractions, Partial fraction, Resolving into Partial fraction, Application of Partial Fraction in Chemical Kinetics and Pharmacokinetics

□ Logarithms

Introduction, Definition, Theorems/Properties of logarithms, Common logarithms, Characteristic and Mantissa, worked examples, application of logarithm to solve pharmaceutical problems.

□ Function:

Real Valued function, Classification of real valued functions,

□ Limits and continuity :

Introduction, Limit of a function, Definition of limit of a function (□ - □

definition), $\lim_{x \rightarrow a} \frac{x^n - a^n}{x - a} = na^{n-1}$, $\lim_{x \rightarrow 0} \frac{\sin x}{x} = 1$,

UNIT –II

06 Hours

□ Matrices and Determinant:

Introduction matrices, Types of matrices, Operation on matrices, Transpose of a matrix, Matrix Multiplication, Determinants, Properties of determinants, Product of determinants, Minors and co-Factors, Adjoint or adjugate of a square matrix, Singular and non-singular matrices, Inverse of a matrix, Solution of system of linear equations using matrix method, Cramer's rule, Characteristic equation and roots of a square matrix, Cayley-Hamilton theorem, Application of Matrices in solving Pharmacokinetic equations

UNIT – III

06 Hours

□ Calculus

Differentiation : Introductions, Derivative of a function, Derivative of a constant, Derivative of a product of a constant and a function, Derivative of the sum or difference of two functions, Derivative of the product of two functions (product formula), Derivative of the quotient of two functions (Quotient formula) – **Without Proof**, Derivative of x^n w.r.t.x, where n is any rational number, Derivative of e^x , Derivative of $\log_e x$, Derivative of a^x , Derivative of trigonometric functions from first principles (**without Proof**), Successive Differentiation, Conditions for a function to be a maximum or a minimum at a point. Application

UNIT – IV

06 Hours

□ Analytical Geometry

Introduction: Signs of the Coordinates, Distance formula,

Straight Line : Slope or gradient of a straight line, Conditions for parallelism and perpendicularity of two lines, Slope of a line joining two points, Slope – intercept form of a straight line

Integration:

Introduction, Definition, Standard formulae, Rules of integration, Method of substitution, Method of Partial fractions, Integration by parts, definite integrals, application

UNIT-V

06 Hours

- **Differential Equations** : Some basic definitions, Order and degree, Equations in separable form, Homogeneous equations, Linear Differential equations, Exact equations, **Application in solving Pharmacokinetic equations**

- **Laplace Transform** : Introduction, Definition, Properties of Laplace transform, Laplace Transforms of elementary functions, Inverse Laplace transforms, Laplace transform of derivatives, Application to solve Linear differential equations, **Application in solving Chemical kinetics and Pharmacokinetics equations**

Recommended Books (Latest Edition)

1. Differential Calculus by Shanthinarayan
2. Pharmaceutical Mathematics with application to Pharmacy by Panchaksharappa Gowda D.H.
3. Integral Calculus by Shanthinarayan
4. Higher Engineering Mathematics by Dr.B.S.Grewal

Semester II

BP 201T. HUMAN ANATOMY AND PHYSIOLOGY-II (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

Objectives: Upon completion of this course the student should be able to:

1. Explain the gross morphology, structure and functions of various organs of the human body.
2. Describe the various homeostatic mechanisms and their imbalances.
3. Identify the various tissues and organs of different systems of human body.
4. Perform the hematological tests like blood cell counts, haemoglobin estimation, bleeding/clotting time etc and also record blood pressure, heart rate, pulse and respiratory volume.
5. Appreciate coordinated working pattern of different organs of each system
6. Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

Course Content:

Unit I

10 hours

☐ **Body fluids and blood**

- ☐ Body fluids, composition and functions of blood, hemopoiesis, formation of hemoglobin, anemia, mechanisms of coagulation, blood grouping, Rh factors, transfusion, its significance and disorders of blood, Reticulo endothelial system.

☐ **Lymphatic system**

Lymphatic organs and tissues, lymphatic vessels, lymph circulation and functions of lymphatic system

Unit II

10 hours

☐ **Cardiovascular system**

Heart – anatomy of heart, blood circulation, blood vessels, structure and functions of artery, vein and capillaries, elements of conduction system of heart and heart beat, its regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of blood pressure, pulse, electrocardiogram and disorders of heart.

Unit III

06 hours

☐ **Digestive system**

Anatomy of GI Tract with special reference to anatomy and functions of stomach, (Acid production in the stomach, regulation of acid production through parasympathetic nervous system, pepsin role in protein digestion) small intestine

and large intestine, anatomy and functions of salivary glands, pancreas and liver, movements of GIT, digestion and absorption of nutrients and disorders of GIT.

□ **Respiratory system**

Anatomy of respiratory system with special reference to anatomy of lungs, mechanism of respiration, regulation of respiration

Unit IV

□ **Respiratory system**

10 hours

Lung Volumes and capacities transport of respiratory gases, artificial respiration, and resuscitation methods.

□ **Urinary system**

Anatomy of urinary tract with special reference to anatomy of kidney and nephrons, functions of kidney and urinary tract, physiology of urine formation, micturition reflex and role of kidneys in acid base balance, role of RAS in kidney and disorders of kidney.

Unit V

09 hours

□ **Reproductive system**

Anatomy of male and female reproductive system, Functions of male and female reproductive system, sex hormones, physiology of menstruation, fertilization, spermatogenesis, oogenesis, pregnancy and parturition

□ **Introduction to genetics**

Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance

BP 207 P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject.

1. Introduction to hemocytometry.
2. Enumeration of white blood cell (WBC) count
3. Enumeration of total red blood corpuscles (RBC) count
4. Determination of bleeding time
5. Determination of clotting time
6. Estimation of hemoglobin content
7. Determination of blood group.
8. Determination of erythrocyte sedimentation rate (ESR).
9. Determination of heart rate and pulse rate.
10. Recording of blood pressure.
11. Determination of tidal volume and vital capacity.
12. Study of digestive, respiratory, cardiovascular systems, urinary and reproductive systems with the help of models, charts and specimens.
13. Recording of basal mass index .
14. Study of family planning devices and pregnancy diagnosis test.
15. Demonstration of total blood count by cell analyser
16. Permanent slides of vital organs and gonads.

Recommended Books (Latest Editions)

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,Riverview,MI USA

4. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
6. Textbook of Human Histology by Inderbir Singh, Jaypee brothers medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brothers medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

Reference Books:

1. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje ,Academic Publishers Kolkata

BP202T. PHARMACEUTICAL ORGANIC CHEMISTRY –I (Theory)

45 Hours

Scope: This subject deals with classification and nomenclature of simple organic compounds, structural isomerism, intermediates forming in reactions, important physical properties, reactions and methods of preparation of these compounds. The syllabus also emphasizes on mechanisms and orientation of reactions.

Objectives: Upon completion of the course the student shall be able to

1. write the structure, name and the type of isomerism of the organic compound
2. write the reaction, name the reaction and orientation of reactions
3. account for reactivity/stability of compounds,
4. identify/confirm the identification of organic compound

Course Content:

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained

To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT-I

07 Hours

□ Classification, nomenclature and isomerism

Classification of Organic Compounds

Common and IUPAC systems of nomenclature of organic compounds

(up to 10 Carbons open chain and carbocyclic compounds)

Structural isomerisms in organic compounds

UNIT-II 10 Hours

□ Alkanes*, Alkenes* and Conjugated dienes*

sp^3 hybridization in alkanes, Halogenation of alkanes, uses of paraffins. Stabilities of alkenes, sp^2 hybridization in alkenes

E_1 and E_2 reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and evidences. E_1 versus E_2 reactions, Factors affecting E_1 and E_2 reactions. Ozonolysis, electrophilic addition reactions of alkenes, Markownikoff's orientation, free radical addition reactions of alkenes, Anti Markownikoff's orientation.

Stability of conjugated dienes, Diel-Alder, electrophilic addition, free radical addition reactions of conjugated dienes, allylic rearrangement

UNIT-III 10 Hours

□ **Alkyl halides***

SN₁ and SN₂ reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations.

SN₁ versus SN₂ reactions, Factors affecting SN₁ and SN₂ reactions

Structure and uses of ethylchloride, Chloroform, trichloroethylene, tetrachloroethylene, dichloromethane, tetrachloromethane and iodoform.

- **Alcohols***- Qualitative tests, Structure and uses of Ethyl alcohol, chlorobutanol, Cetosteryl alcohol, Benzyl alcohol, Glycerol, Propylene glycol

UNIT-IV 10 Hours

□ **Carbonyl compounds* (Aldehydes and ketones)**

Nucleophilic addition, Electromeric effect, aldol condensation, Crossed Aldol condensation, Cannizzaro reaction, Crossed Cannizzaro reaction, Benzoin condensation, Perkin condensation, qualitative tests, Structure and uses of Formaldehyde, Paraldehyde, Acetone, Chloral hydrate, Hexamine, Benzaldehyde, Vanilin, Cinnamaldehyde.

UNIT-V

08 Hours

□ **Carboxylic acids***

Acidity of carboxylic acids, effect of substituents on acidity, inductive effect and qualitative tests for carboxylic acids, amide and ester

Structure and Uses of Acetic acid, Lactic acid, Tartaric acid, Citric acid, Succinic acid. Oxalic acid, Salicylic acid, Benzoic acid, Benzyl benzoate, Dimethyl phthalate, Methyl salicylate and Acetyl salicylic acid

- **Aliphatic amines*** - Basicity, effect of substituent on Basicity. Qualitative test, Structure and uses of Ethanolamine, Ethylenediamine, Amphetamine

BP208P. PHARMACEUTICAL ORGANIC CHEMISTRY -I (Practical)

4 Hours / week

1. Systematic qualitative analysis of unknown organic compounds like
 1. Preliminary test: Color, odour, aliphatic/aromatic compounds, saturation and unsaturation, etc.
 2. Detection of elements like Nitrogen, Sulphur and Halogen by Lassaigne's test
 3. Solubility test
 4. Functional group test like Phenols, Amides/ Urea, Carbohydrates, Amines, Carboxylic acids, Aldehydes and Ketones, Alcohols, Esters, Aromatic and Halogenated Hydrocarbons, Nitro compounds and Anilides.
 5. Melting point/Boiling point of organic compounds
 6. Identification of the unknown compound from the literature using melting point/ boiling point.
 7. Preparation of the derivatives and confirmation of the unknown compound by melting point/ boiling point.
 8. Minimum 5 unknown organic compounds to be analysed systematically.
2. Preparation of suitable solid derivatives from organic compounds
3. Construction of molecular models

Recommended Books (Latest Editions)

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar , Volume-I
3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
4. Organic Chemistry by P.L.Soni
5. Practical Organic Chemistry by Mann and Saunders.
6. Vogel's text book of Practical Organic Chemistry
7. Advanced Practical organic chemistry by N.K.Vishnoi.
8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.
9. Reaction and reaction mechanism by Ahluwaliah/Chatwal.

BP203 T. BIOCHEMISTRY (Theory)

45 Hours

Scope: Biochemistry deals with complete understanding of the molecular levels of the chemical process associated with living cells. The scope of the subject is providing biochemical facts and the principles to understand metabolism of nutrient molecules in physiological and pathological conditions. It is also emphasizing on genetic organization of mammalian genome and hetero & autocatalytic functions of DNA.

Objectives: Upon completion of course student shall be able to

1. Understand the catalytic role of enzymes, importance of enzyme inhibitors in design of new drugs, therapeutic and diagnostic applications of enzymes.
2. Understand the metabolism of nutrient molecules in physiological and pathological conditions.
3. Understand the genetic organization of mammalian genome and functions of DNA in the synthesis of RNAs and proteins.

Course Content:

UNIT I

10 Hours

☐ **Carbohydrate metabolism**

Glycolysis – Pathway, energetics and significance

Citric acid cycle- Pathway, energetics and significance

HMP shunt and its significance; Glucose-6-Phosphate dehydrogenase (G6PD) deficiency

Glycogen metabolism Pathways and glycogen storage diseases (GSD)

Gluconeogenesis- Pathway and its significance

Hormonal regulation of blood glucose level and Diabetes mellitus

☐ **Biological oxidation**

Electron transport chain (ETC) and its mechanism.

Oxidative phosphorylation & its mechanism and substrate level phosphorylation

Inhibitors ETC and oxidative phosphorylation/Uncouplers

UNIT II

10 Hours

☐ **Lipid metabolism**

β -Oxidation of saturated fatty acid (Palmitic acid)

Formation and utilization of ketone bodies; ketoacidosis

De novo synthesis of fatty acids (Palmitic acid)

Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D

Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, fatty liver and obesity.

□ **Amino acid metabolism**

General reactions of amino acid metabolism: Transamination, deamination & decarboxylation, urea cycle and its disorders

Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenylketonuria, Albinism, alcaptonuria, tyrosinemia)

Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline

Catabolism of heme; hyperbilirubinemia and jaundice

UNIT III

10 Hours

□ **Nucleic acid metabolism and genetic information transfer**

Biosynthesis of purine and pyrimidine nucleotides

Catabolism of purine nucleotides and Hyperuricemia and Gout disease Organization of mammalian genome

Structure of DNA and RNA and their functions

DNA replication (semi conservative model)

Transcription or RNA synthesis

Genetic code, Translation or Protein synthesis and inhibitors

UNIT IV

08 Hours

□ **Biomolecules**

Introduction, classification, chemical nature and biological role of carbohydrate, lipids, nucleic acids, amino acids and proteins.

□ **Bioenergetics**

Concept of free energy, endergonic and exergonic reaction, Relationship between free energy, enthalpy and entropy; Redox potential.

Energy rich compounds; classification; biological significances of ATP and cyclic AMP

UNIT V

07 Hours

□ Enzymes

Introduction, properties, nomenclature and IUB classification of enzymes

Enzyme kinetics (Michaelis plot, Line Weaver Burke plot)

Enzyme inhibitors with examples

Regulation of enzymes: enzyme induction and repression, allosteric enzymes regulation

Therapeutic and diagnostic applications of enzymes and isoenzymes Coenzymes –Structure and biochemical functions

BP 209 P. BIOCHEMISTRY (Practical)

4 Hours / Week

1. Qualitative analysis of carbohydrates (Glucose, Fructose, Lactose, Maltose, Sucrose and starch)
2. Identification tests for Proteins (albumin and Casein)
3. Quantitative analysis of reducing sugars (DNSA method) and Proteins (Biuret method)
4. Qualitative analysis of urine for abnormal constituents
5. Determination of blood creatinine
6. Determination of blood sugar
7. Determination of serum total cholesterol
8. Preparation of buffer solution and measurement of pH
9. Study of enzymatic hydrolysis of starch
10. Determination of Salivary amylase activity
11. Study the effect of Temperature on Salivary amylase activity.
12. Study the effect of substrate concentration on salivary amylase activity.

Recommended Books (Latest Editions)

1. Principles of Biochemistry by Lehninger.
2. Harper's Biochemistry by Robert K. Murry, Daryl K. Granner and Victor W. Rodwell.
3. Biochemistry by Stryer.
4. Biochemistry by D. Satyanarayan and U.Chakrapani
5. Textbook of Biochemistry by Rama Rao.
6. Textbook of Biochemistry by Deb.
7. Outlines of Biochemistry by Conn and Stumpf
8. Practical Biochemistry by R.C. Gupta and S. Bhargavan.
9. Introduction of Practical Biochemistry by David T. Plummer. (3rd Edition)
10. Practical Biochemistry for Medical students by Rajagopal and Ramakrishna.
11. Practical Biochemistry by Harold Varley.

BP 204T.PATHOPHYSIOLOGY (THEORY)

45Hours

Scope: Pathophysiology is the study of causes of diseases and reactions of the body to such disease producing causes. This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge required to practice medicine safely, confidently, rationally and effectively.

Objectives: Upon completion of the subject student shall be able to –

1. Describe the etiology and pathogenesis of the selected disease states;
2. Name the signs and symptoms of the diseases; and
3. Mention the complications of the diseases.

Course content:

Unit I

10Hours

□ Basic principles of Cell injury and Adaptation:

Introduction, definitions, Homeostasis, Components and Types of Feedback systems, Causes of cellular injury, Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage), Morphology of cell injury – Adaptive changes (Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia), Cell swelling, Intra cellular accumulation, Calcification, Enzyme leakage and Cell Death Acidosis & Alkalosis, Electrolyte imbalance

- **Basic mechanism involved in the process of inflammation and repair:**

Introduction, Clinical signs of inflammation, Different types of Inflammation, Mechanism of Inflammation – Alteration in vascular permeability and blood flow, migration of WBC's, Mediators of inflammation, Basic principles of wound healing in the skin, Pathophysiology of Atherosclerosis

Unit II

10Hours

- **Cardiovascular System:**

Hypertension, congestive heart failure, ischemic heart disease (angina, myocardial infarction, atherosclerosis and arteriosclerosis)

- **Respiratory system:** Asthma, Chronic obstructive airways diseases.
- **Renal system:** Acute and chronic renal failure .

Unit II

10Hours

- **Haematological Diseases:**

Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalassemia, hereditary acquired anemia, hemophilia

- **Endocrine system:** Diabetes, thyroid diseases, disorders of sex hormones
- **Nervous system:** Epilepsy, Parkinson's disease, stroke, psychiatric disorders: depression, schizophrenia and Alzheimer's disease.
- **Gastrointestinal system:** Peptic Ulcer
-

Unit IV

8 Hours

- Inflammatory bowel diseases, jaundice, hepatitis (A,B,C,D,E,F) alcoholic liver disease.
- **Disease of bones and joints:** Rheumatoid arthritis, osteoporosis and gout
- **Principles of cancer:** classification, etiology and pathogenesis of cancer
- **Diseases of bones and joints:** Rheumatoid Arthritis, Osteoporosis, Gout
- **Principles of Cancer:** Classification, etiology and pathogenesis of Cancer

Unit V

7 Hours

- **Infectious diseases:** Meningitis, Typhoid, Leprosy, Tuberculosis

Urinary tract infections

- **Sexually transmitted diseases:** AIDS, Syphilis, Gonorrhea

Recommended Books (Latest Editions)

1. Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins & Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier; 2014.
2. Harsh Mohan; Text book of Pathology; 6th edition; India; Jaypee Publications; 2010.
3. Laurence B, Bruce C, Bjorn K. ; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12th edition; New York; McGraw-Hill; 2011.
4. Best, Charles Herbert 1899-1978; Taylor, Norman Burke 1885-1972; West, John B (John Burnard); Best and Taylor's Physiological basis of medical practice; 12th ed; united states;
5. William and Wilkins, Baltimore; 1991 [1990 printing].
6. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston; Davidson's Principles and Practice of Medicine; 21st edition; London; ELBS/Churchill Livingstone; 2010.
7. Guyton A, John .E Hall; Textbook of Medical Physiology; 12th edition; WB Saunders Company; 2010.
8. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; 9th edition; London; McGraw-Hill Medical; 2014.
9. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia; WB Saunders Company; 1997.
10. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3rd edition; London; Churchill Livingstone publication; 2003.

Recommended Journals

1. The Journal of Pathology. ISSN: 1096-9896 (Online)
2. The American Journal of Pathology. ISSN: 0002-9440
3. Pathology. 1465-3931 (Online)
4. International Journal of Physiology, Pathophysiology and Pharmacology. ISSN: 1944-8171 (Online)
5. Indian Journal of Pathology and Microbiology. ISSN-0377-4929.

BP205 T. COMPUTER APPLICATIONS IN PHARMACY (Theory)

30 Hrs (2 Hrs/Week)

Scope: This subject deals with the introduction Database, Database Management system, computer application in clinical studies and use of databases.

Objectives: Upon completion of the course the student shall be able to

1. know the various types of application of computers in pharmacy
2. know the various types of databases
3. know the various applications of databases in pharmacy

Course content:

UNIT – I

06 hours

Number system: Binary number system, Decimal number system, Octal number system, Hexadecimal number systems, conversion decimal to binary, binary to decimal, octal to binary etc, binary addition, binary subtraction – One's complement, Two's complement method, binary multiplication, binary division

Concept of Information Systems and Software : Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project

UNIT –II

06 hours

Web technologies: Introduction to HTML, XML, CSS and Programming languages, introduction to web servers and Server Products

Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database

UNIT – III

06 hours

Application of computers in Pharmacy – Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology and adherence monitoring

Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System

UNIT – IV

06 hours

Bioinformatics: Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine Discovery

UNIT-V

06 hours

Computers as data analysis in Preclinical development: Chromatographic data analysis(CDS), Laboratory Information management System (LIMS) and Text Information Management System(TIMs)

BP210P. COMPUTER APPLICATIONS IN PHARMACY (Practical)

1. Design a questionnaire using a word processing package to gather information about a particular disease.
2. Create a HTML web page to show personal information.
3. Retrieve the information of a drug and its adverse effects using online tools
4. Creating mailing labels Using Label Wizard , generating label in MS WORD
5. Create a database in MS Access to store the patient information with the required fields Using access
6. Design a form in MS Access to view, add, delete and modify the patient record in the database
7. Generating report and printing the report from patient database
8. Creating invoice table using – MS Access
9. Drug information storage and retrieval using MS Access
10. Creating and working with queries in MS Access
11. Exporting Tables, Queries, Forms and Reports to web pages
12. Exporting Tables, Queries, Forms and Reports to XML pages

Recommended books (Latest edition):

1. Computer Application in Pharmacy – William E.Fassett –Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.
2. Computer Application in Pharmaceutical Research and Development –Sean Ekins – Wiley-Interscience, A John Willey and Sons, INC., Publication, USA
3. Bioinformatics (Concept, Skills and Applications) – S.C.Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002(INDIA)
4. Microsoft office Access - 2003, Application Development Using VBA, SQL Server, DAP and Infopath – Cary N.Prague – Wiley Dreamtech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi - 110002

BP 206 T. ENVIRONMENTAL SCIENCES (Theory)

30 hours

Scope:Environmental Sciences is the scientific study of the environmental system and the status of its inherent or induced changes on organisms. It includes not only the study of physical and biological characters of the environment but also the social and cultural factors and the impact of man on environment.

Objectives: Upon completion of the course the student shall be able to:

1. Create the awareness about environmental problems among learners.
2. Impart basic knowledge about the environment and its allied problems.
3. Develop an attitude of concern for the environment.
4. Motivate learner to participate in environment protection and environment improvement.
5. Acquire skills to help the concerned individuals in identifying and solving environmental problems.
6. Strive to attain harmony with Nature.

Course content:

Unit-I

10hours

The Multidisciplinary nature of environmental studies

Natural Resources

Renewable and non-renewable resources:

Natural resources and associated problems

a) Forest resources; b) Water resources; c) Mineral resources; d) Food resources; e) Energy resources; f) Land resources: Role of an individual in conservation of natural resources.

Unit-II

10hours

Ecosystems

☐ Concept of an ecosystem.

☐ Structure and function of an ecosystem.

☐ Introduction, types, characteristic features, structure and function of the ecosystems: Forest ecosystem; Grassland ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)

Unit- III

10hours

Environmental Pollution: Air pollution; Water pollution; Soil pollution

Recommended Books (Latest edition):

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
5. Clark R.S., Marine Pollution, Clarendon Press Oxford
6. Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p
7. De A.K., Environmental Chemistry, Wiley Eastern Ltd.
8. Down of Earth, Centre for Science and Environment

SEMESTER III

BP301T. PHARMACEUTICAL ORGANIC CHEMISTRY –II (Theory)

45 Hours

Scope: This subject deals with general methods of preparation and reactions of some organic compounds. Reactivity of organic compounds are also studied here. The syllabus emphasizes on mechanisms and orientation of reactions. Chemistry of fats and oils are also included in the syllabus.

Objectives: Upon completion of the course the student shall be able to

1. write the structure, name and the type of isomerism of the organic compound
2. write the reaction, name the reaction and orientation of reactions
3. account for reactivity/stability of compounds,
4. prepare organic compounds

Course Content:

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained

To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT I

10 Hours

☐ Benzene and its derivatives

- A. Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule
- B. Reactions of benzene - nitration, sulphonation, halogenation- reactivity, Friedelcrafts alkylation- reactivity, limitations, Friedelcrafts acylation.
- C. Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction
- D. Structure and uses of DDT, Saccharin, BHC and Chloramine

UNIT II

10 Hours

- ☐ **Phenols*** - Acidity of phenols, effect of substituents on acidity, qualitative tests, Structure and uses of phenol, cresols, resorcinol, naphthols
- ☐ **Aromatic Amines*** - Basicity of amines, effect of substituents on basicity, and synthetic uses of aryl diazonium salts

UNIT III

10 Hours

☐ Fats and Oils

- a. Fatty acids – reactions.

- b. Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils.
- c. Analytical constants – Acid value, Saponification value, Ester value, Iodine value, Acetyl value, Reichert Meissl (RM) value – significance and principle involved in their determination.

UNIT IV

08 Hours

☐ **Polynuclear hydrocarbons:**

- a. Synthesis, reactions
- b. Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene, Diphenylmethane, Triphenylmethane and their derivatives

UNIT V

07 Hours

☐ **Cyclo alkanes***

Stabilities – Baeyer's strain theory, limitation of Baeyer's strain theory, Coulson and Moffitt's modification, Sachse Mohr's theory (Theory of strainless rings), reactions of cyclopropane and cyclobutane only

BP305P. PHARMACEUTICAL ORGANIC CHEMISTRY -II (Practical)

4 Hrs/week

- I Experiments involving laboratory techniques
 - ☐ Recrystallization
 - ☐ Steam distillation
- II Determination of following oil values (including standardization of reagents)
 - ☐ Acid value
 - ☐ Saponification value
 - ☐ Iodine value
- III Preparation of compounds
 - ☐ Benzanilide/Phenyl benzoate/Acetanilide from Aniline/ Phenol /Aniline by acylation reaction.
 - ☐ 2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline/
 - ☐ Acetanilide by halogenation (Bromination) reaction.
 - ☐ 5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid / Nitro benzene by nitration reaction.
 - ☐ Benzoic acid from Benzyl chloride by oxidation reaction.
 - ☐ Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.
 - ☐ 1-Phenyl azo-2-naphthol from Aniline by diazotization and coupling reactions.
 - ☐ Benzil from Benzoin by oxidation reaction.
 - ☐ Dibenzal acetone from Benzaldehyde by Claisen Schmidt reaction
 - ☐ Cinnamic acid from Benzaldehyde by Perkin reaction
 - ☐ *P*-Iodo benzoic acid from *P*-amino benzoic acid

Recommended Books (Latest Editions)

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar , Volume-I
3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
4. Organic Chemistry by P.L.Soni
5. Practical Organic Chemistry by Mann and Saunders.
6. Vogel's text book of Practical Organic Chemistry
7. Advanced Practical organic chemistry by N.K.Vishnoi.

8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.

BP302T. PHYSICAL PHARMACEUTICS-I (Theory)

45Hours

Scope: The course deals with the various physical, physicochemical properties and principle involved in dosage forms, formulations. Theory and practical components of the subject help the student to get a better insight in to various areas of formulation research and development and stability studies of pharmaceuticals.

Objectives: Upon the completion of the course student shall be able to

1. Understand various physicochemical properties of drug molecules in the designing the dosage form
2. Know the principles of chemical kinetics & to use them in assigning expiry date for formulation
3. Demonstrate use of physicochemical properties in evaluation of dosage forms.
4. Appreciate physicochemical properties of drug molecules in formulation research and development

Course Content:

UNIT-I

10 Hours

Solubility of drugs: Solubility expressions, mechanisms of solute solvent interactions, ideal solubility parameters, solvation & association, quantitative approach to the factors influencing solubility of drugs, Dissolution & drug release, diffusion principles in biological systems. Solubility of gas in liquids, solubility of liquids in liquids, (Binary solutions, ideal solutions) Raoult's law, real solutions, azeotropic mixtures, fractional distillation. Partially miscible liquids, Critical solution temperature and applications. Distribution law, its limitations and applications

UNIT-II

10Hours

States of Matter and properties of matter: State of matter, changes in the state of matter, latent heats, vapour pressure, sublimation critical point, eutectic mixtures, gases, aerosols – inhalers, relative humidity, liquid complexes, liquid crystals, glassy states, solid-crystalline, amorphous & polymorphism.

Physicochemical properties of drug molecules: Refractive index, optical rotation, dielectric constant, dipole moment, dissociation constant, determinations and applications

UNIT-III

10Hours

Micromeretics: Particle size and distribution, average particle size, number and weight distribution, particle number, methods for determining particle size by (different methods), counting and separation method, particle shape, specific surface, methods for determining surface area, permeability, adsorption, derived properties of powders,

porosity, packing arrangement, densities, bulkiness & flow properties.

UNIT-IV

08Hours

Complexation and protein binding: Introduction, Classification of Complexation, Applications, methods of analysis, protein binding, Complexation and drug action, crystalline structures of complexes and thermodynamic treatment of stability constants.

UNIT-V

07 Hours

pH, buffers and Isotonic solutions: Sorensen's pH scale, pH determination (electrometric and calorimetric), applications of buffers, buffer equation, buffer capacity, buffers in pharmaceutical and biological systems, buffered isotonic solutions.

BP306P. PHYSICAL PHARMACEUTICS – I (Practical)

4 Hrs/week

1. Determination the solubility of drug at room temperature
2. Determination of pKa value by Half Neutralization/ Henderson Hassel Balch equation.
3. Determination of Partition co- efficient of benzoic acid in benzene and water
4. Determination of Partition co- efficient of Iodine in CCl₄ and water
5. Determination of % composition of NaCl in a solution using phenol-water system by CST method
6. Determination of particle size, particle size distribution using sieving method
7. Determination of particle size, particle size distribution using Microscopic method
8. Determination of bulk density, true density and porosity
9. Determine the angle of repose and influence of lubricant on angle of repose
10. Determination of stability constant and donor acceptor ratio of PABA-Caffeine complex by solubility method
11. Determination of stability constant and donor acceptor ratio of Cupric-Glycine complex by pH titration method

Recommended Books: (Latest Editions)

1. Physical pharmacy by Alfred Martin
2. Experimental pharmaceuticals by Eugene, Parott.
3. Tutorial pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical calculations, Lea &Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, MarcelDekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
7. Physical pharmaceuticals by Ramasamy C and ManavalanR.
8. Laboratory manual of physical pharmaceuticals, C.V.S. Subramanyam, J. Thimma settee

BP 303 T. PHARMACEUTICAL MICROBIOLOGY (Theory)

45Hours

Scope:

- ☐ In the broadest sense, scope of microbiology is the study of all organisms that are invisible to the naked eye- that is the study of microorganisms.
- ☐ Microorganisms are necessary for the production of bread, cheese, beer, antibiotics, vaccines, vitamins, enzymes etc.
- ☐ Microbiology has an impact on medicine, agriculture, food science, ecology, genetics, biochemistry, immunology etc.

Objectives: Upon completion of the subject student shall be able to;

1. Understand methods of identification, cultivation and preservation of various microorganisms
2. Importance of sterilization in microbiology. and pharmaceutical industry
3. Learn sterility testing of pharmaceutical products.
4. Microbiological standardization of Pharmaceuticals.
5. Understand the cell culture technology and its applications in pharmaceutical industries.

Course content:

Unit I

10 Hours

Introduction, history of microbiology, its branches, scope and its importance.

Introduction to Prokaryotes and Eukaryotes

Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count).

Study of different types of phase contrast microscopy, dark field microscopy and electron microscopy.

Unit II

10 Hours

Identification of bacteria using staining techniques (simple, Gram's & Acid fast staining) and biochemical tests (IMViC).

Study of principle, procedure, merits, demerits and applications of Physical, chemical and mechanical method of sterilization.

Evaluation of the efficiency of sterilization methods.

Equipments employed in large scale sterilization.

Sterility indicators.

Unit III

10 Hours

Study of morphology, classification, reproduction/replication and cultivation of Fungi and Virus.

Classification and mode of action of disinfectants

Factors influencing disinfection, antiseptics and their evaluation. For bacteriostatic and bactericidal actions

Evaluation of bactericidal & Bacteriostatic.

Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP.

Unit IV

08 Hours

Designing of aseptic area, laminar flow equipments; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification.

Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids.

Assessment of a new antibiotic and testing of antimicrobial activity of a new substance.

General aspects-environmental cleanliness.

Unit V

07Hours

Types of spoilage, factors affecting the microbial spoilage of pharmaceutical products, sources and types of microbial contaminants, assessment of microbial contamination and spoilage.

Preservation of pharmaceutical products using antimicrobial agents, evaluation of microbial stability of formulations.

Growth of animal cells in culture, general procedure for cell culture, Primary, established and transformed cell cultures.

Application of cell cultures in pharmaceutical industry and research.

BP 307P.PHARMACEUTICAL MICROBIOLOGY (Practical)

4 Hrs/week

1. Introduction and study of different equipments and processing, e.g., B.O.D. incubator, laminar flow, aseptic hood, autoclave, hot air sterilizer, deep freezer, refrigerator, microscopes used in experimental microbiology.
2. Sterilization of glassware, preparation and sterilization of media.
3. Sub culturing of bacteria and fungus. Nutrient stabs and slants preparations.
4. Staining methods- Simple, Grams staining and acid fast staining (Demonstration with practical).
5. Isolation of pure culture of micro-organisms by multiple streak plate technique and other techniques.
6. Microbiological assay of antibiotics by cup plate method and other methods
7. Motility determination by Hanging drop method.
8. Sterility testing of pharmaceuticals.
9. Bacteriological analysis of water
10. Biochemical test (IMViC reactions)
11. Revision Practical Class

Recommended Books (Latest edition)

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. I.P., B.P., U.S.P.- latest editions.
10. Ananthnarayan : Text Book of Microbiology, Orient-Longman, Chennai
11. Edward: Fundamentals of Microbiology.
12. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
13. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company

BP 304 T. PHARMACEUTICAL ENGINEERING (Theory)

45 Hours

Scope: This course is designed to impart a fundamental knowledge on the art and science of various unit operations used in pharmaceutical industry.

Objectives: Upon completion of the course student shall be able:

1. To know various unit operations used in Pharmaceutical industries.
2. To understand the material handling techniques.
3. To perform various processes involved in pharmaceutical manufacturing process.
4. To carry out various test to prevent environmental pollution.
5. To appreciate and comprehend significance of plant lay out design for optimum use of resources.
6. To appreciate the various preventive methods used for corrosion control in Pharmaceutical industries.

Course content:

UNIT-I

10 Hours

- **Flow of fluids:** Types of manometers, Reynolds number and its significance, Bernoulli's theorem and its applications, Energy losses, Orifice meter, Venturimeter, Pitot tube and Rotometer.
- **Size Reduction:** Objectives, Mechanisms & Laws governing size reduction, factors affecting size reduction, principles, construction, working, uses, merits and demerits of Hammer mill, ball mill, fluid energy mill, Edge runner mill & end runner mill.
- **Size Separation:** Objectives, applications & mechanism of size separation, official standards of powders, sieves, size separation Principles, construction, working, uses, merits and demerits of Sieve shaker, cyclone separator, Air separator, Bag filter & elutriation tank.
- **Mixing:** Objectives, applications & factors affecting mixing, Difference between solid and liquid mixing, mechanism of solid mixing, liquids mixing and semisolids mixing. Principles, Construction, Working, uses, Merits and Demerits of Double cone blender, twin shell blender, ribbon blender, Sigma blade mixer, planetary mixers, Propellers, Turbines, Paddles & Silverson Emulsifier,

UNIT-II

10 Hours

- **Crystallization:** Objectives, applications, & theory of crystallization. Solubility curves, principles, construction, working, uses, merits and demerits of Agitated batch crystallizer, Swenson Walker Crystallizer, Krystal crystallizer, Vacuum crystallizer. Caking of crystals, factors affecting caking & prevention of caking.

- **Evaporation:** Objectives, applications and factors influencing evaporation, differences between evaporation and other heat process. principles, construction, working, uses, merits and demerits of Steam jacketed kettle, horizontal tube evaporator, climbing film evaporator, forced circulation evaporator, multiple effect evaporator & Economy of multiple effect evaporator.
- **Heat Transfer:** Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers.

UNIT- III

10 Hours

- **Drying:** Objectives, applications & mechanism of drying process, measurements & applications of Equilibrium Moisture content, rate of drying curve. principles, construction, working, uses, merits and demerits of Tray dryer, drum dryer spray dryer, fluidized bed dryer, vacuum dryer, freeze dryer.
- **Distillation:** Objectives, applications & types of distillation. principles, construction, working, uses, merits and demerits of (lab scale and industrial scale) Simple distillation, preparation of purified water and water for injection BP by distillation, flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation

UNIT-IV

08 Hours

- **Filtration:** Objectives, applications, Theories & Factors influencing filtration, filter aids, filter medias. Principle, Construction, Working, Uses, Merits and demerits of plate & frame filter, filter leaf, rotary drum filter, Meta filter & Cartridge filter, membrane filters and Seidtz filter.
- **Centrifugation:** Objectives, principle & applications of Centrifugation, principles, construction, working, uses, merits and demerits of Perforated basket centrifuge, Non-perforated basket centrifuge, semi continuous centrifuge & super centrifuge.

UNIT- V

07 Hours

- **Plant location, industrial hazards and plant safety:** Plant Layout, utilities and services, Mechanical hazards, Chemical hazards, Fire hazards, explosive hazards and their safety.
- **Materials of pharmaceutical plant construction, Corrosion and its prevention:** Factors affecting during materials selected for Pharmaceutical plant construction, Theories of corrosion, types of corrosion and there prevention. Ferrous and nonferrous metals, inorganic and organic non metals.
- **Material handling systems:** Objectives & applications of Material handling systems, different types of conveyors such as belt, screw and pneumatic conveyors.

Recommended Books: (Latest Editions)

1. Introduction to chemical engineering – Walter L Badger & Julius Banchero, Latest edition.
2. Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson- Latest edition.
3. Unit operation of chemical engineering – McCabe Smith, Latest edition.
4. Pharmaceutical engineering principles and practices – C.V.S Subrahmanyam et al., Latest edition.
5. Remington practice of pharmacy- Martin, Latest edition.
6. Theory and practice of industrial pharmacy by Lachmann., Latest edition.
7. Physical pharmaceuticals- C.V.S Subrahmanyam et al., Latest edition.
8. Cooper and Gunn's Tutorial pharmacy, S.J. Carter, Latest edition.

BP308P - PHARMACEUTICAL ENGINEERING (Practical)

4 Hours/week

- I. Determination of radiation constant of brass, iron, unpainted and painted glass.
- II. Steam distillation – To calculate the efficiency of steam distillation.
- III. To determine the overall heat transfer coefficient by heat exchanger.
- IV. Construction of drying curves (for calcium carbonate and starch).
- V. Determination of moisture content and loss on drying.
- VI. Determination of humidity of air – i) From wet and dry bulb temperatures –use of Dew point method.
- VII. Description of Construction working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier.
- VIII. Size analysis by sieving – To evaluate size distribution of tablet granulations – Construction of various size frequency curves including arithmetic and logarithmic probability plots.
- IX. Size reduction: To verify the laws of size reduction using ball mill and determining Kicks, Rittinger's, Bond's coefficients, power requirement and critical speed of Ball Mill.
- X. Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such other major equipment.
- XI. Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration and Thickness/ viscosity
- XII. To study the effect of time on the Rate of Crystallization.
- XIII. To calculate the uniformity Index for given sample by using Double Cone Blender.

SEMESTER IV

BP401T. PHARMACEUTICAL ORGANIC CHEMISTRY –III (Theory)

45 Hours

Scope: This subject imparts knowledge on stereo-chemical aspects of organic compounds and organic reactions, important named reactions, chemistry of important hetero cyclic compounds. It also emphasizes on medicinal and other uses of organic compounds.

Objectives: At the end of the course, the student shall be able to

1. understand the methods of preparation and properties of organic compounds
2. explain the stereo chemical aspects of organic compounds and stereo chemical reactions
3. know the medicinal uses and other applications of organic compounds

Course Content:

Note: To emphasize on definition, types, mechanisms, examples, uses/applications

UNIT-I

10 Hours

Stereo isomerism

Optical isomerism –

Optical activity, enantiomerism, diastereoisomerism, meso compounds

Elements of symmetry, chiral and achiral molecules

DL system of nomenclature of optical isomers, sequence rules, RS system of nomenclature of optical isomers

Reactions of chiral molecules

Racemic modification and resolution of racemic mixture.

Asymmetric synthesis: partial and absolute

UNIT-II

10 Hours

Geometrical isomerism

Nomenclature of geometrical isomers (Cis Trans, EZ, Syn Anti systems)

Methods of determination of configuration of geometrical isomers.

Conformational isomerism in Ethane, n-Butane and Cyclohexane.

Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity.

Stereospecific and stereoselective reactions

UNIT-III

10 Hours

Heterocyclic compounds:

Nomenclature and classification

Synthesis, reactions and medicinal uses of following compounds/derivatives

Pyrrole, Furan, and Thiophene - Relative aromaticity, reactivity and Basicity of pyrrole

UNIT-IV**8 Hours**

Synthesis, reactions and medicinal uses of following compounds/derivatives

Pyrazole, Imidazole, Oxazole and Thiazole.

Pyridine, Quinoline, Isoquinoline, Acridine and Indole. Basicity of pyridine

Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives

UNIT-V**07 Hours****Reactions of synthetic importance**

Metal hydride reduction (NaBH_4 and LiAlH_4), Clemmensen reduction, Birch reduction, Wolff Kishner reduction.

Oppenauer-oxidation and Dakin reaction.

Beckmanns rearrangement and Schmidt rearrangement.

Claisen-Schmidt condensation

Recommended Books (Latest Editions)

1. Organic chemistry by I.L. Finar, Volume-I & II.
2. A text book of organic chemistry – Arun Bahl, B.S. Bahl.
3. Heterocyclic Chemistry by Raj K. Bansal
4. Organic Chemistry by Morrison and Boyd
5. Heterocyclic Chemistry by T.L. Gilchrist

BP402T. MEDICINAL CHEMISTRY – I (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

Objectives: Upon completion of the course the student shall be able to

1. understand the chemistry of drugs with respect to their pharmacological activity
2. understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
3. know the Structural Activity Relationship (SAR) of different class of drugs
4. write the chemical synthesis of some drugs

Course Content:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*)

UNIT- I

10 Hours

Introduction to Medicinal Chemistry

History and development of medicinal chemistry

Physicochemical properties in relation to biological action

Ionization, Solubility, Partition Coefficient, Hydrogen bonding, Protein binding, Chelation, Bioisosterism, Optical and Geometrical isomerism.

Drug metabolism

Drug metabolism principles- Phase I and Phase II.

Factors affecting drug metabolism including stereo chemical aspects.

UNIT- II

10 Hours

Drugs acting on Autonomic Nervous System

Adrenergic Neurotransmitters:

Biosynthesis and catabolism of catecholamine.

Adrenergic receptors (Alpha & Beta) and their distribution.

Sympathomimetic agents: SAR of Sympathomimetic agents

Direct acting: Nor-epinephrine, Epinephrine, Phenylephrine*, Dopamine,

Methyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline, Salbutamol*, Bitolterol, Naphazoline, Oxymetazoline and Xylometazoline.

- Indirect acting agents: Hydroxyamphetamine, Pseudoephedrine, Propylhexedrine.
- Agents with mixed mechanism: Ephedrine, Metaraminol.

Adrenergic Antagonists:

Alpha adrenergic blockers: Tolazoline*, Phentolamine, Phenoxybenzamine, Prazosin, Dihydroergotamine, Methysergide.

Beta adrenergic blockers: SAR of beta blockers, Propranolol*, Metibranolol, Atenolol, Betazolol, Bisoprolol, Esmolol, Metoprolol, Labetolol, Carvedilol.

UNIT-III

10 Hours

Cholinergic neurotransmitters:

Biosynthesis and catabolism of acetylcholine.

Cholinergic receptors (Muscarinic & Nicotinic) and their distribution.

Parasympathomimetic agents: SAR of Parasympathomimetic agents

Direct acting agents: Acetylcholine, Carbachol*, Bethanechol, Methacholine, Pilocarpine.

Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible):

Physostigmine, Neostigmine*, Pyridostigmine, Edrophonium chloride, Tacrine hydrochloride, Ambenonium chloride, Isoflurophate, Echothiophate iodide, Parathion, Malathion.

Cholinesterase reactivator: Pralidoxime chloride.

Cholinergic Blocking agents: SAR of cholinolytic agents

Solanaceous alkaloids and analogues: Atropine sulphate, Hyoscyamine sulphate, Scopolamine hydrobromide, Homatropine hydrobromide, Ipratropium bromide*.

Synthetic cholinergic blocking agents: Tropicamide, Cyclopentolate hydrochloride, Clidinium bromide, Dicyclomine hydrochloride*, Glycopyrrolate, Methantheline bromide, Propantheline bromide, Benztropine mesylate, Orphenadrine citrate, Biperidine hydrochloride, Procyclidine hydrochloride*, Tridihexethyl chloride, Isopropamide iodide, Ethopropazine hydrochloride.

UNIT- IV

08 Hours

Drugs acting on Central Nervous System

A. Sedatives and Hypnotics:

Benzodiazepines: SAR of Benzodiazepines, Chlordiazepoxide, Diazepam*, Oxazepam, Chlorazepate, Lorazepam, Alprazolam, Zolpidem

Barbiturates: SAR of barbiturates, Barbitol*, Phenobarbital, Mephobarbital, Amobarbital, Butobarbital, Pentobarbital, Secobarbital

Miscellaneous:

Amides & imides: Glutethimide.

Alcohol & their carbamate derivatives: Meprobamate, Ethchlorvynol.

Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

B. Antipsychotics

Phenothiazines: SAR of Phenothiazines - Promazine hydrochloride, Chlorpromazine hydrochloride*, Triflupromazine, Thioridazine hydrochloride, Piperacetazine hydrochloride, Prochlorperazine maleate, Trifluoperazine hydrochloride.

Ring Analogues of Phenothiazines: Chlorprothixene, Thiothixene, Loxapine succinate, Clozapine.

Fluorobutyrophenones: Haloperidol, Droperidol, Risperidone.

Beta amino ketones: Molindone hydrochloride.

Benzamides: Sulpieride.

C. Anticonvulsants: SAR of Anticonvulsants, mechanism of anticonvulsant action

Barbiturates: Phenobarbitone, Methobarbital.

Hydantoins: Phenytoin*, Mephenytoin, Ethotoin

Oxazolidine diones: Trimethadione, Paramethadione

Succinimides: Phensuximide, Methsuximide, Ethosuximide*

Urea and monoacylureas: Phenacemide, Carbamazepine*

Benzodiazepines: Clonazepam

Miscellaneous: Primidone, Valproic acid, Gabapentin, Felbamate

UNIT – V

07 Hours

Drugs acting on Central Nervous System

General anesthetics:

Inhalation anesthetics: Halothane*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane.

Ultra short acting barbiturates: Methohexital sodium*, Thiamylal sodium, Thiopental sodium.

Dissociative anesthetics: Ketamine hydrochloride.*

Narcotic and non-narcotic analgesics

Morphine and related drugs: SAR of Morphine analogues, Morphine sulphate, Codeine, Meperidine hydrochloride, Anileridine hydrochloride, Diphenoxylate hydrochloride, Loperamide hydrochloride, Fentanyl citrate*, Methadone hydrochloride*, Propoxyphene hydrochloride, Pentazocine, Levorphanol tartarate.

Narcotic antagonists: Nalorphine hydrochloride, Levallorphan tartarate, Naloxone hydrochloride.

Anti-inflammatory agents: Sodium salicylate, Aspirin, Mefenamic acid*, Meclofenamate, Indomethacin, Sulindac, Tolmetin, Zomepirac, Diclofenac, Ketorolac, Ibuprofen*, Naproxen, Piroxicam, Phenacetin, Acetaminophen, Antipyrine, Phenylbutazone.

BP406P. MEDICINAL CHEMISTRY – I (Practical)

4 Hours/Week

I Preparation of drugs/ intermediates

- 1 1,3-pyrazole
- 2 1,3-oxazole
- 3 Benzimidazole
- 4 Benztriazole
- 5 2,3- diphenyl quinoxaline
- 6 Benzocaine
- 7 Phenytoin
- 8 Phenothiazine
- 9 Barbiturate

II Assay of drugs

- 1 Chlorpromazine
- 2 Phenobarbitone
- 3 Atropine
- 4 Ibuprofen
- 5 Aspirin
- 6 Furosemide

III Determination of Partition coefficient for any two drugs

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.

7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

BP 403 T. PHYSICAL PHARMACEUTICS-II (Theory)

45Hours

Scope: The course deals with the various physical, physicochemical properties and principle involved in dosage forms, formulations. Theory and practical components of the subject help the student to get a better insight in to various areas of formulation research and development and stability studies of pharmaceuticals.

Objectives: Upon the completion of the course student shall be able to

1. Understand various physicochemical properties of drug molecules in the designing the dosage form
2. Know the principles of chemical kinetics & to use them in assigning expiry date for Formulation
3. Demonstrate use of physicochemical properties in evaluation of dosage forms.
4. Appreciate physicochemical properties of drug molecules in formulation research and Development

Course Content:

UNIT-I

10 Hours

Drug stability: Reaction kinetics: zero, pseudo-zero, first & second order, units of basic rate constants, determination of reaction order. Physical and chemical factors influencing the chemical degradation of pharmaceutical product: temperature, solvent, ionic strength, dielectric constant, specific & general acid base catalysis, Simple numerical problems. Stabilization of medicinal agents against common reactions like hydrolysis & oxidation. Accelerated stability testing in expiration dating of pharmaceutical dosage forms. Photolytic degradation and its prevention

UNIT-II

10 Hours

Rheology: Newtonian systems, law of flow, kinematic viscosity, effect of temperature, non-Newtonian systems, pseudoplastic, dilatants, plastic, thixotropy, thixotropy in formulation, determination of viscosity, capillary, falling Sphere, rotational viscometers

Deformation of solids: Plastic and elastic deformation, Heckel equation, Stress, Strain, Elastic Modulus

UNIT-III

10 Hours

Coarse dispersion: Suspension, interfacial properties of suspended particles, settling in suspensions, formulation of suspensions. Emulsions and theories of emulsification, microemulsion and multiple emulsions; Physical stability of emulsions, preservation of emulsions, rheological properties of emulsions, phase equilibria and emulsion formulation.

UNIT-IV

08 Hours

Surface and interfacial phenomenon: Liquid interface, surface & interfacial tensions,

surface free energy, measurement of surface & interfacial tensions, spreading coefficient, adsorption at liquid interfaces, surface active agents, HLB Scale, solubilisation, detergency, adsorption at solid interface.

UNIT-V

07 Hours

Colloidal dispersions: Classification of dispersed systems & their general characteristics, size & shapes of colloidal particles, classification of colloids & comparative account of their general properties. Optical, kinetic & electrical properties. Effect of electrolytes, coacervation, peptization & protective action.

BP 407P. PHYSICAL PHARMACEUTICS- II (Practical)

3 Hrs/week

1. Determination of surface tension of given liquids by drop count and drop weight method
2. Determination of HLB number of a surfactant by saponification method
3. Determination of Freundlich and Langmuir constants using activated char coal
4. Determination of critical micellar concentration of surfactants
5. Determination of viscosity of liquid using Ostwald's viscometer
6. Determination sedimentation volume with effect of different suspending agent
7. Determination sedimentation volume with effect of different concentration of single suspending agent
8. Determination of viscosity of semisolid by using Brookfield viscometer
9. Determination of reaction rate constant first order.
10. Determination of reaction rate constant second order
11. Accelerated stability studies

Recommended Books: (Latest Editions)

1. Physical Pharmacy by Alfred Martin, Sixth edition
2. Experimental pharmaceutics by Eugene, Parott.
3. Tutorial pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical calculations, Lea & Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, Marcel Dekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C, and Manavalan R.

BP 404 T. PHARMACOLOGY-I (Theory)

45 Hrs

Scope: The main purpose of the subject is to understand what drugs do to the living organisms and how their effects can be applied to therapeutics. The subject covers the information about the drugs like, mechanism of action, physiological and biochemical effects (pharmacodynamics) as well as absorption, distribution, metabolism and excretion (pharmacokinetics) along with the adverse effects, clinical uses, interactions, doses, contraindications and routes of administration of different classes of drugs.

Objectives: Upon completion of this course the student should be able to

1. Understand the pharmacological actions of different categories of drugs
2. Explain the mechanism of drug action at organ system/sub cellular/ macromolecular levels.
3. Apply the basic pharmacological knowledge in the prevention and treatment of various diseases.
4. Observe the effect of drugs on animals by simulated experiments
5. Appreciate correlation of pharmacology with other bio medical sciences

Course Content:

UNIT-I

08 hours

1. General Pharmacology

- a. Introduction to Pharmacology- Definition, historical landmarks and scope of pharmacology, nature and source of drugs, essential drugs concept and routes of drug administration, Agonists, antagonists(competitive and non competitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy.
- b. Pharmacokinetics- Membrane transport, absorption, distribution, metabolism and excretion of drugs .Enzyme induction, enzyme inhibition, kinetics of elimination

UNIT-II

12 Hours

General Pharmacology

- a. Pharmacodynamics- Principles and mechanisms of drug action. Receptor theories and classification of receptors, regulation of receptors. drug receptors interactions signal transduction mechanisms, G-protein–coupled receptors, ion channel receptor, transmembrane enzyme linked receptors, transmembrane JAK-STAT binding receptor and receptors that regulate transcription factors, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action.
- b. Adverse drug reactions.
- c. Drug interactions (pharmacokinetic and pharmacodynamic)
- d. Drug discovery and clinical evaluation of new drugs -Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.

UNIT-III**10 Hours****2. Pharmacology of peripheral nervous system**

- a. Organization and function of ANS.
- b. Neurohumoral transmission, co-transmission and classification of neurotransmitters.
- c. Parasympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics.
- d. Neuromuscular blocking agents and skeletal muscle relaxants (peripheral).
- e. Local anesthetic agents.
- f. Drugs used in myasthenia gravis and glaucoma

UNIT-IV**08 Hours****3. Pharmacology of central nervous system**

- a. Neurohumoral transmission in the C.N.S. special emphasis on importance of various neurotransmitters like with GABA, Glutamate, Glycine, serotonin, dopamine.
- b. General anesthetics and pre-anesthetics.
- c. Sedatives, hypnotics and centrally acting muscle relaxants.
- d. Anti-epileptics
- e. Alcohols and disulfiram

UNIT-V**07 Hours****3. Pharmacology of central nervous system**

- a. Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens.
- b. Drugs used in Parkinson's disease and Alzheimer's disease.
- c. CNS stimulants and nootropics.
- d. Opioid analgesics and antagonists
- e. Drug addiction, drug abuse, tolerance and dependence.

BP 408 P.PHARMACOLOGY-I (Practical)

4Hrs/Week

1. Introduction to experimental pharmacology.
2. Commonly used instruments in experimental pharmacology.
3. Study of common laboratory animals.
4. Maintenance of laboratory animals as per CPCSEA guidelines.
5. Common laboratory techniques. Blood withdrawal, serum and plasma separation, anesthetics and euthanasia used for animal studies.
6. Study of different routes of drugs administration in mice/rats.
7. Study of effect of hepatic microsomal enzyme inducers on the phenobarbitone sleeping time in mice.
8. Effect of drugs on ciliary motility of frog oesophagus
9. Effect of drugs on rabbit eye.
10. Effects of skeletal muscle relaxants using rota-rod apparatus.
11. Effect of drugs on locomotor activity using actophotometer.
12. Anticonvulsant effect of drugs by MES and PTZ method.
13. Study of stereotype and anti-catatonic activity of drugs on rats/mice.
14. Study of anxiolytic activity of drugs using rats/mice.
15. Study of local anesthetics by different methods

Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology

6. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert,
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,

**BP 405 T.PHARMACOGNOSY AND PHYTOCHEMISTRY I (Theory) 45
Hours**

Scope: The subject involves the fundamentals of Pharmacognosy like scope, classification of crude drugs, their identification and evaluation, phytochemicals present in them and their medicinal properties.

Objectives: Upon completion of the course, the student shall be able

1. to know the techniques in the cultivation and production of crude drugs
2. to know the crude drugs, their uses and chemical nature
3. know the evaluation techniques for the herbal drugs
4. to carry out the microscopic and morphological evaluation of crude drugs

Course Content:

UNIT-I

10 Hours

Introduction to Pharmacognosy:

- (a) Definition, history, scope and development of Pharmacognosy
- (b) Sources of Drugs – Plants, Animals, Marine & Tissue culture
- (c) Organized drugs, unorganized drugs (dried latex, dried juices, dried extracts, gums and mucilages, oleoresins and oleo- gum -resins).

Classification of drugs:

Alphabetical, morphological, taxonomical, chemical, pharmacological, chemo and sero taxonomical classification of drugs

Quality control of Drugs of Natural Origin:

Adulteration of drugs of natural origin. Evaluation by organoleptic, microscopic, physical, chemical and biological methods and properties.

Quantitative microscopy of crude drugs including lycopodium spore method, leaf constants, camera lucida and diagrams of microscopic objects to scale with camera lucida.

UNIT-II

10 Hours

Cultivation, Collection, Processing and storage of drugs of natural origin:

Cultivation and Collection of drugs of natural origin
Factors influencing cultivation of medicinal plants.
Plant hormones and their applications.
Polyploidy, mutation and hybridization with reference to medicinal plants

Conservation of medicinal plants

UNIT-III

07 Hours

Plant tissue culture:

Historical development of plant tissue culture, types of cultures, Nutritional requirements, growth and their maintenance.

Applications of plant tissue culture in pharmacognosy. Edible vaccines

UNIT IV 10 Hours Pharmacognosy in various systems of medicine:

Role of Pharmacognosy in allopathy and traditional systems of medicine namely, Ayurveda, Unani, Siddha, Homeopathy and Chinese systems of medicine.

Introduction to secondary metabolites:

Definition, classification, properties and test for identification of Alkaloids, Glycosides, Flavonoids, Tannins, Volatile oil and Resins

UNIT V

08 Hours

Study of biological source, chemical nature and uses of drugs of natural origin containing following drugs

Plant Products:

Fibers - Cotton, Jute, Hemp

Hallucinogens, Teratogens, Natural allergens

Primary metabolites:

General introduction, detailed study with respect to chemistry, sources, preparation, evaluation, preservation, storage, therapeutic used and commercial utility as Pharmaceutical Aids and/or Medicines for the following Primary metabolites:

Carbohydrates: Acacia, Agar, Tragacanth, Honey

Proteins and Enzymes : Gelatin, casein, proteolytic enzymes (Papain, bromelain, serratiopeptidase, urokinase, streptokinase, pepsin).

Lipids(Waxes, fats, fixed oils) : Castor oil, Chaulmoogra oil, Wool Fat, Bees Wax

Marine Drugs:

Novel medicinal agents from marine sources

BP408 P. PHARMACOGNOSY AND PHYTOCHEMISTRY I (Practical)

4 Hours/Week

1. Analysis of crude drugs by chemical tests: (i) Tragacanth (ii) Acacia (iii) Agar (iv) Gelatin (v) starch (vi) Honey (vii) Castor oil
2. Determination of stomatal number and index
3. Determination of vein islet number, vein islet termination and palisade ratio.
4. Determination of size of starch grains, calcium oxalate crystals by eye piece micrometer
5. Determination of Fiber length and width
6. Determination of number of starch grains by Lycopodium spore method
7. Determination of Ash value
8. Determination of Extractive values of crude drugs
9. Determination of moisture content of crude drugs
10. Determination of swelling index and foaming

Recommended Books: (Latest Editions)

1. W.C. Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Saunders & Co., London, 2009.
2. Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9th Edn., Lea and Febiger, Philadelphia, 1988.
3. Text Book of Pharmacognosy by T.E. Wallis
4. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
5. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhale (2007), 37th Edition, Nirali Prakashan, New Delhi.
6. Herbal drug industry by R.D. Choudhary (1996), 1st Edn, Eastern Publisher, New Delhi.
7. Essentials of Pharmacognosy, Dr. S.H. Ansari, 1st edition, Birla publications, New Delhi, 2007
8. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhale
9. Anatomy of Crude Drugs by M.A. Iyengar

SEMESTER V

BP501T. MEDICINAL CHEMISTRY – II (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

Objectives: Upon completion of the course the student shall be able to

1. Understand the chemistry of drugs with respect to their pharmacological activity
2. Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
3. Know the Structural Activity Relationship of different class of drugs
4. Study the chemical synthesis of selected drugs

Course Content:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*)

UNIT- I

10 Hours

Antihistaminic agents: Histamine, receptors and their distribution in the humanbody

H₁-antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Triptelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium

H₂-antagonists: Cimetidine*, Famotidine, Ranitidin.

Gastric Proton pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole

Anti-neoplastic agents:

Alkylating agents: Meclorethamine*, Cyclophosphamide, Melphalan,

Chlorambucil, Busulfan, Thiotepa

Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine

Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin

Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate

Miscellaneous: Cisplatin, Mitotane.

UNIT – II

10 Hours

Anti-anginal:

Vasodilators: Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, Isosorbide dinitrite*, Dipyridamole.

Calcium channel blockers: Verapamil, Bepridil hydrochloride, Diltiazem hydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine.

Diuretics:

Carbonic anhydrase inhibitors: Acetazolamide*, Methazolamide, Dichlorphenamide.

Thiazides: Chlorthiazide*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide,

Loop diuretics: Furosemide*, Bumetanide, Ethacrynic acid.

Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride.

Osmotic Diuretics: Mannitol

Anti-hypertensive Agents: Timolol, Captopril, Lisinopril, Enalapril, Benazepril hydrochloride, Quinapril hydrochloride, Methyldopate hydrochloride,* Clonidine hydrochloride, Guanethidine monosulphate, Guanabenz acetate, Sodium nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.

UNIT- III

10 Hours

Anti-arrhythmic Drugs: Quinidine sulphate, Procainamide hydrochloride, Disopyramide phosphate*, Phenytoin sodium, Lidocaine hydrochloride, Tocainide hydrochloride, Mexiletine hydrochloride, Lorcaïnide hydrochloride, Amiodarone, Sotalol.

Anti-hyperlipidemic agents: Clofibrate, Lovastatin, Cholesteramine and Cholestipol

Coagulant & Anticoagulants: Menadione, Acetomenadione, Warfarin*, Anisindione, clopidogrel

Drugs used in Congestive Heart Failure: Digoxin, Digitoxin, Nesiritide,

Bosentan, Tezosentan.

UNIT- IV

08 Hours

Drugs acting on Endocrine system

Nomenclature, Stereochemistry and metabolism of steroids

Sex hormones: Testosterone, Nandrolone, Progestrones, Oestriol, Oestradiol, Oestrone, Diethyl stilbestrol.

Drugs for erectile dysfunction: Sildenafil, Tadalafil.

Oral contraceptives: Mifepristone, Norgestrel, Levonorgestrol

Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone

Thyroid and antithyroid drugs: L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole.

UNIT – V

07 Hours

Antidiabetic agents:

Insulin and its preparations

Sulfonyl ureas: Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride. Biguanides: Metformin.

Thiazolidinediones: Pioglitazone, Rosiglitazone.

Meglitinides: Repaglinide, Nateglinide.

Glucosidase inhibitors: Acarbose, Voglibose.

Local Anesthetics: SAR of Local anesthetics

Benzoic Acid derivatives; Cocaine, Hexylcaine, Meprylcaine, Cyclomethycaine, Piperocaine.

Amino Benzoic acid derivatives: Benzocaine*, Butamben, Procaine*, Butacaine, Propoxycaine, Tetracaine, Benoxinate.

Lidocaine/Anilide derivatives: Lignocaine, Mepivacaine, Prilocaine, Etidocaine.

Miscellaneous: Phenacaine, Dipreron, Dibucaine.*

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.
7. Organic Chemistry by I.L. Finar, Vol. II.

8. The Organic Chemistry of Drug Synthesis by Lednicher, Vol. 1 to 5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

BP 502 T. FORMULATIVE PHARMACY (Theory)

45 Hours

Scope: Course enables the student to understand and appreciate the influence of pharmaceutical additives and various pharmaceutical dosage forms on the performance of the drug product.

Objectives: Upon completion of the course the student shall be able to

1. Know the various pharmaceutical dosage forms and their manufacturing techniques.
2. Know various considerations in development of pharmaceutical dosage forms
3. Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality

Course content:

3 hours/ week

UNIT-I 07 Hours

Preformulation Studies: Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances.

a. Physical properties: Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism

b. Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization BCS classification of drugs

Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.

UNIT-II

10 Hours

Tablets:

- a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling.
- b. Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating.
- c. Quality control tests: In process and finished product tests

Liquid orals: Formulation and manufacturing consideration of solutions, suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia

UNIT-III

08 Hours

Capsules:

- a. **Hard gelatin capsules:** Introduction, Extraction of gelatin and production of hard gelatin capsule shells. size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules. In process and final product quality control tests for capsules.
- b. **Soft gelatin capsules:** Nature of shell and capsule content, size of capsules, importance of base adsorption and minimum/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules

Pellets: Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets

UNIT-IV

10 Hours

Parenteral Products:

- a. Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity
- b. Production procedure, production facilities and controls.
- c. Formulation of injections, sterile powders, emulsions, suspensions, large volume parenterals and lyophilized products, Sterilization.
- d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests.

Ophthalmic Preparations: Introduction, formulation considerations; formulation of eye drops, eye ointments and eye lotions; methods of preparation; labeling, containers; evaluation of ophthalmic preparations

UNIT-V

10 Hours

Cosmetics: Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens.

Pharmaceutical Aerosols: Definition, propellants, containers, valves, types of aerosol systems; formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies.

Packaging Materials Science: Materials used for packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.

BP 506 P. FORMULATIVE PHARMACY (Practical)

4 Hours/week

1. Preformulation study for prepared granules
2. Preparation and evaluation of Paracetamol tablets
3. Preparation and evaluation of Aspirin tablets
4. Coating of tablets
5. Preparation and evaluation of Tetracycline capsules
6. Preparation of Calcium Gluconate injection
7. Preparation of Ascorbic Acid injection
8. Preparation of Paracetamol Syrup
9. Preparation of Eye drops
10. Preparation of Pellets by extrusion spheronization technique
11. Preparation of Creams (cold / vanishing cream)
12. Evaluation of Glass containers

Recommended Books: (Latest Editions)

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman & J.B. Schwartz
2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman
3. Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman
4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition
5. Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS)
6. Theory and Practice of Industrial Pharmacy by Liberman & Lachman
7. Pharmaceutics- The science of dosage form design by M.E. Aulton, Churchill Livingstone, Latest edition
8. Introduction to Pharmaceutical Dosage Forms by H. C. Ansel, Lea & Febiger, Philadelphia, 5th edition, 2005
9. Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.

BP503.T. PHARMACOLOGY-II (Theory)

45 Hours

Scope: This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on different systems of body and in addition, emphasis on the basic concepts of bioassay.

Objectives: Upon completion of this course the student should be able to

1. Understand the mechanism of drug action and its relevance in the treatment of different diseases
2. Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments
3. Demonstrate the various receptor actions using isolated tissue preparation
4. Appreciate correlation of pharmacology with related medical sciences

Course Content:

UNIT-I

10hours

1. Pharmacology of drugs acting on cardio vascular system

- a. Introduction to hemodynamic and electrophysiology of heart.
- b. Drugs used in congestive heart failure
- c. Anti-hypertensive drugs.
- d. Anti-anginal drugs.
- e. Anti-arrhythmic drugs.
- f. Anti-hyperlipidemic drugs.

UNIT-II

10hours

1. Pharmacology of drugs acting on cardio vascular system

- a. Drug used in the therapy of shock.
- b. Hematinics, coagulants and anticoagulants.
- c. Fibrinolytics and anti-platelet drugs
- d. Plasma volume expanders

2. Pharmacology of drugs acting on urinary system

- a. Diuretics
- b. Anti-diuretics.

UNIT-III

10hours

3. Autocoids and related drugs

- a. Introduction to autocoids and classification
- b. Histamine, 5-HT and their antagonists.
- c. Prostaglandins, Thromboxanes and Leukotrienes.
- d. Angiotensin, Bradykinin and Substance P.
- e. Non-steroidal anti-inflammatory agents
- f. Anti-gout drugs
- g. Antirheumatic drugs

UNIT-IV**08hours****5. Pharmacology of drugs acting on endocrine system**

- a. Basic concepts in endocrine pharmacology.
- b. Anterior Pituitary hormones- analogues and their inhibitors.
- c. Thyroid hormones- analogues and their inhibitors.
- d. Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D.
- d. Insulin, Oral Hypoglycemic agents and glucagon.
- e. ACTH and corticosteroids.

UNIT-V**07hours****5. Pharmacology of drugs acting on endocrine system**

- a. Androgens and Anabolic steroids.
- b. Estrogens, progesterone and oral contraceptives.
- c. Drugs acting on the uterus.

6. Bioassay

- a. Principles and applications of bioassay.
- b. Types of bioassay
- c. Bioassay of insulin, oxytocin, vasopressin, ACTH, d-tubocurarine, digitalis, histamine and 5-HT

BP 507 P. PHARMACOLOGY-II (Practical)

4Hrs/Week

1. Introduction to *in-vitro* pharmacology and physiological salt solutions.
2. Effect of drugs on isolated frog heart.
3. Effect of drugs on blood pressure and heart rate of dog.
4. Study of diuretic activity of drugs using rats/mice.
5. DRC of acetylcholine using frog rectus abdominis muscle.
6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively.
7. Bioassay of histamine using guinea pig ileum by matching method.
8. Bioassay of oxytocin using rat uterine horn by interpolation method.
9. Bioassay of serotonin using rat fundus strip by three point bioassay.
10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
11. Determination of PA_2 value of prazosin using rat anococcygeus muscle (by Schilds plot method).
12. Determination of PD_2 value using guinea pig ileum.
13. Effect of spasmogens and spasmolytics using rabbit jejunum.
14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
15. Analgesic activity of drug using central and peripheral methods

Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill.
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins.
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology.
6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert.
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.

BP504 T. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)

45Hours

Scope: The main purpose of subject is to impart the students the knowledge of how the secondary metabolites are produced in the crude drugs, how to isolate and identify and produce them industrially. Also this subject involves the study of producing the plants and phytochemicals through plant tissue culture, drug interactions and basic principles of traditional system of medicine

Objectives: Upon completion of the course, the student shall be able

1. to know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents
2. to understand the preparation and development of herbal formulation.
3. to understand the herbal drug interactions
4. to carryout isolation and identification of phytoconstituents

Course Content:

UNIT-I

7 Hours

Metabolic pathways in higher plants and their determination

- a) Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway.
- b) Study of utilization of radioactive isotopes in the investigation of Biogenetic studies.

UNIT-II

20 Hours

General introduction, composition, chemistry & chemical classes, general methods of extraction & analysis, biosources, therapeutic uses and commercial applications of following secondary metabolites:

Alkaloids: Vinca, Rauwolfia, Belladonna, Opium,

Phenylpropanoids and Flavonoids: Lignans, Tea, Ruta

Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis

Volatile oils: Mentha, Clove, Cinnamon, Fennel, Coriander,

Tannins: Catechu, Pterocarpus

Resins: Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony

Glycosides: Senna, Aloes, Bitter Almond

Iridoids, Other terpenoids & Naphthaquinones: Gentian, Artemisia, taxus, carotenoids

UNIT-III

10 Hours

Industrial production, estimation and utilization of the following phytoconstituents:
Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine

UNIT IV

8 Hours

Basics of Phytochemistry

Modern methods of extraction, application of latest techniques like Spectroscopy, chromatography and electrophoresis in the isolation, purification and identification of crude drugs.

BP 508 P. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)
4 Hours/Week

1. Morphology, histology and powder characteristics & extraction & detection of: Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander
2. Exercise involving isolation & detection of active principles
 - a. Caffeine - from tea dust.
 - b. Diosgenin from Dioscorea
 - c. Atropine from Belladonna
 - d. Sennosides from Senna
3. Separation of sugars by Paper chromatography
4. TLC of herbal extract
5. Distillation of volatile oils and detection of phytoconstituents by TLC
6. Analysis of crude drugs by chemical tests: (i) Asafoetida (ii) Benzoin (iii) Colophony (iv) Aloes (v) Myrrh

Recommended Books: (Latest Editions)

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Saunders & Co., London, 2009.
2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhale (2007), 37th Edition, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), 1st Edn, Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr.SH.Ansari, 1st edition, Birla publications, New Delhi, 2007
6. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.
7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
10. The formulation and preparation of cosmetic, fragrances and flavours.
11. Remington's Pharmaceutical sciences.
12. Text Book of Biotechnology by Vyas and Dixit.
13. Text Book of Biotechnology by R.C. Dubey.

BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)

45 Hours

Scope: This course is designed to impart basic knowledge on several important legislations related to the profession of pharmacy in India.

Objectives: Upon completion of the course, the student shall be able to understand:

1. The Pharmaceutical legislations and their implications in the development and marketing
2. Various Indian pharmaceutical Acts and Laws
3. The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
4. The code of ethics during the pharmaceutical practice

Course Content:

UNIT-I

10 Hours

Drugs and Cosmetics Act, 1940 and its rules 1945:

Objectives, Definitions, Legal definitions of schedules to the act and rules

Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties.

Manufacture of drugs – Prohibition of manufacture and sale of certain drugs,

Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

UNIT-II

10 Hours

Drugs and Cosmetics Act, 1940 and its rules 1945.

Detailed study of Schedule G, H, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA)

Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties

Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties.

Administration of the act and rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors

UNIT-III

10 Hours

- **Pharmacy Act –1948:** Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; its constitution and functions, Registration of Pharmacists, Offences and

Penalties

- **Medicinal and Toilet Preparation Act –1955:** Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.
- **Narcotic Drugs and Psychotropic substances Act-1985 and Rules:** Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties

UNIT-IV

08 Hours

- **Study of Salient Features of Drugs and magic remedies Act and its rules:** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties
- **Prevention of Cruelty to animals Act-1960:** Objectives, Definitions, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties
- **National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO)-2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

UNIT-V

07 Hours

- **Pharmaceutical Legislations –** A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee
- **Code of Pharmaceutical ethics** Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath
- **Medical Termination of pregnancy act**
- **Right to information Act**
- **Introduction to Intellectual Property Rights (IPR)**

Recommended books: (Latest Edition)

1. Forensic Pharmacy by B. Suresh

2. Text book of Forensic Pharmacy by B.M. Mithal
3. Hand book of drug law-by M.L. Mehra
4. A text book of Forensic Pharmacy by N.K. Jain
5. Drugs and Cosmetics Act/Rules by Govt. of India publications.
6. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
7. Narcotic drugs and psychotropic substances act by Govt. of India publications
8. Drugs and Magic Remedies act by Govt. of India publication
9. Bare Acts of the said laws published by Government. Reference books (Theory)

SEMESTER VI

BP601T. MEDICINAL CHEMISTRY – III (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasis on modern techniques of rational drug design like quantitative structure activity relationship (QSAR), Prodrug concept, combinatorial chemistry and Computer aided drug design (CADD). The subject also emphasizes on the chemistry, mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR), therapeutic uses and synthesis of important drugs.

Objectives: Upon completion of the course student shall be able to

1. Understand the importance of drug design and different techniques of drug design.
2. Understand the chemistry of drugs with respect to their biological activity.
3. Know the metabolism, adverse effects and therapeutic value of drugs.
4. Know the importance of SAR of drugs.

Course Content:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted by (*)

UNIT – I

10 Hours

Antibiotics

Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.

β -Lactam antibiotics: Penicillin, Cephalosporins, β - Lactamase inhibitors, Monobactams

Aminoglycosides: Streptomycin, Neomycin, Kanamycin

Tetracyclines: Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

UNIT – II

10 Hours

Antibiotics

Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.

Macrolide: Erythromycin Clarithromycin, Azithromycin.

Miscellaneous: Chloramphenicol*, Clindamycin.

Prodrugs: Basic concepts and application of prodrugs design.

Antimalarials: Etiology of malaria.

Quinolines: SAR, Quinine sulphate, Chloroquine*, Amodiaquine, Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine.

Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil.

Miscellaneous: Pyrimethamine, Artesunate, Artemether, Atovaquone.

UNIT – III

10 Hours

Anti-tubercular Agents

Synthetic anti tubercular agents: Isoniazid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.*

Anti tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine Streptomycin, Capreomycin sulphate.

Urinary tract anti-infective agents

Quinolones: SAR of quinolones, Nalidixic Acid, Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin

Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine.

Antiviral agents:

Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirdine, Ribavirin, Saquinavir, Indinavir, Ritonavir.

UNIT – IV

08 Hours

Antifungal agents:

Antifungal antibiotics: Amphotericin-B, Nystatin, Natamycin, Griseofulvin.

Synthetic Antifungal agents: Clotrimazole, Econazole, Butoconazole, Oxiconazole, Tioconazole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*.

Anti-protozoal Agents: Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine.

Anthelmintics: Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*, Albendazole, Niclosamide, Oxamniquine, Praziquantel, Ivermectin.

Sulphonamides and Sulfones

Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxazole*, Sulphadiazine, Mefenide acetate, Sulfasalazine.

Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.

Sulfones: Dapsone*.

UNIT – V

07 Hours

Introduction to Drug Design

Various approaches used in drug design.

Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammett's electronic parameter, Taft's steric parameter and Hansch analysis.

Pharmacophore modeling and docking techniques.

Combinatorial Chemistry: Concept and applications of combinatorial chemistry: solid phase and solution phase synthesis.

BP607P. MEDICINAL CHEMISTRY- III (Practical)

4 Hours / week

I Preparation of drugs and intermediates

- 1 Sulphanilamide
- 2 7-Hydroxy, 4-methyl coumarin
- 3 Chlorobutanol
- 4 Triphenyl imidazole
- 5 Tolbutamide
- 6 Hexamine

II Assay of drugs

- 1 Isonicotinic acid hydrazide
- 2 Chloroquine
- 3 Metronidazole
- 4 Dapsone
- 5 Chlorpheniramine maleate
- 6 Benzyl penicillin

III Preparation of medicinally important compounds or intermediates by Microwave irradiation technique

IV Drawing structures and reactions using chem draw®

V Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinskies RO5)

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.

7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

BP602 T. PHARMACOLOGY-III (Theory)

45 Hours

Scope: This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on respiratory and gastrointestinal system, infectious diseases, immuno-pharmacology and in addition, emphasis on the principles of toxicology and chronopharmacology.

Objectives: Upon completion of this course the student should be able to:

1. understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
2. comprehend the principles of toxicology and treatment of various poisonings and
3. appreciate correlation of pharmacology with related medical sciences.

Course Content:

UNIT-I

10hours

1. Pharmacology of drugs acting on Respiratory system

- a. Anti -asthmatic drugs
- b. Drugs used in the management of COPD
- c. Expectorants and antitussives
- d. Nasal decongestants
- e. Respiratory stimulants

2. Pharmacology of drugs acting on the Gastrointestinal Tract

- a. Antiulcer agents.
- b. Drugs for constipation and diarrhoea.
- c. Appetite stimulants and suppressants.
- d. Digestants and carminatives.
- e. Emetics and anti-emetics.

UNIT-II

10hours

3. Chemotherapy

- a. General principles of chemotherapy.
- b. Sulfonamides and cotrimoxazole.
- c. Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolones, tetracycline and aminoglycosides

UNIT-III

10hours

3. Chemotherapy

- a. Antitubercular agents
- b. Antileprotic agents

- c. Antifungal agents
- d. Antiviral drugs
- e. Anthelmintics
- f. Antimalarial drugs
- g. Antiamoebic agents

UNIT-IV

08hours

3. Chemotherapy

- l. Urinary tract infections and sexually transmitted diseases.
- m. Chemotherapy of malignancy.

4. Immunopharmacology

- a. Immunostimulants
 - b. Immunosuppressant
- Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

UNIT-V

07hours

5. Principles of toxicology

- a. Definition and basic knowledge of acute, subacute and chronic toxicity.
- b. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity
- c. General principles of treatment of poisoning
- d. Clinical symptoms and management of barbiturates, morphine, organophosphorus compound and lead, mercury and arsenic poisoning.

6. Chronopharmacology

- a. Definition of rhythm and cycles.
- b. Biological clock and their significance leading to chronotherapy.

BP 608 P. PHARMACOLOGY-III (Practical)

4Hrs/Week

1. Dose calculation in pharmacological experiments
2. Antiallergic activity by mast cell stabilization assay
3. Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.
4. Study of effect of drugs on gastrointestinal motility
5. Effect of agonist and antagonists on guinea pig ileum
6. Estimation of serum biochemical parameters by using semi- autoanalyser
7. Effect of saline purgative on frog intestine
8. Insulin hypoglycemic effect in rabbit
9. Test for pyrogens (rabbit method)
10. Determination of acute oral toxicity (LD50) of a drug from a given data
11. Determination of acute skin irritation / corrosion of a test substance
12. Determination of acute eye irritation / corrosion of a test substance
13. Calculation of pharmacokinetic parameters from a given data
14. Biostatistics methods in experimental pharmacology(student's t test, ANOVA)
15. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)

**Experiments are demonstrated by simulated experiments/videos*

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology
6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert,
8. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
9. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,
10. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

BP 603 T. HERBAL DRUG TECHNOLOGY (Theory)

45 hours

Scope: This subject gives the student the knowledge of basic understanding of herbal drug industry, the quality of raw material, guidelines for quality of herbal drugs, herbal cosmetics, natural sweeteners, nutraceutical etc. The subject also emphasizes on Good Manufacturing Practices (GMP), patenting and regulatory issues of herbal drugs

Objectives: Upon completion of this course the student should be able to:

1. understand raw material as source of herbal drugs from cultivation to herbal drug product
2. know the WHO and ICH guidelines for evaluation of herbal drugs
3. know the herbal cosmetics, natural sweeteners, nutraceuticals
4. appreciate patenting of herbal drugs, GMP .

Course content:

UNIT-I

6 Hours

Herbs as raw materials

Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation
Source of Herbs

Selection, identification and authentication of herbal materials
Processing of herbal raw material

Biodynamic Agriculture

Good agricultural practices in cultivation of medicinal plants including Organic farming. Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.

UNIT-II

05 Hours

- a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy
- b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika, Churna, Lehya and Bhasma.

UNIT-III 7 Hours Nutraceuticals

General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases.

Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina

Herbal-Drug and Herb-Food Interactions: General introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.

UNIT-IV

10 Hours

Herbal Cosmetics

Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products.

Herbal excipients:

Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes.

Herbal formulations :

Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes

UNIT- V

10 Hours

Evaluation of Drugs WHO & ICH guidelines for the assessment of herbal drugs
Stability testing of herbal drugs.

Patenting and Regulatory requirements of natural products:

- a) Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy
- b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.

Regulatory Issues - Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.

UNIT-VI

07 Hours

General Introduction to Herbal Industry

Herbal drugs industry: Present scope and future prospects.

A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.

Schedule T – Good Manufacturing Practice of Indian systems of medicine

Components of GMP (Schedule – T) and its objectives

Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.

BP 609 P. HERBAL DRUG TECHNOLOGY (Practical)

4 hours/ week

1. To perform preliminary phytochemical screening of crude drugs.
2. Determination of Ash value
3. Determination of moisture content of crude drugs
4. Determination of Extractive values of crude drugs
5. Determination of the alcohol content of Asava and Arista
6. Preparation of herbal cosmetics
7. Preparation and standardization of herbal formulation
8. Determination of swelling index and foaming index
9. Monograph analysis of herbal drugs from recent Pharmacopoeias
10. Analysis of fixed oils

Recommended Books: (Latest Editions)

1. Textbook of Pharmacognosy by Trease & Evans.
2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
3. Pharmacognosy by Kokate, Purohit and Gokhale
4. Essential of Pharmacognosy by Dr.S.H.Ansari
5. Pharmacognosy & Phytochemistry by V.D.Rangari
6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
7. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

BP 604 T. BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

45 Hours

Scope: This subject is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply Biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of Biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

Objectives: Upon completion of the course student shall be able to:

1. Understand the basic concepts in biopharmaceutics and pharmacokinetics.
2. Use plasma data and derive the pharmacokinetic parameters to describe the process of drug absorption, distribution, metabolism and elimination.
3. Critically evaluate biopharmaceutic studies involving drug product equivalency
4. Design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
5. detect potential clinical pharmacokinetic problems and apply basic pharmacokinetic principles to solve them

Course Content:

UNIT-I

10 Hours

Introduction to Biopharmaceutics

Absorption; Mechanisms of drug absorption through GIT, factors influencing drug absorption through GIT, absorption of drug from Non per oral extra-vascular routes, Distribution of drugs Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs

UNIT- II

10 Hours

Drug Elimination renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs

Bioavailability and Bioequivalence: Objectives of bioavailability studies, absolute and relative bioavailability, measurement of bioavailability, in-vitro drug dissolution models, in-vitro, in-vivo correlations, bioequivalence studies, methods to enhance the bioavailability.

UNIT- III 10 Hours Pharmacokinetics: Introduction to Pharmacokinetics models, Compartment models, Non compartment models, physiological models, One compartment open model. a. Intravenous Injection (Bolus) b. Intravenous infusion, extra vascular administrations, calculations of K_a , K_E . From plasma and urinary excretion data

UNIT- IV

08 Hours

Multicompartment models: Two compartment open model. IV bolus

Multiple – Dosage Regimens:

- a). Repetitive Intravenous injections – One Compartment Open Model
- b). Repetitive Extravascular dosing – One Compartment Open model

UNIT- V 07 Hours Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity.

c. Michaelis-menton method of estimating parameters, Biotransformation of drugs

Recommended Books: (Latest Editions)

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition, Prentice-Hall International edition. USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: By Milo Gibaldi Donald, R. Mercel Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick
8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and
9. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
10. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
11. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Robert F Notari Marcel Dekker Inc, New York and Basel, 1987.
12. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania

BP 605 T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)

45 Hours

Scope:

- ☐ Biotechnology has a long promise to revolutionize the biological sciences and technology.
- ☐ Scientific application of biotechnology in the field of genetic engineering, medicine and fermentation technology makes the subject interesting.
- ☐ Biotechnology is leading to new biological revolutions in diagnosis, prevention and cure of diseases, new and cheaper pharmaceutical drugs.
- ☐ Biotechnology has already produced transgenic crops and animals and the future promises lot more.
- ☐ It is basically a research-based subject.

Objectives: Upon completion of the subject student shall be able to;

1. Understanding the importance of Immobilized enzymes in Pharmaceutical Industries
2. Genetic engineering applications in relation to production of pharmaceuticals
3. Importance of Monoclonal antibodies in Industries
4. Appreciate the use of microorganisms in fermentation technology

Unit I

10 Hours

- a) Brief introduction to Biotechnology with reference to Pharmaceutical Sciences.
- b) Enzyme Biotechnology- Methods of enzyme immobilization and applications.
- c) Biosensors- Working and applications of biosensors in Pharmaceutical Industries.
- d) Brief introduction to Protein Engineering.
- e) Use of microbes in industry. Production of Enzymes- General consideration - Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase.
- f) Basic principles of genetic engineering.

Unit II

10 Hours

- a) Study of cloning vectors, restriction endonucleases and DNA ligase.
- b) Recombinant DNA technology. Application of genetic engineering in medicine.
- c) Application of r DNA technology and genetic engineering in the products:
- d) Interferon b) Vaccines- hepatitis- B c) Hormones- Insulin.
- e) Brief introduction to PCR

Types of immunity- humoral immunity, cellular immunity

Unit III

10 Hours

- a) Structure of Immunoglobulins
- b) Structure and Function of MHC
- c) Hypersensitivity reactions, Immune stimulation and Immune suppressions.
- d) General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity.
- e) Storage conditions and stability of official vaccines
- f) Hybridoma technology- Production, Purification and Applications

Unit IV

08Hours

- a) Immuno blotting techniques- ELISA, Western blotting, Southern blotting.
- b) Genetic organization of Eukaryotes and Prokaryotes
- c) Microbial genetics including transformation, transduction, conjugation, plasmids and transposons.
- d) Introduction to Microbial biotransformation and applications.
- e) Mutation.

Unit V

07 Hours

- a. Types of mutation/mutants
- b) Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring.
- c) Large scale production fermenter design and its various controls.
- d) Study of the production of - penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin,

Recommended Books (Latest edition):

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
2. RA Goldshy et. al., : Kuby Immunology.
3. J.W. Goding: Monoclonal Antibodies.
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.
5. Zaborsky: Immobilized Enzymes, CRC Press, Degrand, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

BP606TPHARMACEUTICAL QUALITY ASSURANCE (Theory)

45 Hours

Scope: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.

Objectives: Upon completion of the course student shall be able to:

- ☐ understand the cGMP aspects in a pharmaceutical industry
- ☐ appreciate the importance of documentation
- ☐ understand the scope of quality certifications applicable to pharmaceutical industries
- ☐ understand the responsibilities of QA & QC departments

Course content:

UNIT – I

10 Hours

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP

Total Quality Management (TQM): Definition, elements, philosophies

ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines

Quality by design (QbD): Definition, overview, elements of QbD program, tools

ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration

NABL accreditation : Principles and procedure

UNIT - II 10 Hours Organization and personnel: Personnel responsibilities, training, hygiene and personal records. **Premises:** Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

Equipments and raw materials: Equipments selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

UNIT – III 10 Hours Quality Control: Quality control test for containers, rubber closures and secondary packing

materials.

Good Laboratory Practices: General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities

UNIT – IV 08 Hours Complaints: Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.

Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

UNIT – V 07 Hours Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation.

Warehousing: Good warehousing practice, materials management

Recommended Books: (Latest Edition)

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.
4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP's – P P Sharma.
6. ISO 9000 and Total Quality Management – Sadhank G Ghosh
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices – Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines

SEMESTER VII

BP701T. INSTRUMENTAL METHODS OF ANALYSIS (Theory)

45 Hours

Scope: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart a fundamental knowledge on the principles and instrumentation of spectroscopic and chromatographic technique. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

Objectives: Upon completion of the course the student shall be able to

1. Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis
2. Understand the chromatographic separation and analysis of drugs.
3. Perform quantitative & qualitative analysis of drugs using various analytical instruments.

Course Content:

UNIT –I

10 Hours

UV Visible spectroscopy

Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations.

Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors- Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode.

Applications - Spectrophotometric titrations, Single component and multi component analysis

Fluorimetry

Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications

UNIT –II

10 Hours

IR spectroscopy

Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations

Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications

Flame Photometry-Principle, interferences, instrumentation and applications

Atomic absorption spectroscopy- Principle, interferences, instrumentation and applications

Nepheloturbidometry- Principle, instrumentation and applications

UNIT –III

10 Hours

Introduction to chromatography

Adsorption and partition column chromatography-Methodology, advantages, disadvantages and applications.

Thin layer chromatography- Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications.

Paper chromatography-Introduction, methodology, development techniques, advantages, disadvantages and applications

Electrophoresis– Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications

UNIT –IV

08 Hours

Gas chromatography - Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications

High performance liquid chromatography (HPLC)-Introduction, theory, instrumentation, advantages and applications.

UNIT –V

07 Hours

Ion exchange chromatography- Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications

Gel chromatography- Introduction, theory, instrumentation and applications

Affinity chromatography- Introduction, theory, instrumentation and applications

BP705P. INSTRUMENTAL METHODS OF ANALYSIS (Practical)

4 Hours/Week

- 1 Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
- 2 Estimation of dextrose by colorimetry
- 3 Estimation of sulfanilamide by colorimetry
- 4 Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy
- 5 Assay of paracetamol by UV- Spectrophotometry
- 6 Estimation of quinine sulfate by fluorimetry
- 7 Study of quenching of fluorescence
- 8 Determination of sodium by flame photometry
- 9 Determination of potassium by flame photometry
- 10 Determination of chlorides and sulphates by nephelo turbidometry
- 11 Separation of amino acids by paper chromatography
- 12 Separation of sugars by thin layer chromatography
- 13 Separation of plant pigments by column chromatography
- 14 Demonstration experiment on HPLC
- 15 Demonstration experiment on Gas Chromatography

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

BP 702 T. INDUSTRIAL PHARMACY (Theory)

45 Hours

Scope: This course is designed to impart fundamental knowledge on pharmaceutical product commercialization from laboratory to market

Objectives: Upon completion of the course, the student shall be able to:

1. Know the process of pilot plant and scale up of pharmaceutical dosage forms
2. Understand the process of technology transfer from lab scale to commercial batch
3. Know different laws and acts that regulate pharmaceutical industry in India and US
4. Understand the approval process and regulatory requirements for drug products

Course Content:

UNIT-I

10 Hours

Pilot plant scale up techniques: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to Platform technology

UNIT-II

10 Hours

Technology development and transfer: WHO guidelines for Technology Transfer: Terminologies, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packing materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TOT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; Technology of Transfer (TOT) related documentation - confidentiality agreements, licensing, MoUs, legal issues

UNIT-III

10 Hours

Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals

Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.

UNIT-IV

08 Hours

Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP

UNIT-V

07 Hours

Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Common Technical Document (CTD), Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

Recommended Books: (Latest Editions)

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http://en.wikipedia.org/wiki/Regulatory_Affairs.
2. International Regulatory Affairs Updates, 2005. available at <http://www.iraup.com/about.php>
3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
4. Regulatory Affairs brought by learning plus, inc. available at <http://www.cgmp.com/ra.htm>.

BP 703T. PHARMACY PRACTICE (Theory)

45 Hours

Scope: In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. In community pharmacy, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling for improved patient care in the community set up.

Objectives: Upon completion of the course, the student shall be able to

1. know various drug distribution methods in a hospital
2. appreciate the pharmacy stores management and inventory control
3. monitor drug therapy of patient through medication chart review and clinical review
4. obtain medication history interview and counsel the patients
5. identify drug related problems
6. detect and assess adverse drug reactions
7. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states
8. know pharmaceutical care services
9. do patient counseling in community pharmacy;
10. appreciate the concept of Rational drug therapy.

Unit I:

10 Hours

a) Hospital and its organization

Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non- clinical basis, Organization Structure of a Hospital, and Medical staffs involved in the hospital and their functions.

b) Hospital pharmacy and its organization

Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists.

c) Adverse drug reaction

Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting

drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management.

d) Community Pharmacy

Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale drug store.

Unit II:

10 Hours

a) Drug distribution system in a hospital

Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, Dispensing of drugs to ambulatory patients, and Dispensing of controlled drugs.

b) Hospital formulary

Definition, contents of hospital formulary, Differentiation of hospital formulary and Drug list, preparation and revision, and addition and deletion of drug from hospital formulary.

c) Therapeutic drug monitoring

Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring.

d) Medication adherence

Causes of medication non-adherence, pharmacist role in the medication adherence, and monitoring of patient medication adherence.

e) Patient medication history interview

Need for the patient medication history interview, medication interview forms.

f) Community pharmacy management

Financial, materials, staff, and infrastructure requirements.

Unit III:

10 Hours

a) Pharmacy and therapeutic committee

Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation.

b) Drug information services

Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.

c) Patient counseling

Definition of patient counseling; steps involved in patient counseling, and Special cases that require the pharmacist

d) Education and training program in the hospital

Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education.

e) Prescribed medication order and communication skills

Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescribers and patients.

Unit IV

8 Hours

a)

Budget

preparation and implementation

Budget preparation and implementation

b) Clinical Pharmacy

Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care.

c) Over the counter (OTC) sales

Introduction and sale of over the counter, and Rational use of common over the counter medications.

Unit V

7 Hours

a) Drug store management and inventory control

Organisation of drug store, types of materials stocked and storage conditions, Purchase and inventory control: principles, purchase procedure, purchase order, procurement and stocking, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure

b) Investigational use of drugs

Description, principles involved, classification, control, identification, role of hospital pharmacist, advisory committee.

c) Interpretation of Clinical Laboratory Tests

Blood chemistry, hematology, and urinalysis

Recommended Books (Latest Edition):

1. Merchant S.H. and Dr. J.S.Quadry. *A textbook of hospital pharmacy*, 4th ed. Ahmadabad: B.S. Shah Prakakshan; 2001.
2. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. *A textbook of Clinical Pharmacy Practice- essential concepts and skills*, 1st ed. Chennai: Orient Longman Private Limited; 2004.
3. William E. Hassan. *Hospital pharmacy*, 5th ed. Philadelphia: Lea & Febiger; 1986.
4. Tipnis Bajaj. *Hospital Pharmacy*, 1st ed. Maharashtra: Career Publications; 2008.
5. Scott LT. *Basic skills in interpreting laboratory data*, 4th ed. American Society of Health System Pharmacists Inc; 2009.
6. Parmar N.S. *Health Education and Community Pharmacy*, 18th ed. India: CBS Publishers & Distributers; 2008.

Journals:

1. Therapeutic drug monitoring. ISSN: 0163-4356
2. Journal of pharmacy practice. ISSN : 0974-8326
3. American journal of health system pharmacy. ISSN: 1535-2900 (online)
4. Pharmacy times (Monthly magazine)

BP 704T: NOVEL DRUG DELIVERY SYSTEMS (Theory)

45 Hours

Scope: This subject is designed to impart basic knowledge on the area of novel drug delivery systems.

Objectives: Upon completion of the course student shall be able

1. To understand various approaches for development of novel drug delivery systems.
2. To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation

Course content:

Unit-I

10 Hours

Controlled drug delivery systems: Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates. Approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations

Polymers: Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems.

Unit-II

10 Hours

Microencapsulation: Definition, advantages and disadvantages, microspheres /microcapsules, microparticles, methods of microencapsulation, applications

Mucosal Drug Delivery system: Introduction, Principles of bioadhesion / mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems

Implantable Drug Delivery Systems: Introduction, advantages and disadvantages, concept of implants and osmotic pump

Unit-III

10 Hours

Transdermal Drug Delivery Systems: Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches

Gastroretentive drug delivery systems: Introduction, advantages, disadvantages, approaches for GRDDS – Floating, high density systems, inflatable and gastroadhesive systems and their applications

Nasopulmonary drug delivery system: Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers

Unit-IV

08 Hours

Nanotechnology and its Concepts: Concepts and approaches for targeted drug delivery systems, advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications

Unit-V

07 Hours

Ocular Drug Delivery Systems: Introduction, intra ocular barriers and methods to overcome –Preliminary study, ocular formulations and ocuserts

Intrauterine Drug Delivery Systems: Introduction, advantages and disadvantages, development of intra uterine devices (IUDs) and applications

Recommended Books: (Latest Editions)

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

Journals

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian Drugs (IDMA)
3. Journal of Controlled Release (Elsevier Sciences)
4. Drug Development and Industrial Pharmacy (Marcel & Decker)
5. International Journal of Pharmaceutics (Elsevier Sciences)

SEMESTER VIII

BP801T. BIOSTATISTICS AND RESEARCH METHODOLOGY (Theory)

45 Hours

Scope: To understand the applications of Biostatistics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel.

Objectives: Upon completion of the course the student shall be able to

- Know the operation of M.S. Excel, SPSS, R and MINITAB[®], DoE (Design of Experiment)
- Know the various statistical techniques to solve statistical problems
- Appreciate statistical techniques in solving the problems.

Course content:

Unit-I

10 Hours

Introduction: Statistics, Biostatistics, Frequency distribution

Measures of central tendency: Mean, Median, Mode- Pharmaceutical examples

Measures of dispersion: Dispersion, Range, standard deviation, Pharmaceutical problems

Correlation: Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceutical examples

Unit-II 10 Hours Regression: Curve fitting by the method of least squares, fitting the lines $y = a + bx$ and $x = a + by$, Multiple regression, standard error of regression- Pharmaceutical Examples **Probability:** Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties - problems

Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples

Parametric test: t-test(Sample, Pooled or Unpaired and Paired), ANOVA, (One way and Two way), Least Significance difference

Unit-III

10 Hours

Non Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test

Introduction to Research: Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism

Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph

Designing the methodology: Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

Unit-IV

8 Hours

Blocking and confounding system for Two-level factorials

Regression modeling: Hypothesis testing in Simple and Multiple regression models

Introduction to Practical components of Industrial and Clinical Trials Problems:

Statistical Analysis Using Excel, SPSS, MINITAB[®], DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach

Unit-V

7Hours

Design and Analysis of experiments:

Factorial Design: Definition, 2^2 , 2^3 design. Advantage of factorial design

Response Surface methodology: Central composite design, Historical design, Optimization Techniques

Recommended Books (Latest edition):

1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. NewYork.
2. Fundamental of Statistics – Himalaya Publishing House- S.C.Guptha
3. Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam,
4. Design and Analysis of Experiments – Wiley Students Edition, Douglas and C. Montgomery

BP 802T SOCIAL AND PREVENTIVE PHARMACY

Hours: 45

Scope:

The purpose of this course is to introduce to students a number of health issues and their challenges. This course also introduced a number of national health programmes. The roles of the pharmacist in these contexts are also discussed.

Objectives:

After the successful completion of this course, the student shall be able to:

- ☐ Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide.
- ☐ Have a critical way of thinking based on current healthcare development.
- ☐ Evaluate alternative ways of solving problems related to health and pharmaceutical issues

Course content:

Unit I:

10 Hours

Concept of health and disease: Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick.

Social and health education: Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention.

Sociology and health: Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health

Hygiene and health: personal hygiene and health care; avoidable habits

Unit II: 10 Hours Preventive medicine: General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse

Unit III: 10 Hours National health programs, its objectives, functioning and outcome of the following:

HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National

programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.

Unit IV:

08 Hours

National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program

Unit V:

07 Hours

Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school.

Recommended Books (Latest edition):

1. Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2nd Edition, 2010, ISBN: 9789380704104, JAYPEE Publications
2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications
3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, 2014, ISBN: 9789351522331, JAYPEE Publications
4. Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications
5. Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011, ISBN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS.
6. Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad

Recommended Journals:

1. Research in Social and Administrative Pharmacy, Elsevier, Ireland

BP803ET. PHARMACEUTICAL MARKETING (Theory)

45 Hours

Scope:

The pharmaceutical industry not only needs highly qualified researchers, chemist, technical people but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry. Sales & Marketing which grooms the people for taking a challenging role in Sales and Product management. The career in product management starts from having hands on experience in sales and marketing only.

Course Objective: The course aim is to provide an understanding of marketing concepts and techniques and the application of the same in the pharmaceutical industry.

Unit I 10 Hours Marketing:

Definition, general concepts, and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behavior; industrial buying behavior.

Pharmaceutical market:

Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation & targeting. Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist. Analyzing the Market; Role of market research.

Unit II 10 Hours Product decision:

Meaning, Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.

Unit III 10 Hours Promotion:

Meaning and methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.

Unit IV 10 Hours Pharmaceutical marketing channels:

Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management.

Professional sales representative (PSR):

Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.

Unit V 10 Hours Pricing:

Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority).

Emerging concepts in marketing:

Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.

Recommended Books: (Latest Editions)

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S & Nanakamari, S: Marketing Managemnt: Global Perspective, Indian Context, Macmillan India, New Delhi.
7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.

BP804 ET: PHARMACEUTICAL REGULATORY SCIENCE (Theory)

45Hours

Scope: This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, drug products in regulated countries like US, EU, Japan, Australia and Canada. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products in regulated countries.

Objectives: Upon completion of the subject student shall be able to;

1. Know about the process of drug discovery and development
2. Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
3. Know the regulatory approval process and their registration in Indian and international markets

Course content:

Unit I

10Hours

New Drug Discovery and development

Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

Unit II

10Hours

Regulatory Approval Process

Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA) in US. Changes to an approved NDA / ANDA.

Regulatory authorities and agencies

Overview of regulatory authorities of United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)

Unit III

10Hours

Registration of Indian drug product in overseas market

Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical

Document (eCTD), ASEAN Common Technical Document (ACTD)research.

Unit IV

08Hours

Clinical trials

Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safety monitoring in clinical trials

Unit V

07Hours

Regulatory Concepts

Basic terminologies, guidance, guidelines, regulations, laws and acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book

Recommended books (Latest edition):

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185. Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
8. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
9. Drugs: From Discovery to Approval, Second Edition By Rick Ng

BP 805T: PHARMACOVIGILANCE (Theory)

45 hours

Scope: This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions.

Objectives:

At completion of this paper it is expected that students will be able to (know, do, and appreciate):

1. Why drug safety monitoring is important?
2. History and development of pharmacovigilance
3. National and international scenario of pharmacovigilance
4. Dictionaries, coding and terminologies used in pharmacovigilance
5. Detection of new adverse drug reactions and their assessment
6. International standards for classification of diseases and drugs
7. Adverse drug reaction reporting systems and communication in pharmacovigilance
8. Methods to generate safety data during pre clinical, clinical and post approval phases of drugs' life cycle
9. Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
10. Pharmacovigilance Program of India (PvPI)
11. ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning
12. CIOMS requirements for ADR reporting
13. Writing case narratives of adverse events and their quality.

Course Content

Unit I

10 Hours

Introduction to Pharmacovigilance

- ☐ History and development of Pharmacovigilance
- ☐ Importance of safety monitoring of Medicine
- ☐ WHO international drug monitoring programme
- ☐ Pharmacovigilance Program of India(PvPI)

Introduction to adverse drug reactions

- ☐ Definitions and classification of ADRs
- ☐ Detection and reporting
- ☐ Methods in Causality assessment
- ☐ Severity and seriousness assessment
- ☐ Predictability and preventability assessment
- ☐ Management of adverse drug reactions

Basic terminologies used in pharmacovigilance

- ☐ Terminologies of adverse medication related events
- ☐ Regulatory terminologies

Unit II

10 hours

Drug and disease classification

- ☐ Anatomical, therapeutic and chemical classification of drugs
- ☐ International classification of diseases
- ☐ Daily defined doses
- ☐ International Non proprietary Names for drugs

Drug dictionaries and coding in pharmacovigilance

- ☐ WHO adverse reaction terminologies
- ☐ MedDRA and Standardised MedDRA queries
- ☐ WHO drug dictionary
- ☐ Eudravigilance medicinal product dictionary

Information resources in pharmacovigilance

- ☐ Basic drug information resources
- ☐ Specialised resources for ADRs

Establishing pharmacovigilance programme

- ☐ Establishing in a hospital
- ☐ Establishment & operation of drug safety department in industry
- ☐ Contract Research Organisations (CROs)
- ☐ Establishing a national programme

Unit III

10 Hours

Vaccine safety surveillance

- ☐ Vaccine Pharmacovigilance
- ☐ Vaccination failure
- ☐ Adverse events following immunization

Pharmacovigilance methods

- ☐ Passive surveillance – Spontaneous reports and case series
- ☐ Stimulated reporting
- ☐ Active surveillance – Sentinel sites, drug event monitoring and registries
- ☐ Comparative observational studies – Cross sectional study, case control study and cohort study
- ☐ Targeted clinical investigations

Communication in pharmacovigilance

- ☐ Effective communication in Pharmacovigilance
- ☐ Communication in Drug Safety Crisis management
- ☐ Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media

Unit IV

8 Hours

Statistical methods for evaluating medication safety data

Safety data generation

- ☐ Pre clinical phase
- ☐ Clinical phase
- ☐ Post approval phase

ICH Guidelines for Pharmacovigilance

- ☐ Organization and objectives of ICH
- ☐ Expedited reporting
- ☐ Individual case safety reports
- ☐ Periodic safety update reports
- ☐ Post approval expedited reporting
- ☐ Pharmacovigilance planning
- ☐ Good clinical practice in pharmacovigilance studies

Unit V**7 hours****Pharmacogenomics of adverse drug reactions****Drug safety evaluation in special population**

- ☐ Paediatrics
- ☐ Pregnancy and lactation
- ☐ Geriatrics

CIOMS

- ☐ CIOMS Working Groups
- ☐ CIOMS Form

CDSCO (India) and Pharmacovigilance

- ☐ D&C Act and Schedule Y
- ☐ Differences in Indian and global pharmacovigilance requirements

Recommended Books (Latest edition):

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert, Jones & Bartlett Publishers.
7. Textbook of Pharmacoepidemiology edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills: G. Parthasarathi, Karin Nyfort Hansen, Milap C. Nahata
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal
11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna

12. <http://www.who.unc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297>
13. <http://www.ich.org/>
14. <http://www.cioms.ch/>
15. <http://cdsco.nic.in/>
16. http://www.who.int/vaccine_safety/en/
17. http://www.ipc.gov.in/PvPI/pv_home.html

BP 806 ET. QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Theory)

Scope: In this subject the student learns about the various methods and guidelines for evaluation and standardization of herbs and herbal drugs. The subject also provides an opportunity for the student to learn cGMP, GAP and GLP in traditional system of medicines.

Objectives: Upon completion of the subject student shall be able to;

1. know WHO guidelines for quality control of herbal drugs
2. know Quality assurance in herbal drug industry
3. know the regulatory approval process and their registration in Indian and international markets
4. appreciate EU and ICH guidelines for quality control of herbal drugs

Unit I

10 hours

Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms

WHO guidelines for quality control of herbal drugs.

Evaluation of commercial crude drugs intended for use

Unit II

10 hours

Quality assurance in herbal drug industry of cGMP, GAP, GMP and GLP in traditional system of medicine.

WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines
WHO Guidelines on GACP for Medicinal Plants.

Unit II I

10 hours

EU and ICH guidelines for quality control of herbal drugs.

Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

Unit IV

08 hours

Stability testing of herbal medicines. Application of various chromatographic techniques in standardization of herbal products.

Preparation of documents for new drug application and export registration GMP requirements and Drugs & Cosmetics Act provisions.

Unit V

07 hours

Regulatory requirements for herbal medicines.

WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems Comparison of various Herbal Pharmacopoeias.

Role of chemical and biological markers in standardization of herbal products

Recommended Books: (Latest Editions)

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I , Carrier Pub., 2006.
4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8.
8. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
9. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981.
10. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
11. WHO. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.
12. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

Hours Scope: This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.

Objectives: Upon completion of the course, the student shall be able to understand

- ☐ Design and discovery of lead molecules
- ☐ The role of drug design in drug discovery process
- ☐ The concept of QSAR and docking
- ☐ Various strategies to develop new drug like molecules.
- ☐ The design of new drug molecules using molecular modeling software

Course Content:

UNIT-I 10 Hours Introduction to Drug Discovery and Development

Stages of drug discovery and development

Lead discovery and Analog Based Drug Design

Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation.

Analog Based Drug Design: Bioisosterism, Classification, Bioisosteric replacement. Any three case studies

UNIT-II 10 Hours Quantitative Structure Activity Relationship (QSAR)

SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammett's substituent constant and Taft's steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.

UNIT-III 10 Hours Molecular Modeling and virtual screening techniques

Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

Molecular docking: Rigid docking, flexible docking, manual docking, Docking based screening. *De novo* drug design.

UNIT-IV 08 Hours Informatics & Methods in drug design

Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

UNIT-V

07 Hours

Molecular Modeling: Introduction to molecular mechanics and quantum mechanics. Energy Minimization methods and Conformational Analysis, global conformational minima determination.

Recommended Books (Latest Editions)

1. Robert GCK, ed., "Drug Action at the Molecular Level" University Park Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.
3. Delgado JN, Remers WA eds "Wilson & Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry" Lea & Febiger.
5. Koro Ikovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.
7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
8. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.

BP808ET: CELL AND MOLECULAR BIOLOGY (Elective subject)

45 Hours

Scope:

- ☐ Cell biology is a branch of biology that studies cells – their physiological properties, their structure, the organelles they contain, interactions with their environment, their life cycle, division, death and cell function.
- ☐ This is done both on a microscopic and molecular level.
- ☐ Cell biology research encompasses both the great diversity of single-celled organisms like bacteria and protozoa, as well as the many specialized cells in multi-cellular organisms such as humans, plants, and sponges.

Objectives: Upon completion of the subject student shall be able to;

- ☐ Summarize cell and molecular biology history.
- ☐ Summarize cellular functioning and composition.
- ☐ Describe the chemical foundations of cell biology.
- ☐ Summarize the DNA properties of cell biology.
- ☐ Describe protein structure and function.
- ☐ Describe cellular membrane structure and function.
- ☐ Describe basic molecular genetic mechanisms.
- ☐ Summarize the Cell Cycle

Course content:

Unit I

10Hours

- a) Cell and Molecular Biology: Definitions theory and basics and Applications.
- b) Cell and Molecular Biology: History and Summation.
- c) Theory of the Cell? Properties of cells and cell membrane.
- d) Prokaryotic versus Eukaryotic
- e) Cellular Reproduction
- f) Chemical Foundations – an Introduction and Reactions (Types)

Unit II

10 Hours

- a) DNA and the Flow of Molecular Structure
- b) DNA Functioning
- c) DNA and RNA
- d) Types of RNA
- e) Transcription and Translation

Unit III

10 Hours

- a) Proteins: Defined **and** Amino Acids
- b) Protein Structure

- c) Regularities in Protein Pathways
- d) Cellular Processes
- e) Positive Control and significance of Protein Synthesis

Unit IV

08 Hours

- a) Science of Genetics
- b) Transgenics and Genomic Analysis
- c) Cell Cycle analysis
- d) Mitosis and Meiosis
- e) Cellular Activities and Checkpoints

Unit V

07 Hours

- a) Cell Signals: Introduction
- b) Receptors for Cell Signals
- c) Signaling Pathways: Overview
- d) Misregulation of Signaling Pathways
- e) Protein-Kinases: Functioning

Recommended Books (latest edition):

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. Edward: Fundamentals of Microbiology.
10. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
11. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
12. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.
13. RA Goldshy et. al., : Kuby Immunology.

BP809ET. COSMETIC SCIENCE(Theory)

45Hours

UNIT I

10Hours

Classification of cosmetic and cosmeceutical products

Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients, preservatives. Classification and application

Skin: Basic structure and function of skin. **Hair:** Basic structure of hair. Hair growth cycle.

Oral Cavity: Common problem associated with teeth and gums.

UNIT II

10 Hours

Principles of formulation and building blocks of skin care products:

Face wash,

Moisturizing cream, Cold Cream, Vanishing cream their relative skin sensory, advantages and disadvantages. Application of these products in formulation of cosmeceuticals.

Principles of formulation and building blocks of Hair care products:

Conditioning shampoo, Hair conditioners, antidandruff shampoo. Hair oils.

Chemistry and formulation of Para-phenylene diamine based hair dye.

Principles of formulation and building blocks of oral care products:

Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.

UNIT III

10 Hours

Sun protection, Classification of Sunscreens and SPF.

Role of herbs in cosmetics:

Skin Care: Aloe and turmeric

Hair care: Henna and amla.

Oral care: Neem and clove

Analytical cosmetics: BIS specification and analytical methods for shampoo, skin-cream and toothpaste.

UNIT IV

08 Hours

Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs.

Principles of Cosmetic Evaluation: Principles of sebumeter, corneometer. Measurement of TEWL, Skin Color, Hair tensile strength, Hair combing properties

Soaps, and syndet bars. Evolution and skin benefits.

UNIT V

07 Hours

Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis.

Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes

Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and body odor.

Antiperspirants and Deodorants- Actives and mechanism of action

References

- 1) Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
- 2) Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th Edition, Vandana Publications Pvt. Ltd., Delhi.

BP810 ET.EXPERIMENTAL PHARMACOLOGY

Suggested title:PHARMACOLOGICAL SCREENING METHODS

45 Hours

Scope: This subject is designed to impart the basic knowledge of preclinical studies in experimental animals including design, conduct and interpretations of results.

Objectives

Upon completion of the course the student shall be able to,

- ☐ Appreciate the applications of various commonly used laboratory animals.
- ☐ Appreciate and demonstrate the various screening methods used in preclinical research
- ☐ Appreciate and demonstrate the importance of biostatistics and research methodology
- ☐ Design and execute a research hypothesis independently

Unit –I	08 Hours
Laboratory Animals: Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals. Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia.	
Unit –II	10 Hours
Preclinical screening models a. Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study. b. Study of screening animal models for Diuretics, nootropics, anti-Parkinson's, antiasthmatics, Preclinical screening models: for CNS activity- analgesic, antipyretic, anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease	

Unit –III Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics	
Unit –IV Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslipidemic, anti aggregatory, coagulants, and anticoagulants Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.	
Research methodology and Bio-statistics Selection of research topic, review of literature, research hypothesis and study design Pre-clinical data analysis and interpretation using Students ‘t’ test and One-way ANOVA. Graphical representation of data	05 Hours

Recommended Books (latest edition):

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. CPCSEA guidelines for laboratory animal facility.
4. Drug discovery and Evaluation by Vogel H.G.
5. Drug Screening Methods by Suresh Kumar Gupta and S. K. Gupta
6. Introduction to biostatistics and research methods by PSS Sundar Rao and J Richard

BP 811 ET. ADVANCED INSTRUMENTATION TECHNIQUES

45 Hours

Scope: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart advanced knowledge on the principles and instrumentation of spectroscopic and chromatographic hyphenated techniques. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

Objectives: Upon completion of the course the student shall be able to

- ☐ understand the advanced instruments used and its applications in drug analysis
- ☐ understand the chromatographic separation and analysis of drugs.
- ☐ understand the calibration of various analytical instruments
- ☐ know analysis of drugs using various analytical instruments.

Course Content:

UNIT-I

10 Hours

Nuclear Magnetic Resonance spectroscopy

Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications

Mass Spectrometry- Principles, Fragmentation, Ionization techniques – Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications

UNIT-II

10 Hours

Thermal Methods of Analysis: Principles, instrumentation and applications of Thermogravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC)

X-Ray Diffraction Methods: Origin of X-rays, basic aspects of crystals, X-ray

Crystallography, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications.

UNIT-III

10 Hours

Calibration and validation-as per ICH and USFDA guidelines

Calibration of following Instruments

Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer,

Fluorimeter, Flame Photometer, HPLC and GC

UNIT-IV

08 Hours

Radio immune assay:Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay

Extraction techniques:General principle and procedure involved in the solid phase extraction and liquid-liquid extraction

UNIT-V

07 Hours

Hyphenated techniques-LC-MS/MS, GC-MS/MS, HPTLC-MS.

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

Semester VIII – Elective course on Pharmaceutical Product Development

No of Hours: 3

Tutorial:1

Credit points:4

Unit-I

10 Hours

Introduction to pharmaceutical product development, objectives, regulations related to preformulation, formulation development, stability assessment, manufacturing and quality control testing of different types of dosage forms

Unit-II

10 Hours

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories

- i. Solvents and solubilizers
- ii. Cyclodextrins and their applications
- iii. Non - ionic surfactants and their applications
- iv. Polyethylene glycols and sorbitols
- v. Suspending and emulsifying agents
- vi. Semi solid excipients

Unit-III

10 Hours

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories

- i. Tablet and capsule excipients
- ii. Directly compressible vehicles
- iii. Coat materials
- iv. Excipients in parenteral and aerosols products
- v. Excipients for formulation of NDDS

Selection and application of excipients in pharmaceutical formulations with specific industrial applications

Unit-IV

08 Hours

Optimization techniques in pharmaceutical product development. A study of various optimization techniques for pharmaceutical product development with specific examples. Optimization by factorial designs and their applications. A study of QbD and its application in pharmaceutical product development.

Unit-V

07 Hours

Selection and quality control testing of packaging materials for pharmaceutical product development- regulatory considerations.

Recommended Books (Latest editions)

1. Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, Charles Bon; Marcel Dekker Inc.
2. Encyclopedia of Pharmaceutical Technology, edited by James Swarbrick, Third Edition, Informa Healthcare publishers.
3. Pharmaceutical Dosage Forms, Tablets, Volume II, edited by Herbert A. Lieberman and Leon Lachman; Marcel Dekker, Inc.
4. The Theory and Practice of Industrial Pharmacy, Fourth Edition, edited by Roop K Khar, S P Vyas, Farhan J Ahmad, Gaurav K Jain; CBS Publishers and Distributors Pvt.Ltd. 2013.
5. Martin's Physical Pharmacy and Pharmaceutical Sciences, Fifth Edition, edited by Patrick J. Sinko, BI Publications Pvt. Ltd.
6. Targeted and Controlled Drug Delivery, Novel Carrier Systems by S. P. Vyas and R. K.Khar, CBS Publishers and Distributors Pvt. Ltd, First Edition 2012.
7. Pharmaceutical Dosage Forms and Drug Delivery Systems, Loyd V. Allen Jr., Nicholas B. Popovich, Howard C. Ansel, 9th Ed. 40
8. Aulton's Pharmaceutics – The Design and Manufacture of Medicines, Michael E. Aulton, 3rd Ed.
9. Remington – The Science and Practice of Pharmacy, 20th Ed.
10. Pharmaceutical Dosage Forms – Tablets Vol 1 to 3, A. Liberman, Leon Lachman and Joseph B. Schwartz
11. Pharmaceutical Dosage Forms – Disperse Systems Vol 1 to 3, H.A. Liberman, Martin, M.R and Gilbert S. Banker.
12. Pharmaceutical Dosage Forms – Parenteral Medication Vol 1 & 2, Kenneth E. Avis and H.A. Libermann.
13. Advanced Review Articles related to the topics.