KAKATIYA UNIVERSITY, WARANGAL

SYLLUBUS FOR MASTER OF PHARMACY (M.PHARM)

TWO YEARS COURSE

From the academic year 2023-2024 onwards

FACULTY OF PHARMACEUTICAL SCIENCES,
KAKATIYA UNIVERSITY NAAC A+ Grade, WARANGAL

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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 20203-24. The regulations framed are subject to modifications from time to time by the authorities of the Kakatiya 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 Phamacy 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 semestershall consist of not less than 90 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 75% 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.

Credit assignment

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.

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.	Pharmacy Practice	MPP
8.	Pharmacology	MPL
9.	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./wk	Marks
Semester I					
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH102T	Drug Delivery Systems	4	4	4	100
MPH103T	Modern Pharmaceutics	4	4	4	100
MPH104T	IPR and Regulatory Affairs	4	4	4	100
MPH105P	Modern Pharmaceutical Analytical Techniques Practical	6	3	6	100
MPH106P	Pharmaceutics-I Practical	6	3	6	100
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	700
Semester II					
MPH201T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH202T	Molecular Pharmaceutics (Nano technology &Targeted Drug Delivery Systems)	4	4	4	100
MPH203T	Pharmaceutical Production Technology	4	4	4	100
MPH204T	Cosmetic and Cosmeceuticals	4	4	4	100
MPH205P	Advanced BioPharmaceutics and Pharmaocokinetics Practical	6	3	6	100
MPH206P	Pharmaceutics-II Practical	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

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

Course Code	Course	Credit Hours	Credit Points	Hrs./w k	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	IPR and Regulatory Affairs	4	4	4	100
MIP105P	Pharmaceutical Analytical Techniques Practical I	6	3	6	100
MIP106P	Industrial Pharmacy-I Practical II	6	3	6	100
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	700
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	Advanced BioPharmaceutics and Pharmaocokinetics Practical	6	3	6	100
MIP206P	Industrial Pharmacy Practical	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

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 -I	4	4	4	100
MPC104T	Chemistry of Natural Products	4	4	4	100
MPC105P	Chemistry of Natural Products Practical	6	3	6	100
MPC106P	Advanced Medicinal Chemistry –I Practical	6	3	6	100
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	700
Semester II					
MPC201T	Spectroscopic Identification of Organic compounds	4	4	4	100
MPC202T	Advanced Organic Chemistry -II	4	4	4	100
MPC203T	Advanced medicinal Chemistry-II	4	4	4	100
MPC204T	Computer Aided Drug Design	4	4	4	100
MPC205P	Advanced Organic Chemistry Practical	6	3	6	100
MPC206P	Advanced Medicinal Chemistry-II Practical	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

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-I	4	4	4	100
MPA103T	Pharmaceutical Validation	4	4	4	100
MPA104T	Food Analysis	4	4	4	100
MPA105P	Modern Pharmaceutical Analytical Techniques	6	3	6	100
MPA106P	Advanced Pharmaceutical Analysis-I	6	3	6	100
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	700
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	Advanced Pharmaceutical Analysis -II	4	4	4	100
MPA205P	Advanced Instrumental Analysis	6	3	6	100
MPA206P	Advanced Pharmaceuti cal Analysis-II	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	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	Modern Pharmaceutical Analytical techniques	6	3	6	100
MQA106P	Quality Asssurance and Quality Control	6	3	6	100
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	700
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 Validation	6	3	6	100
MQA206P	Pharmaceutical Manufacturing Technology	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

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	6	3	6	100
MRA 106P	Regulatory Affairs Practical II	6	3	6	100
	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700
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 III	6	3	6	100
MRA 206P	Regulatory Affairs Practical IV	6	3	6	100
	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

Table – 8: 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	6	3	6	100
MPP 106P	Pharmacy Practice Practical II	6	3	6	100
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	700
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 III	6	3	6	100
MPP 206P	Pharmacy Practice Practical IV	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

Table – 9: 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	6	3	6	100
MPL 106P	Pharmacology Practical II	6	3	6	100
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	700
Semester II					
MPL 201T	Advanced Pharmacology II	4	4	4	100
MPL 202T	Pharmacological and Toxicological Screening Methods-II	4	4	4	100
MPL 203T	Principles of Drug Discovery	4	4	4	100
MPL 204T	Clinical Research and Pharmacovigilence	4	4	4	100
MPL 205P	Pharmacology Practical III	6	3	6	100
MPL 206P	Pharmacology Practical IV	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

Table – 10: 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	Advanced Pharmacognosy-I	6	3	6	100
MPG106P	Phytochemistry	6	3	6	100
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	700
Semester II					
MPG201T	Advanced Pharmacognosy-II	4	4	4	100
MPG202T	Indian System of Medicine	4	4	4	100
MPG203T	Herbal cosmetics	4	4	4	100
MPG204T	Clinical Research and Pharmacovigilence	4	4	4	100
MPG205P	Advanced Pharmacognosy-II	6	3	6	100
MPG206P	Herbal Cosmetics	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

Table – 11: 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

Table – 12: 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 – 13: 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 No-14 Guidelines for Awarding Credit Points for Co-Curricular Awards

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

Journal: The Editorial Board Out side 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 University from time to time.

1. **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 sessional exam and before the end semester exam.

2. **Examinations/Assessments**

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

End semester examinations

The End Semester Examinations for each theory and practical course through semesters I to IV shall be conducted by the respective university and the marks/grades shall be submitted to the university.

Note: In each semester Seminar -50marks and Assignment -50 marks (Non University exam/ Internal assessment)

Table No: 16- Schemes for Internal Assessment and End Semester (Pharmaceutics-MPH)

Course Code	Course	Internal Assessment			End Semester Exams		Total Mar ks
		Sessional Exams		Tot al	Mar ks	Durati on	
		Mar ks	Durati on				
SEMESTER I							
MPH 101T	Modern Pharmaceuti cal Analytical Techniques	25	1.30 Hr	25	75	3Hrs	100
MPH 102T	Drug Delivery System	25	1.30 Hr	25	75	3Hrs	100
MPH 103T	Modern Pharmaceutics	25	1.30 Hr	25	75	3Hrs	100
MPH 104T	IPR and Regulatory Affair	25	1.30 Hr	25	75	3 Hrs	100
MPH 105P	Modern Pharmaceutical Analytical techniques	25	3 Hrs	25	75	4 Hrs	100
MPH 106P	Pharmaceutics-I	25	3 Hrs	25	75	4 Hrs	100
-	Seminar /Assignment	100	-	-		3Hrs	100
Total							700
SEMESTER II							
MPH 201T	Advanced Biopharmac eutics& Pharmacokinetics	25	1.30 Hr	25	75	3 Hrs	100
MPH 202T	Molecular Pharmaceuti cs(Nano Tech and Targeted DDS)	25	1.30 Hr	25	75	3 Hrs	100
MPH 203T	Pharmaceutical Production Technology	25	1.30 Hr	25	75	3 Hrs	100
MPH 204T	Cosmetic and Cosmeceutic Als	25	1.30 Hr	25	75	3 Hrs	100
MPH 205P	Pharmaceutics Practical III	25	3 Hrs	25	75	4 Hrs	100
MPH 206 P	Pharmaceutics Practical IV	25	3 Hrs	25	75	4 Hrs	100
	Seminar /Assignment	100				3Hrs	100
Total							700

Table No: 17- Schemes for Internal Assessment and End Semester (Industrial Pharmacy-MIP)

Course Code	Course	Internal Assessment			End Semester Exams		Total Marks
		Sessional Exams		Total	Marks	Duration	
		Marks	Duration				
SEMESTER I							
MIP101T	Modern Pharmaceutical Analytical Techniques	25	1.30 Hr	25	75	3Hrs	100
MIP102T	Pharmaceutical Formulation Development	25	1.30 Hr	25	75	3 Hrs	100
MIP103T	Novel Drug Delivery Systems	25	1.30 Hr	25	75	3 Hrs	100
MIP104T	Intellectual Property Rights and Regulatory Affairs	25	1.30 Hr	25	75	3 Hrs	100
MIP105P	Pharmaceutical Analytical Techniques	25	3 Hrs	25	75	4Hr	100
MIP106 P	Industrial pharmacy-I	25	3 Hrs	25	75	4 Hrs	100
-	Seminar /Assignment	100	-	-	-	3Hrs	100
Total							700
Semester-II							
Total							700
MIP201T	Advanced Biopharmaceutics Pharmacokinetics	25	1.30 Hr	25	75	3 Hrs	100
MIP202T	Scale up and Technology Transfer	25	1.30 Hr	25	75	3 Hrs	100
MIP203T	Pharmaceutical Production Technology	25	1.30 Hr	25	75	3 Hrs	100
MIP204T	Entrepreneurship Management	25	1.30 Hr	25	75	3 Hrs	100
MIP205P	Advanced Biopharmaceutics Pharmacokinetics	25	3hrs	25	75	4hrs	100
MIP206P	Industrial Pharmacy-II	25	3hrs	25	75	4hrs	100
-	Seminar /Assignment	100	-	-		3Hrs	100
Total							700

Table No: 18- Schemes for Internal Assessment and End Semester (Pharmaceutical Chemistry-MPC)

Course Code	Course	Internal Assessment			End Semester Exams		Total Marks
		Sessional Exams		Tot al	Mar ks	Du rati on	
		Mar ks	Durati on				
SEMESTER I							
MPC101T	Modern Pharmaceutical analytical Techniques	25	1.30 Hr	25	75	3Hrs	100
MPC102T	Advanced Organic Chemistry -I	25	1.30 Hr	25	75	3Hrs	100
MPC103T	Advanced Medicinal Chemistry-I	25	1.30 Hr	25	75	3Hrs	100
MPC104T	Chemistry of Natural Products	25	1.30 Hr	25	75	3Hrs	100
MPC105P	Chemistry Of Natural Products	25	3 Hrs	25	75	4 Hrs	100
MPC106P	Advanced Medicinal Chemistry-I	25	3hrs	25	75	4Hrs	100
-	Seminar /Assignment	100				3Hrs	100
Total							700
SEMESTER II							
MPC201T	Spectroscopic Identification of Organic compounds	25	1.30 Hr	25	75	3 Hrs	100
MPC202T	Advanced Organic Chemistry -II	25	1.30 Hr	25	75	3 Hrs	100
MPC203T	Computer Aided Drug Deisgn	25	1.30 Hr	25	75	3Hrs	100
MPC204T	Advanced Medicinal Chemistry & Screening Methods	25	1.30 Hr	25	75	3Hrs	100
MPC205P	Advanced Organic Chemistry	25	3hrs	25	75	4hrs	100
MPC206P	Advanced Medicinal Chemistry -II	25	3hrs	25	75	4hrs	100
-	Seminar /Assignment	100	-	-	-	3Hrs	100
Total							700

Table No: 19- Schemes for Internal Assessment and End Semester (Pharmaceutical Analysis-MPA)

Course Code	Course	Internal Assessment			End Semester Exams		Total Marks
		Contin uous Mode	Sessional Exams	Tot al	Mark s	Dura tion	
			Mark s / Durati on				
SEMESTER I							
MPA101T	Modern Pharmaceuti cal Analytical Techniques	25	1.30 Hr	25	75	3 Hrs	100
MPA102T	Advanced Pharmaceuti cal Analysis-I	25	1.30 Hr	25	75	3 Hrs	100
MPA103T	Pharmaceuti Cal Validation	25	1.30 Hr	25	75	3 Hrs	100
MPA104T	Food Analysis	25	1.30 Hr	25	75	3 Hrs	100
MPA105P	Modern Pharmaceutical Analytical Techniques	25	3 Hrs	25	75	4 Hrs	100
MPA106P	Pharmaceuti cal Analysis-I	25	3Hrs	25	75	4Hrs	100
-	Seminar /Assignment	100	-	-	-	3Hrs	100
Total							700
SEMESTER II							
MPA201T	Advanced Instrumental Analysis	25	1.30 Hr	25	75	3 Hrs	100
MPA202T	Modern Bio- Analytical Techniques	25	1.30 Hr	25	75	3 Hrs	100
MPA203T	Quality Control and Quality Assurance	25	1.30 Hr	25	75	3 Hrs	100
MPA204T	Advanced Pharmaceutical Analysis -II	25	1.30 Hr	25	75	3 Hrs	100
MPA205P	Advanced Instrumental Analysis-I	25	3 Hrs	25	75	4 Hrs	100
MPA206P	Advanced Pharmaceuti cal Analysis-II	25	3 Hrs	25	75	4 Hrs	100
-	Seminar /Assignment	100	-	-	-	3Hrs	100
Total							700

Table No: 20- Schemes for Internal Assessment and End Semester (Pharmaceutical Quality Assurance-MQA)

Course Code	Course	Internal Assessment			End Semester Exams		Total Marks
		Sessional Exams		Total	Marks	Duration	
		Marks	Duration				
SEMESTER I							
MQA1 01T	Modern Pharmaceutical Analytical Techniques	25	1.30 Hr	25	75	3 Hrs	100
MQA1 02T	Quality Management System	25	1.30 Hr	25	75	3 Hrs	100
MQA1 03T	Quality Control and Quality Assurance	25	1.30 Hr	25	75	3 Hrs	100
MQA1 04T	Product Development and Technology Transfer	25	1.30 Hr	25	75	3 Hrs	100
MQA1 05P	Pharmaceutical Quality Assurance Practical I	25	3 Hrs	25	75	4 Hrs	100
MQA1 06P	Pharmaceutical QualityAssurance Practical -II	25	3 Hrs	25	75	4 Hrs	100
-	Seminar /Assignment	100	-	-	-	3Hrs	100
Total							700
SEMESTER II							
MQA2 01T	Hazards and Safety Management	25	1.30 Hr	25	75	3 Hrs	100
MQA2 02T	Pharmaceutical Validation	25	1.30 Hr	25	75	3 Hrs	100
MQA2 03T	Audits Regulatory Compliance	25	1.30 Hr	25	75	3 Hrs	100
MQA2 04T	Pharmaceutical Manufacturing Technology	25	1.30 Hr	25	75	3 Hrs	100
MQA2 05P	Pharmaceutical Quality Assurance Practical III	25	3 Hrs	25	75	4 Hrs	100
MQA2 06P	Pharmaceutical Quality Assurance Practical IV	25	3Hrs	25	75	4 Hrs	100
	Seminar /Assignment	100				3Hrs	100
Total							700

Table No: 21- Schemes for Internal Assessment and End Semester (Pharmaceutical Regulatory Affairs-MPA)

Course Code	Course	Internal Assessment			End Semester Exams		Total Marks
		Sessional Exams		Total	Marks	Duration	
		Marks	Duration				
SEMESTER I							
MRA10 1T	Good Pharmaceutical Practices	25	1.30 Hr	25	75	3 Hrs	100
MRA10 2T	Documentation and Regulatory Writing	25	1.30 Hr	25	75	3 Hrs	100
MRA10 3T	Clinical Research Regulations	25	1.30 Hr	25	75	3 Hrs	100
MRA10 4T	Regulations and Legislation Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food& Nutraceuticals In India and Intellectual Property Rights	25	1.30 Hr	25	75	3 Hrs	100
MRA10 5T	Pharmaceutical Regulatory Affairs Practical I	25	3Hrs	25	75	3 Hrs	100
MRA10 6T	Pharmaceutical Regulatory Affairs Practical II	25	3Hrs	25	75	3Hrs	100
-	Seminar /Assignment	100	-	-	-	3Hrs	100
Total							700
Semester-II							
MRA20 1T	Regulatory Aspects of Drugs & Cosmetics	25	1.30 Hr	25	75	3Hrs	100
MRA20 2T	Regulatory Aspects of Herbal& Biologicals	25	1.30 Hr	25	75	3 Hrs	100
MRA20 3T	Regulatory Aspects of Medical Devices	25	1.30 Hr	25	75	3 Hrs	100
MRA20 4T	Regulatory Aspects of Food & Nutraceuticals	25	1.30 Hr	25	75	3 Hrs	100
MRA205P	Pharmaceutical Regulatory Affairs Practical III	25	3 Hrs	25	75	4 Hrs	100
MRA206P	Pharmaceutical Regulatory Affairs Practical IV	25	3 Hrs	25	75	4Hrs	100
	Seminar /Assignment	100				3Hrs	100
	Total						700

Table No: 22- Schemes for Internal Assessment and End Semester (Pharmacy Practice-MPP)

Course Code	Course	Internal Assessment			End Semester Exams		Total Marks
		Sessional Exams		Total	Marks	Duration	
		Marks	Duration				
SEMESTER I							
MPP10 1T	Clinical Pharmacy Practice	25	1.30 Hr	25	75	3 Hrs	100
MPP10 2T	Pharmacotherapeutics-I	25	1.30 Hr	25	75	3 Hrs	100
MPP10 3T	Hospital& Community Pharmacy	25	1.30 Hr	25	75	3 Hrs	100
MPP10 4T	Clinical Research	25	1.30 Hr	25	75	3 Hrs	100
MPP10 5P	Pharmacy Practice-I Practical -II	25	3 Hrs	25	75	4 Hrs	100
MPP10 6P	Pharmacy Practice-II Practical -II	25	3Hrs	25	75	4 Hrs	100
-	Seminar /Assignment	100	-	-	-	3Hrs	100
Total							700
SEMESTER II							
MPP20 1T	Principles of Quality Use of Medicines	25	1.30 Hr	25	75	3 Hrs	100
MPP20 2T	Pharmacotherapeutics II	25	1.30 Hr	25	75	3 Hrs	100
MPP20 3T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	25	1.30 Hr	25	75	3 Hrs	100
MPP20 4T	Pharmacoepidemiology& Pharmacoeconomics	25	1.30 Hr	25	75	3 Hrs	100
MPP20 5P	Pharmacy Practice-I Practical -III	25	3 Hrs	25	75	4 Hrs	100
MPP20 6P	Pharmacy Practice-II Practical -IV	25	3Hrs	25	75	4 Hrs	100
-	Seminar /Assignment -	100	-	-	-	3Hrs	100
Total							700

Table No: 23- Schemes for Internal Assessment and End Semester (Pharmacology-MPL)

Course Code	Course	Internal Assessment			End Semester Exams		Tot al Mar ks
		Sessional Exams		Tot al	Mar ks	Durati on	
		Mar ks	Durati on				
SEMESTER I							
MPL10 1T	Modern Pharmaceutical Analytical Techniques	25	1.30 Hr	25	75	3 Hrs	100
MPL10 2T	Advanced Pharmacology-I	25	1.30 Hr	25	75	3 Hrs	100
MPL10 3T	Pharmacological and Toxicological Screening Methods-I	25	1.30 Hr	25	75	3 Hrs	100
MPL10 4T	Cellular and Molecular Pharmacology	25	1.30 Hr	25	75	3 Hrs	100
MPL10 5P	Pharmacology - I	25	3 Hrs	25	75	4 Hrs	100
MPL10 6P	Pharmacology - II	25	3 Hrs	25	75	4 Hrs	100
-	Seminar /Assignment -	100	-	-	-	3Hrs	100
Total							700
SEMESTER II							
MPL20 1T	Advanced Pharmacology II	25	1.30 Hr	25	75	3 Hrs	100
MPL10 2T	Pharmacological and Toxicological Screening Methods-II	25	1.30 Hr	25	75	3 Hrs	100
MPL20 3T	Principles of Drug Discovery	25	1.30 Hr	25	75	3 Hrs	100
MPL20 4T	Clinical research and pharmacovigilance	25	1.30 Hr	25	75	3 Hrs	100
MPL20 5P	Pharmacology -III	25	3 Hrs	25	75	4Hrs	100
MPL20 6P	Pharmacology -IV	25	3 Hrs	25	75	4Hrs	100
-	Seminar /Assignment	100	-	-	-	3Hrs	100
Total							700

Table No: 24- Schemes for Internal Assessment and End Semester (Pharmacognosy-MPG)

Course Code	Course	Internal Assessment			End Semester Exams		Tota l Mar ks
		Sessional Exams		Tot al	Mar ks	Durati on	
		Mar ks	Durati on				
SEMESTER I							
MPG10 1T	ModernPharmaceutical Analytical Techniques	25	1.30 Hr	25	75	3 Hrs	100
MPG10 2T	Advanced Pharmacognosy-1	25	1.30 Hr	25	75	3 Hrs	100
MPG10 3T	Phytochemistry	25	1.30 Hr	25	75	3 Hrs	100
MPG10 4T	Industrial Pharmacognostical Technology	25	1.30 Hr	25	75	3 Hrs	100
MPG10 5P	Advanced Pharmacognosy-I	25	3 Hrs	25	75	4 Hrs	100
MPG10 6P	Phytochemistry	25	3 Hrs	25	75	4 Hrs	100
-	Seminar /Assignment	100	-	-	-	3Hrs	100
Total							700
SEMESTER II							
MPG20 1T	Advanced Pharmacognosy-II	25	1.30 Hr	25	75	3 Hrs	100
MPG10 2T	Indian System of Medicine	25	1.30 Hr	25	75	3 Hrs	100
MPG20 3T	Herbal cosmetics	25	1 .30Hr	25	75	3 Hrs	100
MPG20 4T	Clinical Research and Pharmacovigilence	25	1.30 Hr	25	75	3 Hrs	100
MPG20 5P	Advanced Pharmacognosy-II	25	3 Hrs	25	75	4 Hrs	100
MPG20 6P	Herbal Cosmetics	25	3 Hrs	25	75	4Hrs	100
-	Seminar/Assignment -	100	-	-	-	3Hrs	100
Total							700

Tables – 25: Schemes for internal assessments and end semester examinations (Semester III& IV)

Course Code	Course		Internal Assessment			End Semester Exams		Total Marks
			Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
MRM30 1T	Research Methodology and Biostatistics		25	1.30 Hr	25	75	3 Hrs	100
-	Journal club		-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)		-	-	50	-	-	50
-	Research work		-	-	-	250	4 Hr	250
Total								425
SEMESTER IV								
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75
-	Research work and Colloquium	-	-	-	-	400	4 Hr	400
Total								500

Table – 26: 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 courseincluding 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. Re –Examination of End Semester Examinations

Reexamination of end semester examination shall be conducted as per the schedule given in table 28. The exact dates of examinations shall be notified from time to time.

Table – 27: 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 get his/her CGPA upon successful completion of the courses of I to IV semesters.

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 Performance

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 – 28.

Table – 28: 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 obtainedin 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:

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

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, theSGPA shall then be computed as:

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

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 statusin case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passedby 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:

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

where C1, C2, C3,…. is the total number of credits for semester I,II,III,…. and S_1,S_2, S_3,...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. 7.5 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. Duration of the completion of the Program of the 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.

24. Revaluation I Re totaling 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.

25. Readmission 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) I SEMESTER

THEORY **60 HOURS**

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are 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

UNIT- I **10HRS**

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.

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

UNIT- II **8HRS**

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.

UNIT- III **12 HRS**

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

UNIT- IV **10 HRS**

. 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

UNIT- V **10 HRS**

a) Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays.

b) Thermal techniques: DSC, DTA, TGA, Principle, Instrumentation, factors affecting, advantages and disadvantages and Pharmaceutical applications.

UNIT- VI **8 HRS**

NMR Spectroscopy: Quantum numbers and their role in NMR, Principle, instrumentation, solvent requirements in NMR, Relaxation process, NMR signals in various compounds. Brief outline of FT-NMR and C^{13} NMR, applications of NMR Spectroscopy.

REFERENCE BOOKS:

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)

THEORY **60 Hrs**

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..

UNIT- I **9 Hrs**

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 computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release.

UNIT- II **9 Hrs**

Carriers for Drug Delivery: Polymers / co-polymers introduction, classification, characterization, polymerization techniques, application in CDDS / NDDS, biodegradable & natural polymers.

UNIT- III **9Hrs**

Rate Controlled Drug Delivery Systems: 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 .

UNIT- IV **9 Hrs**

Study of Various DDS: Concepts, design, formulation & evaluation of controlled release oral DDS, GRDDS, Mucoadhesive and buccal DDS, colon specific, liquid sustained release systems, Ocular delivery systems.

UNIT- V **9 Hrs**

Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.

UNIT- VI **9 Hrs**

Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.

UNIT- VII **9 Hrs**

Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines, Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy. 6 Hrs

REFERENCE BOOKS:

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 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) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

MODERN PHARMACEUTICS
(MPH 103T)

THEORY **60 HRS**

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.

UNIT- I **14 Hrs**

a. Preformulation 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.

b. 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

UNIT- II **10Hrs**

Validation : Introduction to Pharmaceutical Validation, Scope & merits and types of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments(Tablet machine, Coating pan, auto clave, FBD, aseptic room), Validation of specific dosage form (solids and liquid). Government regulation, Manufacturing Process Model, DQ, IQ, OQ & PQ of facilities.

UNIT- III **10Hrs**

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 planning and control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.

UNIT- IV **10Hrs**

Compression, compaction and consolidation: Physics of tablet compression, Basic principles of interaction, compression and consolidation, effect of load, friction, distribution of forces in compaction, force volume relationship, Heckel plots, compaction profile, measurement of compression with strain gauge.

UNIT- V **10Hrs**

Dissolution testing: study of factors influencing dissolution, Dissolution data analysis mathematical models of drug release (Higuchi and Peppas)

UNIT- VI **6Hrs**

Linearity (Regression) Concept of significance, Standard deviation, standard error Chi square test, students T-test , ANOVA(one way and two way) test and P value.

REFERENCE BOOKS:

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.

IPR AND REGULATORY AFFAIRS
(MPH 104T)

THEORY **60 Hrs**

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
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements
- To learn the importance

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
- Pharmacovigilence and process of monitoring in clinical trials.

UNIT- I **10Hrs**

Drug product development: Active pharmaceutical ingredients, drug master file(DMF) and impurities. Generic product development: Introduction, Hatch-Waxman act and amendments, GUDUFA, ANDA (505j), ANDA approval process. New drug application (505B1 and 505B2). NDA approval process including IND. Scale up and post approval changes (SUPAC).Bioequivalence and Bioavailability, different types of studies for drug product approval.

UNIT- II **10Hrs**

ICH- Guidelines of ICH – Q7 to Q11, M9. Clinical Trials. HIPPA – new, requirements to clinical study process, Parmacovigilance safety monitoring in clinical trials.

UNIT- III **10Hrs**

ANDA for generic drugs ways and means of US registration for foreign drugs. CMC, Post approval regulatory affairs. Regulation for combination products, medical devices & Biosimilars.

UNIT- IV **10Hrs**

Brief introduction to CDSCO, WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA.

UNIT- V **10Hrs**

Definitions, Need for Patenting, Types of Patents, Conditions to be satisfied by an invention to be Patentable, introduction to patent and patent search. Parts of Patent. Filing of patents. The essential elements of patent. Guidelines for preparation of laboratory notebook, Non-obviousness in patent.

UNIT- VI **10Hrs**

Copy right, Trademark, Geographical indication acts, Patent litigation, 180 days market exclusivity and Doctrine of equivalents.

REFERENCE BOOKS

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

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES PRACTICALS (MPH 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer (Minimum 4 Experiments)
2. Simultaneous estimation of multi component containing formulations by UV/HPLC spectrophotometry (Minimum 4 Experiments)
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

PHARMACEUTICS- I PRACTICALS (MPH 106P)

1. To carry out preformulation studies of drugs, effect of surfactants and pH on the solubility of drugs, compatibility evaluation of drugs and excipients by DSC and FTIR .
2. Formulation and evaluation of SR/CR Tablets and compare In-Vitro dissolution profile of SR/CR Marketed formulation.
3. Formulation and evaluation osmotically controlled DDS
4. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
5. Formulation and evaluation of Mucoadhesive tablets.
6. Formulation and evaluation of transdermal patches.
7. Stability studies of drugs in solutions and solid dosage forms according to ICH guidelines.
8. To study the effect of compressional force, particle size and binders on tablets disintegration time and dissolution of a tablet.
9. To study Micromeritic properties of powders and granulation.
10. Analysis of drug release from CR tablets, Higuchi, Peppas plot, zero order. Similarity factor determination
11. Preparation and evaluation of different polymeric membranes.
12. Validation of Tablet machine, coating pan, dryers, autoclave

SEMESTER-II
ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 201T)

THEORY **60 Hrs**

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

UNIT- I **10Hrs**

Drug Absorption from the Gastrointestinal Tract: 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.

UNIT- II **10Hrs**

Biopharmaceutic considerations in drug product design and In Vitro 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.

UNIT- III **10Hrs**

Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief.

UNIT- IV **10Hrs**

Non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of Kmax and Vmax. Noncompartmental Pharmacokinetics- statistical moment theory and physiological pharmacokinetic model. Altered pharmacokinetics in renal and hepatic diseases. Drug interactions: introduction, the effect of protein binding on interactions, the effect of tissue-binding on interactions, cytochrome p450-based drug interactions, and drug interactions linked to transporters.

UNIT- V **10Hrs**

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.

UNIT- VI **10Hrs**

Application of Pharmacokinetics: Chrono Pharmacokinetics, Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamics of biotechnology drugs Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy),Gene therapies.**10 Hrs**

REFERENCE BOOKS:

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2ndedition, 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.

MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)
(MPH 202T)

THEORY **60 Hrs**

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.

UNIT- I **9Hrs**

Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.

UNIT- II **9Hrs**

Targeting Methods: introduction, types, preparation and evaluation of Nano Particles & Liposomes

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UNIT- III **9Hrs**

Micro Capsules / Micro Spheres: Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.

UNIT- IV **9Hrs**

Pulmonary Drug Delivery Systems: Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.

UNIT- V **9Hrs**

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.

UNIT- VI **8Hrs**

Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

UNIT- VII **7Hrs**

Study of commercial formulations DOXIL, RISPERDAL CONSTA, LUPRON DEPOT, INVEGA SUSTENNA, and LANCOME.

REFERENCE BOOKS

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).

PHARMACEUTICAL PRODUCTION TECHNOLOGY
(MPH 203T)

THEORY **60 HRS**

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.

UNIT- I **10Hrs**

a) 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.

b) Coating Technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

UNIT- II **9Hrs**

Parenteral Production: Plant layout, design area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.

UNIT- III **9Hrs**

Lyophilization & Spray drying Technology: Principles, process, freeze-drying and spray drying equipments.

UNIT- IV **9Hrs**

Capsule Production: Production process, advances in capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered.

UNIT- V **9Hrs**

Disperse Systems Production: Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion, problems encountered.

UNIT- VI **7Hrs**

Packaging Technology: Types of packaging materials, machinery (strip and blister), labeling, package printing for different dosage forms.

UNIT- VII **7Hrs**

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.

REFERENCE BOOKS:

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, Parentral 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.

COSMETICS AND COSMECEUTICALS
(MPH 204T)

THEORY **60 Hrs**

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.

UNIT- I **10Hrs**

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.

UNIT- II **10Hrs**

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.

UNIT- III **10Hrs**

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 syndet bars.

UNIT- IV **10Hrs**

Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

UNIT- V **10Hrs**

Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, pigmentation, prickly heat, wrinkles, body odor, dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

UNIT- VI **10Hrs**

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.

REFERENCE BOOKS

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. 3 rd edition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.

ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS PRACTICALS (MPH205P)

1. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
2. Comparison of dissolution of two different marketed products /brands
3. Comparison of diffusion studies of two different marketed products /brands
4. Protein binding studies of a highly protein bound drug & poorly protein bound drug
5. Calculation of all Pharmacokinetic parameters from the I.V. Bolus Data.
6. Calculation of all Pharmacokinetic parameters from the Urinary Data of I.V. Bolus Injection.
7. Calculation of all Pharmacokinetic parameters from the I.V. Infusion Data.
8. Calculation of all Pharmacokinetic parameters from the Extravascular Data – Residual Method.
9. Calculation of all Pharmacokinetic parameters from the Extravascular Data – Wagner Nelson method
10. Bioavailability studies of Paracetamol (Animal).

PHARMACEUTICS-II PRACTICALS (MPH206P)

1. Formulation and evaluation of tablets
2. Formulation and evaluation of capsules
3. Formulation and evaluation of injections
4. Formulation and evaluation of emulsion
5. Formulation and evaluation of suspension.
6. Formulation and evaluation of enteric coating tablets.
7. Preparation and evaluation of a freeze dried formulation.
8. Preparation and evaluation of a spray dried formulation.
9. To study the effect of temperature change , non solvent addition, incompatible polymer addition in microcapsules preparation
10. Preparation and evaluation of Alginate beads
11. Formulation and evaluation of gelatin /albumin microspheres
12. Formulation and evaluation of liposomes/niosomes
13. Formulation and evaluation of spherules
14. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff
15. Formulation and Evaluation of cosmetic products pertaining to skin, hair and teeth.

INDUSTRIALPHARMACY (MIP)
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(MIP 101T)

THEORY **60 HOURS**

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are 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

UNIT- I **10Hrs**

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.

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

UNIT- II **8Hrs**

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.

UNIT- III **12Hrs**

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.

UNIT- IV **12Hrs**

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

UNIT- V **10Hrs**

a) Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays.

b) Thermal techniques: DSC, DTA, TGA, Principle, Instrumentation, factors affecting, advantages and disadvantages and Pharmaceutical applications.

UNIT- VI **8Hrs**

NMR Spectroscopy: Quantum numbers and their role in NMR, Principle, instrumentation, solvent requirements in NMR, Relaxation process, NMR signals in various compounds. Brief outline of FT-NMR and C^{13} NMR, applications of NMR Spectroscopy.

REFERENCE BOOKS:

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

PHARMACEUTICAL FORMULATION DEVELOPMENT
(MIP 102T)

THEORY **60 Hrs**

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

UNIT- I **10Hrs**

Preformulation Studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods for determination of incompatability.

UNIT- II **12Hrs**

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.

UNIT- III **12Hrs**

Solubility: Importance, experimental determination, phase solubility analysis, pH-solubility profile, solubilization techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid state manipulation, micellar solubilization and hydrotropy.

UNIT- IV **12Hrs**

Dissolution: Theories, mechanisms of dissolution, in-vitro dissolution testing models – sink and non-sink in dissolution. Factors influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products. Data handling and correction factor in dissolution calculation. Biorelevent media, in-vitro and in-vivo correlations, levels of correlations.

UNIT- V **12Hrs**

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.

REFERENCE BOOKS:

1. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice Of rd Industrial Pharmacy, 3 ed., Varghese Publishers, Mumbai 1991. th
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: nd tablets Vol. I-III, 2 ed., CBS Publishers & distributors, New Delhi, 2005.
4. Conners KA. A Text book of pharmaceutical analysi 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. rd
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3 ed., CBS publications, New Delhi, 2008. Rd
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3 CBS Publishers & distributors, New Delhi, 2005. ed.,
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006. th
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4 Inc, New York, 2005.
11. W. Grimm - Stability testing of drug products. ed., Marcel Dekker
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999. 13. Beckett AH, Stenlake JB. Practical pharmaceutical th chemistry, Part I & II., 4 2004. ed., CBS Publishers & distributors, New Delhi,
14. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
15. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
16. United States Pharmacopoeia. United States Pharmacopeial 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)

THEORY **60 Hrs**

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

UNIT- I **10Hrs**

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 computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release.

UNIT- II **8Hrs**

Carriers for Drug Delivery: Polymers / co-polymers introduction, classification, characterization, polymerization techniques, application in CDDS / NDDS, biodegradable & natural polymers.

UNIT- III **8Hrs**

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.

UNIT- IV **8Hrs**

Study of Various DDS: Concepts, design, formulation & evaluation of controlled release oral DDS, GRDDS, Mucoadhesive and buccal DDS, colon specific, liquid sustained release systems, Ocular delivery systems.

UNIT- V **6Hrs**

Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.

UNIT- VI **6Hrs**

Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.

UNIT- VII **10Hrs**

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. Study of commercial formulations DOXIL, RISPERDAL CONSTA, LUPRON DEPOT, INVEGA SUSTENNA, and LANCOME.

UNIT-VIII **6Hrs**

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

REFERENCE BOOKS:

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.

IPR AND REGULATORY AFFAIRS
(MPH 104T)

THEORY **60 Hrs**

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
- Pharmacovigilence and process of monitoring in clinical trials.

UNIT- I **10Hrs**

Drug product development: Active pharmaceutical ingredients, drug master file(DMF) and impurities. Generic product development: Introduction, Hatch-Waxman act and amendments, GUDUFA, ANDA (505j), ANDA approval process. New drug application (505B1 and 505B2). NDA approval process including IND. Scale up and post approval changes (SUPAC).Bioequivalence and Bioavailability, different types of studies for drug product approval.

UNIT- II **10Hrs**

ICH- Guidelines of ICH – Q7 to Q11, M9. Clinical Trials. HIPPA – new, requirements to clinical study process, Parmacovigilance safety monitoring in clinical trials.

UNIT- III **10Hrs**

ANDA for generic drugs ways and means of US registration for foreign drugs. CMC, Post approval regulatory affairs. Regulation for combination products, medical devices & Biosimilars.

UNIT- IV **10Hrs**

Brief introduction to CDSCO, WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA.

UNIT- V **10Hrs**

Definitions, Need for Patenting, Types of Patents, Conditions to be satisfied by an invention to be Patentable, introduction to patent and patent search. Parts of Patent. Filing of patents. The essential elements of patent. Guidelines for preparation of laboratory notebook, Non-obviousness in patent.

UNIT-VI **10Hrs**

Copy right, Trademark, Geographical indication acts, Patent litigation, 180 days market exclusivity and Doctrine of equivalents.

REFERENCE BOOKS:

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

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
PRACTICALS (MIP 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer (Minimum 4 Experiments)
2. Simultaneous estimation of multi component containing formulations by UV/HPLC spectrophotometry (Minimum 4 Experiments)
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

INDUSTRIAL PHARMACY – I
PRACTICALS (MIP 106P)

1. To carry out preformulation studies of drugs like effect of surfactants and pH on the solubility of drugs, compatibility evaluation of drugs and excipients by DSC and FTIR .
2. Formulation and evaluation of SR/CR Tablets and compare In-Vitro dissolution profile of SR/CR Marketed formulation.

3. Formulation and evaluation osmotically controlled DDS
4. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
5. Formulation and evaluation of Mucoadhesive tablets.
6. Formulation and evaluation of transdermal patches.
7. Stability studies of drugs in solutions and solid dosage forms according to the ICH guidelines.
8. To study the effect of compressional force, particle size and binders on tablets disintegration time and dissolution of a tablet.
9. To study Micromeritic properties of powders and granulation.
10. Preparation and evaluation of different polymeric membranes.
11. To study the effect of temperature change , non solvent addition, incompatible polymer addition in microcapsules preparation
12. Preparation and evaluation of Alginate beads
13. Formulation and evaluation of gelatin /albumin microspheres
14. Formulation and evaluation of liposomes/niosomes

SEMESTER-II
ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS
(MPH 201T)

THEORY **60Hrs**

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

UNIT- I **10Hrs**

Drug Absorption from the Gastrointestinal Tract: 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.

UNIT- II **10Hrs**

Biopharmaceutic considerations in drug product design and In Vitro 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.

UNIT- III **10Hrs**

Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief.

UNIT- IV **10Hrs**

Non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of Kmax and Vmax. Noncompartmental Pharmacokinetics- statistical moment theory and physiological pharmacokinetic model. Altered pharmacokinetics in renal and hepatic diseases. Drug interactions: introduction, the effect of protein binding on interactions, the effect of tissue-binding on interactions, cytochrome p450-based drug interactions, and drug interactions linked to transporters. 10 Hrs

UNIT- V **10Hrs**

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.

UNIT- VI **10Hrs**

Application of Pharmacokinetics: Chrono pharmacokinetics, Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamics of biotechnology drugs Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.

REFERENCE BOOKS:

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2ndedition, 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.

SCALE UP AND TECHNOLOGY TRANSFER
(MIP 202T)

THEORY **60 Hrs**

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.

UNIT- I **10Hrs**

Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parenteral 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, parenteral, 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. 12 Hrs

UNIT- I **12Hrs**

Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation

UNIT- III **12Hrs**

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.

UNIT- IV **12Hrs**

Process validation: Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.

UNIT- V **12Hrs**

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

REFERENCE BOOKS:

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,nVarghese 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, Parentral 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)

THEORY **60 HRS**

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.

UNIT- I **10Hrs**

a) 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.

b) Coating Technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

UNIT- II **9Hrs**

Parenteral Production: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.

UNIT- III **9Hrs**

Lyophilization & Spray drying Technology: Principles, process, freeze-drying and spray drying equipments.

UNIT- IV **9Hrs**

Capsule Production: Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered.

UNIT- V **9Hrs**

Disperse Systems Production: Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion, problems encountered.

UNIT- VI **7Hrs**

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

UNIT- VII **7Hrs**

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, Parentral 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
(MIP 204T)

THEORY **60 Hrs**

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

UNIT- I **12Hrs**
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.

UNIT- II **12Hrs**
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.

UNIT- III **12Hrs**
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.

UNIT- IV **12Hrs**
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.

UNIT- V **12Hrs**
Preparing Project Proposal To Start On New Enterprise Project work – Feasibility report; Planning, resource mobilization 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. Health & Co., Toranto.
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 SEM –II

ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS PRACTICALS (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. Comparison of diffusion studies of two different marketed products /brands
4. Protein binding studies of a highly protein bound drug & poorly protein bound drug
5. Calculation of all Pharmacokinetic parameters from the I.V. Bolus Data.
6. Calculation of all Pharmacokinetic parameters from the Urinary Data of I.V. Bolus Injection.
7. Calculation of all Pharmacokinetic parameters from the I.V. Infusion Data.
8. Calculation of all Pharmacokinetic parameters from the Extravascular Data – Residual Method.
9. Calculation of all Pharmacokinetic parameters from the Extravascular Data – Wagner Nelson method
10. Bioavailability studies of Paracetamol (Animal).

INDUSTRIAL PHARAMCY-II PRACTICALS (MIP 206P)

1. Formulation and evaluation of tablets
2. .Formulation and evaluation of capsules
3. Formulation and evaluation of injections
4. Formulation and evaluation of emulsion
5. .Formulation and evaluation of suspension.
6. Formulation and evaluation of enteric coating tablets.
7. Preparation and evaluation of a freeze dried formulation.
8. Preparation and evaluation of a spray dried formulation.
9. Validation of Rotary tablet machine.
10. Validation of Coating pan.
11. Validation of tray dryer.
12. Validation of Autoclave and aseptic room.
13.

PHARMACEUTICAL QUALITY ASSURANCE (MQA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MQA 101T)

THEORY **60 Hrs**

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

UNIT- I **10Hrs**

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, 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) Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

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

UNIT- II **10Hrs**

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.

UNIT- III **10Hrs**

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.

UNIT- IV **10Hrs**

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolationof 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

UNIT- V **10Hrs**

a) Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
b) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
c) X ray Crystallography: Production of X rays, Different X ray
d) methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

UNIT- VI **10Hrs**

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

REFERENCE BOOKS:

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, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern 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)

THEORY **60 Hrs**

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

Unit-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 studiesCost of Quality: Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, Preventing cost of quality 10 Hrs

Unit-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. 10 Hrs

Unit-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. 10 Hrs

Unit-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. 10 Hrs

Unit-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.

10 Hrs

Unit-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 10 Hrs

REFERENCE BOOKS:

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)

THEORY **60 Hrs**

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.

Unit-1: **12 Hrs**

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, Qualityassurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.

Unit-2: **12 Hrs**

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.

Unit-3: **10 Hrs**

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).

Unit-4: **12 Hrs**

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.

Unit-5: **12 Hrs**

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.

REFERENCE BOOKS:

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.
14. Packaging of Pharmaceuticals.
15. Schedule M and Schedu

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (MQA 104T)

THEORY **60 Hrs**

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

Unit-1: **12 Hrs**

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.

Unit-2: **12 Hrs**

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.

Unit-3: **12 Hrs**

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.

Unit-4: **12 Hrs**

Pharmaceutical packaging: Pharmaceutical dosage form and their packaging requirments, 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.

Unit-5: **12 Hrs**

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.

REFERENCE BOOKS:

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. Patrevale. 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.

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MQA 105P) PRACTICALS

Modern Pharmaceutical Analytical Techniques

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. Ascending & radial paper chromatography
4. Thin layer chromatography
5. Determination of functional groups by FT-IR
6. Effect Of Concentration On Viscosity
7. Experiments based on HPLC
8. Experiments based on Gas Chromatography
9. Estimation of riboflavin/quinine sulphate by fluorimetry
10. Determination of Quenching effect of Quinine sulphate by potassium iodide solution by Fluorometry
11. Estimation of sodium/potassium by flame photometry or AAS
12. Potentiometric titration of strong acid and strong base
13. Determination of Pka and Log p of drugs.
14. Determination of flow properties and rheological behavior of semi-solid or liquid formulations
15. Determination of bioavailability of poorly soluble drugs using solid dispersion technique

QUALITY CONTROL AND QUALITY ASSURANCE
(MQA 106 P)

1. Preparation and In-process quality control test for immediate released tablets
2. Development of stability study protocol
3. Estimation of process capability
4. Assay of raw materials as per official monographs
5. Testing of related and foreign substances in drugs and raw materials
6. To carry out pre formulation study for tablets, parenterals (2 experiments).
7. To study the effect of pH on the solubility of drugs
8. Quality control tests for Primary and secondary packaging materials
9. Accelerated stability studies (1 experiment)
10. Improved solubility of drugs using surfactant systems (1 experiment)
11. Improved solubility of drugs using co-solvency method (1 experiment)
12. Investigating the compatibility of drug substances with different excipients to identify potential interactions or degradation.
13. Determining the solubility of a drug substance in various solvents or excipients to identify suitable formulations and enhance bioavailability.
14. Developing and testing different formulations with varying excipient compositions, concentrations, and dosage forms to identify the most suitable formulation.
15. Optimizing the manufacturing process parameters (such as blending time, compression force, drying temperature, or coating conditions, to achieve desired product attributes, such as uniformity, content uniformity, and stability).
16. 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

SEMESTER-II
HAZARDS AND SAFETY MANAGEMENT (MQA 201T)

THEORY **60 Hours**

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

Unit-1: **12 Hrs**

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.

Unit-2: **12 Hrs**

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.

Unit-3: **12 Hrs**

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

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Unit-4: **12 Hrs**

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.

Unit-5: **12 Hrs**

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.

REFERENCE BOOKS:

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 Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

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PHARMACEUTICAL VALIDATION (MQA 202T)

THEORY **60 Hours**

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

Unit-1: **10Hrs**

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).

Unit-2: **10 Hrs**

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.

Unit-3: **10 Hrs**

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.

Unit-4: **10 Hrs**

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 and USP.

Unit-5: **10 Hrs**

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

Unit-6: **10 Hrs**

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.

REFERENCE BOOKS:

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,
5. (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)

THEORY **60 Hours**

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

Unit-1: **12 Hrs**

Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies .

Unit-2: **12 Hrs**

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.

Unit-3: **12 Hrs**

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.

Unit-4: **12 Hrs**

Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.

Unit-5: **12 Hrs**

Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.

REFERENCE BOOKS:

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)

THEORY **60 Hours**

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

Unit-1: **12 Hrs**

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.

Unit-2: **12 Hrs**

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).

Unit-3: **12 Hrs**

Lyophilization technology: Principles, process, equipment 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.

Unit-4: **12 Hrs**

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.

Unit-5: **12 Hrs**

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.

REFERENCE BOOKS:

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.

QUALITY ASSURANCE PRACTICAL – III PRACTICALS (MQA 205P)

Pharmaceutical validation

1 Organic contaminants residue analysis by HPLC
2 System suitability parameters for Gradient HPLC
3 Estimation of Metallic contaminants by Flame photometer
4 Identification of antibiotic residue by TLC
5 Estimation of Hydrogen Sulphide in Air.
6 Estimation of Chlorine in Work Environment.
7 Sampling and analysis of SO2 using Colorimetric method
8 Qualification of following Pharma equipment

a. Autoclave

b. Hot air oven

C.Powder Mixer (Dry)

d.Tablet Compression Machine

9 Validation of an analytical method for a drug by UV& HPLC
10 Validation of a processing area
11 Qualification of at least two analytical instruments
12 Cleaning validation of one equipment
13 Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)

QUALITY ASSURANCE PRACTICAL – IV PRACTICALS (MQA 206P)

Pharmaceutical Manufacturing Technology

1. Check list for Bulk Pharmaceutical Chemicals vendors
2. Check list for tableting production.
3. Check list for sterile production area
4. Check list for Water for injection.
5. Demonstrating the process of tablet compression using a tablet punching machine.
6. Hands-on training on capsule filling machines to understand the process of filling powders, pellets, or granules into hard gelatin capsules
7. Formulation and manufacturing of creams and ointments.
8. Performing quality control tests on pharmaceutical products, including identification tests, assay determination, dissolution testing, and content uniformity tests.
9. Practical exercises on Good Manufacturing Practices (GMP)
10. Preparation of suppositories using different bases and active ingredients.
11. Practical sessions on regulatory requirements and compliance in pharmaceutical manufacturing
12. Design of plant layout: Sterile and non-sterile
13. Case study on application of QbD Case study on application of PAT.

PHARMACEUTICAL REGULATORY AFFAIRS
GOOD REGULATORY PRACTICES (MRA 101T)

THEORY **60 Hours**

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

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Unit-1: **12 Hrs**

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.

Unit-2: **12 Hrs**

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

Unit-3: **12 Hrs**

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.

Unit-4: **12 Hrs**

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.

Unit-5: **12 Hrs**

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

REFERENCE BOOKS

1.Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth Edition Drugs and the Pharmaceutical Sciences, Vol.168

DOCUMENTATION AND REGULATORY WRITING (MRA 102T)

THEORY **60 Hours**

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 submissionas per the requirements of agencies
- Follow up the submissions and post approval document requirements

Unit-1: **12 Hrs**

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)

Unit-2: **12 Hrs**

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

Unit-3: **12 Hrs**

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.

Unit-4: **12 Hrs**

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).

Unit-5: **12 Hrs**

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.

REFERENCE BOOKS

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

CLINICAL RESEARCH REGULATIONS (MRA 103T)

THEORY **60 Hours**

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

Unit-1: Clinical Drug Development Process

- 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 **12 hrs**

Unit-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**

Unit-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**

Unit-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

Regulatory Guidance on Efficacy and Safety ICH Guidance's

E4 –Dose Response Informationto 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 biostatics principle applied in clinical research 12 hrs

Unit-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
CFR21Part320: Bioavailabilityandbioequivalence 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 WatchGuidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic AssessmentEuropean Union: EMA Guidance
EU Directives 2001
EudraLex (EMEA) 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**

REFERENCE BOOKS

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, LLM 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.Drugs & Cosmetics Act & Rules and Amendments

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

THEORY **60 Hours**

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

Unit-1: Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules (with latest amendments):

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. 10 Hrs

Unit-2: Regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities 10 hrs

 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

Unit-3: Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards 10 Hrs

Unit-4: Bioavailability and Bioequivalence data (BA &BE), BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study Stability requirements: ICH and WHO Guidelines for Drug testing in animals/Preclinical StudiesAnimal testing: Rationale for conducting studies, CPCSEA Guidelines Ethical guidelines for human participants ICMR-DBT Guidelines for Stem Cell Research 10 Hrs

Unit-5: Intellectual Property Rights: Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. IPR vs Regulatory Affairs. 10 Hrs

REFERENCE BOOKS

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.

CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA)

REGULATORY AFFAIRS PRACTICAL - I (MRA 105P)

List of Experiments:

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)Labeling comparison between brand & generics.
5. Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM
6. Case studies on response with scientific rationale to USFDA Warning Letter
7. Preparation of submission checklist of IMPD for EU submission.
8. Comparison study of marketing authorization procedures in EU.

REGULATORY AFFAIRS PRACTICAL –II
(MRA 106 P)

List of Experiments:

1. Case studies on Change Management/ Change control. Deviations and Corrective & Preventive Actions (CAPA)
2. Import of drugs for research and developmental activities
3. GMP Audit Requirements as per CDSCO
4. Preparation of checklist for registration of IND as per ICH CTD format.
5. Preparation of checklist for registration of NDA as per ICH CTD format.
6. Preparation of checklist for registration of ANDA as per ICH CTD format.
7. Comparative study of DMF system in US, EU and Japan
8. Preparation of regulatory submission using eCTD software
9. Documentation of raw materials analysis as per official monographs
10. Preparation of audit checklist for various agencies
11. Preparation of submission to FDA using eCTD software
12. Preparation of submission to EMA using eCTD software
13. Preparation of submission to MHRA using eCTD software

SEMESTER II
REGULATORY ASPECTS OF DRUGS & COSMETICS (MRA 201T)

THEORY **60 Hours**

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 countriesIt 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

Unit-1. USA & 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. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA and Canada. **12 Hrs**

Unit-2: European Union & 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. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union & Australia. **12 HRS**

Unit-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**

Unit-4.Emerging Market: Introduction, Countries covered, Study of the world map,study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC)

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) **12 hrs**

Unit-5. Brazil, ASEAN, CIS and GCC Countries: 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. **12 hrs**

REFERENCE 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. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc

REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS (MRA 202T)

THEORY **60 Hours**

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

Unit1: 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-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-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-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,

LabelRequirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilence Network) **12 hrs**

5.Herabal Producats: Quality, safety and legislation for herbal products in India, USA and European Union **12 hrs**

REFERENCE BOOKS

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano , David S. Mantus ; Informa ,2008

2.Development of Vaccines: From Discovery to Clinical Testing; Manmohan Singh , Indresh K. Srivastava ;Wiley, 2011

3.BiologicalDrugProducts:DevelopmentandStrategies;Wei Wang , Manmohan Singh ; wiley ,2013

REGULATORY ASPECTS OF MEDICAL DEVICES (MRA 203T)

THEORY **60 Hours**

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

Unit-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.

IMDRF/GHTF: Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN). **12 Hrs**

Unit-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) 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 **12 hrs**

Unit-3: 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. **12Hrs**

Unit- 4 : 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 **12 hrs**

Unit-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**

REFERENCE BOOKS:

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 MedinaCountry Specific Guidelines from official websites

REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS (MRA 204T)

THEORY **60 Hours**

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.

Unit-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**

Unit-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**

Unit-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

Unit-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**

Unit-5: European Union: European Food Safety Authority (EFSA): Organization and Functions. EU Directives and regulations for 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. **12 Hrs**

REFEERENCE BOOKS:

1. Regulation of Functional Foods and Nutraceuticals: A Global Perspective by Clare M. Hasler (Wiley Online Library)

2. Handbook of Nutraceuticals by Yashwant Pathak

REGULATORY AFFAIRS PRACTICAL - III (MRA 205P)

List of Experiments:

1. Preparation of Biologics License Applications (BLA)
2. Preparation of documents required for Vaccine Product Approval
3. Comparison of clinical trial application requirements of US, EU and India of Biologics
4. Preparation of Checklist for Registration of Blood and Blood Products
5. Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization
6. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization
7. Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization
8. Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization
9. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization
10. Preparation of document required for the approval of herbal products of diverse dosage forms(3products) as per regulations requirements

REGULATORY AFFAIRS PRACTICAL - IV (MRA 206 P)

1. Checklists for 510k and PMA for USmarket
2. Checklist for CE marking for various classes of devices for EU
3. STED Application for Class III Devices
4. Audit Checklist for Medical Device Facility
5. Clinical Investigation Plan for Medical Devices
6. Preparation and submission of medical devices for approval (3 products)
7. GMP of manufacturing of medical devices of diverse nature (3 products)
8. preparation and submission of nutraceuticals devices for approval (3 products)

PHARMACY PRACTICE

CLINICAL PHARMACY PRACTICE (MPP 101T)

THEORY **60 Hours**

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

Unit-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**

Unit-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**

Unit-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: Hematological tests, Renal function tests, Liver function tests

12 hrs

Unit-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**

Unit-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

REFERENCE BOOKS:

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)

THEORY **60 Hours**

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)

Etiopathogenesis and pharmacotherapy of diseases associated with following systems

Unit-1: Cardiovascular system: Hypertension, Congestive cardiac failure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias.

Unit-2-Respiratory system: Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases Endocrine system: Diabetes, Thyroid diseases

Unit-3: Gastrointestinal system: Pepticulcerdiseases,Reflux esophagitis, Inflammatory bowel diseases, Jaundice & hepatitis

Unit-4: Gastrointestinal system: Cirrhosis, Diarrhea and Constipation, Drug-induced liver disease, Hematological diseases: Anemia, Deep vein thrombosis, Drug induced hematological disorders

Unit-5: Bone and joint disorders: Rheumatoid arthritis, Osteoarthritis, Gout, Osteoporosis

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

REFERENCE BOOKS:

1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange Robins SL. Pathologic basis of disease -W.B. Saunders publication

HOSPITAL & COMMUNITY PHARMACY(MPP 103T)

THEORY **60 Hours**

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

Unit-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**

Unit-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**

Unit-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. 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 **12 Hrs**

Unit-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 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.

12 hrs

Unit-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 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 . **12 hrs**

REFERENCE BOOKS:

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

CLINICAL RESEARCH (MPP 104T)

THEORY **60 Hours**

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 imparts 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

Unit-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**

Unit-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 **12hrs**

Unit-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**

Unit-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**

Unit-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**

REFERENCE BOOKS:

1. Principles and practice of pharmaceutical medicine, Second edition. Authors:Lionel. D. Edward, Aadrew.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.

Relevant review articles from recent medical and pharmaceutical literature

PHARMACY PRACTICE PRACTICAL – I (MPP 105P)

The students are required to be posted to various clinical wards for their exposure with therapeutic management and other clinical aspects. They are expected to have experience and do a tutorial as well as case presentation in the following clinical conditions. The students have to make at least 10 case presentations covering most common diseases found in the hospital to which the college is attached. The student should also submit a record of the cases presented. The list of clinical cases presented should include follow-up of the clinical cases mentioned below from the day of admission till discharge and presented in the SOAP (Subjective, Objective, Assessment and Plan) format.

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. ABC Analysis of a given list of medications (one)
8. Preparation of content of a medicine, with proper justification, for the inclusion in the hospital formulary (one)
9. Formulation and dispensing of a given IV admixtures (one)

REFERENCE BOOKS

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

PHARMACY PRACTICE PRACTICAL – II (MPP 106P)

The students are required to be posted to various clinical wards for their exposure with therapeutic management and other clinical aspects. They are expected to have experience and do a tutorial as well as case presentation in the following clinical conditions. The students have to make at least 10 case presentations covering most common diseases found in the hospital to which the college is attached. The student should also submit a record of the cases presented. The list of clinical cases presented should include follow-up of the clinical cases mentioned below from the day of admission till discharge and presented in the SOAP (Subjective, Objective, Assessment and Plan) format.

1. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight). The cases may be selected from the following Wards:
   - Gastroenterology
   - Cardiology
   - Pulmonology
   - Orthopedics
   - Endocrinology
   - Dermatology
2. Preparation of a patient information leaflet (two)
3. Preparation of Study Protocol (one)
4. Preparation of Informed Consent Form (one)

REFERENCE BOOKS

1. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia
2. Thomas J Johnson, Critical Care Pharmacotherapeutics
3. Collen D L, Sneha B S, Fundamental Skills for Patient Care in MPP
4. Patient Assessment in Pharmacy, by Yolanda M H
5. Relevant review articles from recent medical and pharmaceutical literature

SEMESTER-II
PRINCIPLES OF QUALITY USE OF MEDICINES (MPP 201T)

THEORY **60 Hours**

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

Unit-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**

Unit-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**

Unit-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**

Unit-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**

Unit-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. **12hrs**

REFERENCE BOOKS:

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

PHARMACOTHERAPEUTICS II (MPP 202T)

THEORY **60 Hours**

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

Unit-1: Nervous system: Epilepsy, Parkinson's disease, Stroke, Headache, Alzheimer's disease, Neuralgias and Pain pathways and Pain management. **12 hrs**

Unit-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**

Unit-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**

Unit-4 : Infectious diseases: Meningitis, HIV and opportunistic infections, Rheumatic fever, Dengue fever, H1N1, Helmenthiasis, Fungal infections
Gynecological disorders: Dysmenorrhea, Hormone replacement therapy. **12 hrs**

Unit-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 **12 hrs**

REFERENCE BOOKS

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 Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins

CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING (MPP 203T)

THEORY **60 Hours**

Scope:

This course is designed to enable students to understand the basics 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

Unit-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**

Unit-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**

Unit-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**

Unit-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**

Unit-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;Psychiatricconditions:Lithium,Fluoxetine,Amitriptyline;
Organ transplantations: Cyclosporine; Cytotoxic Agents: Methotrexate, 5-FU, Cisplatin; Antibiotics:Vancomycin,Gentamicin, Meropenem **12 hrs**

REFERENECE BOOKS:

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. Iippincott 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. Iippincott Williams & Wilkins, USA.
8. Evans, Schentag, Jusko. Applied pharmacokinetics. American Society of Health system Pharmacists, USA.

9. Michael E. Winter. Basic Clinical Pharmacokinetics. Iippincott 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.

Relevant review articles from recent medical and pharmaceutical literature

PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (MPP 204T)

THEORY **60 Hours**

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.

Unit-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, Incidencerate,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**

Unit-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**

Unit-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**

Unit-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**

Unit-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**

REFERENCE BOOKS:

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.

   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

PHARMACY PRACTICE PRACTICAL -III (MPP 205P)

The students are required to be posted to various clinical wards for their exposure with therapeutic management and other clinical aspects. They are expected to have experience and do a tutorial as well as case presentation in the following clinical conditions. The students have to make at least 10 case presentations covering most common diseases found in the hospital to which the college is attached. The student should also submit a record of the cases presented. The list of clinical cases presented should include follow-up of the clinical cases mentioned below from the day of admission till discharge and presented in the SOAP (Subjective, Objective, Assessment and Plan) format.

List of Experiments (12)

1. Causality assessment of adverse drug reactions (three)
2. Detection and management of medication errors (three)
3. Calculation of Bioavailability and Bioequivalence from the given data (two)
4. Interpretation of Therapeutic Drug Monitoring reports of a given patient (two)
5. Assessment of drug interactions in the given prescriptions
6. Answering drug information questions

REFERENCE BOOKS:

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. Clinical Pharmacy and Pharmacotherapeutics by Ravi Shankar, Pharma med Press

Chisholm - Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication

PHARMACY PRACTICE PRACTICAL -IV (MPP 206 P)

List of Experiments (12)

1. Presentation of clinical cases of nervous system diseases adopting SOAP (Subjective, Objective, Assessment and Plan)
2. Presentation of clinical cases of psychiatric disorders adopting SOAP (Subjective, Objective, Assessment and Plan)
3. Presentation of clinical cases of infectious diseases adopting SOAP (Subjective, Objective, Assessment and Plan)
4. Presentation of clinical cases of gynecological disorders adopting SOAP (Subjective, Objective, Assessment and Plan)
5. Presentation of clinical cases of cancer disease adopting SOAP (Subjective, Objective, Assessment and Plan)
6. Presentation of clinical cases of renal system disorders adopting SOAP (Subjective, Objective, Assessment and Plan)
7. Develop pharmacokinetic skills by using NONMEM WinNonlin software.
8. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model
9. Calculation of various Pharmacoeconomic outcome analysis for the given data
10. Rational use of medicines in special population admitted in the wards

REFERENCE BOOKS:

1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics. New York: McGraw 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. Iippincott Williams & Wilkins.
4. Steven How-Yan Wong, Irving Sunshine. Handbook of AnalyticalTherapeutic Drug Monitoring and Toxicology. CRC Press, USA.
5. Joseph T. Dipiro, William J. Spruill, William E. Wade, Robert A.Blouin and Jane M. Pruemer Concepts in Clinical Pharmacokinetics. AmericanSociety of Health-System Pharmacists, USA.

Malcolm Rowland, Thomas N. Tozer. Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. Iippincott Williams & Wilkins, USA.

PHARMACOLOGY (MPL)
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(MPL 101T)

THEORY **60 HOURS**

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are 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

Unit-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.

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. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. **10HRS**

Unit-2:. 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. **8HRS**

Unit-3. 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**

Unit-4. 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 **12 HRS**

Unit-5 a) Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays.
b) Thermal techniques: DSC, DTA, TGA, Principle, Instrumentation, factors affecting, advantages and disadvantages and Pharmaceutical applications. **10 HRS**

Unit-6: NMR Spectroscopy: Quantum numbers and their role in NMR, Principle, instrumentation, solvent requirements in NMR, Relaxation process, NMR signals in various compounds. Brief outline of FT-NMR and C^{13} NMR, applications of NMR Spectroscopy.
8 HRS

REFERENCE BOOKS:

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

ADVANCED PHARMACOLOGY - I (MPL 102T)

THEORY **60 HOURS**

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

Unit-1: GeneralPharmacology

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. **10 Hrs**

Unit-2: Neurotransmission

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. **10 Hrs**

Unit-3: 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

10 hrs

Unit-4: Centrel 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 **10 hrs**

Unit-5: Cardiovascular Pharmacology:
Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants , anticoagulants, fibrinolytics and anti- platelet drugs

Unit-6: Autocoid pharmacology: The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists. **10Hrs**

REFERENCE BOOKS

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.

Green Pathophysiology for Pharmacists

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

THEORY **60 HOURS**

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

Unit-1: Laboratory Animals: 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. **12 hrs**

Unit-2: 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 co ordination, 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. **12 hrs**

Unit-3: 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 allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti -emetic, anti- diarrheal and laxatives.

12 hrs

Unit-4: Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.
Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods. **12 hrs**

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

REFERENCE BOOKS:

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

CELLULAR AND MOLECULAR PHARMACOLOGY (MPL 104T)

THEORY **60 HOURS**

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-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 hrs**

Unit-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**

Unit-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**

Unit-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**

Unit-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**

REFERENCE BOOKS:

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)

Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et la

PHARMACOLOGY PRACTICAL - I (MPL 105P)

List of experiments

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. Handling of laboratory animals.
8. Various routes of drug administration.
9. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
10. Functional observation battery tests (modified Irwin test)
11. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
12. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
13. Evaluation of diuretic activity.
14. Evaluation of antiulcer activity by pylorus ligation method.
15. Oral glucose tolerance test.

REFERENCE Books:

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

PHARMACOLOGY PRACTICAL -II (MPL 106 P)

1. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
2. Isolation of RNA from yeast
3. Estimation of proteins by Braford/Lowry's in biological samples.
4. Estimation of RNA/DNA by UV Spectroscopy
5. Gene amplification by PCR.
6. Protein quantification Western Blotting.
7. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
8. Cell viability assays (MTT/Trypan blue/SRB).
9. DNA fragmentation assay by agarose gel electrophoresis.
10. DNA damage study by Comet assay.
11. Apoptosis determination by fluorescent imaging studies.
12. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
13. Enzyme inhibition and induction activity
14. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
15. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

REFERENCE BOOKS:

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

SEMESTER-II
ADVANCED PHARMACOLOGY - II (MPL 201T)

THEORY **60 Hours**

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-1: Endocrine Pharmacology

Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones

Anti-thyroiddrugs,Oral hypoglycemicagents,Oral contraceptives, Corticosteroids.

Drugs affecting calcium regulation **12 hrs**

Unit-2 Chemotherapy : Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs **12 hrs**

Unit-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**

Unit-4 GIT Pharmacology

Antiulcer 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**

Unit-5: Free radicals Pharmacology : Generation of free radicals, role of free radicals in etiopathology of various diseasessuch 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**

REFEERENCE BOOKS:

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

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)

THEORY **60 Hours**

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.

Unit-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**

Unit-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**

Unit-3 Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II) Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies **12 hrs**

Unit-4: 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 **12 hrs**

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

REFERENCE BOOKS:

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.Principles of toxicology by Karen E. Stine, Thomas M. Brown

PRINCIPLES OF DRUG DISCOVERY
(MPL 203 T)

THEORY **60 Hours**

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-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

Unit-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**

Unit-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 Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening. **12 hrs**

Unit-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**

Unit-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**

REFERENCE BOOKS:

1. MouldySioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott MarkelIn. 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.

J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey

CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL 204T)

THEORY **60 Hours**

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-1: 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 **10 hrs**

Unit-2: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. **10 hrs**

Unit-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. **10 hrs**

Unit-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

10 hr

Unit-5: Methods, ADR reportingandtoolsusedin 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-6:Pharmacoepidemiology, pharmacoeconomics, safety pharmacology **10 hrs**

REFERENCE BOOKS:

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

PHARMACOLOGICAL PRACTICAL -III (MPL 205P)

List of Experiments

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 PA2 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

REFERENCE BOOKS:

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. A practical book of Pharmacology by Ramesh Alluri
10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)

A Complete Textbook of Medical Pharmacology by Dr. S. K Srivastava published by A P C Avichal Publishing Company

PHARMACOLOGICAL PRACTICAL -IV (MPL 206 P)

List of Experiments

1. Drug absorption studies by averted rat ileum preparation.
2. Acute oral toxicity studies as per OECD guidelines.
3. Acute dermal toxicity studies as per OECD guidelines.
4. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
5. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
6. Protocol design for clinical trial.(3 Nos.)
7. Design of ADR monitoring protocol.
8. In-silico docking studies. (2 Nos.)
9. In-silico pharmacophore based screening.
10. In-silico QSAR studies.
11. ADR reporting

REFERENCE BOOKS

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. Experimental Pharmacology by M.C.Prabhakar.
5. Practicals in Pharmacology by R.K.Goel
6. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and William Thomsen
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.

PHARMACOGNOSY (MPG)

SEMESTER-I

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

(MIP 101T)

THEORY **60 HOURS**

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are 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

Unit-1: **10Hrs**

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.

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

Unit-2: **8Hrs**

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.

Unit-3: **12Hrs**

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.

Unit-4: **10Hrs**

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

Unit-5: **10Hrs**

a) Potentiometry: Principle ,Workinf, Ion Selective electrodes and applications of potentiometry.

b) Thermal techniques: DSC, DTA, TGA, Principle, Instrumentation, factors affecting, advantages and disadvantages and Pharmaceutical applications.

Unit-6: **8Hrs**

NMR Spectroscopy: Quantum numbers and their role in NMR, Principle, instrumentation, solvent requirements in NMR, Relaxation process, NMR signals in various compounds. Brief outline of FT-NMR and C^{13} NMR, applications of NMR Spectroscopy.

REFERENCE BOOKS:

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

ADVANCED PHARMACOGNOSY - I (MPG 102T)

THEORY **60 HOURS**

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 Use the biotechnological techniques for obtaining and in impropving the quality of the natural products/Medicinal plants

1. UNIT I **10Hrs**

A brief account on Chemical and Pharmacological aspects and uses of the following medicinal plants-

1. **Immunomodulators** a. Asparagus racemosusb. Withania somnifera
2. **Hepatoprotectives** a. Phyllanthus amarus b. Silybum marianum
3. **Cardioprotectives** a. Coleus forskolin b. Allium sativum
4. **Antivirals** a. Oregano vulgare b. Sambucus nigra
5. **Antidiabetics** a. Gymnema sylvestre b. Momordica charantia

UNIT-II **10Hrs**

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.

UNIT-III **10Hrs**

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 neutraceuticals, 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.

UNIT IV: 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) Vitamins
g) Tocotrienols and Tocopherols
h) Andrographolide, Glycolipids, Gugulipids, Withanolides,

Vascine, Taxol

i) Miscellaneous **10 hrs**

UNIT-V Secondary metabolism in tissue cultures with emphasis on production of medicinal agents- Production of Secondary metabolites from callus culture and suspension culture with emphasis on production of biomedicinals like- Ajmalicine, Shikonin, Carotenoids and Rosemarinic acid. **10 hrs**

UNIT-VI

Biotransformation and Trangenesis: Biotransformation of Plant Cell Culture and its importance in secondary metabolite production. Bioreactors for pilot and large scale cultures of plant cells. Hairy root cultures and their applications. **10 hrs**

REFERENCES (Latest Editions of)

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

13.Cultivation of medicinal and aromatic crops, AA Farooqui and B.S. Sreeramu. University Press, 2001.
14 . Medicinal plant biotechnology by Ciddi Veeresham
15. Pharmaceuticals biotechnology by S.P. Vyas & V.K. Dixit
16.Biotechnological applications to tissue culture by Shargool, Peter D, Shargoal, CKC Press
17.Natural Products from Plants, 1st edition, by Peter B. Kaufman, CRC Press, New York, 1998
18.Recent Advances in Phytochemistry- Vol. 1&4: Scikel Runeckles- Appleton Century crofts.
19.Text book of Pharmacognosy, C.K.Kokate, Purohit, Ghokhale, Nirali Prakasshan, 1996.
20.Pharmacognosy and Pharmacobiotechnology, Ashutoshkar, New Age Publications, New Delhi.

PHYTOCHEMISTRY (MPG 103T)

THEORY **60 HOURS**

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

UNIT-I **10 Hrs**

Isolation, characterization and purification with a special reference to their importance in herbal industries of following phytopharmaceuticals containing drugs.

a. Alkaloids: Ephedrine, Quinine, Strychnine, Piperine, Berberine, Taxol, Vinca alkaloids

b. Glycosides: Digitoxin, Glycyrrhizin, Sennosides, Quercetin, Bacosides

c. Steroids: Hecogenin, Guggulsterone, Withanolides

d. Coumarins: Umbelliferone

UNIT-II **10 Hrs**

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 : artemesin, andrographolides. Clinical studies emphasising on phases of clinical trials, protocol design for lead molecules.

UNIT-III **10 Hrs**

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

UNIT_IV: Phytochemical finger printing: HPTLC and LCMS/GCMS applications in the characterization of herbal extracts. Structure elucidation of phytoconstituents. **10 Hrs**

UNIT-V: Structure elucidation of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (1H, 13C)

a. Carvone, Citral, Menthol
b. Luteolin, Kaempferol Nicotine, Caffeine iv) Glycyrrhizin **10 hrs**

REFERENCE BOOKS:

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
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)

THEORY **60 HOURS**

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.

UNIT-1 **12 hrs**

Herbal drug industry:

a) Study of infrastructure, staff requirements, project profile, plant and equipment applicable to herbal drug industry. Plant design, layout and construction. Pilot plant scale –up techniques.

b) GMP and GLP

UNIT-II: Regulatory requirements for setting herbal drug industry:

Global marketing management. Regulatory requirements Export - Import (EXIM) policy. TRIPS : Quality assurance in herbal/ natural drug products. Concepts of TQM, ISO-9000.

Recent guidelines of DCGI on herbal formulations **12 hrs**

UNIT-III Monographs of herbal drugs: General parameters of monograph of herbal drugs in Ayurvedic Pharmacopoeia, Herbal Pharmacopoeia and American Pharmacopoeia **12 hrs**

UNIT-IV: **12 hrs**

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

UNIT:V **12 hrs**

Patents: Patenting of herbal drugs: Benefits of patent protection, Patent application, drafting and filing an application. Indian and international patent laws, proposed amendments as applicable to herbal/natural products and process. Geographical indication, Copyright, Patentable subject maters, novelty, non-obviousness, utility, patent processing and grant of patents

Reference books

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), Ist 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. RangarI (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), IInd 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.

ADVANCED PHARMACOGNOSY PRACTICAL – I (MPG I05P)

1.Detection of Phytoconstituents by test tubes and TLC methods, such as
a.Alkaloids,
b.b. Steroids, Triterpenoids and their glycosides and saponins,
c. Anthracene glycosides d. Flavanoids and their glycosides
e. Coumarinsm f. Tannins
2.a. Identification of alkaloids in a mixture by TLC
e.g. Atropine, Caffeine , Ergot, Piperine, Quinine, Reserpine, Strychnine and Brucine
3.Isolation of the following Phytoconstituents
a.Caffeine from Tea Leaves
b.Caffeine from marketed product
c.Strychnine and Brucine from Nux-Vomica by Column chromatography.
d.Piperine from black pepper
e.Citric acid from Lemon
f.Nicotine from Tobacco
g.Pectin from Orange peels
4.Detection, extraction, and estimation of volatile oils by Clevenger's method (Hydrodistillation method), TLC of volatile oils and their pure constituents.
5.Isolation of starch from potatoes and rice
6.Isolation of Bixin from Bixa orellana
7.Isolation of Lawsone from Henna
8.Isolation of Curcuminoids from Curcuma Longa
9.Identification of bioactive constituents from plant extracts

Phytochemistry (MPG I06P)

1. Extraction of Carotene from Carrot
2. Extraction of Hesperidin from orange peels
3. Extraction of Glyrrhizic acid from *Glycyrrhiza glabra*
4. Extraction of Rutin from *Nicotiana tobaccum*
5. Extraction of oleo-resin from ginger
6. TLC studies of Phytoconstituents
7. Estimation of phytoconstituents by various analytical methods (UV, FTIR)

Extraction of Quercetin from Onion using column chromatography

SEMESTER-II
ADVANCED PHARMACOGNOSY - II (MPG 201T)

THEORY **60 HOURS**

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

Unit-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**

Unit-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, detection of heavy metals, pesticide residues, phytotoxin, microbial contamination in herbs and their formulations. **12 hrs**

Unit-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**

Unit-4: Analytical Profiles of herbal drugs: Andrographis paniculata, Boswellia serata, Coleus forskholii, Curcuma longa, Embelica officinalis, Psoralea corylifolia. **12 hrs**

Unit-5: Biological screening of herbal drugs: Introduction and Need for Phyto-Pharmacological Screening, New Strategies for evaluatingNatural 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. **12Hrs**

REFERENCE BOOKS:

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. Modem 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 Pulok K Mukherjee, Business Horizons Pharmaceutical Publishers, New Delhi.
10. Indian Herbal Pharmacopoeia, IDMA, Mumbai.
11. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI, 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)

THEORY **60 HOURS**

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.

Unit-1: Fundamental concepts of Ayurveda, Siddha, Unani and Homoeopathy systems of medicine 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). **12 Hrs**

Unit-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**

Unit-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 formulation. **12 hrs**

Unit-4: Schedule T-GMP of Indian Systems

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 **12Hrs**

Unit-5:

TKDL, Geographical indication Bill, Government bills in AYUSH, ISM, CCRAS, CCRS, CCRH, CCRU. **12 Hrs**

REFERENCE BOOKS:

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, bRITISH 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 Dietitics 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 203T)

THEORY **60 HOURS**

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

Unit-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**

Unit-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**

Unit-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 :
Tonic, Bleaches, Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails. **12 hrs**

Unit-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**

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

REFERENCE BOOKS:

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. Aromatheraphy (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

CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPG 204T)

THEORY **60 HOURS**

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-1: 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 **10 hrs**

Unit-2: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. **10 hrs**

Unit-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. **10 hrs**

Unit-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

10 hr

Unit-5: Methods, ADR reportingandtoolsusedin 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-6: Pharmacoepidemiology, pharmacoeconomics, safety pharmacology **10 Hrs**

REFERENCE BOOKS:

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

PHARMACEUTICAL CHEMISTRY

MODERN PHARMACEUTICALANALYTICAL TECHNIQUES (MPC101T)

THEORY **60 Hours**

Scope: The appreciable knowledge will be gained by the students in the Modern Analytical Techniques and can apply the theories in the Analysis of various bulk drugs and their formulations. The students will also be in a position to apply their knowledge in developing the new methods for the determination and validate the procedures.

Objectives: The course is designed to impart the knowledge in different analytical techniques like UV-Visible, IR, GC, HPLC etc so that it can be used in the analysis of bulk drugs and formulations.

UNIT I **12Hours**

Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation

A. Column Chromatography: Adsortion and partition, materials used for separation, solvent system, procedure and method of detection. Theory, principles involved in separation, apparatus, column materials, number of theoretical plates, elution, method of detection. Modifications like VLC, Flash, MPLC, their advantage over open column CC.

B. Paper Chromatography: Theory, different techniques employed, filter papers used, qualitative and quantitative detection

UNIT II **12Hours**

A. Thin Layer Chromatography: Theory, principles of separation, apparatus, coating materials, spotting, solvent systems, detection, Uses of TLC: Finding the number of compounds; the class of compounds; Testing for purity/ detection of impurities; identifying compounds-Co-TLC,Mixed TLC; isolating compounds in a pure form-preparative TLC; Two dimensional TLC.

B. HPTLC: Theory and principle, instrumentation, elution techniques and pharmaceutical applications

C. A comparative study; how is HPTLC is different from TLC, apparatus; Coating materials-particle size; detection; uses.

UNIT II **12Hours**

a. Gas Chromatography: Introduction, fundamentals, instrumentation, columns: preparation and operation, detection; derivatization.

b. HPLC and UPLC: Principles and instrumentation, solvents and columns used Operational modes, detection and applications.

UNIT III **12Hours**

A.Electrophoresis:Principle,Instrumentation,Workingconditions,factors affectingseparation and applications ofthefollowing:a) Paperelectrophoresisb)Gelelectrophoresisc)Capillary electrophoresis d) Zone electrophores e) Moving boundaryelectrophoresis f)Isoelectricfocusing

B.X rayCrystallography: Production of X rays, Different X raymethods, Bragg's law, Rotating crystal technique, X ray powdertechnique,Typesof crystalsandapplicationsofX-raydiffraction.

UNIT IV **12Hours**

A.UV-Visible spectroscopy: Theory and instrumentation in brief. Chromophore; Auxochrome; Types of electronic transitions; Solvent effects; Quantitative estimation of Riboflavin, Paracetamol, Diclofenac, Metronidazole,Aspirin..

B.IR spectroscopy: Theory, Modes of Molecular vibrations, Samplehandling, Instrumentation of Dispersive and Fourier – TransformIR Spectrometer, Factors affecting vibrational frequencies, Quantitative estimation of APIs using IR spectroscopy.

UNIT V **12Hours**

A. Spectroflourimetry: Theory of Fluorescence, Factors affectingfluorescence, Quenchers, Instrumentation and Applications offluorescence spectrophotometer.

B. Flame emission spectroscopy and Atomic absorptionspectroscopy: Principle, Instrumentation, Interferences andApplications.

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, Vol 11, Marcel. Dekker Series

8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.

9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

ADVANCED ORGANIC CHEMISTRY – I (MPC102T)

THEORY **60Hours**

Scope: 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:

The aim of the course is to impart knowledge to the students of:

- Nucleophilic aliphatic substitution,
- lectrophilic aromatic substitution
- Elimination reaction,their mechanism and applications.
- Knowledge of some named organic reactions, synthetic reagents and their application will be imparted.
- Another important objective of the course is to introduce the student to the chemistry of heterocyclic compounds as drugs, by and large, have heterocyclic rings.
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Unit-I

Nucleophilic aliphatic substitution: **12Hours**

S_N1 and S_N2 reactions; mechanism and kinetics; structure and reactivity; stereochemistry; SN1 Vs SN2; role of solvent; substitution Vs elimination; necleophilic substitution – alkyl halides Vs alcohols; SN1 and rearrangement; stability of carbocations, carbanions, free radicals, carbenes and nitrenes:Their method of formation and synthetic applications.

Unit-II **10Hours**

Electrophilic aromatic substitution: reactions; mechanism; proof for the mechanism; sulfonation – a reversible reaction; theory of reactivity; theory of orientation; orientation and synthesis.

Unit-III **10Hours**

Elimination reactions: E1 and E2 mechanisms of alkyl halides and alcohols; evidence; E1 Vs E2; elimination Vs substitution; 1,1 and 1,2- elimination; E1CB; Saytzeff's rule; Hofmann rule/elimination; stereochemistry of E2 reactions; elimination from alicyclic compounds.

Unit-IV **14Hours**

a) **Study of mechanism and synthetic applications of following named Reactions**:Ugi reaction, Diekmann reaction, Sandmeyer reaction, Mannich reaction, Vilsmeyer-Haack reaction, Beckmann rearrangement, Fries rearrangement, Phillip's condensation and Michael addition reaction.

b) Synthetic Reagents & Applications:

Aluminium isopropoxide, N-bromosuccinamide, diazomethane, dicyclohexyl carbodimide, Witting reagent, Osmium tetroxide, diethyl azodicarboxylate,Triphenyl phosphine, Lithium aluminium hydride, Sodium borohydride, DCC (N,N-diacylohexyl carbodiamide) reagent.

Unit-V **14Hours**

A.Heterocylic chemistry: Structures of heterocylic compounds; aromatic and nonaromatic heterocylces; nomenclature;

B.Five-membered ring compounds with one heteroatom: Pyrroles, Furans and Thiophenes; Aromaticity; acidity; basicity; two synthetic methods for each class; reactions; electrophillic substitution; reactions with acids, carbenes, nitrenes; oxidizing and reducing agents; Diels-Alder reaction; photochemical reactions; alkylation of pyroles; metalation of furans; reactions of thiophenes with nucleophiles.Compare the reactivity of Pyrroles, Furans and Thiophenes.

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C.Six-membered heterocyclic ring compounds with one heteroatom: Pyridines: nomenclature; physical and spectroscopic properties; tautomerism; synthetic methods; chemical reactions – with acids, electrophilic and nucleophilic substitution, Diels-Alder reactions, quaternization, reaction with oxidizing and reducing agents; hetaryne formation; ring opening reactions; reactions with free radicals; photochemical reactions; the Claisen rearrangement; derivatives of pyridine – alkyl and aryl pryidinesl halopyridines, aminopyridines, pyridine N-oxide, hydroxypyridines, pyridine aldhydes and ketones

D. Synthesisof heterocyclic compounds:

Two methods of synthesis and reactions of the following heterocylic compounds or their derivatives; a) quinolines b) isoquinolines c) indoles d) pridazines e) pyrimidines f) pyrazines g) thiazoles h) imidazoles i) oxazoles

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 Woihers., Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Pearson Education Lts, 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, Tandom and Gowel, Oxford & IBH Publishers.
7. Principles of Organic Synthesis, ROC Norman and JM Coxan, Nelson Thorns.
8. Organic Synthesis - Special Techniques. VK Ahluwalia and R Agarwal, Narosa Publishers.
9. Organic Reaction Mechanisms IVth Edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.
10. Heterocyclic Chemistry – J.A.Joule, K.Mills and G.F. Smith 3rd Edition, CRC press.
11. Heterocyclic Chemistry – Thomas L.Gilchrist, 3rd Edition, Pearson publications
12. Heterocyclic Chemistry – Raj K. Bansal, 7th Edition, New age International Publishers.

ADVANCED MEDICINAL CHEMISTRY (MPC 103T)

THEORY **60 Hrs**

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.

Objective:

The objective of the course is to impart knowledge in

- 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
- The course is also imparts knowledge about different classes of drugs, their origin, mechanism of action, use, toxicity etc.

Unit-I **12Hours**

A brief review of the following topics:

a. Sources Of New Drugs;
b. Leads From Natural Products;
c. Molecular Modifications;
d. Random Screening;
e. High Throught Put Screening;
f. In silico Screening;
g. Structural Features And Pharmacological Acivity;
h. Prodrugs;
i. Soft Drugs;
j. Isosterism

Unit-II **12Hours**

An account of their origin and development, classification, structures, mechanism of action, SAR, uses and toxicity of:

a. Analgesics (non-opioid) and antipyretics
b. Non-steroidal anti-inflammatory agents
c. Synnthesis of Paracetamol, Ibuprofen, Aceclofenac
d. Antidiabetic agents
e. Synnthesis of Tolbutamide, Chlopropamide, Glipizide, Glimepride, Metformin
d. Screening methods of these classes

Unit-III **12Hours**

An account of their origin and development, classification, structures, mechanism of action, SAR, uses and toxicity of:

a. β-Adrenergic blockers
b. ACE inhibitors
c. Diuretics
d. Synthesis of Propranolol, Hydralazine, Minoxidil, Captopril, Lisinopril, Furosemide,Hydrochlorthiazide
e. H_1- receptor antagonists
f. H_2-receptor antagonists
g. Gastric-Proton Pump Inhibitors
h. Synthesis of Levocitrizine, Ranitidine, Omeprazole
i. Screening methods of these classes

Unit-IV **12Hours**

An account of their origin and development, classification, structures, mechanism of action, SAR, uses and toxicity of:

a. Anthihyperlipidemic agents
b. Phosphodiesterase inhibitors
c. Quinolone antibacterial agents.
d. Screening methods of these classes

Unit-V **12Hours**

An account of their origin and development, classification, structures, mechanism of action, SAR, uses and toxicity:

a. Anticancer agents
b. Antiviral agents
c. Immunosupressants and immunostimulatns
d. Synthesis of Chlorambucil, Methotrexate, Stavudine
e. Screening methods of these classes

Books Recommended:

1. Textbook of Wilson and Gisvolds organic medicinal and pharmaceutical by Charles Owens Wilon, 12th edition , 2010, publisher: Lippincott Williams & Wilkins .Foye's principles of medicinal chemistry
2. Burger's medicinal chemistry and drug discovery
3. Organic chemistry of synthetic drugs – Lednier
4. Screening methods in pharmacology – Robert A. Turner.
5. Drug Evaluation – Vogel.
6. Evaluation of Drug Activities – Lawrence and Bachrach.
7. Methods in Pharmacology – Swarbrick.
8. Medicinal Chemistry-Surendranath Pandeya,Volume I and Volume II
9. Medicinal Chemistry-Ashutosh kar, New Age International Publications
10. Pharmacopoeias

CHEMISTRY OF NATURAL PRODUCTS (M P C 104 T)

THEORY **60Hrs**

Scope:
The subject is designed to provide a detailed knowledge about chemistry, biological activity, mechanism of action, SAR, toxicity, and use of medicinal compounds of natural origin, their semisynthetic derivatives and development of clinically used drugs taking natural products as leads.

Objectives:
The objectives of this course are to impart knowledge to students of :

- Different types of natural compounds, their chemistry and medicinal importance.
- How natural compounds act as drugs per se and as lead molecules in drug discovery.
- How structures are important for biological activity and how a change in structure affects biological activity.
- How biotechnology is contributing to the development of pharmaceuticals of natural origin.

UNIT - I **10Hrs**

(a) **Natural products as leads in drug discovery and development :**
How natural products acted as lead molecules in drug discovery and development with emphasis on the source of the natural compound, history/origin, how synthetic drugs were devoloped from them .
From:

a. Salicin to aspirin
b. Quinine to antimalarials
c. Cocaine to local anaesthetics
d. Curare alkaloids to neuromuscular blocking drugs.
e. Fungal metabolites to modern statins
f. Snake venom to antihypertensives

(b) Recombinant DNA technology and drug discovery.

UNIT - II **10Hrs**

a. **Alkaloids of opium:** Structure of morphine; peripheral groups;
modification in pheripheral groups and effect on analgesic / biologic activity; relative potencies; opioid receptors; endorphins and enkephalins.
b. **Ring analogues of morphine;** morphinans-levorphanol and butorphanol; benzomorphans-pentazocine and phenazociane; aminotetralins-dezocine;4-phenylpiperidines-meperidine (pethidine); 4-Anilidopiperidines or the fentanyl group-fentanyl, alfentanyl, sufentanyl, remifentanil, lofentanil; diphenylheptanone derivatives-methadone; structures; receptor affinities; relative potencies; advantages of these compounds; structural difference
between 4-phenyl and 4-anilidopiperidines.
c. **Opioid antidiarrheals-**How structural modification of 4-phenylpiperidines and methadone led to the discovery of diphenoxylate and loperamide structures. Mode of action; usage; metabolism

of diphenoxylate; diphenoxin ; combination with atropine; binding of these compounds to opioid receptor; abuse potential; use.

d. **Antitissue agents (opioid)**

Study of codeine, hydrocodone hydromorphone, noscapine,
dextromethorphan, levopropoxyphene, pholcodine. Their structures, relative advantages, uses. Relationship between levorphanol and dextromethorphan; between levopropoxyphene and methadone.

e. **Morphine antagonists-** Nalorphine, levallorphan, naloxone, naltrexone,nalmefene, cyclazocine. Structures; a comparative study of the structures of levorphanol and levallorphan, oxymorphone, naloxone and naltrexone, cyclazocine and pentazocine; receptor affinities; relative advantages, uses.

UNIT - III **10Hours**

Anticancer agents of natural origin :

a.Anticancer agents of plant origin: Source; structures; description of the structural features; SAR; semisynthetic derivatives; mechanism of action; toxicity; and uses of :

(1)Vincristine and vinblastine

(2) Podophyllotoxin

(3) Taxol

(4) Camptothecin

(b) Anticancer antibiotics: source; structures; descriptions of the structural features; mechanism of action; SAR; and uses of the following antibiotics :

(1)Dactinomycin

(2)Daunorubicin, doxorubicin (adriamycin), idarubicin; metabolism of daunorubicin and doxorubicin; analogous of doxorubicin - esorubicin,
epirubicin, pirarubicin, valrubicin.

(3)A brief account of nogalamycin, menogaril, mithramycin, mitomycins,streptozocin

(c) Anticancer agents from marine organisms: bryostatin, dolostatin .

Unit IV **20Hours**

Steroids:

(a) **Definition**; numbering the carbons and labelling the rings; some basic steroid skeleta; nomenclature; sterochemistry; chemical and physical properties of steroids; changes to modify pharmacokinetics properties of steroids.

(b) **Sources of steroid drugs:** source and structures of cholesterol, ergosterol, stigmasterol and diosgenin, history of development of steroid industry. Marker's synthesis .

(c) **Steroidal antiinflammatory agents:** structures; SAR; routes of
administration; main pharmacologic effects - immuno-suppression, anti-allergic and antiinflammatory; therapeutic users; toxicity; contraindications; esters and salts of corticoids and their formulation suitability. A detailed study of the following classes with additional information indicated.

(i) **Systemicglucocorticoids**: list of compounds and their derivatives; classification; interconversion of cortisone and hydrocortisone; prednisone and prednisolone; rationale behind development of so many glucocorticoids; effect of substituent groups on glucocorticoid / mineralocorticoid activity; relative potencies; derivatives; formulation.

(ii) **Topical glucocorticoids**; systemic absorption; determining relative potency; classification; compounds used; formulations; the 21-chloro corticoids; non-fluorinated compounds; their relation to known corticoids; metabolism of prednicarbate and its low systemic side effects.

(iii) **Inhaled and intranasal glucocorticoids**: pharmacokinetics properties/qualities desirable for these compounds; modification of pharmacokinetics through modification of structures and its consequences; special qualities of the new inhaled and intranasal glucocorticoids; characteristics of inhaled glucocorticoids used in asthma and allergic rhinitis; names of inhalers.

(iv) **Ophthalmic glucocorticoids**: Difference in structure between ophthalmic and other glucocorticoids.

(d) **Steroidal antifertility agents:** History; estrogens; pregnane progestins;androstanes; importances of ethisterone; development of 19-norandrostanes; structures; mechanism of action; role of estrogens; regimens; toxicity; metabolism of desogestrel and norgestimate; androgenic activity; uses of medroxyprogesterone, norethindrone, magestrol acetate. Progestin antagonists. Steroid receptors - new insights.

(e) **Anabolic steroids:** Rationale for development; 19-norandrogens (19-nortestosterone derivatives); androstanes; oxasteroids; heterocyclic ring fused compounds; experimental compounds; structures; therapeutic uses; side effects.

(f) **Steroids in the treatment of cancers:** Estrogens; antiestrogens;aromatase inhibitors; progestins; progestin antagonists; androgens and anabolic steroids; antiandrogens; 5α- reductase inhibitors;gonadotropin inhibitors; glucocorticoids.

UNIT V **10Hours**

Cephalosporins:

Historical background; classification; structures; numbering the ring system; nomenclature; degradation; spectrum of activity; SAR; β-lactamase resistance; antipseudomonal cephalosporins; mechanism of action; uses; toxicity; development of new cephalosporins-recent advances; prodrugs in cephalosporins; penicillins Vs cephalosporins-a comparative account of the structural features and biological activity; β-lactamase inhibitors; mechanism of β-lactamase inhibition; monobactams.

REFERENCE

1. Textbook of Wilson and Gisvolds organic medicinal and pharmaceutical by Charles Owens Wilon, 12th edition, 2010, publisher: Lippincott Williams & Wilkins.
2. Foyes principles of medicinal chemistry, 7th edition by Lemke, Thomas L, 8th edition, 2019, Lippincott Williams & Wilkins.
3. Burgers medicinal chemistry, drug discovery and development by Donald J.Abraham, 8 volumes, 8th edition, 2021.
4.Organic Chemistry Of Natural Products, volumes 1&2, Gurdeep Chatwal, Himalaya publishing house.
5. Organic chemistry of natural products, volumes 1&2, O.P.Agarwal.
6. Organic chemistry, volume 2, I.L.Finar, 5th edition, 1975.
7. Elements of biotechnology, P.K.Gupta, Rastogi publishers.
8. Pharmaceutical biotechnology, S.P.Vyas & V.K.Dikshit, CBS Publishers.

CHEMISTRY OF NATURAL PRODUCTS (MPC 105 P)

1. Isolation and purification of some of the following natural products.
    a. Piperine from black pepper
    b. Strychnine and Brucine from Strychnos nuxvomica seeds
    c. Caffeine from Tea Powder
    d. Curcumin from Turmeric
    e. Bixin from Bixa orellana seeds
    f. Diosgenin from Diascoria tubers
    g. Sennosides from Senna leaves
    h. Embelin from Emblica ribes fruits

    The use of column, flash and vacuum liquid chrmatographies for isolating some of the above mentioned phytoconstituents.
1. Identification of alkaloids in mixture by TLC.
2. Preparative TLC for separation and isolation
3. Identification of phytoconstituents like alkaloids, steroids, flavanoids etc in plant extracts by TLC.
4. Separation of sugars/amino acids by paper chromatography.
5. Separation of compounds by HPLC
6. Analysis of recorded spectra of some simple organic compounds.
7. Tests to detect alkaloids, steroids, flavanoids and their glycosides.

Books Recommended:

1. Natural products, a laboratory guide – Rephael Ikan.
2. Laboratory hand book for the fraction of natural extracts – Peter J. Houghton & Amala Raman.
3. An Atlas of TLC – H. Wagner.

ADVANCED MEDICINAL CHEMISTRY –I (MPC106P)

1. Synthesis, purification and identification some of the following drugs.

a) Sulfanilmide b) Uracil c) Phenytoin d) Ibuprofen e) para-Amino salicylic acid (PAS) f) Paracetamol g) Atenolol (h) proranolol. i) Benzocaine

2. Screening for the following activities

. CNS – Rota rod experiment Catatonia testing
. Experiments on isolated tissues – Testing for anti-histaminic and anti-cholinergic activities.
. Local anesthetic activity.

3. Spectral analysis:

. Spectra to be recorded for some compounds and analyzed.
. Analysis of pre-recorded spectra.

Books Recommended:

Practical Organic Chemistry – Vogel.

Organic chemistry of synthetic drugs – Lednicer.

SEMESTER-II

Spectroscopic Identification of Organic Compounds (MPC201T)

THEORY **60 Hours**

Objective:

Students of M. Pharm, Pharmaceutical/Medicinal Chemistry branch carry out research in III and IV semesters. They synthesize organic compounds or isolate natural compounds and screen them for biological activity. They have to characterize the compounds. This helps in identifying organic compounds by spectroscopic means.The aim of this course is to train the student in the spectroscopic techniques so that he will be able to interpret different spectra and elucidate/confirm the structure of compounds he has isolated/ synthesized. Therefore, the emphasis while teaching the subject should be on the applications of the techniques. A detailed study of applications of the following spectroscopic techniques in the determination of structure of the following classes of compounds with the help of simple examples is to be taught. (i) Alkanes and cycloalkanes (ii) Alkenes and alkynes (iii) Aldehydes and ketones (iv) Alcohols and phenols(v) Carboxylic acids and derivatives (vi) Aromatic compounds and arenes (vii) Amines (viii) Alkyl and aryl halides (ix) Simple heterocyclic compounds.

The following techniques to be taught:

Unit I: **10 Hours**

a. **UV Spectroscopy**: Woodward-Fieser rules; Applications of UV-Visible spectroscopy in structural elucidation; Study of keto-enol tautomerism; Solving problems. **(3-4 Hours)**
b. **IR spectroscopy:** Theory and instrumentation in brief. Molecular vibrations; Factors influencing vibrational frequencies; Sampling techniques; Finger print region; Study of Keto-enol tautomerism; intra & inter-molecular hydrogen bonding; Studying progress in Chemical reactions; geometric and rational isomerism; Conformational analysis; spectral features of Classes of compounds indicated above. Solving problems. **(6-7 Hours)**

Unit II: Mass spectrometry: **12 Hours**

Theory and instrumentation. Ionization techniques-EI, CI, ESI, FAB, MALDI etc. High resolution MS; Molecular ions; important features of molecular ion peak; Determination of molecular formula; Mc Lafferty rearrangement; Metastable ions or peaks; Isotope peaks, The nitrogen rule; general fragmentation modes; Fragmentation in the classes of compounds indicated above. Problems and their solution.

Unit III: ^{1}H NMR **10 Hours**

Theory and instrumentation in brief. Solvents; Number of signals chemical equivalence, stereochemical equivalence in predicting the number of signals. intensity of signals; Chemical shift; factors influencing chemical shift; Spin-Spin Coupling; Coupling Constants;long- range coupling; Shielding and deshielding; Magnetic anisotropy; Protons on oxygen and nitrogen; Proton exchange; NMR spectra of the classes of compounds indicated above. Problems and their solution.

Unit IV: ^{13}C NMR, DEPT and 2DNMR **18 Hours**

a. Differences between ^{1}H and ^{13}C NMR; Chemical shifts and scale; proton-coupled and proton- decoupled ^{13}C spectra; Off-resonance decoupling; Solvents; Coupling of carbon to deuterium, fluorine and phosphorus; Spectra of the classes of compounds indicated above. Problems and their solution.

b. An account of DEPT. Interpretation of DEPT spectra.

c.A brief account of the following 2D NMR techniques with emphasis on the interpretation of the spectra and their use.

(a) COSY (b) HETCOR (c) HSQC, HMBC (d)HMBC

Problems and their solution: Students are to be provided with the spectra of simple compounds and taught their interpretation. How they help in confirming the structural features, the ^{1}H and ^{13}C NMR assignments of compounds is to be taught.

UNIT V: Problems and their solution. **10 Hours**

Determination of structures using a combination of spectra/spectral data. Here the emphasis is on solving problems through interpretation of different spectra or data like UV, IR, Mass, ^{1}H and ^{13} C NMR including 2D-NMR spectra. Simple problems to be worked from books like Pavia, Silverstein, Field etc., mentioned under the "Books recommended" sections, apart from other books.

Books Recommended:

1. Organic Chemistry-Morrison and Boyd-along with the study guide.
2. Spectroscopy-Pavia, Lampman, Kriz, Vyvyan - Publisher: Book/cole, Cengage learning.
3. Spectroscopic methods of identification of organic compounds-Silverstein, Webster, Kiemle, Bryce. 8th edition - Wiley.
4. Structure elucidation by modern NMR, a work book - Duddeck, Detrich and Toth.
5. Elementary organic spectroscopy-Y. R. Sharma. Publisher:S.Chand.
6. Spectroscopy of organic compounds-P.S.Kalsi. Publisher : New Age International Publisher.
7. Organic structures from spectra- L.D.Field, H.L.Li, A.M.Magill-6th edition-Wiley.
8. Organic structures from 2DNMR spectra-L.D.Field, H.L.Li, A.M.Magill-Published 2015-Wiley.
9. Websites

ADVANCED ORGANIC CHEMISTRY – II (MPC 202T)

THEORY **60 Hours**

Objective :

The aim of the course is to impart knowledge to the student of:

- retrosynthesis
- chiral synthesis
- green chemistry
- peptide chemistry
- catalysis

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Unit I: **12Hours**

Synthonapproach and retrosynthesis applications

i. Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules.

Functional group interconvertion and addition (FGI and FGA), chemioselectivity, regioselectivity.

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.

Unit II: **12Hours**

Stereochemistry and chiral 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.**Chiral drug synthesis:** Introduction to chiral drugs; importance of stereochemistry in drug action; concepts of eutomer; distomer and eudesmic ratio, stereospecific and stereoselective synthesis; synthesis of chiral drugs like Ibuprofen, Propranolol, Ramipril, Levofloxacin.

Unit III **12Hours**

a. Green chemistry: Introduction, Green reagents; ionic solvents; phase transfer catalysis in green synthesis; application of phase transfer catalysts in green synthesis of heterocyclic compounds; Williamson's synthesis, Witting reactions.

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. Microwave assisted synthesis: Introduction; microwave reactions in water (Hofmann elimination, hydrolysis and oxidation); microwave reactions in organic solvents; solid state reactions; advantages of microwave technique.

Unit IV **12Hours**

a. Chemistry of peptides:
Definition, C-terminal and N-terminal concept,end group analysis, A brief account on pharmaceutical importance of peptides and proteins.
b. Coupling reactions in peptide synthesis
c. Principles of **s**olid 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
d. Segment and sequential strategies for solution phase peptide synthesis with any two case studies

Unit V **12Hours**
Catalysis:
Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages
a. Heterogeneous catalysis – Preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.
b. 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
c. Phase transfer catalysis- theory and applications

REFERENCES

1. "Advanced Organic chemistry, Reaction, mechanisms and structure", JMarch, John Wiley and sons, New York.
2. "Mechanism and structure in organic chemistry", ES Gould, Hold Rinchartand Winston,NewYork.
3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers., OxfordUniversity 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, Wily India
7. Principles of organic synthesis, ROCNorman and JMCoxan, Nelson thorns
8. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal,Narosa Publishers.
9. Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar,Narosa Publishers.
10. Theory and practice of Green Chemistry-Paul T Anastas and John C.Warner
11. New trends in Green Chemistry-V.K.Ahulwalia and M.Kidwai
12. Chiro Technology-Roger A.Sheldon

COMPUTER AIDED DRUG DESIGN (MPC 203T)

THEORY **60 Hrs**

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
- Analyze effectivity of new molecules from medicinal chemistry perspective
- Correlate biological responses of molecules with different attributes

Unit 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 : Hydrophobicity (The partition coefficient (*P*), The substituent hydrophobicity constant (π),*P* versus π); Electronic effects (The Hammett substituent constant (sigma σx), and steric effects (Taft steric and MR parameters) .Methods to calculate physicochemical parameters, with examples such as calculation of log P of chlorobenzene, benzamide and *m*-chlorobenzamide : Hammett equation Experimental and theoretical approaches for the determination of these physicochemical parameters explanation for steric and electronic factors and Craig plot and Topliss scheme. Quantitative Structure Activity Relationships(QSAR): 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.

Unit 2: Pharmacophore Mapping and Virtual Screening **12 Hrs**

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. Different chemical and drug databases used in virtual screening.

Unit 3: Molecular Modeling and Docking **12 Hrs**

a) Molecular and Quantum Mechanics in drug design. Brief introduction to DFT (Denisty Functional Theory)

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. Different types of Scoring functions. Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, choline esterase (AchE & BChE)

Unit 4: Molecular Properties and Drug Design 12 Hrs

a) Prediction and analysis of ADMET (Absorption, Distribution, Metabolism, Excretion and Toxicity) 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. methods and mathematical expressions, Protein structure validation, active site prediction

Unit 5: Molecular dynamic simulation (MDS) studies 12 Hrs

Introduction to MDS and software tools employed. Different file formats in GROMACS. Detailed process of protein in water and protein-ligand complex in water MDS. Analysis of MDS trajectories: RMSD (Root Mean Square Deviation), RMS F(Root Mean Square Square Fluctuation), Radius of Gyration and hydrogen bond analysis. Brief mathematical concept of MM- PBSA (Molecular Mechanics- Poisson-Boltzmann Surface Area)

REFERENCES

1. Computational and structural approaches to drug discovery, Robert MStroud 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, ElsevierPublishers.
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. Justin A. Lemkul. From Proteins to Perturbed Hamiltonians: A Suite of Tutorials for the GROMACS-2018 Molecular. Simulation Package [Article v1.0]. Living J. Comp. Mol. Sci. 2019, 1(1), 5068. https://doi.org/10.33011/livecoms.1.1.5068 (MDS) 8. https://doi.org/10.3390/pr9010071 Outi M. H. Salo-Ahen, Ida Alanko, et al., Molecular Dynamics Simulations in Drug Discovery and Pharmaceutical Development. Development. Processes 2021, 9, 71. https://doi.org/10.3390/pr9010071
9. Gonçalo C. Justino1,2 | Catarina P. Nascimento2 | Marta C. Justino2,3. Molecular dynamics simulations and analysis for bioinformatics undergraduate students. Biochem Mol Biol Educ. 2021;49:570–582. DOI: 10.1002/bmb.21512
10. Computational Medicinal Chemistry for Drug Discovery. Edited By Patrick Bultinck, Hans De Winter Wilfried Langenaeker, Jan P. Tollenaere
11. Ercheng Wang, Huiyong Sun, Junmei Wang, Zhe Wang, Hui Liu, John Z. H. Zhang, and Tingjun Hou. End-Point Binding Free Energy Calculation with MM/PBSA and MM/GBSA: Strategies and Applications in Drug Design Chemical Reviews 2019 119 (16), 9478-9508. DOI: 10.1021/acs.chemrev.9b00055
12. Tingjun Hou, Junmei Wang, Youyong Li, and Wei Wang. Assessing the Performance of the MM/PBSA and MM/GBSA Methods. 1. The Accuracy of Binding Free Energy Calculations Based on Molecular Dynamics Simulations. Journal of Chemical Information and Modeling 2011 51 (1), 69-82. DOI: 10.1021/ci100275a
13. Samuel Genheden & Ulf Ryde (2015) The MM/PBSA and MM/GBSA methods to estimate ligand-binding affinities, Expert Opinion on Drug Discovery, 10:5, 449-461, DOI: 10.1517/17460441.2015.1032936

ADVANCED MEDICINAL CHEMISTRY -II (MPC 204T)

THEORY **60 Hours**

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**.**

Objective:

The objective of the course is to impart an in-depth knowledge of synthetic drugs belonging to different classes, their origin, mechanism of action, SAR, use and toxicity.

Unit I: **12Hours**

Psychopharmacological agents: Biochemical basis of mental disorders; abnormal protein factors; endogenous amines and related substances; faulty energy metabolism; genetic disorders and nutritional disorders; phenothiazines – chemistry; synthesis. Screening methods; pharmacological actions; SAR; mechanism of action; uses; toxicity; ring analogues of phenothiazines; fluorobutyrophenones; Development of atypical antipsychotics. of Chlorpromazine, Prochlorperazine, Fluphenazine, Haloperidol.

Unit II: **12Hours**

Anxiolytics, Sedatives And Hypnotics:Screening methods;Benzodiazepines and related compounds; barbiturates; other classes; mechanism of acition, SAR; uses and toxicity Synthesis of Chlordiazepoxide, Diazepam, Alprazolam, Phenobarbital, Meprobamate**.**

Unit III: **12Hours**

Antidepressants: MAO inhibitors; tricylic antidepressants; SAR; mechanism of action; uses; toxicity other classes like: selective serotonin reuptake inhibitors, selective 5-HT and NE reuptake inhibitors; selective serotoninergic reuptake inhibitors and 5-HT2A antagonists; 5-HT1A agonists and partial agonists and α2-antagonists. Syntheis of Tranycypromine, Amitriptyline, Fluoxetine, Buspirone**.**

Unit IV: **12Hours**

Antiepileptics & CNS stimulants:

a.Antiepileptics: Screening methods; classification of epilepsies; symptoms; drugs used; classification; structural feactuers common to drugs; SAR; mechanism of action; toxicity and uses; synthesis of Diphenylhydantion, Carbamazepine, Sodium Valproate.

b. CNS stimulants: an account of the drugs with CNS stimulant activity; structures and uses.

Unit V: **12Hours**

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**.**

Books Recommended:

1. Wilson and Gisvold's text book of pharmaceutical organic medicinal chemistry.
2. Foye's principles of medicinal chemistry.
3. Burger's text book of medicinal chemistry
4. Organic chemistry of synthetic drugs – Lednicer.
5. Screening methods in pharmacology – Robert A. Turner.
6. Drug Evaluation – Vogel.
7. Evaluation of Drug Activities – Lawrence and Bachrach.
8. Methods in Pharmacology – Swarbrick.
9. Medicinal Chemistry-Surendranath Pandeya,Volume I and Volume II
10. Medicinal Chemistry-Ashutosh kar, New Age International Publications
11. Pharmacopoeias

ADVANCED ORGANIC CHEMISTRY – I (MPC205P)

Some of the following experiments to be taught.

1. **Basic Techniques:**

a) Calibration of thermometer and finding melting point, mixed melting point and boiling point.
b) Purification and drying of organic solvents
c) Crystallization
d) Distillation, Fractional Distillation, Distillation under reduced pressure

2. Separation and identification of organic compounds from binary mixtures:

Solid-solid, solid-liquid and liquid-liquid – atleast one mixture of each category to be done.

3. Synthesis of some of the following heterocyclic compounds:

a) Quinoline b) benzimidazole/derivative c) flavone/chromone d) indole/derivative e) phenothiazine f) oxazole/oxazolone g) benzoxazole h) 3,5 dimethylisoxazole

4. Some of the following reactions:

1. Beckmann rearrangement 2) Fries rearrangement 3) Acetylation, methylation 4) Metal/acid reductions 5) Oppenauer oxidation 6) Friedel-Craafts alkylation & Acylation 7) Nitration using different reagents

Books Recommended:

Practical Organic Chemistry – Vogel.

ADVNCED MEDICINAL CHEMISTRY (MPC206P)

1. Synthesis, purification and identification of some of the following drugs;
    a) Dapsone
    b) Benzocaine
    c) Hydralazine
    d) Imipramine
    e) Sufadiazine

2. Synthesis using microwave oven: one experiment to be conducted
3. Screening for the following activities:
    a) Analgesic activity
    b) Anti inflammatory activity
    c) Acute toxicity studies
    d) Antibacterial and antifungal activity
    e) Free radical scavenging and anti-oxidant activities

4. Spectral analysis
Spectra to be recorded for some compounds and analyzed.
Analysis of pre-recorded spectra

2. Impurity profiling for one or two sa

Books Recommended:

1.Practical Organic Chemistry – Vogel.
2.Organic chemistry of synthetic drugs – Lednicer.

PHARMACEUTICAL ANALYSIS

.MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA 101T)

THEORY **60 Hours**

Scope: The appreciable knowledge will be gained by the students in the Modern Analytical Techniques and can apply the theories in the Analysis of various bulk drugs and their formulations. The students will also be in a position to apply their knowledge in developing the new methods for the determination and validate the procedures.

Objectives: The course is designed to impart the knowledge in different analytical techniques like UV-Visible, IR, GC, HPLC etc so that it can be used in the analysis of bulk drugs and formulations.

UNIT I **12Hours**

Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation

A. Column Chromatography: Adsortion and partition, materials used for separation, solvent system, procedure and method of detection. Theory, principles involved in separation, apparatus, column materials, number of theoretical plates, elution, method of detection. Modifications like VLC, Flash, MPLC, their advantage over open column CC.

B. Paper Chromatography: Theory, different techniques employed, filter papers used, qualitative and quantitative detection

UNIT II **12Hours**

A. Thin Layer Chromatography: Theory, principles of separation, apparatus, coating materials, spotting, solvent systems, detection, Uses of TLC: Finding the number of compounds; the class of compounds; Testing for purity/ detection of impurities; identifying compounds-Co-TLC, Mixed TLC; isolating compounds in a pure form-preparative TLC; Two dimensional TLC.

B. HPTLC: Theory and principle, instrumentation, elution techniques and pharmaceutical applications

C. A comparative study; how is HPTLC is different from TLC, apparatus; Coating materials-particle size; detection; uses.

UNIT II **12Hours**

a. Gas Chromatography: Introduction, fundamentals, instrumentation, columns: preparation and operation, detection; derivatization.

b. HPLC and UPLC: Principles and instrumentation, solvents and columns used, Operational modes, detection and applications.

UNIT III **12Hours**

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 electrophores 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.

UNIT IV **12Hours**

A.UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect; Quantitative estimation of Riboflavin, Paracetamol, Diclofenac, Metronidazole,Aspirin..
B.IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier – Transform IR Spectrometer, Factors affecting vibrational frequencies, Quantitative estimation of APIs using IR spectroscopy.

UNIT V **12Hours**

A. Spectro flourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
B. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

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, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

ADVANCED PHARMACEUTICAL ANALYSIS-I (MPA 102T)

THEORY **60 Hrs**

Scope: The principles and procedures for the determination of various pharmaceutical bulk drugs and their formulations belonging to different categories are discussed in detail. The applications of the important reagents like MBTH, FC, PDAB, 2, 3, 5 - triPhenyltetrazolium salt , . 2,6 di - ChloroquinoneChlorimide ,N - (1-naphthyl) ethylenediaminedihydrochloride (B.M. Reagent), Carr price reagent etc. in the determination of the pharmaceuticals are also discussed.

Objective: The quantitative determination of various organic compounds is clearly understood. The spectral analysis, dissolution parameters and microbial assays are also learned.

UNIT I **12Hours**

a.Impurity and stability studies:

Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as perICH guidelines

b.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

c. Impurities in residual solvents:

General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents

UNIT II **12Hours**

A. and procedures involved in the determination of the official compounds in IP with the following analytical techniques

- A. Non-aqueous
- B. Oxidation-reduction
- C. Complexometric
- D. Diazotization methods
- E. Neutralization
- F. Acid – Base

B.A detailed study of the principles and procedures involved in the quantitative determination of the following organic functional groups

- A. Amines
- B. Esters
- C. Carbonyl compounds
- D. Hydroxy and carboxyl
- E. Amino Acids

UNIT III **12Hours**

a. Reference Standards: Types, preparation methods and uses.
b. **Principles and procedures** involved in using the following reagents in the determination of pharmaceutical dosage forms official in IP

a. MBTH (3-methyl-2-benzothiazolone hydrazone)
b. F.C. Reagent (Folin-Ciocalteu)
c. PDAB (para-Dimethyl Amino Benzaldehyde)
d. 2, 3, 5 - triPhenyltetrazolium salt
e. 2,6 di -ChloroquinoneChlorimide
f. N - (1-naphthyl) ethylenediaminedihydrochloride (B.M. Reagent)
g. Carr – Price Reagent
h. 2,4 – DNP

UNIT – IV **12Hours**

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.

UNIT-V **12Hours**

a. 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.

b. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)

c. Microbiological assays and Biological tests: Antimicrobial effectiveness testing, microbial limit tests, sterility test. Antibiotics-microbial assays, bacterial endotoxins test.

TEXT BOOKS:

1. Pharmaceutical Chemistry by Becket and Stanlake
2. Pharmaceutical Analysis by Higuchi, Bechmman and Hassan
3. Instrumental Methods of Chemical Analysis By B.K. Sharma
4. A Text Book of Pharmaceutical Analysis by Kennenth A. Conners
5. Organic spectroscopy by Y.R Sharma Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
6. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

REFERENCES:

1. Remington's Pharmaceutical Sciences by Alfonso and Gennaro
2. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D. Sethi
3. Indian Pharmacopoeia 2010
4. Journals (Indian Drugs, IJPS etc.)

PHARMACEUTICAL VALIDATION (MPA 103T)

THEORY **60 Hrs**

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.

Objective: 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

UNIT I **12Hours**

Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.

Validation of Manufacturing Equipment, Qualification of Analytical Instruments and Laboratory equipments.

UNIT II **12Hours**

Validation of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC.

Validation of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

UNIT III **12Hours**

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).

UNIT IV **12Hours**

Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP. Validate the manufacturing facilities

UNIT V **12Hours**

a. 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 pharmaceutica industry; Global ramification and financial implications.

b. Patent: 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.

c. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.

REFERENCES:

1. 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. Pharmaceutical Facilities: Design, Layouts and Validation, Potdar,Pharmamed Press
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, 2nd Ed.
10. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam

FOOD ANALYSIS (MPA 104T)

THEORY **60 Hrs**

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.

Objective 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
- Pharmaceuticals (API & Dosage forms)
- And also student shall have the knowledge on food regulations and legislations

UNIT I **12Hours**

a. Carbohydrates: Classification and properties of food carbohydrates, General methods of analysis 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

UNIT II **12Hours**

Probiotics: Definition, history, importance, mode of action, identification advantages and disadvantages of probiotics. Applications of Probiotics

UNIT III **12Hours**

Lipids: Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils.

UNIT IV **12Hours**

Vitamins: Classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series

UNIT V **12Hours**

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.

TEXT BOOKS:

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
6. 18th edition, 2005.Theory and Practice of Industrial Pharmacy by Lieberman and Lachman

REFERENCE BOOKS:

1. Remington's Pharmaceutical Sciences by Alfonso and Gennaro
2. David Pearson. The Chemical Analysis of Foods, 7th ed., Churchill Livingstone, Edinburgh, 1976.
3. Nielsen S. Introduction to the chemical analysis of foods. Jones & Bartlett Publishers, Boston, 1974
4. Indian Pharmacopoeia 2012

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB (MPA 105P)

LIST OF EXPERIMENTS:

1. Calibration of glasswares
2. Calibration of pH meter
3. Calibration of UV-Visible spectrophotometer
4. Calibration of HPLC instrument
5. Assay of Ibuprofen
6. Assay of Paracetamol
7. Determine the λ max of KMnO 4
8. Assay of metronidazole by using U.V spectroscopy
9. Assay of paracetamol by using U.V spectroscopy
10. Assay of aspirin by using U.V
11. Simultaneous estimation of paracetamol and caffeine
12. Colorimetric estimation of metronidazole by PDAB
13. Identification of Amino acids by Thin Layer Chromatography
14. Identification of Alkaloids by Thin Layer Chromatography
15. Identification of Amino acids by Papar Chromatography
16. Calibration curve of riboflavin by U.V
17. Assay of nimesulide by U.V
18. Assay of caffeine by HPLC
19. Assay of nimesulide by HPLC
20. Assay of aceclofenac by U.V
21. Simultaneous estimation of paracetamol and ibuprofen
22. Calibration of ondansetron
23. Determination of viscosity of different polymeric solutions
24. Effect Of Concentration On Viscosity

ADVANCED PHARMACEUTICAL ANALYSIS-I LAB (MPA 106P)

LIST OF EXPERIMENTS:

1. Assay of Diclofenac sodium by using U.V spectrophotometer
2. Spectrophotometric determination of nimesulide by colorimetry
3. Assay of ascorbic acid
4. Colorimetric estimation of metronidazole by vanilline
5. Colorimetric estimation of metronidazole by PDAB
6. Estimation of creatinine in urine by alkaline pictrate (jaffe's method)
7. Assay of aceclofenac by FC reagent
8. Assay of Atropine sulphate
9. Assay of ammonium chloride
10. Assay of magnesium carbonate
11. Assay of Mohr's salt
12. Determination of quinine sulphate by fluorimetry
13. Determination of amount of amine salts by titration in aqueous solutions
14. Assay of ascorbic acid
15. Asaay of riboflavin
16. Determination of sulphates by nephlometry
17. Potentiometric titration of strong acid and strong base
18. Potentiometric titration of weak acid and strong base
19. Conductometric titration of strong acid and strong base
20. Spectrophotometric determination of nimesulide by colorimetry

SEMESTER-II

ADVANCED INSTRUMENTAL ANALYSIS (MPA 201T)

THEORY **60 Hours**

Scope: This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are , X-ray crystallography, super critical chromatography and hyphenated techniques.

Objective: By the completion of topics the students will come out with the thorough knowledge of various spectral aspects of X-Ray, IR, SEM, ORD etc which help them in further projects works and also industrial opportunities.

Unit I: **10 Hours**

a. UV Spectroscopy: Woodward-Fieser rules; Applications of UV-Visible spectroscopy in structural elucidation; Study of keto-enol tautomerism; Solving problems. **(3-4 Hours)**

b. IR spectroscopy: Theory and instrumentation in brief. Molecular vibrations; Factors influencing vibrational frequencies; Sampling techniques; Finger print region; Study of Keto-enol tautomerism; intra & inter-molecular hydrogen bonding; Studying progress in Chemical reactions; geometric and rational isomerism; Conformational analysis; spectral features of Classes of compounds indicated above. Solving problems. **(6-7 Hours)**

Unit II: Mass spectrometry: **12 Hours**

Theory and instrumentation. Ionization techniques-EI, CI, ESI, FAB, MALDI etc. High resolution MS; Molecular ions; important features of molecular ion peak; Determination of molecular formula; Mc Lafferty rearrangement; Metastable ions or peaks; Isotope peaks, The nitrogen rule; general fragmentation modes; Fragmentation in the classes of compounds indicated above. Problems and their solution.

Unit III: ^{1}H NMR **10 Hours**

Theory and instrumentation in brief. Solvents; Number of signals chemical equivalence, stereochemical equivalence in predicting the number of signals. intensity of signals; Chemical shift; factors influencing chemical shift; Spin-Spin Coupling; Coupling Constants;long- range coupling; Shielding and deshielding; Magnetic anisotropy; Protons on oxygen and nitrogen; Proton exchange; NMR spectra of the classes of compounds indicated above. Problems and their solution.

UNIT IV **12 Hours**

a. Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.

b. Super critical fluid chromatography: Principles, instrumentation, pharmaceutical applications.

c. **Scanning electron microscope (SEM):** Principles, Instrumentation and applications. Optical Rotatory Dispersion (ORD), Circular Dichroism, Cotton effect, Octane rule and applications.

UNIT V **12 Hours**

a. DSC: Principle, thermal transitions, instrumentation (Heat flux and power- compensation designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, Sources of errors) and their influence, advantages and disadvantages, pharmaceutical applications.

b. DTA: Principle, instrumentation, advantage and disadvantage, pharmaceutical application, derivative differential thermal analysis (DDTA).

c. TGA: Principle, instrumentation, factors affecting results, advantages and disadvantages, pharmaceutical application.

REFERENCES:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
3. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
4. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
5. Organic Chemistry by I. L. Finar
6. Quantitative Analysis of Drugs by D. C. Garrett
7. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi

MODERN BIO-ANALYTICAL TECHNIQUES (MPA 202T)

THEORY **60 Hrs**

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

Objective: 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

UNIT I **12 Hours**

Extraction of drugs and metabolites from biological matrices: 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.

UNIT II **12 Hours**

Biopharmaceutical Consideration: 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.

UNIT III **12 Hours**

Bioanalysis and bioanalytical method validation:
a. Types of body fluids, requirement of analysis, matrix effects, non-biological analytical samples.
b. Bioanalytical method validation: USFDA and EMEA guidelines. Acceptance criteria in comparison to non-biological samples.

UNIT IV **12 Hours**
Cell culture techniques

a. 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.
b.Principles and applications of cell viability assays (MTT assays)
c. Principles and applications of flow cytometry.

UNIT V **12 Hours**

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, New York. 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 Jercy. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, New York, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jersey, 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

QUALITY CONTROL AND QUALITY ASSURANCE (MPA 203T)

THEORY **60 Hrs**

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, ocumentation, quality certifications, GLP and regulatory affairs.

Objective : The study of this subject builds the confidence in the minds on the students to develop and formulate high quality pharmaceutical products.

Unit I **12 Hours**

Concept of quality assurance, total quality management, philosophy of GMP, cGMP and GLP, organization and functioning of accreditation bodies: ISO 9000, ISO 14000, NBL and OSHA 18000

Unit II **12 Hours**

a. Organization and personal, responsibilities, training hygiene

b. Premises: Location, design, plan layout, construction, maintenance and sanitations, environmental control, sterile area, control of contamination

c. Equipments: selection, purchase, specifications, maintenance, clean in place, sterilized in place - Raw – materials; purchase specifications, maintenance of stores, selection of vendors, controls and raw materials

Unit III **12 Hours**

Manufacture and controls on dosage forms

a. Manufacturing documents, master formula records, batch formula records, standard operating procedures, Quality audits of manufacturing processes and facilities

b. In process quality control on various dosage forms sterile, biological products and non-sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc.

c. Guideline for Quality Assurance of Human Blood Products and large volume parenterals.

Unit-IV **12 Hours**

a. Packaging and labeling controls, line clearance and other packaging materials.

b. Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities – finished products release: quality review, quality audits and batch release document.

Unit V **12 Hours**

a. Distribution and Distribution records: Handling of returned goods recovered materials and reprocessing.

b. Complaints and recalls, evaluation of complaints recall procedures, related records and documents.

TEXT BOOKS:

1. The International Pharmacopoeia Vol 1,2,3,4, 3rd edition: General methods of analysis quality specifications for Pharmaceutical substances, Excipients, dosage forms.
2. Quality Assurance of Pharmaceuticals. A compendium of guidelines and related material Vol.1 and Vol.2, WHO (1999) 3. GMP- Mehra
4. Pharmaceutical Process Validation – Berry and Nash

REFERENCE BOOKS:

1. Basic tests for Pharmaceutical substances – WHO (1988)
2. Basic tests for Pharmaceutical substances – WHO (1991)
3. How to practice GMP's – P.P.Sharma
4. The Drugs and Cosmetic Act 1940 – Vijay Malik
5. Q.A. Manual - D.H. Shah
6. SOP Guide lines - D.H. Shah
7. Quality Assurance Guide – OPP

ADVANCED PHARMACEUTICAL ANALYSIS - II (MPA 204T)

Scope: The principles and procedures for the determination of various pharmaceutical bulk drugs and their formulations belonging to different categories are discussed in detail. The applications of the important reagents like GLC, GC-MS, HPLC, HPTLC, UV/Vis, LC-MS, MS-MS etc. in the determination of the pharmaceuticals are also discussed.

Objective: The qualitative and quantitative determination of various organic compounds is clearly understood. The chromatographic techniques, elemental analysis, evaluation of cosmetic products are also learned.

Unit I **12 Hours**

a. Elemental analysis such as determination of sodium, potassium, calcium, phosphorous, sulphur, chlorine, bromine and Iodine,
B. Optical rotator dispersion technique for the analysis of chiral compounds

Unit II **12 Hours**

An advanced study of the principles and procedures involved in the instrumental methods and applications of Flame Photometry, Fluorimetry, Nephelo - Turbidimetry and Refractrometry, Study of general principles and methods for the determination of Proteins, Carbohydrates, Fats, Crude fibre, Moisture and Nitrogen

Unit III **12 Hours**

a.Adulteration and Deterioration: Introduction, types of adulteration/substitution of herbal drugs, Causes and Measure of 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
b. Testing of natural products and drugs: Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products, protocol.

Unit IV **12 Hours**

a. 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.
b. 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.

Unit V **12 Hours**

a.Identification and quantitative determination of preservatives, Antioxidants, Colouring materials, Emulsifiers and Stabilizers in Pharmaceutical formulation
b.Methodology involved

Moisture content determination in dosage forms
Alcohol determination
Essential oil determination
Surfactant analysis

REFERENCES:

1. Remington's Pharmaceutical Sciences – Alfonso and Gennaro
2. Pharmaceutical Chemistry – Becket and Stanlake
3. Quantitative Analysis of Drugs in Pharmaceutical Formulations – P.D. Sethi
4. Pharmaceutical Analysis – Higuchi, Bechmman and Hassan
5. Theory and Practice of Industrial Pharmacy – Liebermann and Lachmann
6. Indian Pharmacopoeia – 1996
7. Instrumental Methods of Chemical Analysis – B.K. Sharma
8. A Text Book of Pharmaceutical – Kenneth A. Conners
9. P. Pharmaceutical Analysis – II. The experiments should be conducted based on theory

ADVANCED INSTRUMENTAL ANALYSIS (MPA 205P)

1. Preparation and In-process quality control test for immediate released tablets
2. System suitability parameters for shimadzu gradient HPLC
3. Analytical method development for given drug by using shimadzu gradient HPLC
4. 4.Determination of linearity and range by using shimadzu gradient HPLC
5. Determination of accuracy and precision by using shimadzu gradient HPLC
6. Determination of specificity by using shimadzu gradient HPLC
7. Determination of robustness by using shimadzu gradient HPLC
8. Determination of ruggedness by using shimadzu gradient HPLC
9. Determination of Limit of Detection and Limit of Quantitation by using shimadzu gradient HPLC
10. Analytical method development for IBUPROFEN by using U.V spectroscopy
11. Determination of linearity and range by using U.V spectroscopy
12. Determination of accuracy and precision by using U.V spectroscopy
13. Determination of specificity by using U.V spectroscopy
14. Determination of robustness by using U.V spectroscopy
15. Determination of ruggedness by using U.V spectroscopy
16. Determination of Limit of Detection and Limit of Quantitation by using U.V spectroscopy
17. Assay of ibuprofen by using U.V spectroscopy
18. Standard addition method in support of determination of accuracy of the method by using U.V spectroscopy
19. . Stability testing of drug substances as per ICH
20. Short term stability studies at different p H
21. p H dependent saturation solubility testing of given API
22. Determination of drug release kinetics of given CR tablets by dissolution testing method
23. Optimization of solvent system for immiscible liquids byternary phase diagram

ADVANCED PHARMACEUTICAL ANALYSIS-II PRACTICALS (MPA 206P)

1. Determination of Acid value
2. Determination of Fatty acid
3. Determination of Saponification value
4. Determination of Ester value
5. Determination of Peroxide value
6. Determination of Acetyl value
7. Determination of Iodine value
8. Determination of Hydroxyl value
9. Determination of the percentage of sodium chloride by Mohr's method
10. Determination of the percentage of sodium chloride by Volhard's method
11. Estimation of Sulphate ions by Nephelometry
12. Determination of Linearity and Range of an analytical method tp determine the content of sulphate ions by Nephelometry
13. Determination of Accuracy and Precision of an analytical method tp determine the content of sulphate ions by Nephelometry
14. Determination of LOD and LOQ of an analytical method tp determine the content of sulphate ions by Nephelometry
15. Determination of amount of amines present in HydroxtlaminHC
16. Estimation of Sodium ions by Flame photometry
17. Determination of unknown concentration of Quinine sulphatFluorometry
18. Determination of Quenching effect of Quinine sulphate by potassium iodide solution in Fluorometry
19. Estimation of unknown concentration of Glycerin by Abbe' Refractometry
20. Estimation of unknown concentration of Tartaric acid by Polarimetry
21. Assay of Diclofenac sodium and Paracetamol by SEM by using U.V spectrophotometer
22. Assay of Ibuprofen and Paracetamol by SEM by using U.V spectrophotometer
23. Assay of Diclofenac sodium by using U.V spectrophotometer 96

Semester III

MRM 301T - Research Methodology & Biostatistics

(Common to all specializations)

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. 10 Hrs

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 (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values. 10 Hrs

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. 10 hrs

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. 10 hrs

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care. 10 hrs

Reference Books

1. Philip Kotler and Kevin Lane Keller : Marketing Management , Prentice Hall of India , NewDelhi.

2.Arun Kumar , Meenakshi : Marketing Management ,Vikas Publishing, india