Revised Regulations for the Master of Pharmacy Degree Program (w.e.f. June 2016)

Credit Based Semester System

JSS UNIVERSITY

SRI SHIVARATHREESHWARA NAGAR
MYSURU – 570 015, KARNATAKA

CHAPTER – I: REGULATIONS

1. Short Title and Commencement

These regulations shall be called as "Master of Pharmacy (M. Pharm.) Degree Program - Credit Based Semester System (CBSS) of the JSS University, Mysuru" (M.Pharm-CBSS). They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by the authorities of the University.

2. Minimum qualification for admission

A Pass in the following examination

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.)

Provided that,

Every student, selected for admission to M. Pharm. program in JSS University, Mysuru 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: If the candidate had passed his/her qualifying degree (B.Pharm.) from universities other than JSS University, Mysuru, it is mandatory to submit a migration certificate obtained from the respective university.

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 JSS University, Mysuru.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

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

6. Attendance and progress

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

7. Program/Course credit structure

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

7.1. Credit assignment

7.1.1. Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory course consists of lecture (L) and Practical (P) course consists of hours spent in the laboratory/hospital. 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/hospital) 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/hospital hours per week throughout semester carries a credit of 2.

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

7.2. Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree by JSS University, Mysuru 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, Practicals, Seminars, Assignments, Research work, Discussions with the supervisor, Research Audits, Journal club and Co-Curricular activities over the duration of four semesters. The credits are distributed semester-wise as shown in Table-15.

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 log book, research audit, and Dissertation shall be maintained by the department / teaching staff of respective courses.

9. Course of study

The specializations offered in M.Pharm. Program are given in Table – 1.

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

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

The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Table – 2 to 14. 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 14.

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MCC101T	Cosmeceuticals – Biology	4	4	4	100
MCC102T	Cosmetics - Formulation Science	4	4	4	100
MCC103T	Quality Assurance	4	4	4	100
MCC104T	Safety and Efficacy Evaluation	4	4	4	100
MCC105P	Cosmeceutics Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
Semester II					
MCC201T	Cosmeceuticals	4	4	4	100
MPA203T	Cosmetic Analysis and Evaluation	4	4	4	100
MCC202T	Cosmectics- Industry and Regulatory	4	4	4	100
MPH203T	Computer Aided Drug Development System	4	4	4	100
MCC203P	Cosmeceutics Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MIP101T	Pharmaceutical Formulation Development	4	4	4	100
MIP102T	Advanced drug Delivery System	4	4	4	100
MIP103T	Drug Regulations and Intellectual Property Rights	4	4	4	100
MIP104P	Industrial Pharmacy Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
Semester II					
MPH202T	Advanced Biopharmaceutics and Pharmacokinetics	4	4	4	100
MIP201T	Scale up and Technology Transfer	4	4	4	100
MIP202T	Pharmaceutical Production Technology	4	4	4	100
MIP203T	Entrepreneurship Management	4	4	4	100
MIP204P	Industrial Pharmacy Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPA102T	Advanced Pharmaceutical Analysis	4	4	4	100
MQA102T	Quality control and Quality Assurance	4	4	4	100
MPA103T	Food Analysis	4	4	4	100
MPA104P	Pharmaceutical Analysis Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
Semester II					
MPA201T	Advanced Instrumental Analysis	4	4	4	100
MPA202T	Modern Bio-Analytical Techniques	4	4	4	100
MQA202T	Pharmaceutical Validation	4	4	4	100
MPA203T	Cosmetic Analysis and Evaluation	4	4	4	100
MPA204P	Pharmaceutical Analysis Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPB101T	Microbial And Cellular Biology	4	4	4	100
MPB102T	Bioprocess Engineering and Technology	4	4	4	100
MPB103T	Advanced Pharmaceutical Biotechnology	4	4	4	100
MPB104P	Pharmaceutical Biotechnology Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
Semester II					
MPB201T	Proteins and protein Formulation	4	4	4	100
MPB202T	Immunotechnology	4	4	4	100
MPB203T	Bioinformatics and Computer Technology	4	4	4	100
MPB204T	Biological Evaluation of Drug Therapy	4	4	4	100
MPB205P	Pharmaceutical Biotechnology Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPC101T	Advanced Organic Chemistry -I	4	4	4	100
MPC102T	Advanced Medicinal chemistry	4	4	4	100
MPC103T	Chemistry of Natural Products	4	4	4	100
MPC104P	Pharmaceutical Chemistry Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
Semester II					
MPA201T	Advanced Instrumental Analysis	4	4	4	100
MPC201T	Advanced Organic Chemistry -II	4	4	4	100
MPC202T	Computer Aided Drug Design	4	4	4	100
MPC203T	Pharmaceutical Process Chemistry	4	4	4	100
MPC204P	Pharmaceutical Chemistry Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH101T	Modified Release Drug Delivery System	4	4	4	100
MPH102T	Modern Pharmaceutics	4	4	4	100
MPH103T	Pharmaceutical Regulatory Affairs	4	4	4	100
MPH104P	Pharmaceutics Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
Semester II					
MPH201T	Molecular Pharmaceutics(Nano Tech and Targeted DDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH203T	Computer Aided Drug Delivery System	4	4	4	100
MPH204T	Cosmetics and Cosmeceuticals	4	4	4	100
MPH205P	Pharmaceutics Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPG101T	Advanced Pharmacognosy-I	4	4	4	100
MPG102T	Phytochemistry	4	4	4	100
MPG103T	Industrial Herbal drug technology	4	4	4	100
MPG104P	Pharmacognosy Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
Semester II					
MPG201T	Medicinal Plant biotechnology	4	4	4	100
MPG202T	Advanced Pharmacognosy-II	4	4	4	100
MPG203T	Indian system s of medicine	4	4	4	100
MPG204T	Herbal cosmetics	4	4	4	100
MPG205P	Pharmacognosy Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table – 9: Course of study for (Pharmacology)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPL101T	Advanced Pharmacology-I	4	4	4	100
MPL102T	Pharmacological and Toxicological Screening Methods-I	4	4	4	100
MPL103T	Cellular and Molecular Pharmacology	4	4	4	100
MPL104P	Experimental Pharmacology Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
Semester II					
MPL201T	Advanced Pharmacology II	4	4	4	100
MPL202T	Pharmacological and Toxicological Screening Methods-II	4	4	4	100
MPL203T	Principles of Drug Discovery	4	4	4	100
MPL204T	Clinical Pharmacology	4	4	4	100
MPL205P	Experimental Pharmacology practical- II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table – 10: Course of study for M. Pharm. (Pharmacy Practice)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPP101T	Clinical Pharmacy Practice	4	4	4	100
MPP102T	Pharmacotherapeutics-I	4	4	4	100
MPP103T	Hospital & Community Pharmacy	4	4	4	100
MPP104T	Clinical Research	4	4	4	100
MPP105P	Pharmacy Practice Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
Semester II					
MPP201T	Principles of Quality Use of Medicines	4	4	4	100
MPP202T	Pharmacotherapeutics II	4	4	4	100
MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	4	4	100
MPP204T	Pharmacoepidemiology & Pharmacoeconomics	4	4	4	100
MPP205P	Pharmacy Practice Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table – 11: Course of study for M. Pharm. (Pharmaceutical Quality Assurance)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MQA101T	Quality Management System	4	4	4	100
MQA102T	Quality Control and Quality Assurance	4	4	4	100
MQA103T	Product Development and Technology Transfer	4	4	4	100
MQA104P	Pharmaceutical Quality Assurance Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
Semester II					
MQA201T	Hazards and Safety Management	4	4	4	100
MQA202T	Pharmaceutical Validation	4	4	4	100
MQA203T	Audits and Regulatory Compliance	4	4	4	100
MQA204T	Pharmaceutical Manufacturing Technology	4	4	4	100
MQA205P	Pharmaceutical Quality Assurance Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table – 12: Course of study for M. Pharm. (Pharmaceutical Regulatory Affairs)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MRA101T	Good Pharmaceutical Practices	4	4	4	100
MRA102T	Pharmaceutical Regulations in India	4	4	4	100
MRA103T	International Pharmaceutical Regulations I	4	4	4	100
MRA104T	Clinical Research Regulations	4	4	4	100
MRA105T	Pharmaceutical Regulatory Affairs Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
Semester II					
MRA201T	Documentation and Regulatory Writing	4	4	4	100
MRA202T	Biologics Regulations	4	4	4	100
MRA203T	International Pharmaceutical Regulations II	4	4	4	100
MRA204T	Medical Device Regulations	4	4	4	100
MRA205P	Pharmaceutical Regulatory Affairs Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

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

Course Code	Course	Credit Hours	Credit Points
MRM101T	Research Methodology and Biostatistics*	4	4
-	Journal club	1	1
-	Discussion / Presentation (Proposal Presentation)	2	2
-	Research Work	28	14
	Total	**35**	**21**

***** Non University Exam

Table – 14: Course of study for M. Pharm. IV Semester
(Common for All Specializations)

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

Table – 15: Semester wise credits distribution

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

*Credit Points for Co-curricular Activities

Table – 16: Guidelines for Awarding Credit Points for Co-curricular Activities

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

Note: International Conference: Held Outside India
International Journal: The Editorial Office outside India

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

10. Program Committee

1. The M. Pharm. programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.

2. The composition of the Programme Committee shall be as follows:

   A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M.Pharm. specialization and four student representatives (two from each academic year), nominated by the Head of the institution.

3. Duties of the Programme Committee:

   i. Periodically reviewing the progress of the classes.
   ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
   iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.

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

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table – 17 – 28.

11.1. End semester examinations

The End Semester Examinations for each theory and practical course through semesters I to IVshall be conducted by the University except for the subject with asterix symbol (*) in table 28 for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the University.

Tables – 17: Schemes for internal assessments and end semester examinations (Cosmeceutics)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MCC101T	Cosmeceuticals – Biology	10	15	1 Hr	25	75	3 Hrs	100
MCC102T	Cosmetics - Formulation Science	10	15	1 Hr	25	75	3 Hrs	100
MCC103T	Quality Assurance	10	15	1 Hr	25	75	3 Hrs	100
MCC104T	Safety and Efficacy Evaluation	10	15	1 Hr	25	75	3 Hrs	100
MCC105P	Cosmeceutical s Practical I	20	30	6 Hrs	50	100	12 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MCC201T	Cosmeceuticals	10	15	1 Hr	25	75	3 Hrs	100
MPA204T	Cosmetic Analysis and Evaluation	10	15	1 Hr	25	75	3 Hrs	100
MCC202T	Cosmectics- Industry and Regulatory	10	15	1 Hr	25	75	3 Hrs	100
MPH203T	Computer Aided Drug Development System	10	15	1 Hr	25	75	3 Hrs	100
MCC203P	Cosmeceuticals Practical II	20	30	6 Hrs	50	100	12 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

Tables – 18: Schemes for internal assessments and end semester examinations (Industrial Pharmacy)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MIP101T	Pharmaceutical Formulation Development	10	15	1 Hr	25	75	3 Hrs	100
MIP102T	Advanced drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MIP103T	Drug Regulations and Intellectual Property Rights	10	15	1 Hr	25	75	3 Hrs	100
MIP104P	Industrial Pharmacy Practical I	20	30	6 Hrs	50	100	12 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MPH201T	Advanced Biopharmaceutics and Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100
MIP201T	Scale up and Technology Transfer	10	15	1 Hr	25	75	3 Hrs	100
MIP202T	Pharmaceutical Production Technology	10	15	1 Hr	25	75	3 Hrs	100
MIP203T	Entrepreneurship Management	10	15	1 Hr	25	75	3 Hrs	100
MIP204P	Industrial Pharmacy Practical II	20	30	6 Hrs	50	100	12 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

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

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analytical technique	10	15	1 Hr	25	75	3 Hrs	100
MPA102T	Advanced Pharmaceutical Analysis	10	15	1 Hr	25	75	3 Hrs	100
MQA102T	Quality Control and Quality Assurance	10	15	1 Hr	25	75	3 Hrs	100
MPA103T	Food Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA104P	Pharmaceutical Analysis-I	20	30	6 Hrs	50	100	12 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MPA201T	Advanced Instrumental Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA202T	Modern Bio-Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MQA202T	Pharmaceutical validation	10	15	1 Hr	25	75	3 Hrs	100
MPA203T	Cosmetic Analysis and Evaluation	10	15	1 Hr	25	75	3 Hrs	100
MPA204P	Pharmaceutical Analysis-II	20	30	6 Hrs	50	100	12 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

Tables – 20: Schemes for internal assessments and end semester examinations (Pharmaceutical Biotechnology)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPB101T	Microbial And Cellular Biology	10	15	1 Hr	25	75	3 Hrs	100
MPB102T	Bioprocess Engineering and Technology	10	15	1 Hr	25	75	3 Hrs	100
MPB103T	Advanced Pharmaceutical Biotechnology	10	15	1 Hr	25	75	3 Hrs	100
MPB104P	Pharmaceutical Biotechnology Practical I	20	30	6 Hrs	50	100	12 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MPB201T	Proteins and protein Formulation	10	15	1 Hr	25	75	3 Hrs	100
MPB202T	Immunotechnology	10	15	1 Hr	25	75	3 Hrs	100
MPB203T	Bioinformatics and Computer Technology	10	15	1 Hr	25	75	3 Hrs	100
MPB204T	Biological Evaluation of Drug Therapy	10	15	1 Hr	25	75	3 Hrs	100
MPB205P	Pharmaceutical Biotechnology Practical II	20	30	6 Hrs	50	100	12 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

Tables – 21: Schemes for internal assessments and end semester examinations (Pharmaceutical Chemistry)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPC101T	Advanced Organic Chemistry -I	10	15	1 Hr	25	75	3 Hrs	100
MPC102T	Advanced Medicinal chemistry	10	15	1 Hr	25	75	3 Hrs	100
MPC103T	Chemistry of Natural Products	10	15	1 Hr	25	75	3 Hrs	100
MPC104P	Pharmaceutical Chemistry Practical I	20	30	6 Hrs	50	100	12 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MPA201T	Advanced Instrumental Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPC201T	Advanced Organic Chemistry -II	10	15	1 Hr	25	75	3 Hrs	100
MPC202T	Computer Aided Drug Design	10	15	1 Hr	25	75	3 Hrs	100
MPC203T	Pharmaceutical Process Chemistry	10	15	1 Hr	25	75	3 Hrs	100
MPC204P	Pharmaceutical Chemistry Practical II	20	30	6 Hrs	50	100	12 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

Tables – 22: Schemes for internal assessments and end semester examinations (Pharmaceutics)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPH101T	Modified Release Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH102T	Modern Pharmaceutics	10	15	1 Hr	25	75	3 Hrs	100
MPH103T	Pharmaceutical Regulatory Affair	10	15	1 Hr	25	75	3 Hrs	100
MPH104P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	12 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MPH201T	Molecular Pharmaceutics(Nano Tech and Targeted DDS)	10	15	1 Hr	25	75	3 Hrs	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100
MPH203T	Computer Aided Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH204T	Cosmetic and Cosmeceuticals	10	15	1 Hr	25	75	3 Hrs	100
MPH205P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	12 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

Tables – 23: Schemes for internal assessments and end semester examinations (Pharmacognosy)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPG101T	Advanced Pharmacognosy-1	10	15	1 Hr	25	75	3 Hrs	100
MPG102T	Phytochemistry	10	15	1 Hr	25	75	3 Hrs	100
MPG103T	Industrial Herbal drug technology	10	15	1 Hr	25	75	3 Hrs	100
MPG104P	Pharmacognosy Practical I	20	30	6 Hrs	50	100	12 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MPG201T	Medicinal Plant biotechnology	10	15	1 Hr	25	75	3 Hrs	100
MPG202T	Advanced Pharmacognosy-II	10	15	1 Hr	25	75	3 Hrs	100
MPG203T	Indian system of medicine	10	15	1 Hr	25	75	3 Hrs	100
MPG204T	Herbal cosmetics	10	15	1 Hr	25	75	3 Hrs	100
MPG205P	Pharmacognosy Practical II	20	30	6 Hrs	50	100	12 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

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

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPL101T	Advanced Pharmacology-I	10	15	1 Hr	25	75	3 Hrs	100
MPL102T	Pharmacological and Toxicological Screening Methods-I	10	15	1 Hr	25	75	3 Hrs	100
MPL103T	Cellular and Molecular Pharmacology	10	15	1 Hr	25	75	3 Hrs	100
MPL104P	Pharmacology Practical I	20	30	6 Hrs	50	100	12 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MPL201T	Advanced Pharmacology II	10	15	1 Hr	25	75	3 Hrs	100
MPL202T	Pharmacological and Toxicological Screening Methods-II	10	15	1 Hr	25	75	3 Hrs	100
MPL203T	Principles of Drug Discovery	10	15	1 Hr	25	75	3 Hrs	100
MPL204T	Clinical Pharmacology	10	15	1 Hr	25	75	3 Hrs	100
MPL205P	Pharmacology Practical II	20	30	6 Hrs	50	100	12 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

Tables – 25: Schemes for internal assessments and end semester examinations (Pharmacy Practice)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPP101T	Clinical Pharmacy Practice	10	15	1 Hr	25	75	3 Hrs	100
MPP102T	Pharmacotherapeutics-I	10	15	1 Hr	25	75	3 Hrs	100
MPP103T	Hospital & Community Pharmacy	10	15	1 Hr	25	75	3 Hrs	100
MPP104T	Clinical Research	10	15	1 Hr	25	75	3 Hrs	100
MPP105P	Pharmacy Practice Practical I	20	30	6 Hrs	50	100	12 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MPP201T	Principles of Quality Use of Medicines	10	15	1 Hr	25	75	3 Hrs	100
MPP202T	Pharmacotherapeutics II	10	15	1 Hr	25	75	3 Hrs	100
MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	10	15	1 Hr	25	75	3 Hrs	100
MPP204T	Pharmacoepidemiology & Pharmacoeconomics	10	15	1 Hr	25	75	3 Hrs	100
MPP205P	Pharmacy Practice Practical II	20	30	6 Hrs	50	100	12 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

Tables – 26: Schemes for internal assessments and end semester examinations (Pharmaceutical Quality Assurance)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MQA101T	Quality Management System	10	15	1 Hr	25	75	3 Hrs	100
MQA102T	Quality Control and Quality Assurance	10	15	1 Hr	25	75	3 Hrs	100
MQA103T	Product Development and Technology Transfer	10	15	1 Hr	25	75	3 Hrs	100
MQA104P	Pharmaceutical Quality Assurance Practical I	20	30	6 Hrs	50	100	12 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MQA201T	Hazards and Safety Management	10	15	1 Hr	25	75	3 Hrs	100
MQA202T	Pharmaceutical Validation	10	15	1 Hr	25	75	3 Hrs	100
MQA203T	Audits and Regulatory Compliance	10	15	1 Hr	25	75	3 Hrs	100
MQA204T	Pharmaceutical Manufacturing Technology	10	15	1 Hr	25	75	3 Hrs	100
MQA205P	Pharmaceutical Quality Assurance Practical II	20	30	6 Hrs	50	100	12 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

Tables – 27: Schemes for internal assessments and end semester examinations (Pharmaceutical Regulatory Affairs)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MRA101T	Good Pharmaceutical Practices	10	15	1 Hr	25	75	3 Hrs	100
MRA102T	Pharmaceutical Regulations in India	10	15	1 Hr	25	75	3 Hrs	100
MRA103T	International Pharmaceutical Regulations I	10	15	1 Hr	25	75	3 Hrs	100
MRA104T	Clinical Research Regulations	10	15	1 Hr	25	75	3 Hrs	100
MRA105T	Pharmaceutical Regulatory Affairs Practical I	20	30	6 Hrs	50	100	12 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MRA201T	Documentation and Regulatory Writing	10	15	1 Hr	25	75	3 Hrs	100
MRA202T	Biologicals Regulations	10	15	1 Hr	25	75	3 Hrs	100
MRA203T	International Pharmaceutical Regulations II	10	15	1 Hr	25	75	3 Hrs	100
MRA204T	Medical Device Regulations	10	15	1 Hr	25	75	3 Hrs	100
MRA205P	Pharmaceutical Regulatory Affairs Practical II	20	30	6 Hrs	50	100	12 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

Note: The 12 Hours duration of end semester practical examination shall equally be distributed to two examination days.

Tables – 28: Schemes for internal assessments and end semester examinations (Semester III& IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
MRM101T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
-	Research work*	-	-	-	-	350	1 Hr	350
							Total	**525**
SEMESTER IV								
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Department Research Audit)	-	-	-	75	-	-	75
-	Research work and Colloquium	-	-	-	-	400	1 Hr	400
							Total	**500**

***Non University Examination**

11.2. Internal assessment: Continuous mode

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

Table – 29: Scheme for awarding internal assessment: Continuous mode

Theory	
Criteria	**Maximum Marks**
Attendance (Refer Table – 30)	8
Student – Teacher interaction	2
Total	**10**
Practical	
Attendance (Refer Table – 30)	10
Practical Record	05
Viva voce	05
Total	**20**

Table – 30: Guidelines for the allotment of marks for attendance

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

11.2.1. Sessional Exams

Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical sessional examinations is given below. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables 17 – 28.

Question paper pattern for sessinal theory examinations

I. Long Answers (Answer 1 out of 2) = 1 x 10 = 10
II. Short Answers (Answer 4 out of 5) = 4 x 5 = 20

Total = 30 marks

Question paper pattern for sessional practical examinations

I. Synopsis	=	10
II. Experiment - I	=	25
III. Experiment – II	=	15
IV. Viva voce	=	10

Total	=	60 marks
		---

12. Promotion and award of grades

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

13. Carry forward of marks

In case a student fails to secure a minimum of 50% of marks 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. Schedule for end semester examinations

The end semester examinations shall be conducted as per the schedule given in Table – 31. The exact dates of examinations shall be notified from time to time.

Table – 31: Tentative schedule of end semester examinations

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

Question paper pattern for end semester theory examinations

I. Long Answers (Answer 3 out of 4)	=	3 x 10 = 30
II. Short Answers (Answer 9 out of 11)	=	9 x 5 = 45

Total	=	75 marks

Question paper pattern for end semester practical examinations

I. Synopsis	=	15
II. Experiment - I	=	40
III. Experiment – II	=	30
IV. Viva voce	=	15

Total	=	100 marks
		---

16. Allowed to keep terms (ATKT):

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

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

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

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

17. Grading of performances

17.1. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in **Table – 32:**

Table – 32: Letter grades and grade points equivalent to Percentage of marks and performances

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

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

18. The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3, C4 and C5 and the student's grade points in these courses are G1, G2, G3, G4 and G5, respectively, and then students' SGPA is equal to:

$$\text{SGPA} = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4 + C_5G_5}{C_1 + C_2 + C_3 + C_4 + C_5}$$

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

$$\text{SGPA} = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4 * \text{ZERO} + C_5G_5}{C_1 + C_2 + C_3 + C_4 + C_5}$$

19. Cumulative Grade Point Average (CGPA)

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

subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier.The CGPA is calculated as:

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

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

20. Declaration of class

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

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

21. Project work

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

21.1. Discussion / Presentation:

21.1.1. Discussion: Every student shall spend a minimum of 1 hour per week with his/her supervisor to discuss about the research work. A Log book shall be maintained by the students that shall be endorsed by the supervisor regularly. The supervisor shall award a maximum of 15 marks for the discussinons held during III and IV semeseters.

21.1.2 Proposal Presentation / Research Audit: Every student shall be evaluated for the proposal presentation in the III semester and research audit (prior to the submission of dissertation) in the IV semester by the department faculty members for 35 marks and 60 marks for Proposal Presentation and Research Audit respectively.

21.2. Evaluation of Reseearch Work in III Semester

The progress of the research work done by the student shall be assessed by the project supervisor for a total of 350 marks based on the regularity, student work log book, and extent of literature review.

21.3. Evaluation of Reseearch Work in IV Semester

The internal and external examiners appointed by the University shall evaluate the research work 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	25 Marks
Methodology adopted	75 Marks
Results and Discussions	100 Marks
Conclusions and Outcomes	50 Marks
Total	**250 Marks**

Evaluation of Presentation:

Presentation of work	75 Marks
Question and answer skills	50 Marks
Communication skills	25 Marks
Total	**150 Marks**

22. Seminar / Assignment

122.1. Seminar: Each student shall be given a seminar topic by the department relevant to the field of specialization and the same shall be presented (for a minimum of 30 minutes per student) by the students as per the schedule given by the department. The seminar shall be evaluated for 50 marks by the department faculty members against each criterion given below. The average of the marks awarded by individual faculty members shall be submitted to the Universtiy.

Criteria for evaluation of seminar: The seminars shall be evaluated based on but not limited to the following criteria.

1. Format of the presentation
2. Clarity of the presentation
3. Communication skill
4. Effective use of audio visual aids
5. Extent of subject understanding
6. Relevance of references
7. Ability to defend/answer questions
8. Time management

22.2. Assignemnt: Each student shall be given an assignment topic (different from the seminar topic) by the department relevant to the field of specialization and the same shall be submitted (a minimum of 25 pages) as a typed and spiral bound book on or before the date given by the department. The assignment shall be evaluated for 50 marks by the concerned subject teacher pertaining to topic of the assignment.

Criteria for evaluation of assignement: The assignemnts shall be evaluated based on but not limited to the following criteria.

1. Relevance with the content
2. Use of source material
3. Organization and mechanical accuracy
4. Cohesion & coherence
5. Command on Language
6. Timely submission

23. Journal Club

Each student shall deliver a journal club presentation during his/her III and IV semester. The published research articles relevant to the field of specialization shall be selected for journal club discussion in consultation with the department faculty members and the same shall be presented (for a minimum of 30 minutes per student) by the students as per the schedule given by the department. The journal club presentation shall be evaluated for 25 marks by the department faculty members against each criterion given below. The average of the marks awarded by individual faculty members shall be submitted to the Universtiy.

Criteria for evaluation of journal club presentation: The journal club presentations shall be evaluated based on but not limited to the following criteria.

1. Format of presentation
2. Communication skills
3. Appropriate interventions made by the students (about methodology, sample size, statistical tools, etc.)
4. Discussions on the topic

24. Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the 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.

25. Award of degree

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

26. Duration for completion of the program of study

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

27. Revaluation / Retotaling of answer papers

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

28. Re-admission after break of study

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

SYLLABUS

COSMECEUTICS

(MCC)

COSMECEUTICALS-BIOLOGY (MCC101T)

Scope:

- To impart knowledge on the biological aspects of – skin and hair
- To understand basic problems associated with skin and hair.
- To understand the mechanism of Skin irritation, allergy and allergic reactions that are major causes for skin problems
- To equip students with the knowledge of alternate methods to animal testing.

Objectives:

- To have stronger scientific basis in developing cosmeceutical products.
- To appreciate and contribute to areas of alternate to animal testing.

Theory **60 Hours**

1. Skin **12 Hrs**

Structure and functions of skin, Baby's skin and problems unique to baby's skin, Age-associated morphological and histological changes in human skin. Difference between baby's skin and adult skin, Ethnic and gender differences in skin properties. Etiology and current treatment for psoriasis. Wound healing process

12Hrs

2. Immunology

Types of skin allergic reaction, immunological mechanism of skin allergy.

Terminologies used: Contact dermatitis, Irritant Contact Dermatitis, allergic Contact dermatitis, photo-irritant contact dermatitis, phototoxicity, contact urticaria syndrome

General concepts of skin irritancy: Principles and molecular mechanisms of skin irritation, evaluation, factors predisposing to cutaneous irritation. Cosmetic and occupational Irritants. **12Hrs**

3. Irritation study models

Artificial skin modeling – Human reconstituted epidermis and skin, Skin organ culture models and other new types of skin equivalents

Skin sensizitization and sensitivity testing, patch test, open patch test, prophetic patch test, repeated insult test, photo-patch test, Skin sensitivity testing for creams, deodorants and antiperspirants, depilatories , hair dyes, lipsticks and nail polish.

4. Nail and eye: **12Hrs**

Anatomy of nail.Common problems associated with nail- Brittleness ,striations, splitting, pitting and fungal infections. Anatomy and physiology of eye. Allergic reactions specific to eye.

12Hrs

5. Hair:

The Structure and Properties of Hair, hair growth cycle. Hair-fall aetiology and current treatment. Racial differences in hair structure.

Microbiology:

Pharmacopeial methods of evaluation of preservative efficacy.

REFERENCES

1. Harry's Cosmeticology. 8th edition
2. Poucher's perfume cosmetics and Soaps, 10th edition
3. Cosmetics - Formulation, manufacture and quality control PP.Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I.Maibach. 3rdedition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.
7. United states Pharmacoepia

COSMETICS – FORMULATION SCIENCE (MCC102T)

SCOPE:

- To impart knowledge on the fundamental principles of cosmetic product development.
- To understand key ingredients used in cosmetics and cosmeceuticals
- To understand the building blocks in the formulation of cosmetic products.

OBJECTIVES:

- Upon completion of the course, the students will be able to:
- Know various key ingredients used to develop cosmetics.
- Combine the ingredients together to develop cosmetics with desired sensory.

THEORY **60 HOURS**

Formulation Principles: **12Hrs**

a) Definition of Cosmetics as per EU and Indian Guidelines
b) Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and underarms. Examples of marketed product.
c) Formulation requirements for ethnic needs.
d) Cosmetic product development process

12Hrs

Formulation Building blocks:

a) Building blocks for different product formulations of cosmetics/cosmeceuticals:
b) Surfactants- Classification and application.
c) Emollients and rheological additives: classification and application.
d) Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy.
e) Perfumes; Classification of perfumes. Perfume ingredients listed as allergens.
f) Application of various product forms in cosmetics: Solution, creams, lotion, ointment, paste, gels, stick, tablets, capsules, powders and aerosol. Examples from marketed product.

3. Skin cleansing and care **12Hrs**

Dry skin, skin moisturisation,

Skin Cleansing: Building blocks and formulation of Soap, syndet bars, face wash, body wash, face mask. Their relative advantages and disadvantages

Skin Care: Classification, requirement of an Ideal skin cream.

Building blocks and formulation of cold cream, vanishing cream, moisturizing cream, moisturizing gel, body lotion, petroleum Jelly.

12Hrs

4. Hair

Hair Care**:** Ideal requirement of a shampoo.

Building blocks and formulation of shampoos, Hair conditioners, Hair oil , hair cream. and hair styling gels

Chemistry and formulation of Parapheylene diamine based Hair dyes.

12Hrs

5. Oral care, color cosmetics, deodorants and baby care

Oral Care: Ideal requirement of a toothpaste. Building blocks and formulation of tooth paste and mouth wash.

Color Cosmetics**:** Building blocks and formulation of Lipstick, Mascara, nail polish and Face Powder.

Deodorants and antiperspirants: Ingredients and mechanism of action

Baby Care: Approach to baby care formulations.

REFERENCES:

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

QUALITY ASSURANCE (MCC103T)

SCOPE:

This course deals with the various quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, documentation, to understand about validation types, methodology application and how it can be applied to industry and thus to improve the quality of the products. Impart fundamental knowledge about quality management Syste. This knowledge can be applied in QA of cosmetics.

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Objectives:

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

- The cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation.
- Explain the aspect of validation
- Apply the knowledge of validation to manufacturing, instruments and equipments
- To understand the quality evaluation of products
- Need of Quality management system in Industry
- This knowledge can be used to evolve stringent QA systems for cosmeceuticals

THEORY **60 HOURS**

12Hrs

1. **Introduction to Quality**

   Definition - Quality assurance and Quality control, concept of TQM, GMP, ICH, Brief study of ICH common technical documents – Q1-Q11, Quality by design, six sigma concept, ISO 9000 & 14000.

   Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, Quality audit reports and documents, quality reports, distribution records, Common Technical Document and Drug Master Files, Medical Devices, Electronic Common Technical Documentation, complaints and evaluation of complaints, Handling of return goods, recalling and waste disposal.

   12Hrs

2. **cGMP of Pharmaceutical manufacturing:**

   Evolution and Principles of cGMP, Schedule-M, WHO-GMP requirements, European Union (EU) and United States Food and Drug Administration (USFDA) guidelines on Pharmaceutical manufacturing. URS, FAT, DQ, SAT, IQ, OQ, PQ of machines and equipment.Clean room standards for different countries and names.

12Hrs

3. **Introduction to Pharmaceutical Validation:**
   Definition, Manufacturing Process Model, scope of Validation, Advantage of Validation, Organization for Validation, Validation Master plan, Types of validation, Design Qualification, Installation Qualification, Operational Qualification & Performance Qualification of facilities. A Review of Prospective, Concurrent, Retrospective Validation & Revalidation including the use of Statistical Process Control (SPC).

12Hrs

4. **Quality Management System :**
   Quality risk management**:** Introduction, risk assessment, risk control, risk review, risk Management tools, HACCP, risk ranking and filtering.
   Change Control, Deviation-(planned and unplanned), Corrective Action and Preventive Action (CAPA), Handling of nonconformance, Vendor evaluation process, Out of specification (OOS), Annual Product Review, batch reconciliation and finished goods release, Market recalls & Market complaints.

12Hrs

5. **Quality Control Process**
   In process quality control and finished products quality control for following formulation in pharma industry: Liquids – Suspension, Emulsion, solutions, Ointments, creams, Jelly's, Parenterals , ophthalmic.
   Quality control test for containers, closures and secondary packing materials.

REFERENCES

1. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
2. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
3. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
4. ICH guidelines
5. ISO 9000 and total quality management
6. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
7. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
8. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
9. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
10. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
11. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
12. Lachman L Liberman Theory and practice of industrial pharmacy by 3 rd edition
13. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.

SAFETY AND EFFICECY EVALUVATION (MCC 104T)

SCOPE

Have basic knowledge on the cell line safety studies, principles of animal testing and human clinical trials for application in cosmeceuticals and dermatological products.

OBJECTIVES:

Upon completion of the course, the student shall be able to have basic understanding of

- cell line studies
- Procedure and method of conducting safety and efficacy study using animals
- Procedure and stages of human clinical trials.

THEORY **60 HOURS**

1. Cell biology **12Hrs**

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

2. 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.

3. Principles of cell line studies **12Hrs**

Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays .
Principles and applications of flow cytometry
Principles of cell line studies -- Skin irritation, phototoxicity, mutagenicity genotoxiticity.
Melanocyte-keratinocyte coculture model to assess *in vitro* regulators of pigmentation.

4. Principles of preclinical Animal testing **12Hrs**

CPCSEA guidelines to conduct experiments on animals, Regulatory guidelines for conducting toxicity studies OECD.

General principles of preclinical screening, screening methods for Immunosuppressant and immunomodulators, antioxidants, and wound healing activity,

5. Human clinical studies: **12Hr**

Various Phases of clinical trails
Designing of methods of clinical trials (randomization and blinding)
Ethics in research:
Historical aspects - Helsinki declaration, Nuremberg code, Belmont report
Ethical guidelines for biomedical research on human participants-ICMR
Ethical committee constitution, responsibilities and procedure
Informed consent process
Roles and responsibilities of clinical trial personnel as per ICH GCP (sponsor, investigator, clinical research associate, clinical research coordinators, auditors and regulatory authority)
Designing of clinical study documents (case report form, protocol and informed consent)

12Hrs

6. 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

References:

1. Cooper, G. M., & Ganem, D. The Cell: A Molecular Approach.6th ed. Sinauer Associates. Sunderland, USA.
2. Dickenson, J., Freeman, F., Mills, C. L., Thode, C., & Sivasubramaniam, S. Molecular pharmacology: from DNA to drug discovery. John Wiley & Sons.
3. Helgason, C. D., & Miller, C. L. Basic cell culture protocols. Totowa, NJ.: Humana Press.
4. Davis, J. M. (Ed.). Basic cell culture: a practical approach. IRL Press.
5. Masters, J. R. (Ed.). Animal cell culture: a practical approach (pp. 3-10). Oxford: Oxford University Press.
6. Ausubel, F. M. Current protocols in molecular biology: volume I-VI. John Wiley & Sons.
7. Gupta, S. K. Drug Screening Methods (Preclinical Evaluation of New Drugs). Jaypee publishers. New Delhi.
8. Ghosh, M. N. Fundamentals of experimental Pharmacology. 6th ed. Prof. M. N. Ghosh Publisher: Hilton and Company, Kolkata

9. Laurence, D. R., Bennett, P. N., & Brown, M. J. (1997). Clinical Pharmacology Churchill Livingstone. New York
10. Walker, R., & Edwards, C. Clinical pharmacy and therapeutics. Churchill Livingstone, London.
11. Shargel, L., & Swanson, L. N. Comprehensive pharmacy review. Lippincott Williams & Wilkins.
12. B. Masters., Anthony J. Trevor. Basic and Clinical Pharmacology. 12th ed. McGraw-Hill, Medical Publication Division, New York.

PRACTICALS(MCC105P):

Dermatology ward visits:

A) Visit to dermatology ward and Submitting case report on common skin problems
Specific examples: Acne, Litchen planus, Psoriasis, Rosacea, Sebbhoric dermatitis, Vitiligo, warts, Corns and calluses, eczema, Ichthyosis, dandruff, hair-fall, nail infections.

B) Analysis in detail selecting a specific skin problem.

Lab Practicals

1) Cytotoxicity studies using cell lines,
2) Preservative efficacy test
3) *In vitro* assay for antibacterial efficacy.
4) Isolation and identification of DNA from various sources (Bacteria)
5) Isolation of RNA from yeast
6)) Estimation of RNA/DNA by UV Spectroscopy
7) Gene amplification by PCR..
8) Cell viability assays (MTT/Trypan blue/SRB).
9) DNA damage study by Comet assay.
10) Development of skin cream cream, shampoo and toothpaste base

COSMECEUTICALS (MCC201T)

SCOPE:

- To impart knowledge on the fundamental principles of cosmeceuticals product development.
- To understand the building blocks in the formulation of cosmeceutical products.
- To develop knowledge in design and development of cosmeceuticals- focusing on safety, stability, sensory and delivery of actives.

OBJECTIVES:

Upon completion of the course, the students will be able to Know

- Various key ingredients used to develop cosmeceuticals.
- Combine the ingredients together to develop cosmeceuticals with desired sensory and efficacy.

THEORY **60 HOURS**

1. Sun protection, pigmentation and wrinkles **12Hrs**

Sun Protection: Solar spectrum, UV A and UV B rays of the sun. Skin damages caused by over exposure to sunlight, organic and in-organic sunscreens, SPF and Tan protection. Challenges in developing sunscreen formulations. Global regulatory aspects of sunscreen products. Case study on sunscreen products in the market.

Skin Pigmentation and Wrinkles: Melanogenesis and ethnic differences. Ways to control skin pigmentation. Actives and mechanism of action. Building blocks and formulation of a skin anti-blemish cream. Skin bleaches and skin lightening.
Case study on skin lightening products in the market.

Skin wrinkles: Factors that leads to skin wrinkles. Role of anti-oxidants in reducing skin wrinkles. Building block and formulation of an anti-wrinkle product. Case study on anti-aging/antiwrinkle product in the market.

12Hrs

2. Acne, Prickly heat, Dandruff and oral care

Causes for acne, prickly heat and dandruff and current treatment.
Building blocks and formulation of products for treatment of acne, prickly heat and dandruff.

Case study of marketed products.

Oral care:

Basic understating of the cause of Bleeding gums, sensitive teeth, plague, halitosis.
Role of antimicrobial agents, anti oxidants and astringents for oral care.
Denture cleansers. Building blocks and formulation of anti-cavity, tooth sensitivity relief and teeth-whitening tooth paste. Case study on the marketed products

12Hrs

3. Herbal Cosmetics

Herbal ingredients used in Hair care, skin care and oral care.
Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers.
Challenges in formulating herbal cosmetics.

12Hrs

4. Dermal Drug Delivery

Factors affecting dermal drug delivery. Role of penetration enhancers in dermal delivery.
Dermal drug delivery systems: Nano particles, Liposomes, patches, Ionotophoresis, sonophoresis, electroporation, micro-needles.

12Hrs

5. Packaging

Functions and principles of pack design. Plastics: Type of plastics and application
Metal, glass, laminates and paper boards. Basic principles in testing quality of packaging materials Relative merits and demerits of various packaging materials.

REFERNECES

1. Harry's Cosmeticology. 8^{th} edition.
2. Poucher's perfume cosmetics and Soaps, 10th edition
3. Cosmetics - Formulation, manufacture and quality control PP.Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I.Maibach. 3rdedition
5. S.P.Vyas and Roop K.Khar Controlled Drug Delivery system, Concepts and Advances
6. Cosmetic and Toiletries recent suppliers catalogue.
7. CTFA directory.

COSMETIC ANALYSIS & EVALUATION (MPA204T)

SCOPE

This course is designed to impart knowledge on analysis of cosmetic raw materials and finished products. Performance evaluation of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.

OBJECTIVES

At completion of this course student shall be able to understand

- Determination of physical constants of cosmetic raw materials
- Cosmetic raw materials, additives and their analysis
- Analysis of finished cosmetic products
- Principles of performance evaluation of cosmetic products.

THEORY **60Hrs**

12 hrs

1. Determination of acid value, ester value, Saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powders, density, viscosity of cosmetics raw materials.

   12 hrs

2. Study on the quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.

   12 hrs

3. Indian standard specifications laid down for sampling and testing of various cosmetics in finished forms such as baby care powders, skin care products, dental products, personal hygiene preparations, lips sticks, hair products and skin creams by the Bureau Indian Standards.

   12 hrs

4. Principles of equipment used to measure product performance of skin and hair care products - Sebumeter, corneometer, trans-epidermal water loss, Skin color, hair tensile properties, hair combing properties.
   Performance evaluation of shampoos, antiperspirants, deodorants, sunscreens, foam baths and abrasiveness of dentifrices.

   12 hrs

5. Study of specialized additives- quality parameters and analysis of rheology modifiers, preservatives, emollients, hair conditioners and fragrances

REFERENCES:

1. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi
2. Indian Standard specification, for raw materials, BIS, New Delhi.
3. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
4. Harry's Cosmeticology 8th edition
5. Suppliers catalogue on specialized cosmetic excipients
6. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
7. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition,

COSMETICS- INDUSTRY AND REGULATORY (MCC202T)

SCOPE:

- To impart knowledge on the basic regulatory aspects relating to cosmetics
- To understand the manufacturing equipments and GMP as per regulatory guidelines
- To understand the aspects of technology transfer from R&D to manufacturing.

Objectives:

Upon completion of the course, the students will be able to:

- Effectively design products and documentation that meets regulatory requirements
- Implement smooth transfer of technology from design stage to factory production.

Theory **60 Hours**

1. Indian Regulations **12Hrs**

Indian Regulation for cosmetics:

Regulatory provisions relating to import and manufacturing of cosmetics – conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

Misbranded and spurious cosmetics.

Indian regulatory requirement for factory premises, location and surrounding, designing of plant layout, building, light, ventilation, water supply, disposal of waste, first aid, packaging facilities, sanitation in manufacturing premises and health clothing and sanitary requirement of staff.

12Hrs

2. Manufacturing & ASEAN standards

Equipments used in the manufacturing of creams, shampoo and toothpaste. GMP guidelines as per ASEAN standards for cosmetics

12Hrs

3. European Union Guidelines

Summary of features of EU guidelines for cosmetics: Ingredients, safety assessment, labeling, the product information package, GMP, animal testing and efficacy testing. Cosmeceuticals as OTC and quasi drugs.

12Hrs

4. Technology transfer

Significance of pilot plant scale up studies.

Stability studies: Change in parameter to be observed, Photostability, accelerated stability testing- Temperature humidity, freest thaw and stress test. Aerosol product stability studies. Technology transfer of formulations from R&D to factory- Documentations.

12Hrs

5. Private Regulatory bodies:

a)Enviornmental and safety concerns of certain cosmetic ingredients that are debated and discussed. – Nano sized sunscreens, triclosan, formaldehyde liberators, Polythene beads, Sodium and ammonium laureth sulfates, phthalates.

b) Study of salient features of cosmetic safety data base developed by private body, and International Nomenclature of Cosmetic Ingredients (INCI).

c)Principles of cosmetovigilance.

d)Product claim development and advertisement; Role of ASCI.

REFERENCES

1. Harry's Cosmeticology. 8th edition
2. Cosmetics - Formulation, manufacture and quality control PP.Sharma, 4th edition
3. ASEAN definition of Cosmetics and illustrative list by category of Cosmetic products.
4. EU regulation (EC) no. 1223/2009 of the European parliament and of the council of 30th November 2009, on cosmetic products.
5. Theory and Practice of Industrial Pharmacy by Lachmann and Libermann

COMPUTER AIDED DRUG DEVELOPMENT SYSTEM (MPH203T)

Scope

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

Objectives

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

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

THEORY **60Hrs**

1. **Computers in Pharmaceutical Research and Development**: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameter ,Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling

   Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application

   12Hrs

2. **Computational Modeling Of Drug Disposition:** Introduction ,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.

   12 Hrs

3. **Computer-aided formulation development**:**:** Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis

   12 Hrs

4. **Computer-aided biopharmaceutical characterization**: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis,Virtual trial, Fed vs. fasted state, In vitro dissolution and *in vitro-in vivo* correlation, Biowaiver considerations

   Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.

   Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems

   12 Hrs

5. **Artificial Intelligence (AI), Robotics and Computational fluid dynamics:** General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

   12 Hrs

REFERENCES

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

PRACTICALS (MCC203P):

1. Design and formulate unique Cream, shampoo, face wash, toothpaste, moisturizing gel, lip balm, hair oil.
2. Study private body guidelines for green/premium cosmetics of Ecocert/Cosmos, and suggest changes in the formulations.
3. Design and Development of cosmeceutical product for the treatment of dry skin, wrinkles, acne, blemishes, dandruff, and bleeding gums.
4. Case study report of products in the market- Sun-protection, aging, acne, pigmentation, prickly heat, dandruff, hair-fall, teeth cavities, bleeding gums, teeth whitening, Comparing labeled formulation ingredients and product claims.
5. Quantitative analysis of rancidity in hair oils and Lipsticks
6 .Determination of aryl amine content and Developer in hair dye
7. Determination of foam height and SLS content of Shampoo.
8. Determination of total fatty matter in creams (Soap, Skin and hair Creams)
9. DoE Using Design Expert® Software
10.Formulation data analysis Using Design Expert® Software
11.Quality-by-Design in Pharmaceutical Development

INDUSTRIAL PHARMACY
(MIP)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUE (MPA101T)

Scope

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

Objectives

After completion of course student is able to know,

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

THEORY **60 HOURS**

UNIT I **12 Hrs**

UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, choice of solvents and solvent effect and applications of UV-Visible spectroscopy. **04 Hrs**

IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopy **04 Hrs**

Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectroscopy. **02 Hrs**

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications. **02 Hrs**

UNIT II **12 Hrs**

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 **08 Hrs**
Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. **04 Hrs**

UNIT III **12 Hrs**

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization techniques like electron impact, chemical, field desorption, FAB and MALDI, APCI, ESI, APPI Analyzers and detectors. Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

UNIT IV **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 V **12 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 **8 Hrs**

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. **4 Hrs**

REFERENCES

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

PHARMACEUTICAL FORMULATION DEVELOPMENT (MIP101T)

Scope

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

Objectives

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

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

THEORY **60Hrs**

12 Hrs

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

12 Hrs

2. Formulation Additives: Study of different formulation additivies, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science, determination methods, drug excipient interactions. Design of experiments – factorial design for product and process development.

12 Hrs

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

12 Hrs

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

12 Hrs

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

REFERENCES:

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, Varghese Publishers, Mumbai.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, B.I. Publications Pvt. Ltd, Noida.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets, CBS Publishers & distributors, New Delhi.
4. Conners KA. A Text book of pharmaceutical analysi Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England.
5. Yalkowsky SH. Techniques of solubilisation of drugs. Marcel Dekker Inc., . New York.
6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi.
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, CBS publications, New Delhi.
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, CBS Publishers & distributors, New Delhi.
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, Marcel Dekker Inc, New York.
11. W. Grimm - Stability testing of drug products.
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore.
13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I & II., CBS Publishers & distributors, New Delhi.
14. Indian Pharmacopoeia. Controller of Publication. Delhi.
15. British Pharmacopoeia. British Pharmacopoeia Commission Office, London.
16. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA.

ADVANCED DRUG DELIVERY SYSTEMS (MIP102T)

Scope

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

Objective

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

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

THEORY **60Hrs**

12 Hrs

1. **Concept & Models for NDDS:** Classification of rate controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release.
   Carriers for Drug Delivery: Polymers / co-polymers-introduction, classification, characterization, polymerization techniques, application in CDDS / NDDS, biodegradable & natural polymers.

12 Hrs

2. **Study of Various DDS:** Concepts, design, formulation & evaluation of controlled release oral DDS, Mucoadhesive DDS (buccal, nasal, pulmonary) Pulsatile, colon specific, liquid sustained release systems.

12 Hrs

3. **Transdermal Drug Delivery Systems:** Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems.
   Sub Micron Cosmeceuticals: Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, oral cavity, eye etc and it's regulatory aspects.

12 Hrs

4. **Targeted Drug Delivery Systems:** Importance, concept, biological process and events involved in drug targeting, design, formulation & evaluation, methods in

drug targeting – nanoparticles, liposomes, niosomes, pharmacosomes, resealed erythorocytes, microspheres, magnetic microspheres. Specialized pharmaceutical emulsions – multiple emulsions, micro-emulsions.

Protein / Peptide Drug Delivery Systems: Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stability and destabilization.

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

12 Hrs

5. **Dosage Forms for Personalized Medicine**: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.

REFERENCES:

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

DRUG REGULATIONS AND INTELECTUAL PROPRTY RIGHTS (MIP103T)

Scope

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

Objectives

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

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

THEORY **60Hrs**

12 Hrs

1. Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filling of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in Patent.

12 Hrs

2. Role of GATT, TRIPS, and WIPO.

12 Hrs

3. Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating Indian Pharmaceutical sector,

12 Hrs

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

12 Hrs

5. Regulatory requirements for contract research organization. Regulations for Biosimilars.

REFERENCE:

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

PRACTICALS (MIP104P)

Industrial pharmacy practical component includes experiments covering important topics of the courses Modern Pharmaceutical Analytical Techniques, Pharmaceutical Formulation Development, Customized drug Delivery System and Drug Regulations and Intellectual Property Rights.

List of Experiments (20)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer (one)
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry (one)
3. Experiments based on HPLC (one)
4. Experiments based on Gas Chromatography (one)
5. Estimation of riboflavin/quinine sulphate by fluorimetry (one)
6. Estimation of sodium/potassium by flame photometry (one)
7. Effect of surfactants on the solubility of drugs. (one)
8. Effect of pH on the solubility of drugs. (one)
9. Dissolution methods of transdermal drug delivery systems. (one)
10. Stability testing of solution and solid dosage forms for photo degradation. (one)
11. Stability studies of drugs in dosage forms at 25 ^{o}C, 60% RH and 40 ^{o}C, 75% RH (one)
12. Compatibility evaluation of drugs and excipients (one)
13. Preparation and evaluation of different polymeric membranes. (one)
14. Formulation and evaluation of sustained release oral matrix tablet. (one)
15. Formulation and evaluation of sustained release oral reservoir system. (one)
16. Formulation and evaluation of microspheres / microcapsules. (one)
17. Formulation and evaluation of transdermal films. (one)
18. Design and evaluation of face wash, body- wash, creams, lotions, shampoo, toothpaste, lipstick. (one)
19. Registering for different Intellectual Property Rights in India(one)
20. Comparative study of DMF system in US, EU and Japan(one)

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH202T)

Scope

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

Objectives

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

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

THEORY **60Hrs**

12Hrs

1. **Drug Absorption From The Gastrointestinal Tract**: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting passive drug absorption, Factors affecting drug absorption: physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form . Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex, Structure of Octanol.

   Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

12Hrs

2. **Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance**: Introduction, Biopharmaceutic Factors Affecting Drug Bioavailability, Rate-Limiting Steps in Drug Absorption, Physicochemical Nature of the Drug Formulation Factors Affecting Drug Product Performance, Drug Product Performance, *In Vitro*: Dissolution and Drug Release Testing, Compendial Methods of Dissolution, Alternative Methods of Dissolution Testing, Meeting Dissolution Requirements, Problems of Variable Control in Dissolution Testing Performance of Drug Products: *In Vitro–In Vivo* Correlation, Dissolution Profile Comparisons, Drug Product Stability, Considerations in the Design of a Drug Product, Drug Product Considerations

12Hrs

3. **Pharmacokinetics**: Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model- IV bolus, IV infusion, Extra-vascular; Multi Compartment model: Two compartment - model in brief, Non-Linear Pharmacokinetics: Cause of non-linearity, Michaelis – Menten equation, Estimation Kmax and Vmax. Drug interactions: Introduction, The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters.

12Hrs

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

12Hrs

5. **Application of Pharmacokinetics:** Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Relationship between Pharmacokinetics and Pharmacodynamics: Generation of a pharmacokinetic–pharmacodynamic (PKPD) equation, Pharmacokinetic and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology

drugs: Introduction, Proteins and peptides ,Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy),Gene therapies.

REFERENCES:

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

SCALE UP AND TECHNOLOGY TRANSFER (MIP202T)

Scope

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

Objectives:

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

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

THEORY **60Hrs**

12Hrs

1.Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parentrals 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, parentrals, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology.

12Hrs

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

12Hrs

3.Equipment Qualification: Importance, IQ, OQ, PQ for equipments – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine.

12Hrs

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

12Hrs

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

REFERENCES:

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

PHARMACEUTICAL PRODUCTION TECHNOLOGY (MIP203T)

Scope

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

Objectives

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

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

THEORY **60Hrs**

12Hrs

1. **Improved Tablet Production:** Tablet production process, unit operation improvements, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, speronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.
   Coating Technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

12Hrs

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

12Hrs

3. **Lyophilization Technology:** Principles, process, freeze-drying equipments.

12Hrs

4. **Capsule Production:** Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered.
   Disperse Systems Production: Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion, problems encountered.
   Packaging Technology: Types of packaging materials, machinery, labelling, package print in for different dosage forms.

12Hrs

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

REFERENCES:

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

ENTREPRENEURSHIP MANAGEMENT (MIP204T)

Scope

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

Objectives:

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

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

THEORY **60Hrs**

12Hrs

1. **Conceptual Frame Work**

   Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management

12Hrs

2. **Entrepreneur**

   Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts.

   Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

12Hrs

3. **Launching And Organising An Enterprise**

   Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilisation - finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

12Hrs

4. **Growth Strategies And Networking**

   Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of

expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study.

12Hrs

5. **Preparing Project Proposal To Start On New Enterprise**

Project work – Feasibility report; Planning, resource mobilisation and implementation.

REFERENCES:

1. Akhauri, M.M.P. Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R.D & Brush, C.G.The Women Entrepreneurs, D.C. Health & Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. et al Practice of Entrepreneurship, ILO, Geneva.

5 .Patel, V.C. Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.

PRACTICALS (MIP205P)

Industrial pharmacy practical component includes experiments covering important topics of the courses Advanced Biopharmaceutics and Pharmacokinetics, Scale up and Technology Transfer, Pharmaceutical Production Technology and Entrepreneurship Management.

List of Experiments (20)

1. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.(one)
2. Comparison of dissolution of two different marketed products /brands(one)
3. Protein binding studies of a highly protein bound drug & poorly protein bound drug. (one)
4. Bioavailability studies of Paracetamol. (one)
5. Pharmacokinetic and IVIVC data analysis by Winnoline^{R} software(one)
6. *In vitro* cell studies for permeability and metabolism (one)
7. Formulation and evaluation of tablets (two)
8. Formulation and evaluation of capsules (one)
9. Formulation and evaluation of injections (two)
10. Formulation and evaluation of emulsion .(two)
11. Formulation and evaluation of suspension.(two)
12. Formulation and evaluation of enteric coating tablets. (one)
13. Review essential elements of Scale-up/Technology Transfer(one)
14. Process validation(one)
15. Presentation and defense of Business identification report(one)
16. Presentation and defense of mini business plan on business to be commenced(one)

PHARMACEUTICAL ANALYSIS

(MPA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUE (MPA101T)

Scope

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

Objectives

After completion of course student is able to know,

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

THEORY **60 HOURS**

UNIT I **12 Hrs**

UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, choice of solvents and solvent effect and applications of UV-Visible spectroscopy. **04 Hrs**

IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopy **04 Hrs**

Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectroscopy. **02 Hrs**

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications. **02 Hrs**

UNIT II **12 Hrs**

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 **08 Hrs**
Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. **04 Hrs**

UNIT III **12 Hrs**

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization techniques like electron impact, chemical, field desorption, FAB and MALDI, APCI, ESI, APPI Analyzers and detectors. Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

UNIT IV **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 V **12 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 **8 Hrs**

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. **4 Hrs**

REFERENCES

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

ADVANCED PHARMACEUTICAL ANALYSIS (MPA102T)

Scope

This subject deals with the various aspects of reagents, quantitative analysis of functional group used in the analytical method development. It also covers the biological testing of various vaccines and impurities

Objectives

- After the completion of the course, it is expected that the student shall be able to know appropriate analytical skills required for the analytical method development.
- Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.
- Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products

THEORY **60 HOURS**

UNIT I **12 Hrs**

Analytical principle and procedure involved in the assay of following methods with special emphasize on official drugs in IP:

a) Complexometric titration b) Non aqueous titration c) Redox titration d) Diazotization titration e) UV – Visible method f) HPLC

UNIT II **12 Hrs**

Analytical principle, procedure and applications of the following reagents:

a) Ninhydrin b) 3-Methyl-2- benzthiazolinone hydrazone [MBTH] c) Folin – Ciocaltau [FC] d) Para-dimethyl-amino benzaldehyde [PDAB] e) Para-dimethyl- amino cinnamaldehyde [PDAC] f) 2, 6- Dichloroquinone chlorimide g) 1,2- napthaquinone-4-sulfonate h) 2,3,5-Triphenyltetrazolium i) 2,4-Dinitro Phenyl hydrazine [DNPH] j) Bratton – Marshall reagent k) 3,5- Dinitro salicylic acid [DNSA]

U**NIT III** **12 Hrs**

Principles and procedure involved in quantitative estimation of following functional groups and elements:

a) Hydroxyl b) Amine c) Carboxyl d) Carbonyl f) Ester g) Methoxyl

a) Sodium b) Potassium c) Calcium d) Halogens e) Phosphorus e) Sulphur

UNIT IV **12 Hrs**

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

UNIT V **12 Hrs**

Impurity and stability studies
Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines **02 Hrs**

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 **03 Hrs**

Impurities in residual solvents
General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, Reporting levels of residual solvents **02 Hrs**

Elemental impurities
Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures **02 Hrs**

Stability studies
Accelerated stability testing & shelf life calculation, WHO and ICH stability testing guideline, Stability zones, photostability testing guidelines, ICH stability guidelines for biological products

03 Hrs

REFERENCES

1. Vogel‘s textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th Edition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, John Wiley & Sons, 1982.
4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers New Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, NewDelhi, 1964.

8. Indian Pharmacopoeia Vol I , II & III 2007, 2010, 2014.
9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005
12. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.
13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

QUALITY CONTROL AND QUALITY ASSURANCE (MQA102T)

Scope:

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

Objectives: Upon completion of this course the student should be able to

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

Theory **60 Hrs**

UNIT- I **12 Hrs**

Concept and evolution of Quality Control and Quality Assurance,

Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines.

Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.

UNIT- II **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-III **12 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 formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products, Quality control test for containers, closures and secondary packing materials.

UNIT-IV **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 Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data.

Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD)

UNIT-V **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.

Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.

REFERENCES

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

FOOD ANALYSIS (MPA104T)

Scope

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

Objectives

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

- Food constituents
- Food additives
- Finished food products
- Pesticides in food

  Student shall have the knowledge on food regulations and legislations.

THEORY **60 Hrs**

UNIT-I **12 Hrs**

a. Carbohydrates – classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, crude fibre and application of food carbohydrates **06 Hrs**

b. Proteins - Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins **06 Hrs**

UNIT-II **12 Hrs**

a. Lipids – Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fats and fatty foods. **08 Hrs**
b. Vitamins – classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series. **04 Hrs**

UNIT-III **12 Hrs**

a. Food additives – Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agent **06 Hrs**

b. Pigments and synthetic dyes - Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes **06 Hrs**

UNIT IV **12 Hrs**

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. **06 Hrs**
b. Analysis of fermentation products like wine, spirits, beer and vinegar. **06 Hrs**

UNIT V **12Hrs**

a. Pesticide analysis
   Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorous and organo chlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products. **07 Hrs**
   b. Legislation regulations of food products with special emphasis on BIS, Agmark andUS-FDA **05 Hrs**

REFERENCES

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

PRACTICALS (MPA105P)

1. Assay of Pharmaceopoeial compounds/formulations by instrumental techniques. – UV/Visible/Fluorimetry/simultaneous estimation by UV/HPLC. (Min 5 expts)
2. Estimation of sodium/potassium/calcium by AAS/FES. (2 expts)
3. Assay of official compounds by titrimetric methods – Diazotisation/complexometry/redox titrations. (2 Expts)
4. Quantitative determination of hydroxyl/amino/carbonyl/carboxyl group. (3 Expts)
5. Colorimetric determination of drugs by using different reagents. (2 Expts)
6. IPQC and FPQC tests for pharmaceutical formulations. (3 Expts)
7. Test for related substances in pharmaceutical formulations. (2 Expts)
8. Monograph analysis of pharmacopoeial formulations. (2 Expts)
9. Determination of total reducing sugar
10. Determination of proteins
11. Determination of saponification value, Iodine value and Acid value in food products
12. Determination of fat content and peroxide value in food products
13. Analysis of natural and synthetic colors in food
14. Determination of preservatives in food

(Minimum 24 experiments to be carried out)

ADVANCED INSTRUMENTAL ANALYSIS (MPA201T)

Scope

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

Objectives

After completion of course student is able to know,

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

Theory 60 Hrs

UNIT I **12 Hrs**

UV and IR spectroscopy: Wood ward – Fieser rule for 1,3- butadienes, cyclic dienes and α, β-carbonyl compounds and interpretation compounds of enones. ATR-IR, NIR, IR Interpretation of organic compounds

UNIT II **12 Hrs**

NMR spectroscopy: 1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds

UNIT III **12 Hrs**

Mass Spectroscopy: Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds

UNIT IV **12 Hrs**

Hyphenated analytical techniques: Principle, Instrumentation and Applications of the following:

a) GC-MS b) LC-MS c) ICP-MS d) LC-NMR e) CE-MS f) High Performance Thin Layer chromatography g) Super critical fluid chromatography h) Ion Chromatography i) I-EC (Ion-Exclusion Chromatography) j) Flash chromatography

UNIT V **12 Hrs**

Thermal methods of analysis: Introduction, principle, instrumentation and application of DSC, DTA and TGA. **04 Hrs**

Radio Immuno Assay: Importance, various components, Principle, Different methods, Limitation & Applications of RIA. **04 Hrs**

Optical Rotatory Dispersion: Principle, Plain curves, Cotton effect, Circular Dichroism, Measurement of rotation angle in ORD and applications **04 Hrs**

REFERENCES

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

MODERN BIO-ANALYTICAL TECHNIQUES (MPA202T)

Scope:

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

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

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

THEORY **60 HOURS**

UNIT I **12 Hrs**

Analysis of drugs in biological matrices

Analysis of drugs in use and drugs in Research and Development **03 Hrs**

Biological matrix and Problems with analysis of biological matrices:

Types and Properties of the biological media, small organic molecules, peptides and protein drugs, prodrugs, formulations, drug metabolites, safety considerations. **09 Hrs**

UNIT II **12 Hrs**

Good Clinical Practice (GCP)

Origin of GCP , Requirements of GCP compliance, Guidelines for GCP, guidelines of ICH, guidelines of ICMR, Ensuring GCP, Documentation of GCP practice, Audit of GCP compliance

UNIT III **12 Hrs**

USFDA & CDSCO Guidelines for BA/BE studies for orally administered drug products:

Introduction, Design and conduct of studies, Facilities to conduct BA/BE studies, SPE sorbents, Retention of BA/BE samples, Maintenance of records of BA/BE studies

UNIT IV **12 Hrs**

Extraction of drugs and metabolites from biological matrices

General principle and procedure involved in the bio-analytical methods such as Protein precipitation, Liquid - Liquid extraction and Solid phase extraction and Membrane Filtration

UNIT V **12 Hrs**

Separation techniques

Bio molecules separation and quantification by HPLC, LC MS/MS, GC/MS and Gel electrophoresis

REFERENCES:

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition. CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercy. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, Newyork, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercy, 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.

PHARMACEUTICAL VALIDATION (MQA202T)

Scope

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

Objectives

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

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

THEORY **60 Hrs**

UNIT-I **12 Hrs**

Introduction to validation: Definition of Qualification and Validation, Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan. **06 Hrs**

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). **06 Hrs**

UNIT-II **12 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-III **12 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-IV **12 Hrs**

Process Validation: Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach.

Analytical method validation: General principles, Validation of analytical method as per ICH guidelines (Q2) and USP**.**

UNIT V **12 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 5.

REFERENCES:

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.

4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco,(Marcel Dekker).

5. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.

6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider

7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press

8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker

9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.

10. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare

11. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press

12. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press

COSMETIC ANALYSIS & EVALUATION (MPA204T)

SCOPE

This course is designed to impart knowledge on analysis of cosmetic raw materials and finished products. Performance evaluation of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.

OBJECTIVES

At completion of this course student shall be able to understand

- Determination of physical constants of cosmetic raw materials
- Cosmetic raw materials, additives and their analysis
- Analysis of finished cosmetic products
- Principles of performance evaluation of cosmetic products.

THEORY **60 Hrs**

UNIT I **12 Hrs**

Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powders, density, viscosity of cosmetics raw materials.

UNIT II **12 Hrs**

Study on the quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.

UNIT III **12 Hrs**

Indian standard specifications laid down for sampling and testing of various cosmetics in finished forms such as baby care powders, skin care products, dental products, personal hygiene preparations, lips sticks, hair products and skin creams by the Bureau Indian Standards.

UNIT IV **12 Hrs**

Principles of equipment used to measure product performance of skin and hair care products - Sebumeter, corneometer, trans-epidermal water loss, Skin color, hair tensile properties, hair combing properties.

Performance evaluation of shampoos, antiperspirants, deodorants, sunscreens, foam baths and abrasiveness of dentifrices.

UNIT V **12 Hrs**

Study of specialized additives- quality parameters and analysis of rheology modifiers, preservatives, emollients, hair conditioners and fragrances

REFERENCES:

1. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi
2. Indian Standard specification, for raw materials, BIS, New Delhi.
3. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
4. Harry's Cosmeticology 8th edition
5. Suppliers catalogue on specialized cosmetic excipients
6. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
7. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition,

PRACTICALS (MPA205P):

1. Comparison of absorption spectra by UV and Wood ward – Fiesure rule.
2. Interpretation of organic compounds by FT-IR. (2 Expts)
3. Interpretation of organic compounds by NMR and Mass spectra. (3 Expts)
4. Determination of purity for API by DSC. (1 Expts)
5. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC/LC MS. (2 Expts)
6. Protocol preparation and performance of analytical/Bioanalytical method validation. (1 Expt)
7. Protocol preparation for the conduct of BA/BE studies according to guidelines (1 Expt)
8. Qualification of analytical instruments – UV VIS Spectrophotometer/FT IR/HPLC/LCMS. (3 Expts)
9. Qualification of equipments – Dissolution apparatus/Disintegration/(2 Expts)
10. Protocol preparation for validation of stream sterilizer/autoclave unit/fluid bed drier. (2 Expts)
11. Quantitative analysis of rancidity (peroxide value) in hair oils and Lipsticks
12. Determination of aryl amine content and Developer in hair dye
13. Determination of foam height and SLS content of Shampoo.
14. Determination of total fatty matter in creams (Soap, Skin and hair Creams)
15. Determination of acid value and saponification value.
16. Determination of calcium thioglycolate in depilatories

PHARMACEUTICAL BIOTECHNOLOGY

(MPB)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUE (MPA101T)

Scope

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

Objectives

After completion of course student is able to know,

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

THEORY **60 HOURS**

UNIT I **12 Hrs**

UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, choice of solvents and solvent effect and applications of UV-Visible spectroscopy. **04 Hrs**

IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopy **04 Hrs**

Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectroscopy. **02 Hrs**

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications. **02 Hrs**

UNIT II **12 Hrs**

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 **08 Hrs**

Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. **04 Hrs**

UNIT III **12 Hrs**

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization techniques like electron impact, chemical, field desorption, FAB and MALDI, APCI, ESI, APPI Analyzers and detectors. Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

UNIT IV **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 V **12 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 **8 Hrs**

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. **4 Hrs**

REFERENCES

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

MICROBIAL AND CELLULAR BIOLOGY(MPB101T)

Scope

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

Objective

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

- Importance of Microorganisms in Industry
- Central dogma of molecular biology
- Structure and function of cell and cell communication
- Cell culture technology and its applications in pharmaceutical industries.
- Microbial pathogenesis

THEORY **60Hrs**

UNIT I **12 Hrs**

Microbiology

Introduction – Prokaryotes and Eukaryotes. Bacteria, fungi, actionomyocytes and virus - structure, chemistry and morphology, cultural, physiological and reproductive features. Methods of isolation, cultivation and maintenance of pure cultures. Industrially important microorganisms - examples and applications

UNIT II **12 Hrs**

Molecular Biology **05 Hrs**

Structure of nucleus and chromosome, Nucleic acids and composition, structure and types of DNA and RNA. Central dogma of molecular biology: Replication, Transcription and transcription.

Gene regulation **02 Hrs**

Gene copy number, transcriptional control and translational control.

RNA processing **05 Hrs**

Modification and Maturation, RNA splicing, RNA editing, RNAamplification. Mutagenesis and repair mechanisms, types of mutants, application of mutagenesisin stain

improvement, gene mapping of plasmids- types purification andapplication. Phage genetics, geneticorganization, phage mutation and lysogeny.

UNIT III **12 Hrs**

Cell structure and function **05 Hrs**

Cell organelles, cytoskeleton & cell movements, basic aspectsof cell regulation, bioenergetics and fuelling reactions of aerobics and anaerobics,secondary metabolism & its applications. Cell communication, cell cycle and apoptosis, mechanism of cell division. Celljunctions/adhesion and extra cellular matrix, germ cells and fertilization, histology – thelife and death of cells in tissues.

Cell Cycle and Cytoskeleton **03Hrs**

Cell Division and its Regulation, G-Protein CoupledReceptors, Kinases, Nuclear receptors, Cytoskeleton & cell movements, IntermediateFilaments.

Apoptosis and Oncogenes **02 Hrs**

Programmed Cell Death, Tumor cells, carcinogens & repair.

Differentiation and Developmental Biology **02 Hrs**

Fertilization, Events of Fertilization, *In vitro* Fertilization, Embryonic Germ Cells, Stem Cells and its Application.

UNIT IV **12 Hrs**

Principles of microbial nutrition **05 Hrs**

Physical and chemical environment for microbial growth, Stability and degeneration of microbial cultures.

Growth of animal cells in culture **07 Hrs**

General procedure for cell culture, Nutrient composition, Primary, established and transformed cell cultures, applications of cell cultures in pharmaceutical industry and research. Growth of viruses in cell culture propagation and enumeration.*In vitro* screening techniques- cytotoxicity, anti-tumor, anti-viral assays.

UNIT V **12 Hrs**

Microbial pathology

Identifying the features of pathogenic bacteria, fungi and viruses.Mechanism of microbial pathogenicity, etiology and pathology of common microbialdiseases and currently recommended therapies for common bacterial, fungal & viralinfections.Mechanism of action of antimicrobial agents and possible sites of chemotherapy.

REFERENCES

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

BIOPROCESS ENGINEERING AND TECHNOLOGY(MPB102T)

Scope

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

Objective

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

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

THEORY **60 Hrs**

UNIT I **12 Hrs**

Introduction to fermentation technology

Basic principles of fermentation **02 Hrs**

Study of the design and operation of bioreactor **04 Hrs**

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

Types of bioreactor **04 Hrs**

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

Computer control of fermentation process **02 Hrs**

System configuration and application

UNIT II **12 Hrs**

Mass transfer and Rheology

Mass transfer **07 Hrs**

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

Rheology **05 Hrs**

Rheological properties of fermentation system and their importance inbioprocessing.

UNIT III **12 Hrs**

Scale up of fermentation process **04 Hrs**

Principles, theoretical considerations, techniques used, media forfermentation, HTST sterilization, advantage and disadvantage, liquidsterilization.

Cultivation and immobilized culture system **04 Hrs**

Cultivation system - batch culture, continuous culture, synchronous cultures, fed batch culture. Graphical plot representing the above systems.

Introduction to immobilization **04 Hrs**

Techniques, immobilization of whole cell, immobilized culture system to prepare fine chemicals.Immobilization of enzymes and their applications in theindustry. Reactors for immobilized systems and perspective of enzymeengineering.

UNIT IV **12 Hrs**

Scale down of fermentation process **08 Hrs**

Theory, equipment design and operation, methods of filtration, solvent extraction, chromatographic separation, crystallization turbidity analysisand cell yield determination, metabolic response assay, enzymatic assay, bioautographic techniques and disruption of cells for product recovery.

Isolation, screening **04 Hrs**

Primary and secondary, maintenance of stockculture, strain improvement for increased yield.

UNIT V **12 Hrs**

Bioprocessing of the industrially important microbialmetabolites **08 Hrs**

a. Organic solvents – Alcohol and Glycerol
b. Organic acids - Citric acids, Lactic acids,
c. Antibiotics - Penicillin, Streptomycin, Griseofulvin,
d. Vitamins - B12, Riboflavin and Vitamin C
e. Amino acids - Glutamic acids, Lysine, Cyclic AMP and GMP

Biosynthetic pathways for some secondary metabolites, microbialtransformation of steroids and alkaloids **02 Hrs**

Regulation governing the manufacturing of biological products **02 Hrs**

REFERENCES

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

ADVANCED PHARMACEUTICAL BIOTECHNOLOGY (MPB103T)

Scope

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

Objective

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

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

THEORY **60 Hrs**

UNIT I **12 Hrs**

Enzyme Technology

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

UNIT II **12 Hrs**

Genetic Engineering **06 Hrs**

Techniques of gene manipulation, cloning strategies,procedures, cloning vectors expression vectors, recombinant selection andscreening, expression in E.coli and yeast. Site directed mutagenesis, polymerase chain reaction, and analysis of DNAsequences. **02 Hrs**

Gene library and cDNA **01 Hrs**

Applications of the above technique in the production of, **03 Hrs**

- Regulatory proteins - Interferon, Interleukins

- Blood products -Erythropoietin
- Vaccines - Hepatitis-B
- Hormones -Insulin

UNIT III **12 Hrs**

Therapeutic peptides **05 Hrs**

Study on controlled and site specified delivery of therapeutic peptides and proteins through various routes of administration.

Transgenic animals **02 Hrs**

Production of useful proteins in transgenic animals and gene therapy.

Human Genome **05 Hrs**

The human genome project-a brief study, Human chromosome – Structure and classification, chromosomal abnormalities – Syndromes

UNIT IV **12Hrs**

Signal transduction **08 Hrs**

Introduction, cell signaling pathways, Ion channels, Sensors and effectors, ON and OFF mechanisms, Spatial and temporal aspects of signaling, cellular process, development, cell cycle and proliferation, neuronal signaling, cell stress, inflammatory responses and cell death, signaling defects and diseases.

Oncogenes **04 Hrs**

Introduction, definition, various oncogenes and their proteins.

UNIT V **12 Hrs**

Microbial Biotransformation **04 Hrs**

Biotransformation for the synthesis of chiral drugs and steroids.

Microbial Biodegradation **04 Hrs**

Biodegradation of xenobiotics, chemical and industrial wastes,
Production of single-cell protein,
Applications of microbes in environmental monitoring.

Biosensors **04 Hrs**

Definition, characteristics of ideal biosensors, types of biosensors, biological recognition elements, transducers, application of biosensors.

REFERENCES

1. Biotechnology-The biological principles: MD Trevan, S Boffey, KH Goulding and P.F. Stanbury.
2. Immobilization of cells and enzymes: HosevearKennadycabral& Bicker staff
3. Principles of Gene Manipulating: RW Old and S.B.Primrose.
4. Molecular Cell Biology: Harvey Lodish, David Baltimore, Arnold Berk, S LawenceZipursky, Paul Matsudaira, James Darnell.
5. Modern Biotechnology: S.B Primrose
6. Gene transfer and expression protocols-methods in Molecular Biology, vol. VII, Edit E.T. Murray
7. Current protocols in Molecular Biology, Vo1.I & II:F.M. Asubel, John wiley Publishers
8. Current protocols in cellular biology, Vo1.1 & II John wiley publishers.
9. Principles of human genetics; by Curt Stern, published by W.H. Freeman, 1960.

PRACTICALS (MPB104P)

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

PROTEINS AND PROTEIN FORMULATIONS (MPB201T)

Scope

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

Objective

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

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

THEORY **60 Hrs**

UNIT I **12 Hrs**

Protein engineering

Concepts for protein engineering. Isolation and purification of proteins, Stability and activity based approaches of protein engineering, Chemical and Physical Considerations in Protein and Peptide Stability, Different methods for protein engineering, gene shuffling, and direct evolution

UNIT II **12 Hrs**

Peptidomimetics

Introduction, classification; Conformationally restricted peptides, design, pseudopeptides, peptidomimetics and transition state analogs; Biologically active template; Amino acid replacements; Peptidomimetics and rational drug design; CADD techniques in peptidomimetics; Development of non peptide peptidomimetics.

UNIT III **12 Hrs**

Proteomics **08 Hrs**

Protein identification and characterization: Methods/strategies, protein identification, de novo protein characterization, Isotope labelling, N- and C-terminal tags.

2-Dimensional gel electrophoresis **04 Hrs**

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

UNIT IV **12 Hrs**

Protein formulation

Different strategies used in the formulation of DNA and proteins, Analytical and biophysical parameters of proteins and DNA in pre-formulation, Liposomes, Neon-spears, Neon-particulate system, Pegilation, Biological Activity, Biophysical Characterization Techniques, Forced degradation studies of protein.

UNIT V **12 Hrs**

Methods of protein sequencing

Various methods of protein sequencing, characterisation, Edman degradation, Tryptic and/or Chymotryptic Peptide Mapping.

REFERENCE

1. H. Lodhishet. Al. Molecular Cell Biology, W. H. Freeman and Company
2. Protein Purification – Hand Book – 1998 Amersham pharmacia biotech
3. EngelbertBuxbaum, Fundamentals of Protein Structure and Function, Springer Science
4. Sheldon J. Park, Jennifer R. Cochran, Protein Engineering and Design, CRC press.
5. Robert K. Skopes. Protein purification, principle and practice, springer link.
6. David Whitford, Proteins-Structure and Function, John Wiley & Sons Ltd.
7. James Swarbrick, Protein Formulation and Delivery, Informa Healthcare USA,Inc.
8. Rodney Pearlman, Y. John Wang Formulation, Characterization, and Stability of Protein Drugs, Kluwer Academic Publishers.

IMMUNOTECHNOLOGY (MPB202T)

Scope

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

Objective

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

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

THEORY **60 Hrs**

UNIT I **12 Hrs**

Fundamental aspects of immunology **06 Hrs**

Introduction, cells and organs of the immune system, cellular basis of Immune response, primary and secondary lymphoid organs, antigen antibody and their structure.
Types of immune responses, anatomy of immune response.
Overview of innate and adaptive Immunity.

Humoral Immunity **03 Hrs**

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

Cell mediated Immunity **03 Hrs**

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

UNIT II **12 Hrs**

Immune Regulation and Tolerance **08 Hrs**

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

Hypersensitivity **02 Hrs**

Hypersensitivity Types I-IV, Hypersensitivity reactions and treatment

Autoimmune diseases **02 Hrs**

UNIT III **12 Hrs**

Vaccine technology **06 Hrs**

Vaccine and their types, conventional vaccines, novel methods for vaccine production, antiidiotype vaccine, DNA vaccine, genetically engineered vaccine, iscoms, synthetic peptides, and immunodiagnostics.

Stem cell technology **06 Hrs**

Stem cell technology and applications to immunology

UNIT IV **12 Hrs**

Hybridoma Technology

Hybridoma techniques – fusion methods for myeloma cells and B-Lymphocytes, selection and screening techniques. Production and purification of monoclonal antibodies and their applications in Pharmaceutical industry.

UNIT V **12 Hrs**

Immunological Disorder **06 Hrs**

Autoimmune disorders and types, pathogenic mechanisms, treatment, experimental models of auto immune diseases, primary and secondary immunodeficiency disorders.

Immunodiagnosis **06 Hrs**

Antigen antibody interaction – Precipitation reaction, Agglutination reactions, Principles and applications of ELISA, Radio Immuno Assay, Western blot analysis, immune-electrophoresis, immuneflorescence, chemiluminescence assay.

References

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

BIOINFORMATICS AND COMPUTATIONAL BIOTECHNOLOGY (MPB203T)

Scope

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

Objectives

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

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

THEORY **60 Hrs**

UNIT I **12Hrs**

Introduction to Bioinformatics **04 Hrs**

Definition and History of Bioinformatics, Internet and Bioinformatics, Introduction to Data Mining, Applications of Data Mining to Bioinformatics,

Biological Database **08 Hrs**

Protein and nucleic acid databases. Structural data bases. Collecting and storing the sequence and Applications of Bioinformatics.

UNIT II **12 Hrs**

Sequence analysis

Sequence alignment, pair wise alignment techniques, multiple sequence analysis, multiple sequence alignment; Flexible sequence similarity searching with the FAST3 program package, the use of CLUSTAL W and CLUSTAL X for the multiple sequence alignment. Tools used for sequence analysis.

UNIT III **12 Hrs**

Protein informatics **05 Hrs**

Introduction; Force field methods; Energ, buried and exposed residues, side chains and neighbours; Fixed regions, hydrogen bonds, mapping properties onto surfaces; Fitting monomers, rms fit of conformers, assigning secondary structures; Sequence alignment-methods, evaluation, scoring; Protein completion, backbone construction and side chain addition; Small peptide methodology, software accessibility, building peptides; Protein displays; Substructure manipulations, annealing.

Protein structure prediction **05 Hrs**

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

Docking **02 Hrs**

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

UNIT IV **12Hrs**

Diversity of Genomes **04 Hrs**

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

Completed Genomes **02 Hrs**

Bacterium, Nematode, Plant and Human

Evolution of Genomes **04 Hrs**

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

Phylogenetic analysis **02 Hrs**

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

UNIT V **12Hrs**

Target searching and Drug Designing

Target and lead, timeline for drug development, target discovery, target modulators, *insilico* gene expression, microarray, and lead discovery, libraries of ligands, active site analysis, and prediction of drug quality.

REFERENCE

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

BIOLOGICAL EVALUATION OF DRUG THERAPY (MPB204T)

Scope

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

Objective

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

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

THEORY **60 Hrs**

UNIT I **12 Hrs**

Biological Standardization **04 Hrs**

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

Preclinical drug evaluation **06 Hrs**

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

Guidelines for toxicity studies **02 Hrs**

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

UNIT II **12 Hrs**

Pyrogens **04 Hrs**

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

Microbiological assay **04 Hrs**

Assay of antibiotics and vitamins.

Biological evaluation of drugs **04 Hrs**

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

UNIT III **12 Hrs**

Biologic Medicines in Development for various diseases — By Therapeutic Category **06 Hrs**

- Genetic Disorders
- Eye Conditions
- Digestive Disorders
- Diabetes/Related Conditions
- Cardiovascular Disease
- Cancer/Related Conditions
- Blood Disorders
- Autoimmune Disorders
- Infectious Diseases
- Neurologic Disorders
- Skin Diseases
- Transplantation

Biologic Medicines in Development for various diseases — by Product Category **06 Hrs**

- Antisense
- Vaccines
- Recombinant Hormones/Proteins
- Monoclonal Antibodies (mAb)
- Interferons
- Growth Factors
- Gene Therapy
- RNA Interference

UNIT IV **12 Hrs**

Regulatory aspects : Biologics and biosimilars **04 Hrs**

An introduction to the regulations and documents necessary for approval of a biological product.

Regulatory consideration **04 Hrs**

Regulatory consideration for pre-clinical testing and clinical testing of biologics and biosimilars.

New Drug Applications for Global Pharmaceutical Product Approvals **04 Hrs**

UNIT V **12 Hrs**

Bioavailability **06 Hrs**

Objectives and consideration in bio-availability studies, Concept of equivalents, Measurements of bio-availability.

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

Pharmacokinetics **06 Hrs**

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

References:

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

SEMESTER- II
PRACTICALS (MPB205P)

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

PHARMACEUTICAL CHEMISTRY
(MPC)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUE (MPA101T)

Scope

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

Objectives

After completion of course student is able to know,

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

THEORY **60 HOURS**

UNIT I **12 Hrs**

UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, choice of solvents and solvent effect and applications of UV-Visible spectroscopy. **04 Hrs**

IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopy **04 Hrs**

Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectroscopy. **02 Hrs**

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications. **02 Hrs**

UNIT II **12 Hrs**

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 **08 Hrs**
Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. **04 Hrs**

UNIT III **12 Hrs**

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization techniques like electron impact, chemical, field desorption, FAB and MALDI, APCI, ESI, APPI Analyzers and detectors. Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

UNIT IV **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 V **12 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 **8 Hrs**

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. **4 Hrs**

REFERENCES

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

ADVANCED ORGANIC CHEMISTRY-1 (MPC102T)

Scope

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

Objectives

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

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

THEORY **60 Hrs**

Unit 1 **12Hrs**

Basic Aspects of Organic Chemistry

a. Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications.
b. Types of reaction mechanisms and methods of determining them,
c. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations.
    i. Nucleophilic uni- and bimolecular reactions (SN_1 and SN_2)
    ii. Elimination reactions (E_1 & E_2; Hoffman and Saytzeff's rule)

Unit 2 **12Hrs**

Study of mechanism synthetic applications of following named Reactions:

Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner-Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeyer-Haack Reaction, Sharpless asymmetric epoxidation, Baeyer-Villiger oxidation

Unit 3 **12Hrs**

Synthetic Reagents & Applications

Aluminium isopropoxide, N-Bromosuccinamide, Diazomethane, N,N'-dicyclohexylcarbodimide, Wilkinson's reagent, Wittig reagent. Osmium tetroxide, Titanium chloride, Diazopropane, Diethyl azodicarboxylate, Triphenylphosphine,

Protecting groups

a. Role of protection in organic synthesis
b. Protection for the hydroxyl group, including 1,2-and1,3-diols: ethers, esters, carbonates, cyclic acetals & ketals
c. Protection for the Carbonyl Group: Acetals and Ketals
d. Protection for the Carboxyl Group: amides and hydrazides, esters
e. Protection for the Amino Group and Amino acids: carbamates and amides

Unit 4 **12Hrs**

Heterocyclic Chemistry

General methods of synthesis of five, six membered and fused heterocylces such as triazole, pyrimidine, quinoline, acridine, phenothiazine and purine. Synthesis of any one representative drug from each heterocyclic nucleus.

Unit 4

12Hrs

Synthon approach and retrosynthesis applications

i. Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconvertion and addition (FGI and FGA)
ii. C-X disconnections; C-C disconnections – alcohols and carbonyl compounds; 1,2-, 1,3-,1,4-, 1,5-, 1,6-difunctionalized compounds
iii. Strategies for synthesis of five and six-membered ring

REFERENCES

1. Advanced Organic chemistry, Reaction, mechanisms and structure, J March, John Wiley and sons, New York.
2. Mechanism and structure in organic chemistry, ES Gould, Hold Rinchart and Winston, NewYork.
3. Organic Chemistry. Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.
4. Organic Chemistry. Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5. Organic Chemistry- Morrison and Boyd Pearson VII Edition
6. A guide to mechanisms in Organic Chemistry – Peter sykes (Orient Longman, New Delhi).
7. Reactive intermediates in organic chemistry – Tandom and Gowel.
8. Organic chemistry- Carey, Vth edition (Viva Books Pvt. Ltd.)
9. Organic synthesis-the disconnection approach, S. Warren, Wily India

10. Principles of organic synthesis, ROC Norman and JM Coxan, Nelson thorns
11. Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar, Narosa Publishers

ADVANCED MEDICINAL CHEMISTRY (MPC103T)

Scope

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

Objectives

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

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

THEORY **60 Hrs**

Unit 1 **12 Hrs**

Drug discovery: Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets.

Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists *vrs* antagonists.

Unit 2 **12 Hrs**

Prodrug Design: Basic concept, Prodrugs of functional group, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.

Combinatorial chemistry and High throughput screening: Different techniques, Solid phase synthesis, Solution phase synthesis, Parallel synthesis, applications of combinatorial chemistry. High Throughput Screening- general outline, importance and application

Unit 3 **12 Hrs**

Analog Design: Introduction, Bioisosteric replacement, rigid analogs, alteration of chain branching, changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.

Stereochemistry and Drug action: Realization that stereo selectivity is a pre-requisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug adsorption, metabolism, distribution and elimination.

Unit4 **12 Hrs**

Rational Design of Enzyme Inhibitors: Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.

Unit 5 **12 Hrs**

Peptidomimetics: Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally.

REFERENCES:

1. D. J. Abraham and D. P. Rotella. Burger's Medicinal Chemistry, Drug Discovery and Development: 8 Volume Set , Wiley-Blackwell, 7th Edition, 2010
2. Burger, Alfred. A guide to the chemical basis of drug design. John Wiley & Sons Inc.
3. Jaime, N. Delgado, and A. Remes William. "Wilson and Gisvolds text book of organic medicinal and Pharmaceutical chemistry.
4. Hansch, Corwin, Peter George Sammes, and John Bodenhan Taylor. Comprehensive medicinal chemistry: the rational design, mechanistic study & therapeutic applications of chemical compounds. Volume 5. Pergamon Pr.
5. Stroud, Robert M., and Janet Finer-Moore. Computational and structural approaches to drug discovery: ligand-protein interactions. Volume 8. Royal Society of Chemistry, 2008.
6. Martin, Yvonne C. Quantitative drug design: a critical introduction. CRC Press, 2010.
7. Foye, William O. Foye's principles of medicinal chemistry. Eds. Thomas L. Lemke, and David A. Williams. Lippincott Williams & Wilkins, 2008.
8. Ariëns, Everhardus Jacobus, ed. Drug Design: Medicinal Chemistry: A Series of Monographs. Volume 4. Elsevier.
9. Williams, Hywel. Smith and Williams' introduction to the principles of drug design. John Wright.
10. Silverman, Richard B., and Mark W. Holladay. The organic chemistry of drug design and drug action. Academic press, 2014.

11. Patrick, Graham L. An introduction to medicinal chemistry. Oxford university press, 2013.
12. Brahmankar, D. M., and Sunil B. Jaiswal. Biopharmaceutics and pharmacokinetics: A treatise. Vallabh prakashan, 2005.
13. Trabocchi, Andrea, and Antonio Guarna. Peptidomimetics in Organic and Medicinal Chemistry. John Wiley & Sons, 2014.

CHEMISTRY OF NATURAL PRODUCTS (MPC104T)

Scope

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

Objectives

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

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

THEORY **60 Hrs**

Unit 1 **12 Hrs**

Study of Natural products as leads for new pharmaceuticals for the following class of drugs:

a. Drugs Affecting the Central Nervous System: Morphine Alkaloids
b. Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide
c. Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol
d. Neuromuscular Blocking Drugs: Curare alkaloids

Unit 2 **12 Hrs**

Alkaloids- General introduction, classification, isolation and purification of alkaloids, general methods of structural determination of alkaloids, structural elucidation of ephedrine

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

Unit 3 **12Hrs**

Steroids- General introduction, chemistry of sterols, sapogenin and cardiac glycosides Stereochemistry and nomenclature of steroids; Structure elucidation of cholesterol

Terpenoids – Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of Menthol.

Unit 4 **12 Hrs**

Recombinant DNA technology and drug discovery:

rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy- Introduction, Clinical application and recent advances in gene therapy

Unit 5 **12 Hrs**

Awareness of the active constituent of certain crude drugs used in Indigenous system

Diabetic therapy – *Gymnema sylvestre*, *Salacia reticulate*, *Pterocarpus marsupiam*, *Swertia chirata*, *Trigonella foenum graccum*; Liver dysfunction – *Phyllanthus niruri*; Antitumor – *Curcuma longa* Linn.

REFERENCES

1. D. J. Abraham. Burger's Medicinal Chemistry, Drug Discovery and Development: Volume 1 & 2, Wiley-Blackwell; 6th Edition, 2003
2. Jaime, N. Delgado, and A. Remes William. "Wilson and Gisvolds text book of organic medicinal and Pharmaceutical chemistry.
3. E. J Ariens. Drug Design, Volume III, Academic press,2009
4. I.L. Finar. Organic Chemistry Volume I and II, Pearson Education; Fifth Edition, 2011
5. R.H.F. Manske and H.L. Holmes. The Alkaloids; Chemistry and Physiology, Volume I, Academic Press.
6. G. R. Chatwall. Organic Chemistry of Natural Products Volume I and II, Himalaya Publishing House
7. O.P. Agarwal. Organic Chemistry of Natural Products Volume I and II, Krishan Prakashan
8. K. Peech and M.V.Tracey. Modern methods of plant analysis
9. Rapheal Khan. Natural Product Chemistry "A laboratory guide". 1991, Academic Press.
10. P.K. Gupta .Elements of Biotechnology
11. S.P.Vyas and V.K.Dixit. Pharmaceutical Biotechnology, CBS publications, 2012
12. S S Purohit. Biotechnology- Fundamentals and Applications, Agrobios publications, 2007
13. Lawrence P. Miller. Phytochemistry Volume-I: The Process and Products of Photosynthesis. Jan Nostrant Rein Hold.
14. Lawrence P. Miller. Phytochemistry Volume-II: Organic Metabolites. Jan Nostrant Rein Hold.
15. Scikel and V. C Runeckles. Recent advances in Phytochemistry. Volume I to IV

16. K. Nakanishi, T. Goto and S. Natori. Natural Products Chemistry. Volume 3, Kodansha Ltd
17. J.B. Harborne. Phytochemical Methods: A Guide to Modern Techniques of Plant Analysis, Springer (India) Pvt. Ltd., 2008

Pharmaceutical Chemistry I (MPC101P)

A. Modern pharmaceutical analysis (5 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

B. To perform the following reactions of synthetic importance (5 experiments)

1. Purification of organic solvents
2. Claisen-Schmidt reaction.
3. Benzyllic acid rearrangement.
4. Beckmann rearrangement.
5. Hoffmann rearrangement
6. Mannich reaction

C. Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4 experiments)

D. Chemistry of Natural Products (5 experiments)

1. Estimation of elements and functional groups in organic natural compounds
2. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, co-chromatographic technique for identification of isolated compounds and interpretation of UV and IR data.
3. Some typical degradation reactions to be carried on selected plant constituents

ADVANCED SPECTRAL ANALYSIS (MPA201T)

Scope

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

Objectives

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

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

THEORY

60Hrs

1. **UV and IR spectroscopy**: Wood ward – Fiesure rule for 1,3- butadienes, cyclic dienes and α, β-carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds.

   12Hrs
2. **NMR spectroscopy**: 1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds.

   12Hrs
3. **Mass Spectroscopy**: Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds. **12Hrs**
4. **Chromatography**: Principle, Instrumentation and Applications of the following:
   a) GC-MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CE-MS g) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I-EC (Ion-Exclusion Chromatography) k) Flash chromatography.

   12Hrs
5. **Thermal methods of analysis** – Introduction, principle, instrumentation and application of DSC, DTA and TGA.
   Raman Spectroscopy: Introduction, Principle, Instrumentation and Applications.

12Hrs

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. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

ADVANCED ORGANIC CHEMISTRY (MPC202T)

Scope

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

Objectives

Upon completion of course, the student shall able to understand

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

THEORY

Unit 1 **12Hrs**

Green Chemistry

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

Unit 2 **12Hrs**

Chemistry of peptides

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

Unit 3 **12Hrs**

Photochemical Reactions

Basic principles of photochemical reactions; Photo-oxidation, photo-addition and photo-fragmentation.

Pericyclic reactions

Mechanism, Types of pericyclic reactions such as cyclo addition, elctrocyclic reaction and sigmatrophic rearrangement reactions with examples

Unit 4 **12Hrs**

Catalysis

a. Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages
b. Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.
c. Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs
d. Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions
e. Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.
f. Phase transfer catalysis - theory and applications

Unit 4 **12Hrs**

Stereochemistry & Asymmetric Synthesis

a. Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn-Ingold-Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L-notation, cis-trans isomerism, E and Z-notation.
b. Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.

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, NewYork.
3. Organic Chemistry. Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.
4. Organic Chemistry. Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5. Organic chemistry. Carey, 5th edition (Viva Books Pvt. Ltd.)
6. Organic synthesis-the disconnection approach, S. Warren, Wily India
7. Principles of organic synthesis, ROC Norman 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

COMPUTER AIDED DRUG DESIGN (MPC203T)

Scope

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

Objectives

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

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

THEORY **60 Hrs**

Unit 1 **12Hrs**

Introduction to Computer Aided Drug Design (CADD): History, different techniques and applications.

Quantitative Structure Activity Relationships: Basics

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

Unit 2 **12Hrs**

Quantitative Structure Activity Relationships: Applications

Hansch analysis, Free Wilson analysis and relationship between them, advantages and disadvantages; deriving 2D-QSAR equations. 3D-QSAR approaches and contour map analysis.

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

Unit 3 **12Hrs**

Molecular Modeling and Docking

a. Molecular and Quantum Mechanics in drug design
b. Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation.
c. Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as HMG-CoA reductase and HIV protease. Agents acting on PPAR receptors.

Unit 4 **12Hrs**

Molecular Properties and Drug Design

a. Prediction and analysis of ADMET properties of new molecules and its importance in drug design.
b. *De novo* drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design.
c. Homology modeling and generation of 3D-structure of protein.

Unit 5 **12Hrs**

Pharmacophore Mapping and Virtual Screening

Concept of pharmacophore, pharmacophore mapping, identification of pharmacophore features and pharmacophore modeling; conformational search used in pharmacophore mapping. Similarity based methods and pharmacophore based screening, pharmacophore and structure based *in silico* virtual screening protocols.

REFERENCES:

1. Stroud, Robert M., and Janet Finer-Moore. Computational and structural approaches to drug discovery: ligand-protein interactions. Vol. 8. Royal Society of Chemistry, 2008.
2. Martin, Yvonne C. Quantitative drug design: a critical introduction. CRC Press, 2010.
3. Ariëns, Everhardus Jacobus, ed. Drug Design: Medicinal Chemistry: A Series of Monographs. Vol. 4. Elsevier, 2013.
4. Smith, H. John, and Hywel Williams. Smith and Williams' introduction to the principles of drug design and action. CRC Press, 2005.
5. Silverman, Richard B., and Mark W. Holladay. The organic chemistry of drug design and drug action. Academic press, 2014.
6. Wolff, Manfred E. "Burger's Medicinal Chemistry and Drug Discovery."American Journal of Therapeutics 3.8 (1996): 608.
7. Patrick, Graham L. An introduction to medicinal chemistry. Oxford university press, 2013.
8. Jaime, N. Delgado, and A. Remes William. "Wilson and Gisvolds text book of organic medicinal and Pharmaceutical chemistry." (1997).
9. Hansch, Corwin, Peter George Sammes, and John Bodenhan Taylor. Comprehensive medicinal chemistry: the rational design, mechanistic study & therapeutic applications of chemical compounds. Vol. 5. Pergamon Pr.
10. Textbook of Drug Design and Discovery, Third Edition, Povl Krogsgaard-Larsen, CRC Press.
11. The Practice of Medicinal Chemistry, by Wermuth C.G. (Author), Publisher: Elsevier Exclusive.

PHARMACEUTICAL PROCESS CHEMISTRY (MPC204T)

Scope

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

Objectives

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

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

THEORY **60 Hrs**

Unit 1 **12 Hrs**

Process chemistry

a. Introduction, Synthetic strategy
b. Stages of scale up process: Bench, pilot and large scale process.
c. In-process control and validation of large scale process.
d. Impurities in API, types and their sources including genotoxic impurities

Unit 2 **12 Hrs**

Unit operations

a. *Extraction:* Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.
b. *Filtration*: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,
c. *Distillation*: Azeotropic and steam distillation
d. *Evaporation*: Types of evaporators, factors affecting evaporation.
e. *Crystallization*: Crystallization from aqueous, non-aqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.

Unit 3 **12 Hrs**

Unit Processes

a. **Nitration:** Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration,
b. **Halogenation:** Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process.
c. **Oxidation**: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H_2O_2, sodium hypochlorite, Oxygen gas, ozonolysis.

Unit 4 **12 Hrs**

Unit Processes

a. **Reduction:** Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.
b. **Fermentation**: Aerobic and anaerobic fermentation. Production of
    i. Antibiotics; Penicillin and Streptomycin,
    ii. Vitamins: B2 and B12
    iii. Statins: lovastatin, simvastatin

Reaction progress kinetic analysis

a. Streamlining reaction steps, route selection,
b. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.

Unit 5 **12 Hrs**

Industrial Safety

a. MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE)
b. Fire hazards, types of fire & fire extinguishers
c. Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001(Environmental Management System), Effluents and its management

REFERENCE:

1. D. J. Abraham. Burger's Medicinal Chemistry, Drug Discovery and Development: Volume 1 & 2, Wiley-Blackwell; 6th Edition, 2003
2. K. Gadamasetti. Process Chemistry in the Pharmaceutical Industry. 1st Edition, CRC Press; 1 edition, 1999
3. Pharmaceutical Manufacturing Encyclopedia, 3rd edition, Volume 2.
4. W.L. McCabe, J.C Smith and P. Harriott. Unit operations of chemical engineering, 7th edition, McGraw Hill
5. H G Brittain. Polymorphism in Pharmaceutical Solids .Dekker Series Volume 95: 1999
6. R. M. Murphy. Introduction to Chemical Processes: Principles, Analysis, Synthesis, 1st Edition, McGraw-Hill education, 2005
7. P. J. Harrington. Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up 1st Edition, Wiley Publications, 2011
8. P.H.Groggins. Unit processes in organic synthesis, 3rd edition, Mcgraw Hill;
9. M. Gopal: Dryden's Outlines of Chemical Technology
10. Clausen, Mattson: Principle of Industrial Chemistry
11. Lowenheim and M.K. Moran: Industrial Chemicals
12. S.D. Shukla and G.N. Pandey. A text book of Chemical Technology Volume II, Vikas Publications
13. J.K. Stille: Industrial Organic Chemistry (PH)
14. B.K.Sharma: Industrial Chemistry
15. Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) guidelines
16. ISO-14001standard/ guidelines

Pharmaceutical Chemistry II Practical (MPC201P)

A. Advanced Spectral Analysis (5 experiments)

1. Comparison of absorption spectra by UV and Wood ward – Fieser rule
2. Interpretation of organic compounds by FT-IR
3. Interpretation of organic compounds by ^{1}H and ^{13}C-NMR
4. Interpretation of organic compounds by Mass spectroscopy
5. Determination of purity by DSC in pharmaceuticals
6. Identification of organic compounds using FT-IR, ^{1}H-NMR, ^{13}C-NMR and Mass spectra

B. To carry out the preparation of following organic compounds (4 experiments)

1. Preparation of 4-chlorobenzhydrylpiperazine (An intermediate for cetrizine HCl).
2. Preparation of 4-iodotolene from p-toluidine.
3. $NaBH_4$ reduction of vanillin to vanillyl alcohol
4. Preparation of umbelliferone by Pechhman reaction
5. Preparation of triphenyl imidazole
6. To perform the Microwave irradiated reactions of synthetic importance

C. Computer Aided Drug Design (6 Experiments)

1. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs
2. Calculation of ADMET properties of drug molecules and its analysis
3. Pharmacophore modeling
4. 2D-QSAR based experiments
5. 3D-QSAR based experiments
6. Docking study
7. 3D-structure of protein by Homology modeling using Fasta sequences.
8. Electronic parameters of molecules by NMDO/DFT method and correlation with the biological activity.

D. Pharmaceutical Process Chemistry (4 experiments)

1. Comparative study of synthesis of APIs/intermediates by different synthetic routes
2. Synthesis of organic compounds by adapting different approaches involving
    a. Oxidation
    b. Reduction/hydrogenation
    c. Nitration
3. Assignments on regulatory requirements in API

PHARMACEUTICS
(MPA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUE (MPA101T)

Scope

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

Objectives

After completion of course student is able to know,

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

THEORY **60 HOURS**

UNIT I **12 Hrs**

UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, choice of solvents and solvent effect and applications of UV-Visible spectroscopy. **04 Hrs**

IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopy **04 Hrs**

Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectroscopy. **02 Hrs**

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications. **02 Hrs**

UNIT II **12 Hrs**

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 **08 Hrs**
Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR

spectroscopy. **04 Hrs**

UNIT III **12 Hrs**

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization techniques like electron impact, chemical, field desorption, FAB and MALDI, APCI, ESI, APPI Analyzers and detectors. Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

UNIT IV **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 V **12 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 **8 Hrs**

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. **4 Hrs**

REFERENCES

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

MODIFIED RELEASE DRUG DELIVERY SYSTEM (MPH101T)

SCOPE

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

OBJECTIVES

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

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

THEORY **60 Hrs**

12 Hrs

1. **SR/CR formulation:** Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers :introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems,Bioelectronic Medicines,3D printing of pharmaceuticals, Telepharmacy.

   12hrs

2. **Rate Controlled Drug Delivery Systems:** Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems;Mechanically activated, PH activated , Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals

   . **12 hrs**

3. **Gastro-Retentive Drug Delivery Systems**: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit.
   Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation,Methods of formulation and its evaluations.

   12hrs

4. **Occular Drug Delivery Systems**: Barriers of drug permeation, Methods to overcome barriers, approchess involed in occular drug delivery system, new ophthalmic drug delivery system(NODS), bioadhesive ophthalmic drug inserts(BODI)

   12 hrs

5. **Trans Dermal Drug Delivery Systems:** Structure of skin and barriers, Penetration enhancers, advantages and disadvandages of TDDS , formulation and evaluation of transdermal drug delivery system

REFERENCES

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

JOURNALS

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

MODERN PHARMACEUTICS (MPH102T)

Scope

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

Objectives

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

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

THEORY **60 HRS**

12 hrs

1. **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.

1**2 Hrs**

2. **Validation :** Introduction to Pharmaceutical Validation, Scope & merits of Validation, , Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities

12 Hrs

3. **cGMP & Industrial Management**: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management

12 Hrs

4. **Compression and compaction**: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility enhancement techniques.

12 Hrs

5. **Study of consolidation parameters**; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckal plats, Similarity factors – f2 and f1,

Higuchi and peppas plot, Linearity Concept of significance, Standard deviation , chi square test , student T-test , Anova test.

REFERENCES

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

PHARMACEUTICAL REGULATORY AFFAIRS (MPH103T)

Scope

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials an 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.

THEORY **60 Hr**

12 hrs

1. **Documentation in pharmaceutical industry**: Master formula record, DMF (drug master file), distribution records. Generic drugs product development Introduction ,hatch- waxman act and amendments , CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro ,ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO

   12 hrs
2. **Regulatory requirement for product approval**: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs

   12 hrs

3. CMC, post approval regulatory affairs.Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison

   12 hrs

4. **Non clinical drug development:** Global submission of IND,NDA,ANDA.Investigation medicinal products dossier, dossier (IMPD) and investigator brochure (IB)

12 hrs

5. **Clinical trials:** Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.

REFERENCES

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

PRACTICALS (MPH104P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer

2.Simultaneous estimation of multi component containing formulations by UV spectrophotometry

3.Experiments based on HPLC

4.Experiments based on Gas Chromatography

5.Estimation of riboflavin/quinine sulphate by fluorimetry

6.Estimation of sodium/potassium by flame photometry

7. To perform *In-vitro* dissolution profile of CR/ SR marketed formulation

8.Formulation and evaluation of sustained release matrix tablets

9.Formulation and evaluation osmotically controlled DDS

10.Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS

11.Formulation and evaluation of Muco adhesive tablets.

12.Formulation and evaluation of trans dermal patches.

13.To carry out preformulation studies of tablets.

14.To carry out preformulation studies of capsules

15.To study the effect of compressional force on tablets disintegration time.

16.To study Micromeritic properties of powders and granulation.

17.To study the effect of particle size on dissolution of a tablet.

18.To study the effect of binders on dissolution of a tablet.

19.To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

20.Accelerated stability studies on various formulations

(temperature dependence, effect of buffers)

MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)(MPH201T)

Scope

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

Objectives

Upon completion of the course student shall be able to understand

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

THEORY **60 Hrs**

12 hrs

1. **Targeted Drug Delivery Systems: C**oncepts and Events involved in targeting drug delivery system and biological process involved in drug targeting.

12 hrs

2. **Targeting Methods**: Introduction and Biological processes involved in
3. Targeting drug delivery system, nano particles and its types, Niosomes, Liposomes,Aquasomes, Phytosomes, Electrosomes. preparation and evaluation process of nano particles formulation

12hrs

4. **Micro Capsules / Micro Spheres:** Types, preparation and evaluation ,
5. Monoclonal Antibodies ; preparation and application, preparation and application of

12hrs

6. **Pulmonary Drug Delivery Systems** : Pulmonary delivery of drugs by inhalation and its types, preparation and evaluation of drug delivery system, Intra Nasal Route Delivery systems

12hrs

7. **Veterinary Drug Delivery Systems:** Tablets and bolus, Feed additives, Drinking water medication, Oral paste and gels, Drenchers and Tubing product

REFERENCES:

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

Journals

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

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH202T)

Scope

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

Objectives

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

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

THEORY **60Hrs**

12Hrs

1. Drug Absorption From The Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting passive drug absorption, Factors affecting drug absorption: physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form . Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex, Structure of Octanol.

Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

12Hrs

2. Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance: Introduction, Biopharmaceutic Factors Affecting Drug

Bioavailability, Rate-Limiting Steps in Drug Absorption, Physicochemical Nature of the Drug Formulation Factors Affecting Drug Product Performance, Drug Product Performance, *In Vitro*: Dissolution and Drug Release Testing, Compendial Methods of Dissolution, Alternative Methods of Dissolution Testing, Meeting Dissolution Requirements, Problems of Variable Control in Dissolution Testing Performance of Drug Products: *In Vitro–In Vivo* Correlation, Dissolution Profile Comparisons, Drug Product Stability, Considerations in the Design of a Drug Product, Drug Product Considerations

12Hrs

3. Pharmacokinetics: Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model- IV bolus, IV infusion, Extra-vascular; Multi Compartment model: Two compartment - model in brief, Non-Linear Pharmacokinetics: Cause of non-linearity, Michaelis – Menten equation, Estimation Kmax and Vmax. Drug interactions: Introduction, The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters.

12Hrs

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

12Hrs

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

REFERENCES:

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

COMPUTER AIDED DRUG DEVELOPMENT (MPH203T)

Scope

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

Objectives

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

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

THEORY **60Hrs**

1. **Computers in Pharmaceutical Research and Development**: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameter ,Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling

   Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application

   12Hrs

2. **Computational Modeling Of Drug Disposition:** Introduction ,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.

   12Hrs

3. **Computer-aided formulation development:** Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis

12Hrs

4. **Computer-aided biopharmaceutical characterization**: Gastrointestinal absorption simulation

   Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and *in vitro-in vivo* correlation, Biowaiver considerations

   Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.

   Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems

12Hrs

5. **Artificial Intelligence (AI), Robotics and Computational fluid dynamics:** General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

12Hrs

REFERENCES:

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

COSMETICS AND COSMECEUTICALS (MPH204T)

Scope

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

Objectives: Upon completion of the course, the students will be able to understand

- The key ingredients used in cosmetics and cosmeceuticals.
- The key building blocks for various formulations.
- Basic science to develop cosmetics and cosmeceuticals

THEORY **60Hrs**

1.Cosmetics – Regulatory **12Hrs**

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 licence, prohibition of manufacture and sale of certain cosmetics, loan licence, offences and penalties.

2. Cosmetics – Biological aspects **12 Hrs**

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.

3. Formulation Building blocks **12 Hrs**

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.

Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.

Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

4. Design of cosmeceutical products **12Hrs**

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

5. Herbal Cosmetics **12Hrs**

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.

RECOMMENDED BOOKS:

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

PRACTICAL (MPH205P)

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

PHARMACOGNOSY
(MPG)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUE (MPA101T)

Scope

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

Objectives

After completion of course student is able to know,

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

THEORY **60 HOURS**

UNIT I **12 Hrs**

UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, choice of solvents and solvent effect and applications of UV-Visible spectroscopy. **04 Hrs**

IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopy **04 Hrs**

Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectroscopy. **02 Hrs**

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications. **02 Hrs**

UNIT II **12 Hrs**

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 **08 Hrs**
Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. **04 Hrs**

UNIT III **12 Hrs**

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization techniques like electron impact, chemical, field desorption, FAB and MALDI, APCI, ESI, APPI Analyzers and detectors. Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

UNIT IV **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 V **12 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 **8 Hrs**

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. **4 Hrs**

REFERENCES

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

ADVANCED PHARMACOGNOSY-1 (MPG102 T)

SCOPE:

To learn and understand the advances in the field of cultivation and production of plant drugs, 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
- Know the various phyto-pharmaceuticals and their source & utilization and medicinal value.
- Know the various nutraceuticals / herbs and their health benefits

THEORY **60 Hour**

UNIT 1 **12 Hrs**

Plant drug cultivation: General introduction to the importance of Pharmacognosy in herbal drug industry, General aspects involved in cultivation of medicinal plants. Factors affecting the cultivation of crude drugs. General aspects involved in the cultivation like Taxol, Artemisia,Guggul,Ginseng, Neem, Gymnema. Good manufacturing practice in collection of crude drugs.

UNIT I1 **12 Hrs**

Marine natural products: Definition, Present status, Classification of important bioactive agents from marine sources. General methods of isolation and purification. Study of Marine toxins, Marine bio medicals falling under the class of Cardiovascular, Anticancer, Antimicrobial,Anti-inflammatory and Antibiotic drugs.

UNIT II1 **12 Hrs**

Nutraceuticals: General introduction , Definition, Classification , Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Probiotics, Prebiotics, Dietary fibres, Cereals and grains, Health drinks, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods. 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) Tea vii) Flax seeds viii) Black cohosh ix) Turmeric.

UNIT 1V **12 Hrs**

Phytopharmaceuticals: Occurrence and Characteristic features (Chemical nature, uses in pharmacy, medicinal and health benefits) of following.

a) Carotenoids – i) α and β - Carotene ii) Lycopene iii) Xanthophyll (Lutein)
b) Limonoids – i) d-Limonene ii) α - Terpineol
c) Saponins – i) Glycyrrhizin ii) Shatavarins
d) Flavonoids – i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin
e) Phenolic acids:- Ellagic acid
f) Tocotrienols and Tocopherols

UNIT V **12 Hrs**

Vegetable Bitters: **6Hrs**

Definition; Biological source, chemical structural description of the bitter principles, actions and therapeutics of following.

i)Gentian ii) Chirata iii) Quassia iv) Calumba v) Calamus vi) Cusparia vii) Orange peel viii) Serpentaria

Vegetable Laxatives: **6Hrs**

Biological source, chemical structural description of active principles, tests for identification/evaluation, action and therapeutics of following.

i) Senna ii) Cascara iii) Rhubarb iv) Aloes v) Isapgol vi) Agar vii) Castor oil

REFERENCES:

1) AA Farooqui and B.S. Sreeramu, Cultivation of medicinal and aromatic crops, 1st edition, by University Press, 2001.
2) Paul M. Dewick, Medicinal natural products (a biosynthetic approach), 1st edition, John Wiley & Sons Ltd., England, 1998.
3) Peter B. Kaufman, Natural Products from Plants, 1st edition, CRC Press, New York, 1998
4) P. Pushpangadam. Ulf Nyman. V.George, Glimpses of Indian Ethano Pharmacology, Tropical Botanic Garden & Research Institute, 1995.
5) Raphael Ikan, Natural products: A lab guide, 2nd Edition, Academic Press 1991.
6) G. E. Trease and W.C. Evans, Pharmacognosy,. 15th Edition W.B. Saunders Edinburgh, New York.
7) Tyler, Brady, Robbers, Pharmacognosy-
8) Peach & M.V. Tracey, Modem Methods of Plant Analysis-, Vol. I&II

9) Scikel Runeckles, Recent Advances in Phytochemistry- Vol. 1&4: - Appleton Century crofts.

10) Paul J. Schewer, Chemistry of Marine Natural Products- 1973.

11) Marine Natural Products-Vol.I to IV.

12) C.K. Atal & B.M. Kapoor, Cultivation of Medicinal Plants.

13) C.K. Atal & B.M. Kapoor, Cultivation and Utilization of Aromatic Plants.

14) RD. Choudhary, Herbal Drug Industryy, 1st edition, Eastern Publisher, New Delhi, 1996.

15) C.K.Kokate, Purohit, Ghokhale, Text book of Pharmacognosy, 4th edition, Nirali Prakasshan, 1996.

16) Ashutoshkar, Pharmacognosy and Pharmacobiotechnology. New Age Publications, New Delhi.

17) T.E. Wallis, Text Book of Pharmacognosy.

PHYTOCHEMISTRY (MPG103T)

Scope:

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

Objectives:

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

- know the different classes of phytoconstituents and their properties and general process of natural product drug discovery
- know the process isolation, purification and identification of phytoconstituents.

THEORY **60 Hrs**

UNIT 1 **12 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. Natural products as a lead source for newer drugs. Optimization of lead compounds with suitable examples from anticancer, CNS, cardiovascular drugs, antitubercular drugs and immunomodulators.

UNIT I1 **12 Hrs**

Extraction and Phytochemical studies: Method of extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used and method of Fractionation. Detection of different classes of Phytoconstituents by test tube and TLC methods, latest techniques including preparative HPLC and Flash column chromatography.

UNIT 1II **12 Hrs**

Study of secondary metabolites: Properties, classification, chemistry and structural elucidation of Alkaloids, Flavonoids, Coumarins, Steroids, glycosides, Tannins and Terpenoids.

UNIT 1V **12 Hrs**

Phytochemical finger printing: HPTLC and LCMS/GCMS characterization of extracts containing alkaloids, saponins, glycosides and flavanoids.

UNIT V **12 Hrs**

Biosynthetic pathways and Radio tracing techniques: Constituents & their Biosynthesis, Isolation, Characterization and purification with a special reference to their importance in herbal industries of following phyto-pharmaceuticals containing drugs:

a) Alkaloids: Ephedrine, Quinine, Strychynine, Piperine, Berberine, Taxol.
b) Glycosides: Digitoxin, Glycyrrhizin, Sennosides, Bacosides
c) Steroids: Hecogenin, guggulosterone and withanolides
d) Coumarin: Umbelliferone.
e) Flavones: Hesperidin, Myrecetin.
f) Volatile oils: Lemongrass oil, Camphor, Menthol, Eugenol.

REFERENCES:

1) I.L. Finar, Organic chemistry Vol.II
2) Trease and Evans, Pharmacognosy by, ELBS.
3) Tylor and Brady, Pharmacognosy.
4) Wallis, Text book of Pharmacognosy.
5) A.C. Mottal, Clark's isolation and Identification of drugs.
6) Wagner & Bladt, Plant Drug Analysis.
7) Wilson and Gisvolds text book of Organic Medicinnal and Pharmaceutical Chemistry by Deorge. R.F.
8) R.H. Thomson, The Chemistry of Natural Products, Edited by, Springer International Edn. 1994.
9) Anees A Siddiqui and SeemiSiddiqui, Natural Products Chemistry Practical Manual.
10) Gurdeep R Chatwa.l Organic Chemistry of Natural Products, Vol. 1&2..
11) Chemistry of Natural Products- Vol. 1 onwards IWPAC.
12) Peach & M.V. Tracey, Modem Methods of Plant Analysis- Vol. I&II

INDUSTRIAL HERBAL DRUG TECHNOLOGY (MPG104T)

Scope:

To understand the Industrial and commercial potential of herbal drugs and integrate traditional medicines of India with modern herbal medicine and also to know regulatory and quality policy for the trade of herbals.

Objective:

By the end of the course the student shall be able to:-

- Know the requirements for setting up the herbal drug industry.
- to know and understand the guidelines for quality of herbal medicines and regulatory issues concerned with herbal medicines including traditional medicines
- To know patenting/IPR of herbals and trade of herbal raw and finished materials.

THEORY **60Hrs**

UNIT 1 **12 Hrs**

Herbal drug industry: Infrastructure of herbal drug industry involved in production of standardized extracts and various dosage forms. Current challenges in upgrading herbal formulations. Entrepreneurship Development, Project selection, project report, technical knowledge, Capital venture, plant design, layout and construction. Pilot plant scale –up techniques, case studies of herbal extracts. Formulation and production management.

UNIT 1I **12 Hrs**

Institution and industries involved in herbal drug research: Indian research institution and industries involved in herbal drug research and commerce. World trade and market of herbal drugs, Global marketing management. Indian and international patent law as applicable herbal drugs and natural products. Export –import (EXIM) policy, TRIPS, IPR. Quality assurance in herbal drug industry. Concepts of TDM, GMP, GLP, ISO-9000.

UNIT II1 **12 Hrs**

Monographs of herbal drugs: Study of monographs of herbal drugs in IP, USP, BP and Ayurvedic pharmacopoeia,Chinese materia medica, WHO guidelines in quality assessment of herbal drugs.

UNIT IV **12 Hrs**

Regulatory affairs in herbal drugs: Basic principles of clinical studies, Safety and toxicology of herbal drugs. Adverse drug reaction in herbal drugs. Effect of herbal medicines on clinical laboratory testing. Regulation and dispensing of herbal drugs.

UNIT V **12 Hrs**

Patents: **5Hrs**

Indian and international patent laws, proposed amendments as applicable to herbal / natural products and process.

Safety monitoring of herbal medicines: **7Hrs**

WHO Guidelines on safety monitoring of herbal medicines in pharmacovigilance systems. Interaction of herbs with other herbs, food and allopathic drugs (Herb- drug Interaction. Herb-Herb Interaction, Herb-Food Interaction) with suitable examples.

REFERENCES:

1. R.D. Choudhary, Herbal drug industryy (1996), Ist Edn, Eastern Publisher, New Delhi.
2. Pulok K Mukharjee, GMP for Botanicals - Regulatory and Quality issues on Phytomedicine (2003), Ist Edition, Business horizons Robert Verpoorte, New Delhi.
3. H.Pande, Herbal Cosmetics, Asia Pacific Business press, Inc, New Delhi.
4. H.Pande, The complete technology book on herbal perfumes and cosmetics, National Institute of Industrial Research, Delhi.
5. Pulok K Mukarjee, Quality control of herbal drugs (2002), Ist Edition, Business Horizons Pharmaceutical Publisher, New Delhi.
6. PDR for Herbal Medicines (2000), 2nd Edition, Medicinal Economic Company, New Jersey.
7. Indian Herbal Pharmacopoeia (2002), Revised Edition, 1DMA, Mumbai.
8. C.K. Kokate, Purohit, Gokhlae, Text book of Pharmacognosy (1996), 4th Edition, Nirali Prakashan, New Delhi.

9. Vinod D. Rangari, Text book of Pharmacognosy and Phytochemistry (2002), Part I & II, Career Publication, Nasik, India.

10. H.Wagner and S.Bladt, Plant drug analysisy, 2nd edition, Springer, Berlin.

11. V. Rajpal, Standardization of Botanicals. Testing and extraction methods of medicinal herbs (2004), Vol.I, Eastern Publisher, New Delhi.

12. J.B.Harborne, Phytochemical Dictionary. Handbook of Bioactive Compounds from Plants, (1999), IInd Edition, Taylor and Francis Ltd, UK.

13. M.Blumenthal, Herbal Medicine. Expanded Commission E Monographs, (2004), IST Edition,

14. D.P.S.Kohli and D.H.Shah, Drug Formulation Manual (1998), II Edition, Eastern Publisher, New Delhi.

PHARMACOGNOSY-1 (MPG105 P)

List of practical (25)

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. Determination of extractive value
8. Determination of volatile oil content of a drug
9. Determination of moisture content
10. Determination of haemolytic activity
11. Determination of bitterness value
12. Determination of foaming index
13. Method of extraction
14. Preliminary Phytochemical screening
15. Thin layer chromatography studies of phyto extracts
16. Demonstration of HPTLC
17. Demonstration of HPLC
18. Demonstration of GC-MS
19. Study of crude drugs under UV light
20. Determination of total solids
21. Determination of ash value
22. Determination of stomatal number and index
23. Determination of vein islet and vein termination number
24. Determination of foreign organic matter by lycopodium spore method
25. Crude fibre in vegetative crude drugs

MEDICINAL PLANT BIOTECHNOLOGY (MPG201T)

Scope

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

Objectives

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

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

THEORY **60Hrs**

UNIT I **12 Hrs**

Introduction to Plant biotechnology: Historical perspectives, prospects for development of plant biotechnology as a source of medicinal agents. Applications in pharmacy and allied fields.

UNIT II **12 Hrs**

Different tissue culture techniques: Nutritional requirements and growth of plant tissue cultures. Organogenesis and embryogenesis. Protoplast fusion, Hairy root multiple shoot cultures and their applications. Micro propagation of medicinal and aromatic plants. Sterilisation methods involved in tissue culture.

UNIT III **12 Hrs**

Immobilisation techniques & Secondary Metabolite Production: Immobilization techniques of plant cell and its application on secondary metabolite Production. Cloning of plant cell: Different methods of cloning and its applications. Advantages and disadvantages of plant cell cloning. Secondary metabolism in tissue cultures with emphasis on production of medicinal agents. Precursors and elicitors on production of secondary metabolites.

UNIT IV **12 Hrs**

Biotransformation and Transgenesis: Biotransformation, bioreactors for pilot and large scale cultures of plant cells and retention of biosynthetic potential in cell culture. Transgenic plants, methods used in gene identification, localization and sequencing of genes. Application of PCR in plant genome analysis.

UNIT V **12 Hrs**

Fermentation technology: Application of Fermentation technology, Production of Vit. B12, Vit. C, Dextrose from starch and cellulose, Streptomycin and single cell proteins

REFERENCES:

1. Bhagwani, Plant tissue culture – Vol 5. (Elsevier)
2. J.R.M.M. Yeoman, Plant cell and Tissue Culture (Lab. Manual).
3. P. K. Gupta, Elements in biotechnology.
4. M. K. Razdan, An introduction to plant tissue culture.
5. John H. D and Lorin W. R, Experiments in plant tissue culture.
6. S. P. Vyas and V. K. Dixit, Pharmaceutical biotechnology.
7. Jeffrey W. Pollard and John M Walker,.Plant cell and tissue cultur.
8. Dixon, Plant tissue culture, Oxford Washington DC, 1985
9. Street, Plant tissue culture by.
10. G. E. Trease and W. C. Evans, Pharmacognosy.
11. Purohit and Mathur, Biotechnology.
12. Shargool.Biotechnological applications to tissue culture.
13. Virroo E. Tyler, Lynn R. Brady and James E. Robberrt, Pharmacognosy.

ADVANCED PHARMACOGNOSY-II (MPG202T)

Scope:

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

Objectives

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

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

THEORY **60Hrs**

UNIT I **12 Hrs**

Herbal remedies – Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of Herbal medicine products, Validation of herbal therapies, Pharmacodynamic and Pharmacokinetic issues, Herbal drug regulations in India.

UNIT II **12 Hrs**

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 crude drugs.

UNIT III **12 Hrs**

Ethnobotany and Ethnopharmacology: Ethnobotany in herbal drug evaluation, Impact of Ethnobotany in traditional medicine, New development in herbals, Drug discovery from Natural Products, Bio-prospecting tools for drug discovery, Role of Ethnopharmacology in drug evaluation, Reverse Pharmacology.

UNIT IV **12 Hrs**

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

UNIT V **12 Hrs**

Biological screening of herbal drugs: Introduction and Need for Phyto-Pharmacological Screening, New Strategies for evaluating Natural Products, *In vitro* evaluation techniques for Antioxidants, Antimicrobial and Anticancer drugs. In vivo evaluation techniques for Anti-inflammatory, Antiulcer, Anticancer, Wound healing, Antidiabetic, Hepatoprotective, Cardio protective, Diuretics and Antifertility.

REFERENCES:

1. P. Pushpangadam. Ulf Nyman. V.George, Glimpses of Indian Ethano Pharmacology. Tropical Botanic Garden & Research Institute, 1995.
2. Raphael Ikan, Natural products: A lab guide 2nd Edition, Academic Press 1991.
3. G. E. Trease and W.C. Evans, Pharmacognosy. 15th Edition W.B. Saunders Edinburgh, New York.
4. Tyler, Brady, Robbers, Pharmacognosy-
5. Peach & M.V. Tracey, Modem Methods of Plant Analysis-, Vol. I&II
6. RD. Choudhary, Herbal Drug Industry, 1st edition, Eastern Publisher, New Delhi, 1996.
7. C.K.Kokate, Purohit, Ghokhale, Text book of Pharmacognosy, 4th edition, Nirali Prakasshan, 1996.
8. T.E. Wallis, Text Book of Pharmacognosy by
9. Pulok K Mukarjee, Quality control of herbal drugs (2002), Ist Edition, Business Horizons Pharmaceutical Publisher, New Delhi.
10. Indian Herbal Pharmacopoeia (2002), Revised Edition, 1DMA, Mumbai.
11. Vinod D. RangarI, Text book of Pharmacognosy and Phytochemistry (2002), Part I & II, Career Publication, Nasik, India.
12. H.Wagner and S.Bladt, Plant drug analysis by 2nd edition, Springer, Berlin.
13. V. Rajpal, Standardization of Botanicals. Testing and extraction methods of medicinal herbs (2004), Vol.I, Eastern Publisher, New Delhi.
14. M.Blumenthal, Herbal Medicine. Expanded Commission E Monographs, (2004), IST Edition,

INDIAN SYSTEMS OF MEDICINE (MPG203T)

Scope

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

Objective

After completion of the course, student is able to

- Understand the basic principles of various Indian systems of medicine
- know the clinical research of traditional medicines, Good Manufacturing Practice of Indian systems of medicine

THEORY **60Hrs**

UNIT I **12 Hrs**

Introduction Ayurveda, Siddha, Unani and Homoeopathy systems of medicine

Historical development Fundamental Principles, Merits and demerits, Different dosage forms,
Ayurveda: Chronological development of Charak Samhita, Sushrut Samhita and Kashyapa Samhita. Ayurvedic Pharmacopoeia Analysis of Ayurvedic Formulations and crude drugs with references to: Identity, purity and quality of crude drugs. **Siddha:** Gunapadam (Siddha Pharmacology), raw drugs/Dhatu/Jeevam in siddha system of medicine, Purification process (Suddhi).

UNIT II **12 Hrs**

Formulation development of various systems of medicine: Salient features of the techniques of preparation of some of the important class of Formulations as per Ayurveda, Siddha, Homeopathy and Unani Pharmacopoeia and texts. Standardization, Shelf life and Stability studies of ISM formulations.

UNIT III **12 Hrs**

Schedule T – Good Manufacturing Practice of Indian systems of medicine:

Components of GMP (Schedule – T) and its objectives, Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records. **06Hrs**

Quality assurance in herbal drug industry of GAP, GMP and GLP in traditional system of medicine. Preparation of documents for new drug application and export registration. Challenges in monitoring the safety of herbal medicines: Regulation, quality assurance and control, National/regional pharmacopoeias. **06Hrs**

UNIT 1V **12 Hrs**

Naturopathy, Yoga and Aromatherapy practices:
a) Naturopathy - Introduction, basic principles and treatment modalities. **03 Hrs**
b) Yoga - Introduction and Streams of Yoga. Asanas, Pranayama, Meditations and Relaxation techniques. **05 Hrs**
c) Aromatherapy – Introduction, aroma oils for common problems, carrier oils. **04 Hrs**

UNIT V **12 Hrs**

Nutrition and Balanced diet: Introduction, Nutrients – functions and deficiencies, Food and toxins, Clinical adverse reactions of herbal medicine, Indian Tribal medicine and Ethno-medicine.

REFERENCES:

1. Ayurvedic Pharmacopoeia (2004), The Controller of Publications, Civil Lines, Govt. of India, New Delhi.
2. H.Panda, Hand Book on Ayurvedic Medicines, National Institute of Industrial Research, New Delhi.
3. Kaviraj Nagendranath Sengupata, Ayurvedic System of Medicine (1998), 2nd Revised Edition, Sri Satguru Publications, New Delhi.
4. Ayurvedic Pharmacopoeia. Formulary of Ayurvedic Medicines (2000), IMCOPS, Chennai.
5. Homeopathic Pharmacopoeia. Formulary of Homeopathic Medicines (2004), IMCOPS, Chennai.
6. Steven B. Kayne, Homeopathic Pharmacy An introduction & Hand book (1997), Churchill Livingstone, New York.
7. Indian Herbal Pharmacopoeia (2002), Revised Edition, 1DMA, Mumbai.
8. British Herbal Pharmacopoeia British (1990), Herbal Medicine Association, UK.
9. Pulok K Mukharjee, GMP for Botanicals - Regulatory and Quality issues on Phytomedicine (2003), First edition, Business Horizons, New Delhi.
10. Indian System of Medicine and Homeopathy in India (2001), Planning and Evaluation Cell, Govt.of India, New Delhi.
11. Swaminathan, Essential of Food and Nutrition (1999), Bappco, Bangalore.

12. F.P. Antia, Clinical Dietitics and Nutrition (1997), 4th Edi, Oxford Universith Press, Delhi.
13. V.K.Yoga, Yoga- The Science of Holistic Living (2005), Vivekananda Yoga Prakashna Publishing, Bangalore.

HERBAL COSMETICS (MPG204T)

Scope

This subject deals with the study of preparation and standardization of herbal cosmetics. This subject gives emphasis to various national and international standards prescribed regarding Drug and cosmetic act.

Objective

After completion of the course, student is able to

- Understand the basic principles of various herbal cosmetic preparations
- Good Manufacturing Practices of herbal cosmetics as per the regulatory authorities

THEORY **60Hrs**

UNIT I **12 Hrs**

Introduction: Herbal cosmetics, Classification& Economic aspects.

Regulatory Provisions relation to manufacture of cosmetics: - License, GMP, offences & Penalties, Import & Export of Herbal cosmetics, Industries involved in the production of Herbal cosmetics.

UNIT II **12 Hrs**

Herbal Cosmetics for the skin: Physiology and chemistry of skin and pigmentation, Cleansing cream, Lotions, Vanishing and Foundation creams, Anti- sun burn preparations, Moisturizing cream , deodorants, Face powders, Face packs, Lipsticks, Bath products, soaps and baby products.

UNIT III **12 Hrs**

Herbal cosmetics for Hair & Scalp: Preparation and standardisation of the following : Shampoos, Conditioners, Tonic, Bleaches, Colorants, Depilatories and Hair oils.

UNIT IV **12 Hrs**

Cosmetics for oral and Nail preparations: Preparation and standardisation of the following

Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails.

UNIT V **12 Hrs**

Analysis of Cosmetics, Toxicity screening and test methods: Quality control and toxicity studies as per Drug and Cosmetics acts.

REFERENCES:

1. Panda H. 2007. Herbal Cosmetics (Hand book), Edition I, Asia Pacific Business Press Inc, New Delhi.
2. Thomson EG. 2006. Modern Cosmetics, Edition I, Universal Publishing Corporation, Mumbai.
3. P.P.Sharma. 2008. Cosmetics- Formulation, Manufacturing & Quality Control, Edition 4, Vandana Publications, New Delhi.
4. Supriya K B. 2005. Handbook of Aromatic Plants, Edition II(Revised and Enlarged), Pointer Publishers, Jaipur.
5. Skaria P. 2007. Aromatic Plants (Horticulture Science Series Vol. 1) , Edition I, New India Publishing Agency, New Delhi.
6. Kathi Keville and Mindy Green.1995. Aromatheraphy (A Complete Guide to the Healing Art), Edition I, Sri Satguru Publications, New Delhi.
7. Chattopadhyay PK. 2000. Herbal Cosmetics & Ayurvedic Medicines (EOU), Edition I, National Institute of Industrial Research, Delhi.
8. Balsam MS & Edward Sagarin. 2008. Cosmetics Science and Technology, Edition II (Vol-II), Wiley Interscience, New York.

PHARMACOGNOSY-1I (MPG205 P)

List of practical (25)

1. Isolation of nucleic acid from cauliflower heads
2. Isolation of RNA from yeast
3. Quantitative estimation of DNA
4. Immobilization of whole cell
5. Establishment of callus culture
6. Establishment of suspension culture
7. Determination of moisture content
8. Determination of swelling index
9. Estimation of aldehyde content
10. Estimation of phenolic content
11. Estimation of total alkaloid from vasaka leaves
12. Estimation of flavonoid content
13. Isolation of aloin from aloe
14. Resin from Indian podophyllum
15. Solanine form potatoes
16. Piperine from black pepper
17. Lawsone from henna
18. Caffeine from tea
19. Preparation and standardization of various simple dosage forms from Ayurvedic, siddha, homoeopathy and Unani formulary.(two experiments)
20. Preparation of certain Aromatherapy formulations (two experiments)
21. Herbal formulation for skin
22. Dermatological preparation
23. Formulation of cough syrup

PHARMACOLOGY(MPL)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUE (MPA101T)

Scope

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

Objectives

After completion of course student is able to know,

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

THEORY **60 HOURS**

UNIT I **12 Hrs**

UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, choice of solvents and solvent effect and applications of UV-Visible spectroscopy. **04 Hrs**

IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopy **04 Hrs**

Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectroscopy. **02 Hrs**

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications. **02 Hrs**

UNIT II **12 Hrs**

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 **08 Hrs**
Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. **04 Hrs**

UNIT III **12 Hrs**

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization techniques like electron impact, chemical, field desorption, FAB and MALDI, APCI, ESI, APPI Analyzers and detectors. Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

UNIT IV **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 V **12 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 **8 Hrs**

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. **4 Hrs**

REFERENCES

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

ADVANCED PHARMACOLOGY-I (MPL101T)

Scope

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

Objectives

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

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

THEORY **60 Hrs**

UNIT-I

General Pharmacology **12 Hrs**

a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding. **06 hrs**

b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects. **06 hrs**

UNIT-II **12 Hrs**

Neurotransmission **06 Hrs**

a. General aspects and steps involved in neurotransmission.

b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline).

c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine).

d. Non-adrenergic non-cholinergic transmission (NANC). Co-transmission

Systemic Pharmacology

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

a. Autonomic Pharmacology **06 Hrs**

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

UNIT-III **12 Hrs**

Central nervous system Pharmacology

General and local anesthetics

Sedatives and hypnotics, drugs used to treat anxiety.

Depression, psychosis, mania, epilepsy, neurodegenerative diseases.

Narcotic and non-narcotic analgesics.

UNIT-IV

Cardiovascular Pharmacology **12 Hrs**

Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia.

Hematinics, coagulants , anticoagulants, fibrinolytics and anti-platelet drugs

UNIT- V

Autocoid Pharmacology **12 Hrs**

The physiological and pathological role of Histamine, Serotonin, Kinins, Prostaglandins Opioid autocoids.

Pharmacology of antihistamines, 5HT antagonists.

REFEERENCES:

1. Brunton, L. L., Lazo, J., & Parker, K. The pharmacological basis of therapeutics. Goodman and Gilmans.. McGraw-Hill, Medical Publication Division, New York.
2. Golan, D. E., Tashjian, A. H., & Armstrong, E. J. Principles of pharmacology: the pathophysiologic basis of drug therapy. Lippincott Williams & Wilkins.
3. Bertram G. Katzung., Susan B. Masters., Anthony J. Trevor. Basic and Clinical Pharmacology. McGraw-Hill, Medical Publication Division, New York.
4. Rang, H. P., Dale, M. M., Ritter, J. M., & Moore, P. K. Pharmacology. Churchill Livingstone. New York.
5. Gibaldi, M., & Prescott, L. F. Handbook of clinical pharmacokinetics. ADIS Health Science Press.
6. E T. Herfindal and Gourley. Textbook of therapeutics: drug and disease management. Lippincott Williams & Wilkins.
7. Leon Shargel., Andrew BC Yu., and Susanna Wu-Pong. Applied biopharmaceutics and pharmacokinetics.McGraw-Hill, Medical Publication Division, New York.

8. Kwon, Y. Handbook of essential pharmacokinetics, pharmacodynamics and drug metabolism for industrial scientists. Springer Science & Business Media.

SCREENING METHODS IN PHARMACOLOGY
(MPL102T)

Scope

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

Objectives

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

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

THEORY **60 Hrs**

Unit-I **12 Hrs**

Laboratory Animals

Common lab 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.

Unit-II **12 Hrs**

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

General principles of preclinical screening. CNS Pharmacology: behavioral and muscle co- ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, antiepileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple

sclerosis. Drugs acting on Autonomic Nervous System.

Unit-III **12 Hrs**

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

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

Unit-IV **12 Hrs**

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

Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antihyperlipidemic, and anticancer agents

Unit V **12 Hrs**

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

Immunosuppressants and immunomodulators

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

Limitations of animal experimentation and alternate animal experiments. Extrapolation of *in vitro* data to preclinical and preclinical to humans.

REFERENCES :

1. Kleiderer, E. C. Biological standardization: By JH Burn, DJ Finney, and LG Goodwin. Oxford University Press, London, New York, Toronto.
2. Indian Pharmacopeia and other Pharmacopeias
3. Turner, R. A. Screening methods in pharmacology. Elsevier.
4. Laurence, D. R., & Bacharach, A. L. Evaluation of drug activities: pharmacometrics (Vol. 900). New York: Academic press.
5. Schwartz, A. Methods in pharmacology.
6. Ghosh, M. N. Fundamentals of experimental Pharmacology Publisher: Hilton and Company, Kolkata.
7. McLeod, L. J. Pharmacological experiments on intact preparations. Churchill Livingstone

8. Vogel, H. G. Drug discovery and evaluation: pharmacological assays. Springer Science & Business Media.
9. Goyal, R. K. Experimental Pharmacology.
10. Gupta, S. K. Drug Screening Methods (Preclinical Evaluation of New Drugs). Jaypee publishers. New Delhi.

CELLULAR AND MOLECULAR PHARMACOLOGY (MPL103T)

Scope:

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

Objectives:

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

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

Unit I **12 Hrs**

Cell biology

Structure and functions of cell and its organelles

Genome organization. Gene expression and its regulation, Cell cycles and its regulation.

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

Necrosis and autophagy.

Unit II **12Hrs**

Cell signaling

Intercellular and intracellular signaling pathways.

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

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

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

Unit III **12Hrs**

Principles and applications of genomic and proteomic tools **06 hrs**

DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting,

Recombinant DNA technology and gene therapy **06 hrs**

Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology.
Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy

Unit IV **12Hrs**

Pharmacogenomics **08 hrs**

Gene mapping and cloning of disease gene. Importance of siRNA and micro RNA
Genetic variation and its role in health/ pharmacology
Polymorphisms affecting drug metabolism
Genetic variation in drug transporters
Genetic variation in G protein coupled receptors
Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics

Immunotherapeutics **04 hrs**

Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice

Unit V **12Hrs**

Cell culture techniques

Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application.
Principles and applications of cell viability assays and glucose uptake assay. Principles and applications of flow cytometry

References:

1. Cooper, G. M., & Ganem, D. The Cell: A Molecular Approach. Sinauer Associates. Sunderland, USA.
2. Licinio J & Wong M Pharmacogenomics: The Search for Individualized Therapies, Wiley. Weinheim (Germany).
3. Bradshaw, R. A., & Dennis, E. A. Handbook of Cell SignalingAcademic Press.
4. Dickenson, J., Freeman, F., Mills, C. L., Thode, C., & Sivasubramaniam, S. Molecular pharmacology: from DNA to drug discovery. John Wiley & Sons.
5. Helgason, C. D., & Miller, C. L. Basic cell culture protocols. Totowa, NJ.: Humana Press.
6. Davis, J. M. (Ed.). Basic cell culture: a practical approach. IRL Press.
7. Masters, J. R. (Ed.). Animal cell culture: a practical approach (pp. 3-10). Oxford: Oxford University Press.

8. Ausubel, F. M. Current protocols in molecular biology: volume I-VI. John Wiley & Sons.

PHARMACOLOGY PRACTICAL- I (MPL104P)

List of Experiments (20)

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

Reference

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Ghosh, M. N. Fundamentals of experimental Pharmacology. Publisher: Hilton and Company, Kolkata.
3. Kulkarni S. K. Handbook of Experimental Pharmacology. Vallabh Prakash publishers, New Delhi.
4. Vogel, H. G. Drug discovery and evaluation: pharmacological assays. Springer Science & Business Media.
5. Silverstein, R. M., Webster, F. X., Kiemle, D. J., & Bryce, D. L. Spectrometric

identification of organic compounds. John Wiley & Sons.
6. Douglas A. Skoog, F. James Holler, Timothy A. Nieman T. A. Principles of instrumental analysis . Eastern press, Bangalore.
7. Mendham, J. Vogels textbook of quantitative chemical analysis. Pearson Education India.
8. Helgason, C. D., & Miller, C. L. Basic cell culture protocols. Totowa, NJ.: Humana Press.
9. Davis, J. M. Basic cell culture: a practical approach. IRL Press.
10. Masters, J. R. Animal cell culture: a practical approach (pp. 3-10). Oxford: Oxford University Press.

ADVANCED PHARMACOLOGY-II (MPL201T)

Scope

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

Objectives

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

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

UNIT-I

Endocrine Pharmacology **12 Hrs**

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

Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids.

Drugs affecting calcium regulation

UNIT-II

Chemotherapy **12 Hrs**

Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.

UNIT-III **12 Hrs**

Chemotherapy **06 Hrs**

Drugs used in Protozoal Infections

Drugs used in the treatment of Helminthiasis

Chemotherapy of cancer

Immunopharmacology **06 Hrs**

Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD.

Immunosuppressants and Immunostimulants

UNIT-IV

GIT Pharmacology **08 Hrs**

Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome.

Chronopharmacology **04 Hrs**

Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer

UNIT-V

Free radicals Pharmacology **04 Hrs**

Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer.

Protective activity of certain important antioxidant

Recent Advances in Treatment of : **08 Hrs**

Alzheimer's disease, Parkinson's disease , Cancer, Diabetes mellitus

References

1. Brunton, L. L., Lazo, J., & Parker, K. The pharmacological basis of therapeutics. Goodman and Gilmans. McGraw-Hill, Medical Publication Division, New York.
2. Golan, D. E., Tashjian, A. H., & Armstrong, E. J. Principles of pharmacology: the pathophysiologic basis of drug therapy. Lippincott Williams & Wilkins.
3. Bertram G. Katzung., Susan B. Masters., Anthony J. Trevor. Basic and Clinical Pharmacology. McGraw-Hill, Medical Publication Division, New York.
4. Rang, H. P., Dale, M. M., Ritter, J. M., & Moore, P. K. Pharmacology. Churchill Livingstone. New York.
5. Gibaldi, M., & Prescott, L. F. Handbook of clinical pharmacokinetics. ADIS Health Science Press.
6. E T. Herfindal and Gourley. Textbook of therapeutics: drug and disease management. Lippincott Williams & Wilkins
7. Leon Shargel., Andrew BC Yu., and Susanna Wu-Pong. Applied biopharmaceutics and pharmacokinetics. McGraw-Hill, Medical Publication Division, New York.
8. Kwon, Y. Handbook of essential pharmacokinetics, pharmacodynamics and drug metabolism for industrial scientists. Springer Science & Business Media.

PRINCIPLES OF TOXICOLOGY
(MPL202T)

Scope:

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

Objectives:

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

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

Unit I **12 Hrs**

Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive)
Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y
OECD principles of Good laboratory practice (GLP)
History, concept and its importance in drug development

Unit II **12 Hrs**

Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines.
Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.
Test item characterization- importance and methods in regulatory toxicology studies

Unit III **12 Hrs**

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

Unit IV **12 Hrs**

IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission.

Safety pharmacology studies- origin, concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies

Unit V **12 Hrs**

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

REFERENCES

1. World Health Organization. (2010). Handbook: good laboratory practice (GLP): quality practices for regulated non-clinical research and development. World Health Organization. (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. Rick, N.G. Drugs: from discovery to approval. John Wiley & Sons.
4. Gad, S. C. Animal models in toxicology. CRC Press
5. OECD test guidelines.
6. Stine, K. E., & Brown, T. M. Principles of toxicology. Crc Press.
7. Guidelines, I. H. T. Guidance on nonclinical safety studies for the conduct of human clinical trials and marketing authorization for pharmaceuticals M3 (R2). In International conference on harmonisation of technical requirements for registration of pharmaceuticals for human use. (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

PRINCIPLES OF DRUG DISCOVERY (MPL203T)

Scope:

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

Objectives:

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

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

Unit-I **12 Hrs**

An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery.

Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

Unit-II **12 Hrs**

Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification.

Protein structure

Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction

Unit-III **12 Hrs**

Rational Drug Design

Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational

Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches

Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

Unit-IV **12 Hrs**

Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design.

Quantitative analysis of Structure Activity Relationship

History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.

Unit-V **12 Hrs**

QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA

Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design

References:

1. Sioud, M. Target Discovery and Validation: Reviews and Protocols (Vol. 2) Emerging Molecular Targetsand Treatment Options. Humana Press Inc.
2. León, D., & Markel, S. In Silico technologies in drug target identification and validation. CRC Press.
3. DiStefano, J. K. (Ed.). Disease gene identification: methods and protocols. Humana Press.
4. Mannhold, R., Krogsgaard-Larsen, P., & Timmerman, H. QSAR: Hansch analysis and related approaches (Vol. 1). H. Kubinyi (Ed.). John Wiley & Sons. Inc., Hoboken, New Jeney.
5. Bvhm, H. J., & Mannhold, R. Structure-based Ligand Design. Methods and Principles in Medicinal Chemistry. K. Gubernator, & H. J. Bohm (Eds.). John Wiley & Sons. Inc., Hoboken, New Jeney.
6. Parrill, A. L., & Reddy, M. R. Rational drug design: novel methodology and practical applications (No. 719). Amer Chemical Society.: Washington, DC.
7. Turner, J. R. New drug development: design, methodology, and analysis (Vol. 27). John Wiley & Sons. Inc., Hoboken, New Jeney.

CLINICAL PHARMACOLOGY (MPL204T)

Scope:

This subject will provide in-depth knowledge of Clinical Pharmacology and current status of clinical research. This will help the student to excel in the field of Clinical Drug Development.

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

UNIT-I **12 Hrs**

Introduction to Clinical Pharmacology **08 Hrs**

Definition, scope and development of clinical pharmacology, role of pharmacist in healthcare system, prescription monitoring and rational use of drugs, essential drugs and national drug policy, pharmacoepidemiology, patient counselling, medication errors and drug information systems.

Concept of Pharmaceutical Care and its Implementation **04 Hrs**

Plan, components and challenges, communication and behavioural skills in clinical pharmacology practice.

UNIT- II **12 Hrs**

Drug Therapy in Specialized Patient Populations

Neonates : **04 Hrs**

Special childhood diseases and their management, national immunization programmes, relevant paediatric management issues as dosages adjusment, pharmacokinetics of development stage and compliance.

Geriatrics : **04 Hrs**

Pharmaceutical care plan based on age related physiological a pharmacokinetic/ pharmacodynamic changes, compliance related issues.

Pregnancy and Lactation : **04 Hrs**

Guidelines and principles of drug therapy during pregnancy and lactation. Management of hypertension, diabetes and epilepsyduring pregnancy.

UNIT- III **12 Hrs**

Clinical Trials

Requirement of clinical trials, Helsinki declaration, ethical and legal issues in clinical trials.

Design (placebo, multicentre clinical trials, randomization, blinding) and different phases of clinical trials (Phase 1 to 4), principles of controlled clinical trials.

Protocol designing, CRF, patient informed consent, patient enrolment, inclusion and exclusion criteria, withdrawals and drop out, run-in period.

Clinical trial team, monitoring of clinical trial, report preparation, deviations in clinical trials.

Clinical data management.

UNIT-IV **12 Hrs**

Basic aspects, terminologies and establishment of Pharmacovigilance

History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects

WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance.

Roles and responsibilities in Pharmacovigilance

UNIT-V **12 Hrs**

Adverse Drug Reactions **04 Hrs**

Incidence, importance, surveillance and their monitoring WHO ADR reporting programmes in India and drug interactions.

National and International Guidelines and Drug Regulations and Recent Development in Clinical Research **04 Hrs**

Good Clinical practice, ICH guidelines, FDA/EMEA documentation preparation.

Telemedicine **04 Hrs**

History and advance in telemedicine, benefits and limitations of telemedicine.

References:

1. Laurence, D. R., Bennett, P. N., & Brown, M. J. (1997). Clinical Pharmacology Churchill Livingstone. New York
2. Walker, R., & Edwards, C. Clinical pharmacy and therapeutics.Churchill Livingstone, London.
3. Shargel, L., & Swanson, L. N. Comprehensive pharmacy review. Lippincott Williams & Wilkins.
4. Posey, L. M., Wells, B. G., & Yee, G. C. Pharmacotherapy a pathophysiologic approach. The McGraw-Hill.New York. Latest Editon.
5. Avery, G. S. Drug treatment (No. Ed. 2). Churchill Livingstone..Bertram G. Katzung., Susan
6. B. Masters., Anthony J. Trevor. Basic and Clinical Pharmacology. 12th ed. McGraw-Hill, Medical Publication Division, New York.

Pharmacology Practical-II (MPL205P)

List of Experiments (20)

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

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References

1. Ghosh, M. N. Fundamentals of experimental Pharmacology. 6th ed. Prof. M. N. Ghosh Publisher: Hilton and Company, Kolkata.
2. Kulkarni S. K. Handbook of Experimental Pharmacology. 3rd ed. Vallabh Prakash publishers, New Delhi.
3. Kitchen, I. Textbook of in vitro practical pharmacology. Blackwell Scientific Publishers.
4. Atta-ur-Rahman, Iqbal choudhary and William J. Thomsen. Bioassay Techniques for Drug Development. CRC Press
5. Leon Shargel., Andrew BC Yu., and Susanna Wu-Pong. Applied biopharmaceutics and pharmacokinetics. McGraw-Hill, Medical Publication Division, New York.
6. Kwon, Y. Handbook of essential pharmacokinetics, pharmacodynamics and drug metabolism for industrial scientists. Springer Science & Business Media

PHARMACY PRACTICE
(MPP)

Clinical Pharmacy Practice (MPP101T)

Scope

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

Objectives

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

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

THEORY **60 Hrs**

UNIT I **12 Hrs**

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)

UNIT II **12 Hrs**

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

UNIT III **12 Hrs**

Patient Data & Practice Skills:
Patient's case history - its structure and significances in drug therapy management, Common medical abbreviations and terminologies used in clinical practice,

Communication skills: verbal and non-verbal communications, its applications in patient care services.

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

UNIT IV **12 Hrs**

Lab Data Interpretation:
Tests associated with cardiac disorders, Pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, Microbiological culture sensitivity tests

UNIT V **12 Hrs**

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

REFERENCES

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

Pharmacotherapeutics -I (MPP102T)

Scope

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

Objectives

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

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

THEORY **60 Hrs**

Etiopathogenesis and pharmacotherapy of diseases associated with following systems

UNIT I **12 Hrs**

Cardiovascular system:

Hypertension, Congestive cardiac failure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias, Rheumatic heart disease

UNIT II **12 Hrs**

Respiratory system:

Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases

Endocrine system:

Diabetes, Thyroid diseases

UNIT III **12 Hrs**

Gastrointestinal system:

Peptic ulcer diseases, Reflux esophagitis, Inflammatory bowel diseases, Jaundice & hepatitis

UNIT IV **12 Hrs**

Gastrointestinal system:

Cirrhosis, Diarrhea and Constipation, Drug-induced liver disease

Hematological diseases:

Anemia, Deep vein thrombosis, Drug induced hematological disorders

UNIT V **12 Hrs**

Bone and joint disorders:

Rheumatoid arthritis, Osteoarthritis, Gout, Osteoporosis

Dermatological Diseases:

Psoriasis, Eczema and scabies, impetigo, drug induced skin disorders

Ophthalmology:

Conjunctivitis, Glaucoma

REFERENCES

1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone Publication
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange Publication
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 Publication

6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins Publication
8. Harrison's. Principles of Internal Medicine - McGraw Hill Publication
9. Relevant review articles from recent medical and pharmaceutical literature

Hospital & Community Pharmacy (MPP103T)

Scope

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

Objectives

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

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

THEORY **60 Hrs**

UNIT I **12 Hrs**

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

UNIT II **12 Hrs**

Hospital Drug Policy:
Hospital Formulary Guidelines and its development, Developing Therapeutic guidelines,

Drug House Management:
Drug procurement process, and methods of Inventory control, Methods of Drug distribution, Intravenous admixtures, Hospital Waste Management

UNIT III **12 Hrs**

Education and training:
Training of technical staff, Training and continuing education for pharmacists, Pharmacy students, Medical staff and students, Nursing staff and students, Formal and informal meetings and lectures, Drug and therapeutics newsletter.

Community Pharmacy Practice:
Definition, roles & responsibilities of community pharmacists, relationship of community pharmacists with other health care providers

Community Pharmacy management:
Legal requirements to start community pharmacy, site selection, lay out & design, drug display, super drug store model, accounts

UNIT IV **12 Hrs**

Prescription:
Legal requirements & interpretation, prescription related problems
Responding to symptoms of minor ailments:
Head ache, pyrexia, menstrual pains, food and drug allergy,
OTC medication:
Rational use of over the counter medications
Medication adherence and Patient referrals to the doctors
ADR monitoring in community pharmacies

UNIT V **12 Hrs**

Health Promotion:
Definition and health promotion activities, family planning, Health screening services, first aid, prevention of communicable and non-communicable diseases, smoking cessation, Child & mother care
Home Medicines Review Program:
Definition, objectives, Guidelines, method and outcomes, Research in community pharmacy

REFERENCES

1. Hassan WE. Hospital Pharmacy. Lec and Febiger Publication.
2. Allwood MC and J T Fell. Textbook of hospital pharmacy. Blackwell Science Ltd.
3. Trevor M Speight and Nicholas H G Holford. Avery's Drug Treatment. Wiley India Pvt. Ltd.
4. Remington's Pharmaceutical Science. John Wiley & Sons
5. Relevant review articles from recent medical and pharmaceutical literature

Clinical Research (MPP104T)

Scope

This course aims to provide the students an opportunity to learn drug development process especially the phases of clinical trials and also the ethical issues involved in the conduct of clincal 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

THEORY **60 Hrs**

UNIT I **12 Hrs**

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

UNIT II **12 Hrs**

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.

UNIT III **12 Hrs**

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

UNIT IV **12 Hrs**

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

UNIT V **12 Hrs**

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

REFERENCES

1. Lionel. D. Edwards, Andrew. J. Fletcher Anthony W Fox, Peter D Stonier. Principles and practice of pharmaceutical medicine. Wiley Blackwell.
2. Julia Lloyd and Ann Raven Ed. Handbook of clinical research. Churchill Livingstone.
3. Giovanna di Ignazio, Gareth Hayes. Principles of Clinical Research. Routledge.
4. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.

5. International Council for Harmonization of Technical requirements for Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice
6. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
7. David Machin, Simon Day and Sylvan Green. Textbook of Clinical Trials. John Wiley & Sons.
8. Richard K Rondel, Sheila A Varley, Colin F Webb. Clinical Data Management. Wiley India Pvt. Ltd.
9. Laurence Brunton, Bruce A Chabner and Bjorn Knollman. Goodman & Gilman's The Pharmacological basis of therapeutics. McGraw Hill Education.
10. Relevant review articles from recent medical and pharmaceutical literature.

Pharmacy Practice Practical - I (MPP101P)

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

List of Experiments (20)

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

Principles of Quality Use of Medicines (MPP201T)

Scope:

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

Objectives:

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

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

THEORY **60 Hrs**

UNIT I **12 Hrs**

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

UNIT II **12 Hrs**

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

UNIT III **12 Hrs**

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

UNIT IV **12 Hrs**

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

UNIT V **12 Hrs**

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

REFERENCES:

1. Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills. Orient Blackswan Pvt. Ltd. – (latest edition)
2. Elizabeth B Andrews, Nicholas Moore. Mann's Pharmacovigilance. Wiley Blackwell (Latest Edition)
3. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange Publication (Latest Edition)
4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teach it. Elsevier Health Sciences. (Latest Edition)
5. Cohen MR. Medication Errors. American Pharmaceutical Association. (Latest Edition)
6. Online:
    - http://medicinesaustralia.com.au/files/2012/05/MA_QUM_External_Reduced.pdf
    - http://curriculum.racgp.org.au/statements/quality-use-of-medicines/
    - http://www.rug.nl/research/portal/files/14051541/Chapter_2.pdf
7. Relevant review articles from recent medical and pharmaceutical literature.

Pharmacotherapeutics -II (MPP202T)

Scope

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

Objectives

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

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

THEORY **60 Hrs**

UNIT I **12 Hrs**

Nervous system:

Epilepsy, Parkinson's disease, Stroke, Headache, Alzheimer’s disease, Neuralgias and Pain pathways and Pain management

UNIT II **12Hrs**

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

UNIT III **12 Hrs**

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

UNIT IV **12 Hrs**

Infectious diseases:

Meningitis, HIV and opportunistic infections, Dengue fever, H1N1, Helmenthiasis, Fungal infections

Gynaecological disorders:

Dysmenorrhea, Hormone replacement therapy

UNIT V **12 Hrs**

Oncology:

General principles of cancer chemotherapy, pharmacotherapy of breast cancer, lung cancer, head & neck cancer, hematological malignancies, Management of nausea and vomiting, Palliative care

REFERENCES

1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone Publication
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange Publication
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 Publication
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins Publication
8. Harrison's. Principles of Internal Medicine - McGraw Hill Publication

9. Relevant review articles from recent medical and pharmaceutical literature

Clinical Pharmacokinetics and Therapeutic Drug Monitoring (MPP203T)

Scope

This course is designed to enable students to understand the 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 enable students to understand the basic concepts of pharmacogenetics, pharmacometrics for modeling and simulation of pharmacokinetic data.

Objectives

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

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

THEORY **60 Hrs**

UNIT I **12 Hrs**

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

UNIT II **12Hrs**

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

UNIT III **12 Hrs**

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

UNIT IV **12 Hrs**

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

UNIT V **12 Hrs**

Therapeutic Drug monitoring:

Introduction, Individualization of drug dosage regimen (Variability – Genetic, age, weight, disease and Interacting drugs), Indications for TDM, Protocol for TDM, Pharmacokinetic/Pharmacodynamic Correlation in drug therapy, TDM of drugs used in the following conditions: Cardiovascular disease: Digoxin, Lidocaine, Amiodarone**;** Seizure disorders: Phenytoin, Carbamazepine, Sodium Valproate**;** Psychiatric conditions: Lithium, Fluoxetine, Amitriptyline; Organ transplantations: Cyclosporine**;** Cytotoxic Agents: Methotrexate, 5-FU, Cisplatin; Antibiotics: Vancomycin, Gentamicin, Meropenem

REFERENCES

1. Leon Shargel and Andrew B C Yu. Applied Biopharmaceutics & Pharmacokinetics. McGraw Hill Education

2. Peter L. Bonate. Pharmacokinetic - Pharmacodynamic Modelling and Simulation. Springer.

3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E. Evans. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring. Lippincott Williams & Wilkins

4. Steven How-Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. CRC Press.

5. Soraya Dhillon, Andrzej Kostrzewski. Clinical Pharmacokinetics. Pharmaceutical Press.

6. Joseph T. Dipiro, William J. Spruill, Robert A. Blouin, Jane M. Pruemer and William E. Wade. Concepts in Clinical Pharmacokinetics. American Society of Health-System Pharmacists.

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

8. William Evans, Jerome J Schentag, William J Jusko. Applied Pharmacokinetics: Principles Therapeutic Drug Monitoring. Lippincott Williams & Wilkins

9. Michael E. Winter. Basic Clinical Pharmacokinetics. Lippincott Williams & Wilkins.

10. Milo Gibaldi. Biopharmaceutics and Clinical Pharmacokinetics. Pharma Book Syndicate.

11. John E. Murphy. Clinical Pharmacokinetics. American Society of Health- System Pharmacists.
12. Relevant review articles from recent medical and pharmaceutical literature

Pharmacoepidemiology & Pharmacoeconomics (MPP204T)

Scope

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

Objectives

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

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

THEORY **60 Hrs**

UNIT I **12 Hrs**

Introduction to Pharmacoepidemiology:
Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements.

Concept of risk:
Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio

UNIT II **12 Hrs**

Pharmacoepidemiological Methods:
Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Oddss ratio, Meta analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of pharmacoepidemiology

UNIT III **12 Hrs**

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.

UNIT IV **12 Hrs**

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).

UNIT V **12 Hrs**
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

REFERENCES

1. Brian L Strom, Stephen E Kimmel, Sean Hennessy. Pharmacoepidemiology. Wiley-Blackwell
2. R Brian Haynes, David L Sackett, Gordon H Guyatt, Peter Tugwell. Clinical Epidemiology: How to Do Clinical Practice Research. Lippincott Williams & Wilkins.
3. Karen L Rascati. Essentials of Pharmacoeconomics. Lippincott Williams & Wilkins.
4. Thomas E Getzen. Health Economics: Fundamentals and Flow of Funds. John Wiley & Sons
5. Andrew Briggs, Mark Sculpher, Karl Claxton. Decision Modelling for Health Economic Evaluation. Oxford University Press.
6. Michael F Drummond, Mark J Sculpher, Karl Claxton, Greg L Stoddart, George W Torrance. Methods for the Economic Evaluation of Health Care Programmes. Oxford University Press.
7. George E Mackinnon. Understanding health outcomes and Pharmacoeconomics. Johnes & Bartlett Publishers
8. Dennis W Grauer. Pharmacoeconomics and outcomes: Applications for patient care. American College of Clinical Pharmacy.
9. Tom Walley, Alan Haycox, Angela Bolland. Pharmacoeconomics. Elsevier Health Sciences.
10. Dennis W Grauer. Pharmacoeconomics and outcomes: Case Studies. American College of Clinical Pharmacy
11. Relevant review articles from recent medical and pharmaceutical literature

Pharmacy Practice Practical - II (MPP205P)

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

List of Experiments (20)

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

PHARMACEUTICAL QUALITY ASSURANCE (MQA)

MODERN PHARMACEUTICAL ANALYSIS (MPA101T)

Scope

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

Objectives

After completion of course student is able to know,

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

THEORY **60 HOURS**

UNIT I **12 Hrs**

UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, choice of solvents and solvent effect and applications of UV-Visible spectroscopy. **04 Hrs**

IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopy **04 Hrs**

Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectroscopy. **02 Hrs**

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications. **02 Hrs**

UNIT II **12 Hrs**

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 **08 Hrs**
Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. **04 Hrs**

UNIT III **12 Hrs**

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization techniques like electron impact, chemical, field desorption, FAB and MALDI, APCI, ESI, APPI Analyzers and detectors. Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

UNIT IV **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 V **12 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 **8 Hrs**

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. **4 Hrs**

REFERENCES

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

QUALITY MANAGEMENT SYSTEMS (MQA101T)

Scope

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

Objectives

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

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

THEORY **60 Hrs**

UNIT I **12 Hrs**

Introduction to Quality **02 Hrs**

Evolution of Quality, Definition of Quality, Dimensions of Quality

Quality as a Strategic Decision **03 Hrs**

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 **04 Hrs**

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

Cost of Quality **03Hrs**

Cost of quality, Categories of cost of Qquality, Models of cost of ouality, Optimising costs, Preventing cost of quality

UNIT II **12 Hrs**

Pharmaceutical quality Management

Basics of Quality Management, Total Quality Management (TQM), Overview 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

UNIT III **12 Hrs**

Six System Inspection model **06 Hrs**

Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system.

Quality systems **06 Hrs**

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.

UNIT IV **12 Hrs**

Drug Stability **04 Hrs**

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 **08Hrs**

Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines

UNIT V **12 Hrs**

Statistical Process control (SPC) **08 Hrs**

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

Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking **04 Hrs**

Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking

REFERENCES:

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

QUALITY CONTROL AND QUALITY ASSURANCE (MQA102T)

Scope:

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

Objectives: Upon completion of this course the student should be able to

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

Theory **60Hrs**

UNIT- I **12 Hrs**

Concept and evolution of Quality Control and Quality Assurance,

Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines.

Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.

UNIT- II **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-III **12 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 formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products, Quality control test for containers, closures and secondary packing materials.

UNIT-IV **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 Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data.

Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD)

UNIT-V **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.

Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.

REFERENCES

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

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (MQA103T)

Scope

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

Objectives:

Upon completion of this course the student should be able to

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

THEORY **60 Hrs**

UNIT I **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 II **12 Hrs**

Preformulation studies

Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Preformulation protocol, Stability testing during product development.

UNIT III **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 IV **12 Hrs**

Pharmaceutical packaging **08 Hrs**

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 **04 Hrs**

Containers, closures and secondary packing materials.

UNIT V **12 Hrs**

Technology transfer **08 Hrs**

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 **04 Hrs**

Development report, technology transfer plan and Exhibit.

REFERENCES

1. Charles G. Smith, James T and O. Donnell. The process of new drug discovery and development. 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. Lachman, Herbert A. Liberman, Joseph B. Schwartz . Tablets Vol. I, II, III. Marcel Dekker Inc. New York.
5. Gibaldi, Lea & Febriger, Philadelphia.Text book of Bio- Pharmaceutics and clinical Pharmacokinetics. Milo

6. V. Patrevale. John I. Disouza. Maharukh T.Rustomji. Pharmaceutical product development. Vandana CRC Press, Group of Taylor and Francis.
7. Abdou H.M. Dissolution, Bioavailability and Bio-Equivalence by Mack Publishing company, Eastern Pennsylvania.
8. Alfonso & Gennaro. Remingtons Pharmaceutical Sciences, 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. D.A. Dean. E.R. Evans, I.H. Hall. Pharmaceutical Packaging technology. Taylor and Francis. London and New York.

QUALITY ASSURANCE PRACTICAL-I (MQA104P)

PRACTICALS

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. **Case studies on**

- Total Quality Management
- Six Sigma
- Change Management/ Change control. Deviations,
- Out of Specifications (OOS)
- Out of Trend (OOT)
- Corrective & Preventive Actions (CAPA)
- Deviations

8 Development of Stability study protocol

9. Estimation of process capability
10. In process and finished product quality control tests for tablets, capsules, parenterals and creams
11. Assay of raw materials as per official monographs
12. Testing of related and foreign substances in drugs and raw materials
13. To carry out preformulation study for tablets, parenterals (2 experiment).
14. To study the effect of pH on the solubility of drugs, (1 experiment)
15. Quality control tests for Primary and secondary packing materials
16. Accelerated stability studies (1 experiment)
17. Improved solubility of drugs using surfactant systems (1 experiment)
18. Improved solubility of drugs using co-solvency method (1 experiment)

HAZARDS AND SAFETY MANAGEMENT (MQA201T)

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.
- Esure that safety in chemical industry.
- Provide comprehensive knowledge on the safety management
- Empower an ideas to clear mechanism and management in different kinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

THEORY **60 Hrs**

UNIT I **12 Hrs**

Multidisciplinary nature of environmental studies **07 Hrs**

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 **05 Hrs**

Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.

UNIT II **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 III **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.

UNIT IV **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 V **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,.

REFERENCES:

1. Y.K. Sing, Environmental Science. New Age International Pvt, Publishers, Bangalore
2. "Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Bharucha Erach, The Biodiversity of India, Mapin 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 (MQA202T)

Scope

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

Objectives

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

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

THEORY **60 Hrs**

UNIT I **12 Hrs**

Introduction to validation **06 Hrs**

Definition of Qualification and Validation, 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 **06 Hrs**

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 II **12 Hrs**

Qualification of manufacturing equipment **06 Hrs**

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 **06 Hrs**

UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.

UNIT III **12 Hrs**

Qualification of laboratory equipments **06 Hrs**

Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus

Validation of Utility systems **06 Hrs**

Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.

UNIT IV **12 Hrs**

Process Validation **10 Hrs**

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 **02 Hrs**

General principles, Validation of analytical method as per ICH guidelines (Q2) and USP.

UNIT V **12 Hrs**

Cleaning Validation **04 Hrs**

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. **04 Hrs**

Computerized system validation **04 Hrs**

Electronic records and digital signature - 21 CFR Part 11 and GAMP 5. **12 Hrs**

REFERENCES:

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

AUDITS AND REGULATORY COMPLIANCE (MQA203T)

Scope:

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

Objectives:

Upon completion of this course the student should be able to

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

THEORY **60 Hrs**

UNIT I **12 Hrs**

Introduction

Objectives, Management of audit**,** Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies

UNIT II

Role of quality systems and audits in pharmaceutical manufacturing environment **12 Hrs**

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 III

Auditing of vendors and production department **12 Hrs**

Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and

weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.

UNIT IV **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 V

Auditing of Quality Assurance and engineering department **12 Hrs**

Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems.

REFERENCES

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

PHARMACEUTICAL MANUFACTURING TECHNOLOGY (MQA204)

Scope

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

Objectives

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

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

THEORY **60Hrs**

UNIT I **12 Hrs**

Pharmaceutical industry developments **04 Hrs**

Licenses for formulation industry, Plant location-Factors influencing**.**

Plant layout **04 Hrs**

Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout.

Production planning **04 Hrs**

General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.

UNIT II **12 Hrs**

Aseptic process technology **04 Hrs**

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 **04 Hrs**

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 **06 Hrs**

With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS).

Lyophilization technology: Principles, process, equipment. **02 Hrs**

UNIT III **12 Hrs**

Non sterile manufacturing process technology **04 Hrs**

Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft).

Advance non-sterile solid product manufacturing technology **06 hrs**

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 **02 Hrs**

Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

UNIT IV

Containers and closures for pharmaceuticals **12 Hrs**

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 V **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.

REFERENCES

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

QUALITY ASSURANCE PRACTICAL-II(MQA205P)

PRACTICALS

1. Organic contaminants residue analysis by HPLC
2. Estimation of Metallic contaminants by Flame photometer
3. Identification of antibiotic residue by TLC
4. Estimation of Hydrogen Sulphide in Air.
5. Estimation of Chlorine in Work Environment.
6. Sampling and analysis of SO_2 using Colorimetric method
7. Qualification of following Pharma equipment
   a. Autoclave b. Hot air oven c. Powder Mixer (Dry) d. Tablet Compression Machine
8. Validation of an analytical method for a drug
9. Validation of a processing area
10. Qualification of at least two analytical instruments
11. Cleaning validation of one equipment
12. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
13. Check list for Bulk Pharmaceutical Chemicals vendors
14. Check list for tableting production.
15. Check list for sterile production area
16. Check list for Water for injection.
17. Design of plant layout: Sterile and non-sterile
18. Case study on application of QbD
19. Case study on application of PAT

PHARMACEUTICAL REGULATORY AFFAIRS

(MRA)

GOOD PHARMACEUTICAL PRACTICES (MRA 101T)

Scope

This course is designed to impart fundamental knowledge on various Good Pharmaceutical Practices viz., cGMP, GLP, GALP and GDP for pharmaceutical industries 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 elements of current Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices, Good Documentation Practices and Good Regulatory Practices.
- The check lists for various Good Pharmaceutical Practices and
- Prepare SOPs for Good Pharmaceutical Practices
- Implement Good Pharmaceutical Practices in the Industries and
- Prepare for the Audit of the Pharmaceutical Industries.

THEORY **60Hrs**

1. **Current Good Manufacturing Practices:** Introduction, US cGMP Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5 **12Hrs**

2. **Good Laboratory Practices:** Introduction,USFDA GLP Regulations (Subpart A to Subpart K),Controlling the GLP inspection process,GLP Documentation,Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations **12Hrs**

3. **Good Automated Laboratory Practices:** Introduction to GALP, Principles of GALP, GALP Requirements, SOPs of GALP, Training Documentation,21 CFR Part 11,General check list of 21CFR Part 11, Software Evaluation checklist. **12Hrs**

4. **Good Distribution Practices:** Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP(Supply chain integrity) **12Hrs**

5. **Quality management systems:** Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed

air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)]and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products. **12Hrs**

REFERENCES

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

PHARMACEUTICAL REGULATIONS IN INDIA (MRA 102T)

Scope:

This course is designed to impart fundamental knowledge on pharmaceutical regulations in India. It prepares the students for basic regulatory requirements in India of drug products for import, export, manufacture, 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 pharmaceutical industry in India.
- Understand the approval process and regulatory requirements for drugs and medical devices

THEORY **60 HOURS**

UNIT I

- **Pharmaceutical Research and Development, Indian Pharmaceutical Industry**

- **Acts and Rules (with latest amendments):**

- Drugs and Cosmetics Act 1940 and its Rules 1945: DPCO and NPPA
- Legal definitions of schedules to the Act and Rules, Import of drugs, Manufacture of drugs, Sale of Drugs, Labelling & Packing of drugs
- Registration of drugs /Medical devices in India **12 Hrs**

UNIT II

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

Organization, Responsibilities, Common Technical Document (CTD), Regulatory requirements and approval procedures for:

- Clinical Trials
- New Drugs
- Medical Devices
- Fixed Dose Combinations

12 Hrs

UNIT III

Regulatory requirements and approval procedures for:

- Existing Drugs
- Traditional Drugs
- Cosmetics
- Narcotics
- Recombinant DNA
- Types of regulatory approval /Licensing
- Nutraceuticals

12 Hrs

UNIT IV

BA/ BE: Bioavailability and Bioequivalence data, BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study

Stability requirements: ICH and WHO

Guidelines for drug testing in animals/ humans

- Animal testing: Rationale for conducting studies, CPCSEA Guidelines
- Human testing: ICMR guidelines ethical guidelines for human participants
- ICMR-DBT Guidelines for Stem Cell Research **12 Hrs**

UNIT V

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

REFERENCES

1. Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Office of India
2. Patent Failure How Judges, Bureaucrats, and Lawyers put innovators at risk by James Bessen and Michael J. Meurer
3. Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee
4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New delhi 2006.
5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA)
6. ICH E6 Guideline ― Good Clinical Practice‖ by ICH Harmonised Tripartite
7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation)

8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO
9. Guidelines for Import and Manufacture of Medical Devices by CDSCO
10. Guidelines from official website of CDSCO

INTERNATIONAL PHARMACEUTICAL REGULATIONS-I (MRA103T)

Scope:

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

Objectives: Upon completion of the 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 and Japan

THEORY **60 Hours**

Unit-I **12 Hours**

Drug product development: New Drug Discovery and development, *in vitro* and *in vivo* drug product performance, BA/BE studies, outsourcing BA/BE studies to Contract research organizations (CRO), Investigator's Brochure (IB), Chemistry and Manufacturing Controls (CMC), Genotoxic impurities.

Regulatory Submissions: Common Technical Document (CTD) modules and granularity, eCTD submissions

Unit-II **12 Hours**

Generic drug product development: Introduction, Concept of generics, Active Pharmaceutical Ingredients, Analytical Method development and validation, Experimental Formulation Development, Scale-up, post approval changes (SUPAC), Post marketing surveillance, process validation and technology transfer, Quality control and quality assurance, Legal and legislative hurdles to Generic drug development, approval and marketing

Unit-III **12 Hours**

USA: Organization structure and functions of FDA. Federal register and Code of Federal Regulations (CFR), History and evolution of United States Federal, Food, Drug and Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, Drug Master Files (DMF) system in US, Regulatory Approval Process for Investigational New Drug

(IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA); Regulatory requirements for Orphan drugs and Combination Products, Changes to an approved NDA / ANDA. Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in USA

Unit-IV **12 Hours**

European Union: Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files (ASMF) system in EU, Content and approval process of IMPD, Marketing Authorization procedures in EU (Centralized procedure, Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU

Unit-V **12 Hours**

Japan: Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in Japan

REFERENCES:

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series,Vol.144
3. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences,Vol.185
   Informa Health care Publishers.
4. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
5. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
6. Drugs: From Discovery to Approval, Second Edition By Rick Ng
7. New Drug Development: A Regulatory Overview, Eighth Edition By Mark Mathieu
8. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
9. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema
10. Country Specific Guidelines from official websites.

CLINICAL RESEARCH REGULATIONS (MRA 104T)

Scope:

This course is designed to impart the fundamental knowledge on the clinical development process of drugs and pharmaceuticals, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in 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)

- Clinical drug development process and different phases of clinical trials
- History, origin and ethics of clinical research
- regulatory requirements for conducting clinical trials and research
- regulations and guidance governing the conduct of clinical research

THEORY **60 Hours**

Unit-I **12 Hours**

Clinical drug development process

- Phases of clinical trials, Clinical Trial protocol
- Phase 0 studies
- Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points
- Phase II studies (proof of concept or principle studies to establish efficacy)
- Phase III studies (Multi ethnicity, multinational, registration studies)
- Phase IV studies (Post marketing authorization studies; pits and practices)
- Ethical principles governing informed consent process
- Patient Information Sheet and Informed Consent Form
- The informed consent process and documentation

Unit-II **12 Hours**

Ethics in Clinical Research:

- Historical Perspectives: Nuremberg Code, Thalidomide study , Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki
- Origin of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines.
- The ethics of randomized clinical trials

- The role of placebo in clinical trials
- Ethics of clinical research in special population
- Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data
- Data safety monitoring boards.
- Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research

Unit-III **12 Hours**

Regulations governing Clinical Trials

USA: Regulations to conduct drug studies in USA (FDA)

- NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug)
- NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant)
- ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product)
- FDA Guidance for Industry - Acceptance of Foreign Clinical Studies
- FDA Clinical Trials Guidance Document: Good Clinical Practice

UK: Clinical Research regulations in UK (MHRA)

EU: Clinical Research regulations in European Union (EMA)

India: Clinical Research regulations in India – Schedule Y

Unit-IV

Clinical Research Related Guidelines **12 Hours**

- Good Clinical Practice Guidelines (ICH GCP E6)
- Indian GCP Guidelines
- ICMR Ethical Guidelines for Biomedical Research
- CDSCO guidelines

Regulatory Guidance on Efficacy and Safety

ICH Guidance's

- E4 – Dose Response Information to support Drug Registration
- E7 – Studies in support of General Population: Geriatrics
- E8 – General Considerations of Clinical Trials
- E10 – Choice of Control Groups and Related Issues in Clinical Trials,
- E 11 – Clinical Investigation of Medicinal Products in the Pediatric Population

Unit-V **12 Hours**

USA & EU Guidance

USA: FDA Guidance

- CFR 21Part 50: Protection of Human Subjects
- CFR 21Part 54: Financial Disclosure by Clinical Investigators
- CFR 21Part 312: IND Application
- CFR 21Part 314: Application for FDA Approval to Market a New Drug
- CFR 21Part 320: Bioavailability and bioequivalence requirements
- CFR 21Part 812: Investigational Device Exemptions
- CFR 21Part 822: Post-market surveillance
- FDA Safety Reporting Requirements for INDs and BA/BE Studies
- FDA Med Watch
- Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment

European Union: EMA Guidance

- EU Directives 2001
- EudraLex (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

REFERENCES:

1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
2. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, 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.

RECOMMENDED WEBSITES:

1. 1. EU Clinical Research Directive 2001: http://www.eortc.be/services/doc/clinical-eudirective-04-april-01.pdf

2. Code of Federal Regulations, FDA:http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
3. Guidelines of International Conference on Harmonization: http://www.ich.org/products/guidelines.html
4. Eudralex Guidelines: http://www.gmpcompliance.info/euguide.htm
5. FDA New Drug Application: http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDrugandCosmetic ActFDCAct/FDCActChapterVDrugsandDevices/ucm108125.htm
6. Medicines and Healthcare products Regulatory Agency: http://www.mhra.gov.uk
7. Central Drugs Standard Control Organization Guidance for Industry: http://cdsco.nic.in/CDSCO-GuidanceForIndustry.pdf
8. ICMR Ethical Guidelines for Biomedical Research: http://icmr.nic.in/ethical_guidelines.pdf

PRACTICALS (MRA105P)

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

DOCUMENTATION AND REGULATORY WRITING (MRA 201T)

Scope

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

Objectives

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

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

THEORY **60 Hours**

12 Hrs

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

12 Hrs

2. ***Dossier preparation and submission:*** Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions

   Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non eCTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission

12 Hrs

3. ***Audits:*** Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection

12 Hrs

4. ***Inspections:*** Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA)

12 Hrs

5. ***Product life cycle management:*** Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Effected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
5. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
6. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
7. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
8. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001
9. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
10. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
11. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
12. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications

BIOLOGICS REGULATIONS (MRA 202T)

Scope

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

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

Objectives

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

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

Theory **60 Hrs**

Unit I

India : Introduction, Applicable Regulations and Guidelines , Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance. GMP and GDP. **12 Hrs**

Unit II

2.USA: Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics

12 Hrs

Unit III

3. European Union: Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ biosimilarity assessment, Plasma master file, TSE/ BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars), pre-clinical and clinical development considerations; stability, safety, advertising, labelling and packing of biologics in EU

12 Hrs

Unit IV

4. **Vaccine regulations in India, US and European Union**: Clinical evaluation, Marketing authorisation, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements

12 Hrs

Unit V

5**. Blood and Blood Products Regulations in India, US and European Union**: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilence Network)

12 Hrs

REFERENCES

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

INTERNATIONAL PHARMACEUTICAL REGULATIONS – II (MRA 203T)

Scope

This course is designed to impart fundamental knowledge on Regulatory Requirements for registration of drugs, medical devices and post approval requirements in WHO and emerging market (rest of world countries) like CIS,GCC, LATAM, ASIAN and African region.

Objectives

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

- Know the regulatory Requirements for drug and medical device registration in emerging market;
- Understand the registration requirements of emerging market by comparison; and
- Prepare dossiers for the registration of the products in emerging market.

THEORY **60 HOURS**

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

   12Hrs

2. **WHO:** WHO GMP,Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product (CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana)

   12Hrs

3. **ASIAN Countries:** Introduction to ACTD, Regulatory Requirements for registration of drugs and post approval requirements in **China and South Korea** & **Association of Southeast Asian Nations (ASEAN) Region** i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand.

   12Hrs

4. **CIS (Commonwealth Independent States):** Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine

   12Hrs

5. **GCC (Gulf Cooperation Council) for Arab states:** Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE

12Hrs

REFERENCES

1. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ListMRAWebsites.pdf
2. Roadmap to an ASEAN economic community Edited by Denis Hew.ISEAS Publications, Singapore 2005, ISBN981-230-347-2
3. ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978-981-230-750-7
4. Building a Future With Brics: The Next Decade for Offshoring, Mark Kobayashi-Hillary, Springer
5. Outsourcing to India: The Offshore Advantage, Mark Kobayashi-Hillary, Springer Trade performance and Regional Integration of the CIS Countries, Lev Freinkman,
6. The world Bank, Washington, DC, ISBN: 0-8212-5896-0
7. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World By Frederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes
   139
8. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low and Lorraine Carlos Salazar (Nov 22, 2010)
9. Doing Business in the Asean Countries, Balbir Bhasin, Business Expert Press ISBN:13:978-1-60649-108-9
10. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Instute of South east asian studies, Singapore

MEDICAL DEVICE REGULATIONS (MRA 204T)

Scope:

This course is designed to impart the fundamental knowledge on the medical devices and *in vitro* diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU and 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 in regulated countries.

Objectives:

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

- basics of medical devices, process of development, ethical and quality considerations
- harmonization initiatives for approval and marketing medical devices
- regulatory approval process for medical devices in US, EU, WHO and Asia
- clinical aspects of medical devices

THEORY **60 Hours**

Unit-I **12 Hours**

Medical Devices: Introduction, differentiating medical devices from IVDs and Combination Products, History of Medical Device Regulation, Product Lifecycle of Medical Devices, Classification of Medical Devices.

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

Unit-II **12 Hours**

Ethics: Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011)

Quality: Quality System Regulations of Medical Devices: ISO 13485, Quality Risk Management of Medical Devices: ISO 14971**,** Validation and Verification of Medical device, Adverse Event Reporting of Medical device

Unit-III **12 Hours**

USA: Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device

Exemption (IDE) and *In vitro* Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of *In vitro* diagnostics, classification and approval process.

Unit-IV **12 Hours**

European Union: Introduction, Classification, Regulatory approval process for Medical Devices
(Medical Device Directive, Active Implantable Medical Device Directive) and *In vitro* Diagnostics (*In Vitro* Diagnostics Directive), CE certification process.
Basics of *In vitro* diagnostics, classification and approval process.

Unit-V **12 Hours**

Medical Device Regulations in World Health Organization (WHO): Registration Procedures, Quality System requirements and Regulatory requirements
Asia: Clinical Trial Regulations specific for Medical Devices, Registration Procedures, Quality System requirements and Regulatory requirements for Japan, India and China

REFERENCES:

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

PRACTICAL (MRA205P)

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