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

Credit Based Semester System

Pharmacy Council of India

Combined Council's Building, Kotla Road,
Aiwan-E-Ghalib Marg,
New Delhi-110 002

CHAPTER – I: REGULATIONS

1. Short Title and Commencement

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

2. Minimum qualification for admission

A Pass in the following examinations

a) B. Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B.Pharm.)

b) Every student, selected for admission to post graduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

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

3. Duration of the program

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

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

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

6. Attendance and progress

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

7. Program/Course credit structure

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

7.1. Credit assignment

7.1.1. Theory and Laboratory courses

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

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

7.2. Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments,Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits are distributed semester-wise as shown in Table V. Courses generally progress in sequence, building competencies and their positioning indicates certain academic

maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

8. Academic work

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

9. Course of study

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

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

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

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

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MCC101T	Cosmeceuticals – Biology	4	4	4	100
MCC102T	Cosmetics - Formulation Science	4	4	4	100
MCC103T	Quality Assurance	4	4	4	100
MCC104T	Cellular and Molecular Pharmacology	4	4	4	100
MCC105P	Cosmeceutics Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
Semester II					
MCC201T	Cosmeceuticals	4	4	4	100
MCC202T	Cosmetic Analysis and Evaluation	4	4	4	100
MCC203T	Cosmectics- Industry and Regulatory	4	4	4	100
MCC204T	Computer Aided Drug Delivery System	4	4	4	100
MCC205P	Cosmeceutics Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MIP101T	Pharmaceutical Formulation Development	4	4	4	100
MIP102T	Customized drug Delivery System	4	4	4	100
MIP103T	Drug Regulations and Intellectual Property Rights	4	4	4	100
MIP104P	Industrial Pharmacy Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
Semester II					
MIP201T	Advanced Biopharmaceutics and Pharmacokinetics	4	4	4	100
MIP202T	Scale up and Technology Transfer	4	4	4	100
MIP203T	Pharmaceutical Production Technology	4	4	4	100
MIP204T	Entrepreneurship Management	4	4	4	100
MIP205P	Industrial Pharmacy Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

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

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

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

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

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPC101T	Advanced Organic Chemistry -I	4	4	4	100
MPC102T	Advanced Medicinal chemistry	4	4	4	100
MPC103T	Chemistry of Natural Products	4	4	4	100
MPC104P	Pharmaceutical Chemistry Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
Semester II					
MPC201T	Advanced Spectral Analysis	4	4	4	100
MPC202T	Advanced Organic Chemistry -II	4	4	4	100
MPC203T	Computer Aided Drug Design	4	4	4	100
MPC204T	Pharmaceutical Process Chemistry	4	4	4	100
MPC205P	Pharmaceutical Chemistry Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

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

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

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPG101T	Advanced Pharmacognosy-1	4	4	4	100
MPG102T	Phytochemistry	4	4	4	100
MPG103T	Industrial Herbal drug technology	4	4	4	100
MPG104P	Pharmacognosy Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
Semester II					
MPG201T	Medicinal Plant biotechnology	4	4	4	100
MPG102T	Advanced Pharmacognosy-II	4	4	4	100
MPG203T	Indian system of medicine	4	4	4	100
MPG204T	Herbal cosmetics	4	4	4	100
MPG205P	Pharmacognosy Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table – 9: Course of study for (Pharmacology)

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

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

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

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

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

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

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

Table – 13: Course of study for M. Pharm. III Semester

(Common for All Specializations)

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

* Non University Exam

Table – 14: Course of study for M. Pharm. IV Semester

(Common for All Specializations)

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

Table – 15: Semester wise credits distribution

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

*Credit Points for Co-curricular Activities

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

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

Note: International Conference: Held Outside India
International Journal: The Editorial Board Outside India

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

10. Program Committee

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

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

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

3. Duties of the Programme Committee:

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

v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessionalexam and before the end semester exam.

11. Examinations/Assessments

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

11.1. End semester examinations

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

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

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MCC101T	Cosmeceuticals – Biology	10	15	1 Hr	25	75	3 Hrs	100
MCC102T	Cosmetics - Formulation Science	10	15	1 Hr	25	75	3 Hrs	100
MCC103T	Quality Assurance	10	15	1 Hr	25	75	3 Hrs	100
MCC104T	Cellular and Molecular Pharmacology	10	15	1 Hr	25	75	3 Hrs	100
MCC105P	Cosmeceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MCC201T	Cosmeceuticals	10	15	1 Hr	25	75	3 Hrs	100
MCC202T	Cosmetic Analysis and Evaluation	10	15	1 Hr	25	75	3 Hrs	100
MCC203T	Cosmectics- Industry and Regulatory	10	15	1 Hr	25	75	3 Hrs	100
MCC204T	Computer Aided Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MCC201T	Cosmeceuticals	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

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

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MIP101T	Pharmaceutical Formulation Development	10	15	1 Hr	25	75	3 Hrs	100
MIP102T	Customized drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MIP103T	Drug Regulations and Intellectual Property Rights	10	15	1 Hr	25	75	3 Hrs	100
MIP104P	Industrial Pharmacy Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MIP201T	Advanced Biopharmaceutics and Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100
MIP202T	Scale up and Technology Transfer	10	15	1 Hr	25	75	3 Hrs	100
MIP203T	Pharmaceutical Production Technology	10	15	1 Hr	25	75	3 Hrs	100
MIP204T	Entrepreneurship Management	10	15	1 Hr	25	75	3 Hrs	100
MIP205P	Industrial Pharmacy Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

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

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA102T	Advanced Pharmaceutical Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA103T	Pharmaceutical Validation	10	15	1 Hr	25	75	3 Hrs	100
MPA104T	Food Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA105P	Pharmaceutical Analysis-I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MPA201T	Advanced Instrumental Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPA202T	Modern Bio-Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPA203T	Quality Control and Quality Assurance	10	15	1 Hr	25	75	3 Hrs	100
MPA204T	Cosmetic Analysis and Evaluation	10	15	1 Hr	25	75	3 Hrs	100
MPA205P	Pharmaceutical Analysis-II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

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

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

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

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPC101T	Advanced Organic Chemistry -I	10	15	1 Hr	25	75	3 Hrs	100
MPC102T	Advanced Medicinal chemistry	10	15	1 Hr	25	75	3 Hrs	100
MPC103T	Chemistry of Natural Products	10	15	1 Hr	25	75	3 Hrs	100
MPC104P	Pharmaceutical Chemistry Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MPC201T	Advanced Spectral Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPC202T	Advanced Organic Chemistry -II	10	15	1 Hr	25	75	3 Hrs	100
MPC203T	Computer Aided Drug Design	10	15	1 Hr	25	75	3 Hrs	100
MPC204T	Pharmaceutical Process Chemistry	10	15	1 Hr	25	75	3 Hrs	100
MPC205P	Pharmaceutical Chemistry Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

***Non University Examination**

11.2. Internal assessment: Continuous mode

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

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

Theory	
Criteria	**Maximum Marks**
Attendance (Refer Table – 30)	8
Student – Teacher interaction	2
Total	**10**
Practical	
Attendance (Refer Table – 30)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	**20**

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

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

11.2.1. Sessional Exams

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

12. Promotion and award of grades

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

13. Carry forward of marks

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

14. Improvement of internal assessment

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

15. Reexamination of end semester examinations

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

Table – 31: Tentative schedule of end semester examinations

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

16. Allowed to keep terms (ATKT):

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

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

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

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

17. Grading of performances

17.1. Letter grades and grade points allocations:

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

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

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

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

18. The Semester grade point average (SGPA)

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

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

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

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

19. Cumulative Grade Point Average (CGPA)

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

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

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

Evaluation of Dissertation Book:

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

Evaluation of Presentation:

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

22. Award of Ranks

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

23. Award of degree

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

24. Duration for completion of the program of study

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

25. Revaluation *I* Retotaling of answer papers

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

26. Re-admission after break of study

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

M. PHARM. PHARMACEUTICS (MPH)

MODERN PHARMACEUTICAL ANALYSIS (MPA101T)

Scope

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

Objectives

After completion of course student is able to know,

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

THEORY **60 HOURS**

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

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

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

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

principles of FT-NMR and ^{13}C NMR. Applications of NMR spectroscopy.

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

4	**Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography	**11 Hrs**
5	**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 **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.	**11 Hrs**
6	**Immunological assays :** RIA (Radio immuno assay), ELISA, Bioluminescence assays.	**5 Hrs**

REFERENCES

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

DRUG DELIVERY SYSTEM (MPH101T)

SCOPE

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

OBJECTIVES

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

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

THEORY **60 Hrs**

10 Hrs

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

10 Hrs

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

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

10 Hrs

4. **Occular Drug Delivery Systems**: Barriers of drug permeation, Methods to overcome barriers.

6 Hrs

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

10 Hrs

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

8 Hrs

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

6 Hrs

REFERENCES

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

JOURNALS

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

MODERN PHARMACEUTICS (MPH102T)

Scope

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

Objectives

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

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

THEORY
60 HRS

10 hrs

1. **Preformation Concepts –** Drug Excipient interactions - different methods, kinetics of stability, Stability testing.
   Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability
   Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation

10 Hrs

2. **Optimization techniques in Pharmaceutical Formulation**: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation.

10 Hrs

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

10 Hrs

4. **cGMP & Industrial Management**: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials

management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management

10 Hrs

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

10 Hrs

6. **Study of consolidation parameters**; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckal 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.

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

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

1
2 hrs

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

12 hrs

3. CMC, post approval regulatory affairs.Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison.
   ICH - Guidelines of ICH-Q,S E,M.
   Regulatory requirements of EU, MHRA, TGA and ROW countries.

   12 hrs

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

   12 hrs

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

   12 hrs

REFERENCES

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

PRACTICALS (MPH104P)

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

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

3.Experiments based on HPLC

4.Experiments based on Gas Chromatography

5.Estimation of riboflavin/quinine sulphate by fluorimetry

6.Estimation of sodium/potassium by flame photometry

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

8.Formulation and evaluation of sustained release matrix tablets

9.Formulation and evaluation osmotically controlled DDS

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

11.Formulation and evaluation of Muco adhesive tablets.

12.Formulation and evaluation of trans dermal patches.

13.To carry out preformulation studies of tablets.

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

15.To study Micromeritic properties of powders and granulation.

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

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

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

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

Scope

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

Objectives

Upon completion of the course student shall be able to understand

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

THEORY

60 Hrs

12 hrs

1. **Targeted Drug Delivery Systems: C**oncepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.

12hrs

2. **Targeting Methods**: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation

12hrs

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

12hrs

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

12hrs

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

REFERENCES:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded,Marcel

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

Journals

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

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH202T)

Scope

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

Objectives

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

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

THEORY **60 Hrs**

12hrs

1. **Drug Absorption From The Gastrointestinal Tract**: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting passive drug absorption, pH–partition theory of drug absorption. Factors affecting drug absorption: physicochemical factors:Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data.Transport model:

Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex, Structure of Octanol, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

12Hrs

2. **Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug ProductPerformance:**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 TestingPerformance of Drug Products. *In Vitro–In Vivo*Correlation, Dissolution Profile Comparisons,Drug Product Stability,Considerations in the Design of a DrugProduct,DrugProductConsiderations.

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. Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products),Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution.

12Hrs

5. **Application of Pharmacokinetics:**Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. phrmacokinetic 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.
- The current technologies in the market
- The various key ingredients and basic science to develop cosmetics and cosmeceuticals
- The scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, sensory, stability, and efficacy.

THEORY **60Hrs**

12Hrs

1. Formulations approaches and Requirements

Definition of cosmetic products as per EU guidelines .Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arms.Formulation requirements for ethnic needs.

12Hrs

2.Plant Lay out, factory requirements and commonly used cosmetics raw materials

Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants- Classification and application. Emollients rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a cream, shampoo and toothpaste.

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

Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

12Hrs

3.Design of special purpose cosmeceutical products

Sun protection, sunscreens classification and regulatory aspects. addressing dry skin, acne,

sun-protection, pigmentation, prickly heat, wrinkles, body odor. Dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth.

12Hrs

3. **Herbal Cosmetics**

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

12Hrs

4. **Formulation of Lip care products and Cosmetic Sfety .**

   Chemistry and formulation of paraphylene diamine based hair colorants.Soaps and syndet bars Labelling requirements for cosmetics Study of salient features of cosmetic safety data base developed by private body, and International Nomenclature of Cosmetic Ingredients (INCI). Review of the list of ingredients on the labels of cosmetics, cosmeceuticals, baby care and men's range of the products in the market and conduct comparative study of the formulations.

RECOMMENDED BOOKS:

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

PHARMACOLOGY

(MPC)

SEMISTER I

1. MODERN PHARMACEUTICAL ANALYSIS

2. ADVANCED PHARMACOLOGY-I

3. PHARMACOLOGICAL AND TOXICOLOGICAL

SCREENING METHODS-I

4. CELLULAR AND MOLECULAR PHARMACOLOGY

Practicals

SEMISTER I

1. ADVANCED PHARMACOLOGY-II

2. TOXICOLOGICAL SCREENING METHODS

3. PRINCIPLES OF DRUG DISCOVERY

4. CLINICAL RESEARCH AND PHARMACOVIGILANCE

5. EXPERIMENTAL PHARMACOLOGY-II

Practicals

*Soft skills should be added in research methodology and biostatistics paper in semester III

*Practical in Modern pharmaceutical with emphasis on analysis case study

MODERN PHARMACEUTICAL ANALYSIS (MPA101T)

Scope

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

Objectives

After completion of course student is able to know,

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

THEORY **60 HOURS**

1.	**UV-Visible spectroscopy**: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. **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 **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. **Flame emission spectroscopy and Atomic absorption spectroscopy**: Principle, Instrumentation, Interferences and Applications.	**12 Hrs**
2	**NMR spectroscopy**: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ^{13}C NMR. Applications of NMR spectroscopy.	**12 Hrs**
3	**Mass Spectroscopy**: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy	**12 Hrs**

4	**Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography	**12 Hrs**
5	**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 **X ray Crystallography**: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	**12 Hrs**

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

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ADVANCED PHARMACOLOGY-I (MPL101T)

Scope

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

Objectives

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

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

THEORY **60 HOURS**

UNIT-I

General Pharmacology

12 Hrs

a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding. 06 hrs

b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects. 06 hrs

UNIT-II

12 Hrs

Neurotransmission

06 Hrs

a. General aspects and steps involved in neurotransmission.

b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline).

c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine].

d. Non adrenergic non cholinergic transmission (NANC). Co-transmission

Systemic Pharmacology

06 Hrs

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

a. Autonomic Pharmacology

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

UNIT-III

12 Hrs

Central nervous system Pharmacology

General and local anesthetics	02 hrs
Sedatives and hypnotics, drugs used to treat anxiety.	02 hrs
Depression, psychosis, mania, epilepsy, neurodegenerative diseases.	05 hrs
Narcotic and non-narcotic analgesics.	03 hrs

UNIT-IV

Cardiovascular Pharmacology

12 Hrs

Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia.	07 hrs
Hematinics, coagulants , anticoagulants, fibrinolytics and anti-platelet drugs	05 hrs

UNIT- V

Autocoid Pharmacology

12 Hrs

The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids.	08 hrs
Pharmacology of antihistamines, 5HT antagonists.	04 hrs

REFEERENCES

1. The Pharmacological basis of therapeutics- Goodman and Gill man‘s
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G -Katzung
4. Pharmacology by H.P. Rang and M.M. Dale.
6. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-I (MPL102T)

Scope

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

Objectives

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

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

THEORY **60 HOURS**

Unit-I

12 Hrs

Laboratory Animals

Common lab animals: Description, handling and applications of different species and strains of animals.	02 hrs
Transgenic animals: Production, maintenance and applications	02 hrs
Anaesthesia and euthanasia of experimental animals.	03 hrs
Maintenance and breeding of laboratory animals.	02 hrs
CPCSEA guidelines to conduct experiments on animals	02 hrs
Good laboratory practice.	01 hrs

Unit-II

12 Hrs

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

General principles of preclinical screening. CNS Pharmacology: behavioral and muscle co ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics

and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple
sclerosis. Drugs acting on Autonomic Nervous System.

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: anti ulcer, anti -emetic, anti-diarrheal and laxatives.

Unit-IV

12 hrs

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

Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antihyperlipidemic, and agents. Anti cancer agents

Unit V

12 hrs

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

Immunosuppressants and immunomodulators 02 hrs

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

08 hrs

Limitations of animal experimentation and alternate animal experiments. 01 hr

Extrapolation of *in vitro* data to preclinical and preclinical to humans. 01 hr

REFERENCES

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Indian Pharmacopeia and other Pharmacopeias
3. Screening methods in Pharmacology by Robert Turner. A
4. Evaluation of drugs activities by Laurence and Bachrach

5. Methods in Pharmacology by Arnold Schwartz.
6. Fundamentals of experimental Pharmacology by M.N.Ghosh
7. Pharmacological experiment on intact preparations by Churchill Livingstone
8. Drug discovery and Evaluation by Vogel H.G.
9. Experimental Pharmacology by R.K.Goyal.
10. Preclinical evaluation of new drugs by S.K. Gupta

CELLULAR AND MOLECULAR PHARMACOLOGY (MPL103T)

Scope:

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

Objectives:

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

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

Unit I

12 Hrs

Cell biology

Structure and functions of cell and its organelles

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

Cell cycles and its regulation.

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

Necrosis and autophagy.

Unit II

12Hrs

Cell signaling

Intercellular and intracellular signaling pathways.

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

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

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

Unit III

12Hrs

Principles and applications of genomic and proteomic tools **06 hrs**

DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting,

Recombinant DNA technology and gene therapy **06 hrs**

Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology.

Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy

Unit IV

12Hrs

Pharmacogenomics **08 hrs**

Gene mapping and cloning of disease gene.

Genetic variation and its role in health/ pharmacology

Polymorphisms affecting drug metabolism

Genetic variation in drug transporters

Genetic variation in G protein coupled receptors

Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics

Immunotherapeutics **04 hrs**

Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice

Unit V

12Hrs

Cell culture techniques

Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application.

Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays

Principles and applications of flow cytometry

Unit VI

Biosimilars

References:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong

3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et la.

Experimental Pharmacology- I (MPL104P)

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

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

3.Experiments based on HPLC

4.Experiments based on Gas Chromatography

5.Estimation of riboflavin/quinine sulphate by fluorimetry

6.Estimation of sodium/potassium by flame photometry

Handling of laboratory animals.

1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by 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. Apoptosis determination by fluorescent imaging studies.
20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
21. Enzyme inhibition and induction activity
22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

References

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

ADVANCED PHARMACOLOGY-II (MPL201T)

Scope

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

Objectives

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

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

UNIT-I

Endocrine Pharmacology

12 Hrs

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

Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids.

Drugs affecting calcium regulation

UNIT-II

Chemotherapy

12 Hrs

Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as 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:

08 Hrs

Alzheimer 's disease, Parkinson's disease , Cancer, Diabetes mellitus

References

1. The Pharmacological basis of therapeutics- Goodman and Gill man's
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G -Katzung
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists

TOXICOLOGICAL SCREENING METHODS (MPL202T)

Scope:

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

Objectives:

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

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

Unit I **12 Hrs**

Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive)
Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y
OECD principles of Good laboratory practice (GLP)
History, concept and its importance in drug development

Unit II **12 Hrs**

Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines.
Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.
Test item characterization- importance and methods in regulatory toxicology studies

Unit III **12 Hrs**

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

PRINCIPLES OF DRUG DISCOVERY (MPL203T)

Scope:

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

Objectives:

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

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

Unit-I **12 Hrs**

An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery.

Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

Unit-II **12 Hrs**

Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification.

Protein structure

Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction

Unit-III **12 Hrs**

Rational Drug Design

Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches

Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

Unit-IV **12 Hrs**

Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design.

Quantitative analysis of Structure Activity Relationship

History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.

Unit-V **12 Hrs**

QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA

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

References

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

CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL204T)

Scope:

This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials.

This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

Objectives:

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

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

UNIT-I **12 hours**

Regulatory Perspectives of Clinical Trials:

Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines

Ethical Committee- Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR

Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process

UNIT- II **12 hours**

Clinical Trials: Types and Design

Experimental Study- RCT and Non RCT,
Observation Study: Cohort, Case Control, Cross sectional

Clinical Trial Study Team
Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management

UNIT- III **12 hours**

Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT

Adverse Drug Reactions: Definition and types. Detection and reporting methods.Severity and seriousness assessment.Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.

UNIT-IV **12 hours**

Basic aspects, terminologies and establishment of pharmacovigilance

History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance

UNIT-V **12 hours**

Methods, ADR reporting and tools used in Pharmacovigilance

International classification of diseases, International Non-proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

UNIT-VI

Pharmacoepi Dermatology , pharmacoeconomics , safety pharmacology

References:

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

Experimental Pharmacology-II (MPL205P)

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

20. In silico docking studies.
21. In silico pharmacophore based screening.
22. In silico QSAR studies.
23. ADR reporting
24. In silico docking studies.

References

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

M. PHARM. PHARMACOGNOSY (MPG)

ADVANCED PHARMACOGNOSY-1 (MPG101 T)

SCOPE:

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

OBJECTIVES:

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

1. Know the advances in the cultivation and production of drugs
2. Know the various phyto-pharmaceuticals and their source & utilization and medicinal value.
3. Know the various nutraceuticals/herbs and their health benefits

Course Description

THEORY **60 Hours**

1. Plant drug cultivation: General introduction to the importance of Pharmacognosy in herbal drug industry, Indian Council of Agricultural Research, Current good agricultural practices, Current good cultivation practices, Current good collection practices, Conservation of medicinal plants- *Ex-situ* and *In-situ* conservation of medicinal plants. **12 Hrs**

2. Marine natural products: General methods of isolation and purification, Study of Marine toxins, Recent advances in research in marine drugs, Problems faced in research on marine drugs such as taxonomical identification, chemical screening and their solution. **12 Hrs**

3. Nutraceuticals: Current trends and future scope, Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibres, Cereals and grains, Health drinks from natural origin, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods, Formulation and standardization of neutraceuticals, Regulatory aspects, FSSAI guidelines, Sources, name of marker compounds and their chemical nature, medicinal uses and health benefits of following

i) Spirulina ii) Soya bean iii) Ginseng iv) Garlic v) Broccoli vi) Green and Herbal Tea vii) Flax seeds viii) Black cohosh ix) Turmeric.

12 Hrs

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

a) Carotenoids – i) α and β - Carotene ii) Xanthophyll (Lutein)
b) Limonoids – i) d-Limonene ii) α – Terpineol
c) Saponins – i) Shatavarins
d) Flavonoids – i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin
e) Phenolic acids- Ellagic acid
f) Tocotrienols and Tocopherols
g) Andrographolide, glycolipids, gugulipids, withanolides, vascine, taxol **12 Hrs**

5. Pharmacovigilance of drugs of natural origin: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for biodrug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. **12 Hrs**

REFERENCES:

1) Cultivation of medicinal and aromatic crops, 1st edition, by AA Farooqui and B.S. Sreeramu. University Press, 2001.
2) Medicinal natural products (a biosynthetic approach), 1st edition, by Paul M. Dewick, John Wiley & Sons Ltd., England, 1998.
3) Natural Products from Plants, 1st edition, by Peter B. Kaufman, CRC Press, New York, 1998
4) Glimpses of Indian Ethano Pharmacology by P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute, 1995.
5) Natural products: A lab guide by Raphael Ikan , 2nd Edition, Academic Press 1991.
6) Pharmacognosy - G. E. Trease and W.C. Evans. 15th Edition W.B. Saunders Edinburgh, New York.
7) Pharmacognosy-Tyler, Brady, Robbers
8) Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol. I&II
9) Recent Advances in Phytochemistry- Vol. 1&4: Scikel Runeckles- Appleton Century crofts.
10) Chemistry of Marine Natural Products- Paul J. Schewer 1973.
11) Marine Natural Products-Vol.I to IV.
12) Cultivation of Medicinal Plants by C.K. Atal & B.M. Kapoor.
13) Cultivation and Utilization of Aromatic Plants By C.K. Atal & B.M. Kapoor

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

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

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

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

PHYTOCHEMISTRY (MPG102T)

Scope:

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

Objectives:

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

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

THEORY

60 Hrs

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

    a) Alkaloids: Ephedrine, Quinine, Strychynine, Piperine, Berberine, Taxol, Vincaalkoloids.
    b) Glycosides: Digitoxin, Glycyrrhizin, Sennosides, Bacosides, Ginsenosides, Quercitin, Rutin.
    c) Steroids: Hecogenin, guggulosterone and withanolides
    d) Coumarin: Umbelliferone.
    e) Terpenoids: Cucurbitacins
    f) Carotenoids: Lycopene, β-carotene.
    g) Camphor, Menthol, Eugenol.

    12 Hrs

2. **Drug discovery and development:** History of herbs as source of drugs and drug discovery, the lead structure selection process, structure development, product discovery process and drug registration, Selection and optimization of lead compounds with suitable examples from anticancer, CNS cardiovascular drugs, antitubercular drugs and immunomodulators, Clinical studies emphasis on phase of clinical trials, protocol design for lead molecules.

    12 Hrs

3. **Extraction and Phytochemical studies:** Recent advances in extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used like microwave assisted extraction, and method of fractionation. Detection of different classes of phytoconstituents by latest CCCET, SCFE techniques including preparative HPLC and Flash column chromatography, AAS.

   12 Hrs

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

   12 Hrs

5. **Pharmacological screening:** In vitro, In vivo screening techniques with reference to antiglycomerate, analgesics, antidiabetic, antilipidemic, anticancer, antiulcer, antiviral, antipsychotic, antilithiatic, Toxicity studies as per OECD guidelines, acute, chronic and clinical toxicity.

   12 Hrs

REFERENCES:

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

INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY (MPG103T)

Scope:

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

Objective:

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

1. Know the requirements for setting up the herbal/natural drug industry.
2. To know and understand the guidelines for quality of herbal/natural medicines and regulatory issues.
3. To know patenting/IPR of herbals/natural drugs and trade of raw and finished materials.

THEORY

60Hrs

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

   12 Hrs

2. **Regulatory requirements for setting herbal drug industry:** Global marketing management. Indian and international patent law as applicable herbal drugs and natural products.

   Export –import (EXIM) policy, TRIPS, IPR.

   Quality assurance in herbal/natural drug products.

   Concepts of TDM, GMP, GLP, ISO-9000.

   12Hrs

3. **Monographs of herbal drugs:** Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic pharmacopoeia, American herbal pharmacopoeia, British herbal pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

   12 Hrs

4. **Testing of natural products and drugs:** Effect of herbal medicines on clinical laboratory testing. Regulation and dispensing of herbal drugs. Stability testing of

natural products, protocols.

12 Hrs

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

12 Hrs

REFERENCES:

1. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
2. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee (2003), Ist Edition, Business horizons Robert Verpoorte, New Delhi.
3. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.
4. The complete technology book on herbal perfumes and cosmetics, by H.Pande, National Institute of Industrial Research, Delhi.
5. Quality control of herbal drugs by Pulok K Mukarjee (2002), 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. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (1996), 4th Edition, Nirali Prakashan, New Delhi.
9. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI (2002), Part I & II, Career Publication, Nasik, India.
10. Plant drug analysis by H.Wagner and S.Bladt, 2nd edition, Springer, Berlin.
11. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern Publisher, New Delhi.
12. Phytochemical Dictionary. Handbook of Bioactive Compounds from Plants by J.B.Harborne, (1999), IInd Edition, Taylor and Francis Ltd, UK.
13. Herbal Medicine. Expanded Commission E Monographs by M.Blumenthal, (2004), IST Edition,
14. Drug Formulation Manual by D.P.S.Kohli and D.H.Shah (1998), II Edition, Eastern Publisher, New Delhi.

PRACTICALS (MPGI04P)

1. Analysis of pharmacopoeial compounds of natural origin and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Analysis of recorded spectra of simple phytoconstituents
4. Experiments based on Gas Chromatography
5. Estimation of sodium/potassium by flame photometry
6. Developmernt of fingerprint of selected medicinal plant extracts commonly used in herbal drug industry viz. ashwagandha, tulsi, bael, amla, ginger, aloe, vidang, senna, lawronia by HPTLC method
7. Method of extraction
8. Phytochemical screening
9. Thin layer chromatography
10. Demonstration of HPLC- estimation of glycyeizin
11. Monograph analysis of clove oil
12. Monograph analysis of castor oil.
13. Identification of bioactive constituents from plant extracts
14. Formulation using qualitative and quantitative methods.

MEDICINAL PLANT BIOTECHNOLOGY (MPG201T)

Scope

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

Objectives

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

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

THEORY **60Hrs**

1. **Introduction to Plant biotechnology:** Historical perspectives, prospects for development of plant biotechnology as a source of medicinal agents. Applications in pharmacy and allied fields. Genetic and molecular biology as applied to pharmacognosy, study of DNA, RNA and protein replication, genetic code, regulation of gene expression, structure and complicity of genome, cell signaling, DNA recombinant technology.

   1
   2 Hrs

2. **Different tissue culture techniques:** Organogenesis and embryogenesis, synthetic seed and monoclonal variation, Protoplast fusion, Hairy root multiple shoot cultures and their applications. Micro propagation of medicinal and aromatic plants. Sterilization methods involved in tissue culture, gene transfer in plants and their applications. **12 Hrs**

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

   12 Hrs

4. **Biotransformation and Transgenesis:** Biotransformation, bioreactors for pilot and large scale cultures of plant cells and retention of biosynthetic potential in cell

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

12 Hrs

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

12 Hrs

REFERENCES:

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

ADVANCED PHARMACOGNOSY-II (MPG202T)

Scope:

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

Objectives

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

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

THEORY

60Hrs

1. **Herbal remedies – Toxicity and Regulations:** Herbals vs Conventional drugs, Efficacy of Herbal medicine products, Validation of herbal therapies, Pharmacodynamic and Pharmacokinetic issues.

   12 Hrs

2. **Adulteration and Deterioration:** Introduction, Types of Adulteration/ Substitution of Herbal drugs, Causes and Measures of Adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phytotoxin, microbial contamination in herbs fruital formulation.

   12 Hrs

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

   12 Hrs

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

   12 Hrs

5. **Biological screening of herbal drugs:** Introduction and Need for Phyto-Pharmacological Screening, New Strategies for evaluating Natural Products, *In vitro* evaluation techniques for Antioxidants, Antimicrobial and Anticancer drugs. In vivo evaluation techniques for Anti-inflammatory, Antiulcer, Anticancer,

Wound healing, Antidiabetic, Hepatoprotective, Cardio protective, Diuretics and Antifertility. **12 Hrs**

REFERENCES:

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

INDIAN SYSTEMS OF MEDICINE (MPG203T)

Scope

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

Objective

After completion of the course, student is able to

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

THEORY

60Hrs

1. **Fundamental concepts of Ayurveda, Siddha, Unani, and Homoeopathy systems of medicine:**
   Different dosage forms of the ISM-
   Ayurveda: Chronological development of Charak Samhita, Sushrut Samhita and Kashyapa Samhita. Ayurvedic Pharmacopoeia Analysis of Ayurvedic Formulations and crude drugs with references to: Identity, purity and quality of crude drugs.
   Siddha: Gunapadam (Siddha Pharmacology), raw drugs/Dhatu/Jeevam in siddha system of medicine, Purification process (Suddhi).
   12Hrs

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

3. **Formulation development of various systems of medicine:** Salient features of the techniques of preparation of some of the important class of Formulations as per Ayurveda,
   Siddha, Homeopathy and Unani Pharmacopoeia and texts. Standardization,

Shelf life and Stability studies of ISM formulations.

12 Hrs

4. **Schedule T – Good Manufacturing Practice of Indian systems of medicine:**

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

   Quality assurance in herbal drug industry of GAP, GMP and GLP in traditional system of medicine. Preparation of documents for new drug application and export registration.

   Challenges in monitoring the safety of herbal medicines: Regulation, quality assurance and control, National/regional pharmacopoeias.

   12 Hrs

5. TKDL, Geographical indication skill, Government skills in AYUSH, ISM, CCRAS, CCRS, CCRH, CCRU.

   12 Hrs

REFERENCES:

1. Ayurvedic Pharmacopoeia (2004), The Controller of Publications, Civil Lines, Govt. of India, New Delhi.
2. Hand Book on Ayurvedic Medicines by H.Panda National Institute of Industrial Research, New Delhi.
3. Ayurvedic System of Medicine by Kaviraj Nagendranath Sengupata (1998), 2nd Revised Edition, Sri Satguru Publications, New Delhi.
4. Ayurvedic Pharmacopoeia. Formulary of Ayurvedic Medicines (2000), IMCOPS, Chennai.
5. Homeopathic Pharmacopoeia. Formulary of Homeopathic Medicines (2004), IMCOPS, Chennai.
6. Homeopathic Pharmacy An introduction & Hand book by Steven B. Kayne (1997), Churchill Livingstone, New York.
7. Indian Herbal Pharmacopoeia (2002), Revised Edition, 1DMA, Mumbai.
8. British Herbal Pharmacopoeia British (1990), Herbal Medicine Association, UK.
9. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee (2003), First edition, Business Horizons, New Delhi.
10. Indian System of Medicine and Homeopathy in India (2001), Planning and Evaluation Cell, Govt.of India, New Delhi.
11. Essential of Food and Nutrition by Swaminathan (1999), Bappco, Bangalore.
12. Clinical Dietitics and Nutrition by F.P. Antia (1997), 4th Edi, Oxford Universith Press, Delhi.
13. Yoga- The Science of Holistic Living by V.K.Yoga (2005), Vivekananda Yoga Prakashna Publishing, Bangalore.

HERBAL COSMETICS (MPG204T)

Scope

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

Objective

After completion of the course, student is able to

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

THEORY

60Hrs

1. **Introduction:** Herbal/natural cosmetics, Classification& Economic aspects. Regulatory Provisions relation to manufacture of cosmetics: - License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics**.**

   12 Hrs

2. **Herbal Cosmetics for the skin:** Physiology and chemistry of skin and pigmentation, hairs, scalp, oral and nail, Cleansing cream, Lotions, Vanishing and Foundation creams, Anti- sun burn preparations, Moisturizing cream , deodorants, Face powders, Face packs, Lipsticks, Bath products, soaps and baby product, Preparation and standardisation of the following :
   Shampoos, Conditioners, Tonic, Bleaches, Colorants, Depilatories and Hair oils, Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails**.**
   12 Hrs

3. **Cosmeceuticals of herbal and natural origin:** Hair growth formulations, Fairness formulations.
   12 Hrs

4. Commonly used herbal cosmetics, raw materials, preservatives, surfactants, humectants, oils, colours, and some functional herbs, preformulation studies, compatibility studies, possible interactions between chemicals and herbs, design of herbal cosmetic formulation.

   12 Hrs

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

REFERENCES:

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

PRACTICALS (MPG205P)

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

M. PHARM. PHARMACEUTICAL QUALITY ASSURANCE (MQA)

MODERN PHARMACEUTICAL ANALYSIS (MPA101T)

Scope

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

Objectives

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

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

THEORY **60 HOURS**

1.	**UV-Visible spectroscopy**: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. **IR spectroscopy**: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. **Flame emission spectroscopy and Atomic absorption spectroscopy**: Principle, Instrumentation, Interferences and Applications.	**14 Hrs**
2	**NMR spectroscopy**: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ^{13}C NMR. Applications of NMR spectroscopy.	**10 Hrs**
3	**Mass Spectroscopy**: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy	**10 Hrs**

4	**Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a) Thin Layer chromatography b) High Performance Thin Layer Chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Ultra High Performance Liquid chromatography h) Affinity chromatography i) Gel Chromatography	**12 Hrs**
5	**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 **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.	**8 Hrs**
6	**Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry. **Thermal Analysis:** Polymer behavior, factors affecting and instrumentation, and working, application of TGA	**4 Hrs**

REFERENCES (Latest edition to be recommended)

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. James Connors

QUALITY MANAGEMENT SYSTEMS (MQA101T)

Scope

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

Objectives

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

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

THEORY **60 Hrs**

1. **Introduction to Quality:** Evolution of Quality, Definition of Quality, Dimensions of Quality

   Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality

   Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behavior, concept of internal and external customers. Case studies.

   Cost of Quality: Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, Preventing cost of quality

12 Hrs

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

   12 Hrs

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

   12 Hrs

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

   12 Hrs

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

   8Hrs

6. **Regulatory Compliance through Quality Management and development of Quality Culture**

Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking

4 Hrs

REFERENCES:

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

QUALITY CONTROL AND QUALITY ASSURANCE (MQA102T)

Scope:

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

Objectives:

Upon completion of this course the student should be able to

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

THEORY

60 Hrs

1. **Introduction:** Concept and evolution and scopes of Quality Control and Quality Assurance,

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

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

   12 Hrs

2. **cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering:** Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.

   12 Hrs

3. **Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3),** purchase specifications and maintenance of stores for raw materials.
   In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).

   10 Hrs

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

   12 Hrs

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

   12 Hrs

REFERENCES

1 Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.

2 Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.

3 Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.

4 How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.

5 The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.

6 Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.

7 ICH guidelines

8 ISO 9000 and total quality management

9 The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.

10 QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.

11 Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.

12 Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.

13 Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.

14 Packaging of Pharmaceuticals.

15 Schedule M and Schedule N.

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (MQA103T)

Scope

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

Objectives:

Upon completion of this course the student should be able to

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

THEORY **60 Hrs**

1. **Principles of Drug discovery and development:** Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA.

   12 Hrs

2. **Preformulation studies:** Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Preformulation protocol, Stability testing during product development.

   12 Hrs

3. **Pilot plant scale up:** Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges.

   12 Hrs

4. **Pharmaceutical packaging:** Pharmaceutical dosage form and their packaging requirments, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing

modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials.

Quality control test: Containers, closures and secondary packing materials.

12 Hrs

5. **Technology transfer:** Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models.

   Documentation in technology transfer: Development report, technology transfer plan and Exhibit.

   12 Hrs

REFERENCES

1. The process of new drug discovery and development. I and II Edition (2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis.
2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
4. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.
5. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rd Edn, Lea & Febriger, Philadelphia.
6. Pharmaceutical product development. Vandana V. Patrevale. John I. Disouza. Maharukh T.Rustomji. CRC Press, Group of Taylor and Francis.
7. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania.
8. Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19th Edn.(1995)OO2C Lippincott;Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
9. The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt. Ltd.
10. Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1st Edition(Reprint 2006). Taylor and Francis. London and New York.

QUALITY ASSURANCE PRACTICAL-I (MQA104P)

PRACTICALS

1. Analysis of pharmacopoeial compounds in bulk and in their formulations (tablet/ capsules/ semisolids) by UV Vis spectrophotometer
2. Simultaneous estimation of multi-drug component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry or AAS
7. **Case studies on**

- Total Quality Management
- Six Sigma
- Change Management/ Change control. Deviations,
- Out of Specifications (OOS)
- Out of Trend (OOT)
- Corrective & Preventive Actions (CAPA)
- Deviations

8 Development of Stability study protocol

9. Estimation of process capability

11. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.

12. Assay of raw materials as per official monographs

13. Testing of related and foreign substances in drugs and raw materials

14. To carry out pre formulation study for tablets, parenterals (2 experiment).

15. To study the effect of pH on the solubility of drugs, (1 experiment)

16. Quality control tests for Primary and secondary packaging materials

17. Accelerated stability studies (1 experiment)

18. Improved solubility of drugs using surfactant systems (1 experiment)

19. Improved solubility of drugs using co-solvency method (1 experiment)

20. Determination of Pka and Log p of drugs.

HAZARDS AND SAFETY MANAGEMENT (MPA201T)

Scope

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

Objectives

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

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

THEORY

60Hrs

1. **Multidisciplinary nature of environmental studies:** Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources

   Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.

   12 Hrs

2. **Air based hazards:** Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non sterile area, Preliminary Hazard Analysis (PHA)

   Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.

   12 Hrs

3. **Chemical based hazards:** Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards, Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.

   12 Hrs

4. **Fire and Explosion**: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion- electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers. **12 Hrs**
5. **Hazard and risk management:** Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools

   Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services

   12 Hrs

REFERENCES:

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. "Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Bharucha Erach, The Biodiversity of India, Mapin 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

1. **Introduction to validation:** Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan.
   Qualification: User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status- Calibration Preventive Maintenance, Change management).

   12 Hrs

2. **Qualification of manufacturing equipment:** Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine.

Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.

12 Hrs

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

4. **Process Validation:** Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach.
   Analytical method validation: General principles, Validation of analytical method as per ICH guidelines (Q2) and USP.
   12 Hrs

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

REFERENCES:

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol.

157,2nd Ed., Marcel Dekker Inc., N.Y.

6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.
10. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
11. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press
12. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press

AUDITS AND REGULATORY COMPLIANCE (MPA203T)

Scope:

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

Objectives:

Upon completion of this course the student should be able to

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

THEORY

60 Hrs

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

   12 Hrs

2. **Role of quality systems and audits in pharmaceutical manufacturing environment:** cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource**,** Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.

   12 Hrs

3. **Auditing of vendors and production department**: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.

   12 Hrs

4. **Auditing of Microbiological laboratory:** Auditing the manufacturing process,

Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.

12 Hrs

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

12 Hrs

REFERENCES

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

PHARMACEUTICAL MANUFACTURING TECHNOLOGY (MPA204T)

Scope

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

Objectives

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

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

THEORY

60Hrs

1. **Pharmaceutical industry developments:** Legal requirements and Licenses for API and formulation industry, Plant location-Factors influencing**.**

   Plant layout: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout.

   Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.

   12Hrs

2. **Aseptic process technology:** Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume**).**

Advanced sterile product manufacturing technology : Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance**.**

Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS).

Lyophilization technology: Principles, process, equipment.

12Hrs

3. **Non sterile manufacturing process technology:** Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft).

   Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.

   Coating technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

   12Hrs

4. **Containers and closures for pharmaceuticals:** Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit

worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material.

12Hrs

5. **Quality by design (QbD) and process analytical technology (PAT):** Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.

REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
6. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
8. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA,

2003.

9. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor & Francis, 1st Edition. UK.
10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA Inc. New york.
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey, 2008.

QUALITY ASSURANCE PRACTICAL-II(MQA204P)

PRACTICALS

1. Organic contaminants residue analysis by HPLC
2. Estimation of Metallic contaminants by Flame photometer
3. Identification of antibiotic residue by TLC
4. Estimation of Hydrogen Sulphide in Air.
5. Estimation of Chlorine in Work Environment.
6. Sampling and analysis of 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

M.PHARM. PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

GOOD REGULATORY PRACTICES (MRA 101T)

Scope

This course is designed to impart fundamental knowledge biological and medical devices on various–Good Regulatory Practices viz., cGMP, GLP, GALP and GDP pharmaceutical industries and understand the rationale behind these requirements and will propose ways and means of complying them.

Objectives

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

- The key elements of current Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices, Good Documentation Practices
- The check lists for various Good Regulatory Practices and
- Prepare SOPs for Good Pharmaceutical Practices
- Implement Good Regulatory Practices in the Health care Industries and
- Prepare for the Audit of the Pharmaceutical Industries.
- Prepare for the rediness and conduct of the audit/inspections

THEORY **60Hrs**

1. **Current Good Manufacturing Practices:** Introduction, US cGMP Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical devices, GHTF guidance docts **12Hrs**

2. **Good Laboratory Practices:** Introduction,USFDA GLP Regulations (Subpart A to Subpart K),Controlling the GLP inspection process,GLP Documentation,Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, ISO **12Hrs**

3. **Good Automated Laboratory Practices:** Introduction to GALP, Principles of GALP, GALP Requirements, SOPs of GALP, Training Documentation,21 CFR Part 11,General check list of 21CFR Part 11, Software Evaluation checklist, ISO. **12Hrs**

4. **Good Distribution Practices:** Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP(Supply chain integrity), GHTF guidance/IMDRF/CDSCO **12Hrs**

5. **Quality management systems:** Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)]and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and

products, ISO 13485, Schedule M III

12Hrs

REFERENCES

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

REGULATIONS LEGISLATIONS FOR FOOD PMBC IN INDIA (MRA 102T)

Scope:

This course is designed to impart fundamental knowledge on regulations and legislations in India with respect to PMBC. It prepares the students for basic regulatory requirements in India of PMB for manufacture, import, registration, export, sale, marketing authorization, clinical trials and intellectual property rights.

Objectives:

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

- Know different Acts and guidelines that regulate PMBC industry in India.
- Understand the approval process and regulatory requirements for drugs and medical devices

THEORY **60 HOURS**

UNIT I

- **Study of Relevant provisions of FPMBC**

- **Acts and Rules (with latest amendments):**

- Drugs and Cosmetics Act 1940 and other Relevant provisions (Rules, Schedules and Guidelines) for approval of FPMBC , Rules 1945: DPCO and NPPA
- Legal definitions of schedules to the Act and Rules, Import of drugs, Manufacture of drugs, Sale of Drugs& Packing of drugs & other related Acts-Narcotic etc

Central Drug Standard Control Organization and State Licensing Authority:

1. Rules, Regulations, Guidelines For Regulatory filling of FPMB to Relevant Regulations
2. Fomat and contents of Regulatory dossier filling
3. Clinical trials /Investigations

- Clinical Trials
  - New Drugs
- Medical Devices
- Fixed Dose Combinations

12 Hrs

UNIT II

Regulatory requirements FNPCMB and approval procedures for:

12 Hrs

UNIT III

Indian Pharmacopoeial standards

- **BIS Standards & ISO and other relevant standards**

UNIT IV

BA/ BE: Bioavailability and Bioequivalence data, BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study

Stability requirements: ICH and WHO

Guidelines for drug testing in animals/Preclinical studies

- Animal testing: Rationale for conducting studies, CPCSEA Guidelines
- ethical guidelines for human participants
- ICMR-DBT Guidelines for Stem Cell Research **12 Hrs**

UNIT V

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

REFERENCES

1. Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Office of India
2. Patent Failure How Judges, Bureaucrats, and Lawyers put innovators at risk by James Bessen and Michael J. Meurer
3. Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee
4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New delhi 2006.
5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA)
6. ICH E6 Guideline ― Good Clinical Practice‖ by ICH Harmonised Tripartite
7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation)
8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO
9. Guidelines for Import and Manufacture of Medical Devices by CDSCO
10. Guidelines from official website of CDSCO

INTERNATIONAL REGULATORY ASPECTS OF FNPCMB (MRA103T)

Scope:

This course is designed to impart the fundamental knowledge on the drug development general regulatory requirements for approval of FNPCMB Japan. It prepares the students to have elimentary knowledge on the regulatory requirements, documentation requirements, and registration procedures for marketing the products in above countries.

Objectives: Upon completion of the course, the student shall be able to understand the Regulatory registration and landscape

THEORY **60 Hours**

Unit-I **12 Hours**

USA and CANADA: Organization structure and functions of FDA. Federal register and Code of Federal Regulations (CFR), History and evolution of United States Federal, Food, Drug and Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, Drug Master Files (DMF) system in US, Regulatory Approval Process for Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA); Regulatory requirements for Orphan drugs and Combination Products, Changes to an approved NDA / ANDA. Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in USA

Unit-II **12 Hours**

EUROPEAN UNION and AUSTRALIA: Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files (ASMF) system in EU, Content and approval process of IMPD, Marketing Authorization procedures in EU (Centralized procedure, Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU

Unit-III **12 Hours**

Japan: Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, Regulatory considerations

for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in Japan

UNIT IV

BRAZIL and CHINA

UNIT V

ASEAN and SOUTH ASIA

REFERENCES:

Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series,Vol.144

1. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences,Vol.185
   Informa Health care Publishers.
2. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
3. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
4. Drugs: From Discovery to Approval, Second Edition By Rick Ng
5. New Drug Development: A Regulatory Overview, Eighth Edition By Mark Mathieu
6. Pharmaceutical Risk Management By Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
7. Preparation and Maintenance of the IND Application in eCTD Format By William K. Sietsema
8. Country Specific Guidelines from official websites.

CLINICAL RESEARCH REGULATIONS (MRA 104T)

Scope:

This course is designed to impart the fundamental knowledge on the clinical development process of FNPCMB, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in INDIA. It prepares the students to learn in detail on various laws, legislations and guidance related to safety, efficacy, ethical conduct and regulatory approval of clinical trials and investigations

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

- Clinical drug development process and different phases of clinical trials, investigations
- History, origin and ethics of clinical research
- regulatory requirements for conducting clinical trials investigations and research
- regulations and guidance governing the conduct of clinical research,

THEORY **60 Hours**

Unit-I **12 Hours**

Basics for Clinical trials for drug development process

- Phases of clinical trials, Clinical Trial protocol
- Phase 0 studies
- Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points
- Phase II studies (proof of concept or principle studies to establish efficacy)
- Phase III studies (Multi ethnicity, global clinical trial, registration studies)
- Phase IV studies (Post marketing authorization studies; pits and practices)
- Ethical principles governing informed consent process
- Patient Information Sheet and Informed Consent Form
- The informed consent process and documentation

Unit-II **12 Hours**

Basic CT for MD Ethics in Clinical Research:

- Historical Perspectives: Nuremberg Code, Thalidomide study , Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki
- Origin of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines.
- The ethics of randomized clinical trials
- The role of placebo in clinical trials
- Ethics of clinical research in special population
- Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data

- Data safety monitoring boards.
- Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research

Unit-III **12 Hours**

Regulations governing Clinical Trials

USA: Regulations to conduct drug studies in USA (FDA)

- NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug)
- NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant)
- ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product)
- FDA Guidance for Industry - Acceptance of Foreign Clinical Studies
- FDA Clinical Trials Guidance Document: Good Clinical Practice

EU: Clinical Research regulations in European Union (EMA)

India: Clinical Research regulations in India – Schedule Y

Unit-IV

Clinical Research Related Guidelines **12 Hours**

- Good Clinical Practice Guidelines (ICH GCP E6)
- Indian GCP Guidelines
- ICMR Ethical Guidelines for Biomedical Research
- CDSCO guidelines

Regulatory Guidance on Efficacy and Safety

ICH Guidance's

- E4 – Dose Response Information to support Drug Registration
- E7 – Studies in support of General Population: Geriatrics
- E8 – General Considerations of Clinical Trials
- E10 – Choice of Control Groups and Related Issues in Clinical Trials,
- E 11 – Clinical Investigation of Medicinal Products in the Pediatric Population

Unit-V **12 Hours**

USA & EU Guidance

USA: FDA Guidance

- CFR 21Part 50: Protection of Human Subjects
- CFR 21Part 54: Financial Disclosure by Clinical Investigators
- CFR 21Part 312: IND Application
- CFR 21Part 314: Application for FDA Approval to Market a New Drug
- CFR 21Part 320: Bioavailability and bioequivalence requirements
- CFR 21Part 812: Investigational Device Exemptions

- CFR 21Part 822: Post-market surveillance
- FDA Safety Reporting Requirements for INDs and BA/BE Studies
- FDA Med Watch
- Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment

European Union: EMA Guidance

- EU Directives 2001
- EudraLex (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

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

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

3. ***Audits:*** Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection

4. ***Inspections:*** Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA)

5. ***Product life cycle management:*** Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being 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 203T)

Scope

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

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

Objectives

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

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

Theory **60 Hrs**

Unit I

1.India : Introduction, Applicable Regulations and Guidelines , Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance. GMP and GDP.

12 Hrs

Unit II

2.USA: Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics

12 Hrs

Unit III

3. European Union: Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ biosimilarity assessment, Plasma master file, TSE/ BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars), pre-clinical and clinical development considerations; stability, safety, advertising, labelling and packing of biologics in EU

12 Hrs

Unit IV

4. **Vaccine regulations in India, US and European Union**: Clinical evaluation, Marketing authorisation, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements

12 Hrs

Unit V

5**. Blood and Blood Products Regulations in India, US and European Union**: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (International 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

INDIA MEDICAL DEVICE REGULATIONS (MRA 204T)

Scope:

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

Objectives:

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

- basics of medical devices, process of development, ethical and quality considerations
- harmonization initiatives for approval and marketing medical devices
- regulatory approval process for medical devices in US, EU and Asia
- clinical aspects of medical devices

THEORY **60 Hours**

Unit-I **12 Hours**

Medical Devices: Introduction, differentiating medical devices from IVDs and Combination Products, History of Medical Device Regulation, Product Lifecycle of Medical Devices, Classification of Medical Devices.

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

Unit-II **12 Hours**

Ethics: Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011)

Quality: Quality System Regulations of Medical Devices: ISO 13485, Quality Risk Management of Medical Devices: ISO 14971**,** Validation and Verification of Medical device, Adverse Event Reporting of Medical device

Unit-III **12 Hours**

USA: Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and *In vitro* Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements

21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of *In vitro* diagnostics, classification and approval process.

Unit-IV **12 Hours**

European Union: Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and *In vitro* Diagnostics (*In Vitro* Diagnostics Directive), CE certification process.
Basics of *In vitro* diagnostics, classification and approval process.

Unit-V **12 Hours**

Medical Device Regulations in World Health Organization (WHO): Registration Procedures, Quality System requirements and Regulatory requirements

Asia: Clinical Trial Regulations specific for Medical Devices, Registration Procedures, Quality System requirements and Regulatory requirements for Japan, India and China

REFERENCES:

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

PRACTICAL (MRA205P)

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

M. PHARM. PHARMACEUTICAL BIOTECHNOLOGY (MPB)

MODERN PHARMACEUTICAL ANALYSIS (MPA101T)

Scope

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

Objectives

After completion of course student is able to know,

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

THEORY **60 HOURS**

1. **UV-Visible spectroscopy**: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. **12 Hrs**

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

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

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

2 **NMR spectroscopy**: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of **12 Hrs**

principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

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

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

MICROBIAL AND CELLULAR BIOLOGY (MPB101T)

Scope

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

Objective

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

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

THEORY **60Hrs**

UNIT I

12Hrs

Microbiology

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

UNIT II **12 Hrs**

Molecular Biology **05 Hrs**

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

Gene regulation **02 Hrs**

Gene copy number, transcriptional control and translational control.

RNA processing **05 Hrs**

Modification and Maturation, RNA splicing, RNA editing, 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, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. David Freifelder, Molecular Biology, 2nd edition, Narosa Publishing House.
5. R. Ian Freshney, Culture of animal cells – A manual of Basic techniques, 6th edition, Wileys publication house.
6. David Baltimore,Molecular cell biology, W H Freeman & Co publishers.
7. Cell biology vol-I,II,III by Julio E.Cells
8. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company.

BIOPROCESS ENGINEERING AND TECHNOLOGY (MPB102T)

Scope

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

Objective

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

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

THEORY **60 Hrs**

UNIT I **12 Hrs**

Introduction to fermentation technology

Basic principles of fermentation **02 Hrs**

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

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

Types of bioreactor **04 Hrs**

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

Computer control of fermentation process **02 Hrs**

System configuration and application

UNIT II **12 Hrs**

Mass transfer and Rheology

Mass transfer **07 Hrs**

Theory, diffusional resistance to oxygen requirements of microorganisms, measurements of mass transfer co- efficient and factor affecting them, effects of aeration and agitation on

mass transfer, supply of air, air compressing, cleaning and sterilization of air and plenumventilation, air sampling and testing standards for air purity.

Rheology **05 Hrs**

Rheological properties of fermentation system and their importance in bioprocessing.

UNIT III **12 Hrs**

Scale up of fermentation process **04 Hrs**

Principles, theoretical considerations, techniques used, media for fermentation, HTST sterilization, advantage and disadvantage, liquid sterilization.

Cultivation and immobilized culture system **04 Hrs**

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

Introduction to immobilization **04 Hrs**

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

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, 3rd edition, John Wiley & sons Inc.
3. F.M. Asubel, Current protocols in molecular biology, volume I and II, John Wiley Publishers.
4. Biotol Board, Bioreactor design and product yield, Butterworth and Helhemann publishers.
5. A. H. Patel, Industrial microbiology, 2nd edition, Macmillan India Limited; Second edition

ADVANCED PHARMACEUTICAL BIOTECHNOLOGY (MPB103T)

Scope

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

Objective

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

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

THEORY

60 Hrs

UNIT I

12 Hrs

Enzyme Technology

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

UNIT II

12 Hrs

Genetic Engineering

06 Hrs

Techniques of gene manipulation, cloning strategies,procedures, cloning vectors expression vectors, recombinant selection 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.

SEMESTER – I

PRACTICALS (MPB104P)

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

PROTEINS AND PROTEIN FORMULATIONS (MPB201T)

Scope

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

Objective

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

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

THEORY

60 Hrs

UNIT I

12 Hrs

Protein engineering

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

UNIT II

12 Hrs

Peptidomimetics

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

UNIT III

12 Hrs

Proteomics

08 Hrs

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

2-Dimensional gel electrophoresis

04 Hrs

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

UNIT IV

12 Hrs

Protein formulation

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

UNIT V

12 Hrs

Methods of protein sequencing

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

REFERENCE

1. H. 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 (2007), Springer Science
4. Sheldon J. Park, Jennifer R. Cochran, Protein Engineering and Design (2009), CRC press.
5. Robert K. Skopes. Protein purification, principle and practice (1993), springer link.
6. David Whitford, Proteins-Structure and Function (2005), John Wiley & Sons Ltd.

7. James Swarbrick, Protein Formulation and Delivery (2008) Informa Healthcare USA,Inc.
8. Rodney Pearlman, Y. John Wang Formulation, Characterization, and Stability of Protein Drugs (2002), Kluwer Academic Publishers.

IMMUNOTECHNOLOGY (MPB202T)

Scope

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

Objective

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

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

THEORY **60 Hrs**

UNIT I

12 Hrs

Fundamental aspects of immunology

06 Hrs

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

Humoral Immunity

03 Hrs

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

Cell mediated Immunity

03 Hrs

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

UNIT II **12 Hrs**

Immune Regulation and Tolerance **08 Hrs**

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

Hypersensitivity

02 Hrs

Hypersensitivity Types I-IV, Hypersensitivity reactions and treatment

Autoimmune diseases

02 Hrs

UNIT III

12 Hrs

Vaccine technology

06 Hrs Vaccine and their types, conventional vaccines, novel methods for vaccine production, 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, 2004.
2. S.C. Rastogi, Immunodiagonstics, New Age International, 1996.
3. Ashim Chakravarthy, Immunology and Immunotechnology, Oxford University Press, 2006.
4. E. Benjamini, Molecular Immunology, 2002.

BIOINFORMATICS AND COMPUTATIONAL BIOTECHNOLOGY (MPB203T)

Scope

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

Objectives

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

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

THEORY

60 Hrs

UNIT I

12Hrs

Introduction to Bioinformatics

04 Hrs

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

Biological Database

08 Hrs

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

UNIT II

12 Hrs

Sequence analysis

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

UNIT III

12 Hrs

Protein informatics

05 Hrs

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

Protein structure prediction

05 Hrs

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

Docking

02 Hrs

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

UNIT IV

12Hrs

Diversity of Genomes

04Hrs

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

Completed Genomes

02 Hrs

Bacterium, Nematode, Plant and Human

Evolution of Genomes

04 Hrs

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

Phylogenetic analysis

02 Hrs

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

UNIT V

12Hrs

Target searching and Drug Designing

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

REFERENCE

1. David W. Mount, Bioinformatics Sequence and Genome Analysis, Second Edition – 2005, CBS Publishers and Distributors
2. S. C. Rastogiet. al. Bioinformatics- Concepts Skill and Applications, First Edition –2003, CBS Publishers and Distributors
3. T. E. Creighton, Protein Structure and Molecular Properties, Second Edition-1993 W. H.Freeman and Company
4. Andreas D. Baxevanis, B. F. Francis Ouellette, Bioinformatics; A Practical Guide to the Analysis of Genes and Proteins, 2nd Edition. 2001 John Wiley & Sons, Inc.
5. Arthur M. Lesk, Introduction to Bioinformatics (2002), Oxford University Press.

6. Shui Qing Ye. Bioinformatics: A Practical Approach (2008), Chapman & Hall/CRC.
7. David Posada, Bioinformatics for DNA Sequence Analysis (2008), Humana press.
8. Lesk, A.M. 2002 Introduction to Bioinformatics. Oxford University Press.
9. Letovsky, S.I. 1999 Bioinformatics. Kluwer Academic Publishers.
10. Baldi, P. and Brunak, S. 1998 Bioinformatics. The MIT Press.

BIOLOGICAL EVALUATION OF DRUG THERAPY (MPB204T)

Scope

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

Objective

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

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

THEORY

60 Hrs

UNIT I

12 Hrs

Biological Standardization

04 Hrs

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

Preclinical drug evaluation

06 Hrs

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

06 Hrs

By Therapeutic Category

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

Biologic Medicines in Development for various diseases —

06 Hrs

by Product Category

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

- RNA Interference

UNIT IV

12 Hrs

Regulatory aspects : drugs, biologics and medical devices

04 Hrs

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

Regulatory consideration

04 Hrs

Regulatory consideration for pre-clinical testing and clinical testing of drugs, biologics and medical devices.

New Drug Applications for Global Pharmaceutical Product Approvals

04 Hrs

UNIT V

12 Hrs

Bioavailability

06 Hrs

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

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

Pharmacokinetics

06 Hrs

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

References:

1. Perkins F.T., Hennessen W. Standardization and Control of Biologicals Produced by Recombinant DNA Technology, International Association of Biological Standardization
2. J.H. Burn., Biological Standardization, Oxford University Press
3. Drug Discovery and Evaluation in Pharmacology assay: Vogel

4. Chow, Shein, Ching, Design and analysis of animal studies in pharmaceutical development,
5. Nodine and Siegler, Animal and Clinical pharmacologic Techniques in Drug Evaluation-
6. Screening methods in pharmacology (vol I & II)–R.A. Turner

SEMESTER – II

PRACTICALS (MPB205P)

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