CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES
(AUTONOMOUS)
GUNTUR

ACADEMIC RULES & REGULATIONS

(w.e.f. 2017 PGECET BATCH)

M.PHARMACY

(Semester System)

Chalapathi Institute of Pharmaceutical Sciences
(A U T O N O M O U S)
Accredited by NAAC with "A" Grade, Approved by AICTE, PCI, New Delhi,
Recognized by Department of Technical Education, Govt. of Andhra Pradesh,
Recognized by DSIR for Scientific and Industrial Research,
UGC Under Section 2(f) & 12 B,Chalapathi Nagar, Guntur, Andhra Pradesh,
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CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES

(AUTONOMOUS)

VISION

To inculcate excellence in various fields of pharmacy, mould the institution as centre of excellence in terms of academics and advanced research.

MISSION

Committed to impart quality pharmacy education and research to meet global standards

QUALITY POLICY

Chalapathi Institute of pharmaceutical sciences is committed to impart quality pharmacy education to the growing needs of the society by implementing quality management system on a continual contact basis and continually improved services.

We shall protect the interest of our students and prepare them to meet growing challenges with increased ability to serve the nation and society.

CHALAPATHI INSTITUTE OF PHARMACEUTICAL SCIENCES (AUTONOMOUS)
(Approved in 2nd Academic council meeting dated 02/04/2017)
M.PHARMACY REGULATIONS (New Regulations w.e.f. 2017 PGECET Batch)

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

6. Attendance and progress:

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

7. Program / Course credit structure:

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

7.1. Credit assignment:

7.1.1. Theory and Laboratory courses:

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1 / 2) for practical (laboratory) hours.Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1 / 2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

7.2. Minimum credit requirements:

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

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

8. Academic work:

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

9. Course of study:

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

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

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

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

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

Course Code	Course	Credit Hours	Credit Points	Hrs./ Week	Marks
Semester I					
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH102T	Drug Delivery System	4	4	4	100
MPH103T	Modern Pharmaceutics	4	4	4	100
MPH104T	Regulatory Affair	4	4	4	100
MPH105P	Pharmaceutics Practical I	12	6	12	150
MPH106	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH203T	Computer Aided Drug Delivery System	4	4	4	100
MPH204T	Cosmetic and Cosmeceuticals	4	4	4	100
MPH205P	Pharmaceutics Practical II	12	6	12	150
MPH206	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/ Week	Marks
	Semester I				
MIP101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MIP102T	Pharmaceutial Formulation Development	4	4	4	100
MIP103T	Novel drug delivery systems	4	4	4	100
MIP104T	Intellectual Property Rights	4	4	4	100
MIP105P	Industrial Pharmacy Practical I	12	6	12	150
MIP106	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650
	Semester II				
MIP201T	Advanced Biopharmaceutics and Pharamcokinetics	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
MIP206	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

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

Course Code	Course	Credit Hours	Credit Points	Hrs./ Week	Marks
Semester I					
MPC101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPC102T	Advanced Organic Chemistry	4	4	4	100
MPC103T	Advanced Medicinal Chemistry	4	4	4	100
MPC104T	Chemistry of Natural Products	4	4	4	100
MPC105P	Pharmaceutical Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
MPC201T	Advanced Spectral Analysis	4	4	4	100
MPC202T	Advanced Organic Chemistry - II	4	4	4	100
MPC203T	Computer Aided Drug Design	4	4	4	100
MPC204T	Pharmaceutical Process Chemistry	4	4	4	100
MPC205P	Pharmaceutical Chemistry Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

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

Course Code	Course	Credit Hours	Credit Points	Hrs./ Week	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
MPA106	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPA201T	Advanced Instrumental Analysis	4	4	4	100
MPA202T	Modern Bio-analytical Techniques	4	4	4	100
MPA203T	Quality Control and Quality Assurance	4	4	4	100
MPA204T	Herbal and Cosmetic Analysis	4	4	4	100
MPA205P	Pharmaceutical Analysis Practical II	12	6	12	150
MPA106	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

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

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

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

Course Code	Course	Credit Hours	Credit Points	Hrs./ Week	Marks
Semester I					
MRA101T	Good Regulatory Practice	4	4	4	100
MRA102T	Documentation and Regulatory Writing	4	4	4	100
MRA103T	Clinical Research Regulations	4	4	4	100
MRA104T	Regulation and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, Food & Nutraceuticals in India and Intellectual Property Rights	4	4	4	100
MRA105P	Regulatory Affairs Practical I	12	6	12	150
MRA106	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MRA201T	Regulatory Aspects of Drugs & Cosmetics	4	4	4	100
MRA202T	Regulatory Aspects of Herbal & Biologicals	4	4	4	100
MRA203T	Regulatory Aspects of Medical Devices	4	4	4	100
MRA204T	Regulatory Aspects of Food & Nutraceuticals	4	4	4	100
MRA205P	Regulatory Affairs Practical II	12	6	12	150
MRA206	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

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

Course Code	Course	Credit Hours	Credit Points	Hrs./ Week	Marks
	Semester I				
MPB101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPB102T	Microbial and Cellular Biology	4	4	4	100
MPB103T	Bioprocess Engineering and Technology	4	4	4	100
MPB104T	Advanced Pharmaceutical Biotechnology	4	4	4	100
MPB105P	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 – 9: Course of study for M. Pharm. (Pharmacy Practice)

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

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

Course Code	Course	Credit Hours	Credit Points	Hrs./ Week	Marks
Semester I					
MPL101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPL102T	Advanced Pharmacology-I	4	4	4	100
MPL103T	Pharmacological and Toxicological Screening Methods-I	4	4	4	100
MPL104T	Cellular and Molecular Pharmacology	4	4	4	100
MPL105P	Pharmacology Practical I	12	6	12	150
MPL106	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPL201T	Advanced Pharmacology II	4	4	4	100
MPL202T	Pharmacological and Toxicological Screening Methods	4	4	4	100
MPL203T	Principles of Drug Discovery	4	4	4	100
MPL204T	Clinical Research & Pharmacovigilence	4	4	4	100
MPL205P	Pharmacology Practical II	12	6	12	150
MPL206	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

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

Course Code	Course	Credit Hours	Credit Points	Hrs./ Week	Marks
Semester I					
MPG101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPG102T	Advanced				
	Pharmacognosy - I	4	4	4	100
MPG103T	Phytochemistry	4	4	4	100
MPG104T	Industrial Pharmacognostical Technology	4	4	4	100
MPG105P	Pharmacognosy Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPG201T	Medicinal biotechnology	4	4	4	100
MPG202T	Advanced Pharmacognosy-II	4	4	4	100
MPG203T	Indian system of medicine	4	4	4	100
MPG204T	Herbal cosmetics	4	4	4	100
MPG205P	Pharmacognosy Practical-II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

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

Course Code	Course	Credit Hours	Credit Points
MRM 301T	Research Methodology and Biostatistics*	4	4
MRM 302	Journal club	1	1
MRM 303	Discussion / Presentation (Proposal Presentation)	2	2
MRM 304	Research Work	28	14
	Total	35	21

* Non University Exam

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

Course Code	Course	Credit Hours	Credit Points
MRM 401	Journal Club	1	1
MRM 402	Research Work	31	16
MRM 403	Discussion/Final Presentation	3	3
	Total	35	20

Table – 14: Semester wise credits distribution Semester Credit Points

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

*Credit Points for Co-curricular Activities

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

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

Note: International Conference: Held Outside India

International Journal: The Editorial Board Outside India

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

10. Program Committee

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

2. The composition of the Programme Committee shall be as follows:
   A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M.Pharmacy specialization and four student representatives (two from each academic year), nominated by the Head of the institution.
3. Duties of the Programme Committee:
   i. Periodically reviewing the progress of the classes.
   ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
   iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
   iv. Communicating its recommendation to the Head of the institution on academic matters.
   v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessional exam and before the end semester exam.

11. Examinations/Assessments

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

11.1. End semester examinations

The End Semester Examinations for each theory and practical course through semesters I to IV shall be conducted 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.

11.2. Students should register for two MOOC courses, which shall not be less than three months duration, one in II Semester and the other in III Semester either from the SWAYAM platform (MHRD) or from the University website (list of courses identified by the concerned Department) and to allot 4 credits for each MOOC (2 x 4 = 8 credits) and submit the marks to the Controller of Examinations, ANU through the Head of the Department for incorporating the same in Marks Memo and Consolidated Marks Memo (CML).

11.3. Students be permitted to opt more than two MOOC courses during II and III Semesters of the M.Pharm. course WITHOUT credits but the particulars of the course(s) completed by such students be printed in the marks lists and CML respectively.

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

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total			
			Marks	Duration		Marks	Duration	
SEMESTER I								
MPH101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPH102T	Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH103T	Modern Pharmaceutics	10	15	1 Hr	25	75	3 Hrs	100
MPH104T	Regulatory Affairs	10	15	1 Hr	25	75	3 Hrs	100
MPH105P	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 & 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 – 17 : Schemes for internal assessments and end semester (Industrial Pharmacy - MIP)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total			
			Marks	Duration		Marks	Duration	
SEMESTER I								
MIP101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MIP102T	Pharmaceutical Formulation Development	10	15	1 Hr	25	75	3 Hrs	100
MIP103T	Novel drug delivery systems	10	15	1 Hr	25	75	3 Hrs	100
MIP104T	Intellectual Property Rights	10	15	1 Hr	25	75	3 Hrs	100
MIP105P	Industrial Pharmacy Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
	Total							650
SEMESTER II								
MIP201T	Advanced Biophamaceutics & Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100
MIP202T	Scale up and Technology Transfer	10	15	1 Hr	25	75	3 Hrs	100
MIP203T	Pharmaceutical Production Technology	10	15	1 Hr	25	75	3 Hrs	100
MIP204T	Entrepreneurship Management	10	15	1 Hr	25	75	3 Hrs	100
MIP205P	Industrial Pharmacy Practical - II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
	Total							650

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

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

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams Marks	Sessional Exams Duration	Total	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 & Quality Assurance	10	15	1 Hr	25	75	3 Hrs	100
MPA204T	Herbal & Cosmetic Analysis	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 (Pharmaceutical Quality Assurance - MQA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams Marks	Sessional Exams Duration	Total	Marks	Duration	
SEMESTER I								
MQA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MQA102T	Quality Management system	10	15	1 Hr	25	75	3 Hrs	100
MQA103T	Quality Control & Quality Assurance	10	15	1 Hr	25	75	3 Hrs	100
MQA104T	Product Development & Technology Transfer	10	15	1 Hr	25	75	3 Hrs	100
MQA105P	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 – 21 : Schemes for internal assessments and end semester (Pharmaceutical Regulatory Affairs- MRA)

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	Documentation and Regulatory Writing	10	15	1 Hr	25	75	3 Hrs	100
MRA103T	Clinical Research Regulations	10	15	1 Hr	25	75	3 Hrs	100
MRA104T	Regulations and Legislation for Drugs & Cosmetics Medical Devices Biologicals and Herbals, Food and nutraceuticals in India and Intellectual Property Rights	10	15	1 Hr	25	75	3 Hrs	100
MRA105P	Pharmaceutical Regulatory Affairs Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MRA201T	Regulatory Aspects of Drugs and Cosmetics	10	15	1 Hr	25	75	3 Hrs	100
MRA202T	Regulatory Aspects of Herbal and Biologicals	10	15	1 Hr	25	75	3 Hrs	100
MRA203T	Regulatory Aspects of Medical Devices	10	15	1 Hr	25	75	3 Hrs	100
MRA204T	Regulatory Aspects of Food and Nutraceuticals	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 – 22 : Schemes for internal assessments and end semester (Pharmaceutical Biotechnology - MPB)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total			
			Marks	Duration		Marks	Duration	
SEMESTER I								
MPB101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPB102T	Microbial and Cellular Biology	10	15	1 Hr	25	75	3 Hrs	100
MPB103T	Bioprocess Engineering and Technology	10	15	1 Hr	25	75	3 Hrs	100
MPB104T	Advanced Pharmaceutical Biotechnology	10	15	1 Hr	25	75	3 Hrs	100
MPB105P	Pharmaceutical Biotechnology Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
	Total							650
SEMESTER II								
MPB201T	Proteins & 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 – 23 : Schemes for internal assessments and end semester (Pharmacy Practice - MPP)

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	Pharmaco-therapeutics - 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
MPP202T	Pharmacotherapeutics - II	10	15	1 Hr	25	75	3 Hrs	100
MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	10	15	1 Hr	25	75	3 Hrs	100
MPP204T	Pharmacoepidemiology & Pharmacoeconomics	10	15	1 Hr	25	75	3 Hrs	100
MPP205P	Pharmacy Practice Practical - II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

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

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams Marks	Sessional Exams Duration	Total	Marks	Duration	
SEMESTER I								
MPL101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPL102T	Advanced Pharmacology - I	10	15	1 Hr	25	75	3 Hrs	100
MPL103T	Pharmacological and Toxicological Screening Methods - I	10	15	1 Hr	25	75	3 Hrs	100
MPL104T	Cellular and Molecular Pharmacology	10	15	1 Hr	25	75	3 Hrs	100
MPL105P	Pharmacology-I Practical	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
MPL202T	Pharmacological and Toxicological Screening Methods - II	10	15	1 Hr	25	75	3 Hrs	100
MPL203T	Principles of Drug Discovery	10	15	1 Hr	25	75	3 Hrs	100
MPL204T	Clinical research & pharmacovigilance	10	15	1 Hr	25	75	3 Hrs	100
MPL205P	Pharmacology - II Practical	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

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

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total			
			Marks	Duration		Marks	Duration	
SEMESTER I								
MPG101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPG102T	Advanced Pharmacognosy - I	10	15	1 Hr	25	75	3 Hrs	100
MPG103T	Phytochemistry	10	15	1 Hr	25	75	3 Hrs	100
MPG104T	Industrial Pharmacognostical Technology	10	15	1 Hr	25	75	3 Hrs	100
MPG105P	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
MPG202T	Advanced Pharmacognosy - II	10	15	1 Hr	25	75	3 Hrs	100
MPG203T	Indian system of Medicine	10	15	1 Hr	25	75	3 Hrs	100
MPG204T	Herbal Cosmetics	10	15	1 Hr	25	75	3 Hrs	100
MPG205P	Pharmacognosy Practical - II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

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

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

11.2. **Internal assessment: Continuous mode**

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

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

Theory

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

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

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

11.2.1. Sessional Exams:

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

12. Promotion and award of grades:

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

13. Carry forward of marks:

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

14. Improvement of internal assessment:

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

15. Reexamination of end semester examinations:

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

Table – 29: Tentative schedule of end semester examinations

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

16. Allowed to keep terms (ATKT):

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

A student shall be eligible to carry forward all the courses of I and 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 – 30.

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

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

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

18. The Semester grade point average (SGPA):

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

$$SGPA = \frac{C1G1 + C2G2 + C3G3 + C4G4}{C1 + C2 + C3 + C4}$$

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

$$SGPA = \frac{C1G1 + C2G2 + C3G3 + C4* ZERO}{C1 + C2 + C3 + C4}$$

19. Cumulative Grade Point Average (CGPA):

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

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

$$CGPA = \frac{C1S1 + C2S2 + C3S3 + C4S4}{C1 + C2 + C3 + C4}$$

where C1, C2, C3,.... is the total number of credits for semester I,II,III,.... and S1,S2, S3,....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

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

22. Award of Ranks:

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

23. Award of degree:

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

24. Duration for completion of the program of study:

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

25. Revaluation Retotaling of answer papers:

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

26. Re-admission after break of study:

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

M.PHARMACY

PHARMACEUTICS (MPH)

PHARMACEUTICS (MPH)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)

Scope:

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

Objectives:

After completion of course student is able to know,

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

THEORY **60 Hrs**

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 — 10 Hrs

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 a **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

2 b **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.**

3 **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:
a) Paper chromatography b) Thin Layer chromatography
c) Ion exchange chromatography d) Column chromatography
e) Gas chromatography f) High Performance Liquid chromatography
g) Affinity chromatography **10 Hrs.**

4 a **Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
a) Paper electrophoresis b) Gel electrophoresis
c) Capillary electrophoresis d) Zone electrophoresis
e) Moving boundary electrophoresis f) Iso electric focusing **10 Hrs.**

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

4 c **Immunological Assays:** Radioimmunology assay (RIA), ELISA (Theory & practical) and knowledge on Bioluminescence assays.

5 a **Potentiometry :** Principle, working, Ion selective Electrodes and Application of potentiometry. **10 Hrs.**

5 b **Thermal Techniques:**Principle,thermal transitions and Instrumentation (Heat flux and power-compensation designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGC: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th 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 34

DRUG DELIVERY SYSTEMS
(MPH 102T)

Scope:

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

Objective:

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

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

THEORY **60 Hrs**

1	**Sustained Release(SR) and Controlled Release (CR) formulations:** Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of drug delivery from SR/CR formulation. **Polymers:** introduction, definition, classification, properties and application. **Dosage Forms for Personalized Medicine:** Introduction, definition, pharmacogenetics, categories of patients for Personalized Medicines: Customized drug delivery systems, bioelectronic medicines, 3D printing of pharmaceuticals, Telepharmacy.	10 Hrs
2	**Rate Controlled Drug Delivery Systems:** Principles & fundamentals, types, activation; modulated drug delivery systems; mechanically activated, pH activated, enzyme activated, and osmotic activated drug delivery systems feedback regulated drug delivery systems: principles & fundamentals.	10 Hrs
3	**Gastro-Retentive Drug Delivery Systems:** Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco-adhesion, advantages and disadvantages, mechanism of drug permeation, methods of formulation and its evaluation.	10 Hrs
4 a.	**Occular Drug Delivery Systems:** Barriers of drug permeation, Methods to overcome barriers.	06 Hrs

4b	**Transdermal Drug Delivery Systems:** Introduction, Structure of skin, basic components of TDDS and barriers, Penetration enhancers, Formulation and evaluation.	10 Hrs
4c	**Protein and Peptide Delivery:** Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	08 Hrs
5	**Vaccine delivery systems:** Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	06 Hrs

REFERENCES:

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

JOURNALS:

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

MODERN PHARMACEUTICS
(MPH 103T)

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

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

* Elements of preformulation studies.
* Active Pharmaceutical Ingredients and Generic drug Product development
* Industrial management and GMP considerations.
* Optimization techniques & pilot-plant scale-up techniques
* Stability testing, sterilization process & packaging of dosage forms.

	THEORY	**60 Hrs**
1	**a. Preformulation:** Concepts, different methods of Drug-Excipient interactions, kinetics of stability, stability testing. Theories of dispersion and pharmaceutical dispersion (Emulsion and suspension, SMEDDS) preparation and stability Large and Small Volume Parenterals (LSVP) – physiological and formulation consideration, manufacturing and evaluation.	10 Hrs
	b. Optimization techniques in pharmaceutical formulation: concept and parameters of optimization, optimization techniques in pharmaceutical formulation and processing. statistical design, response surface method, contour designs, factorial designs and application in formulation	10 Hrs
2	**Validation :** Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & PQ of facilities.	10 Hrs
3	**cGMP & Industrial Management:** Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance.	
	Production management: Production organization, materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management (TQM).	10 Hrs

4 **Compression and compaction:** Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles solubility. 10 Hrs

5 **Study of consolidation parameters:** Diffusion parameters, dissolution rate test parameters and pharmacokinetic parameters, Heckel plots, similarity factor and difference factor– f_2 and f_1, Higuchi and Peppas plot, linearity, concept of significance, standard deviation, Chi square test, students t-test, ANOVA test. 10 Hrs.

REFERENCES:

1. Libermann and Lachmann. theory and practice of industrial pharmacy. 4th Edtion, CBS Publishers and Distributors Pvt.Ltd; 2013.
2. Leon Lachmann. Pharmaceutical Dosage forms: Tablets. Volume 1-3., Second edition. Marcel Dekker; 2005.
3. Leon Lachmann. Pharmaceutical Dosage forms: Disperse systems. Volume 1-2. First Edition. Marcel Dekker; 2005.
4. Leon Lachmann. Pharmaceutical Dosage forms: Parenteral medications Volume 1-2. Second Edition.Marcel Dekker; 2005.
5. Gillbert and S. Banker. Modern Pharmaceutics.4th Edtion. Informa Healthcare. Newyork; 2009.
6. Remington's The Science and Practice of Pharmacy. 22nd Edition. Wolters Kluwer (India) Pvt.Ltd; New Delhi: 2013.
7. H.S. Bean & A.H.Beckett, Advances in Pharmaceutical Sciences. Volume 1-5. 2005.
8. Alfred Martin. Physical Pharmacy. 6th Edition.Wolters Kluwer (India) Pvt.Ltd. New Delhi: 2011.
9. Bentley's Textbook of Pharmaceutics. E.A.Rawlins, 8th Edition. Elsevier; 2010.
10. Sidney H. Willig, Good Manufacturing Practices for Pharmaceuticals: A plan for total quality control, 5th Edition. Volume 109. Marcel Dekker; 2005.
11. Quality Assurance Guide, Organization of Pharmaceutical producers of India.
12. D.P.S. Kohli and D.H.Shah, Drug Formulation manual, 3rd Edition. Eastern Publishers: New Delhi; 2012.
13. P.P.Sharma. How to Practice GMP's.5 th Edition.Vandhana Publications: New Delhi; 2006.
14. Robert.A. Nash and Alfred H.Wachter. Pharmaceutical Process Validation. 3rd Edition. Volume 129. Marcel Dekker; 2005.
15. Mark Gibson. Pharmaceutical Preformulations and Formulation. 1st Edition. CRC Press: Florid; 2008.
16. Evans, Anderson, Sweeney and Williams. Applied Production and Operations Management. Volume 1 & 2. 2006.
17. James Swarbrick and James C.Boylan. Encyclopaedia of Pharmaceutical technology, 2nd edition, volume 1-3. Marcel Dekker. 2002.

REGULATORY AFFAIRS
(MPH 104T)

Scope:

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

* To know the approval processes of drugs at various stages.
* To know the chemistry, manufacturing controls and their regulatory importance.
* To learn the documentation requirements for filing of drugs.
* To learn the importance of regulatory guidelines and regulations for getting approvals easily.

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 / e-CTD formats
* Requirements for approvals to conduct clinical trials.
* Process of monitoring clinical trials and pharmacovigiliance.

THEORY **60 Hrs**

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

3	CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and e-CTD format, Industry and FDA liasion. 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 INDA, NDA, ANDA. Investigation of Medicinal Products Dossier (IMPD) and Investigator Brochure (IB).	12 Hrs
5	**Clinical trials:** Developing clinical trial protocols. Institutional review board/ independent ethics committee formation 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. Leon Shargel and Isadore Kanfer, Generic Drug Product Development: Solid Oral Dosage forms, Second edition, Vol.212, Taylor Francis C R C Press, 2014.
2. Ira R. Berry and Robert P.Martin, The Pharmaceutical Regulatory Process, Second Edition, Vol.185, Informa Health care Publishers, 2008.
3. Richard A Guarino, New Drug Approval Process: Accelerating Global Registrations, 5th edition, Vol.190, Taylor Francis C R C Press, 2009.
4. Sandy Weinberg, Guidebook for drug regulatory submissions John Wiley & Sons.Inc, 2009.
5. Douglas J. Pisano, David Mantus, FDA regulatory affairs: a guide for prescription drugs, medical devices and biologics, 2nd edition Informa Health care Publishers, 2008.
6. Fay A.Rozovsky and Rodney K. Adams, Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance Taylor Francis C R C Press, 2003.
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics

PHARMACEUTICS PRACTICALS - I
(MPH 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV-Visible 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 of 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 transdermal 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 Heckel plot, Higuchi and peppas plot and determine similarity factors.

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

Scope:

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

Objectives:

Upon completion of the course student shall be able to understand

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

THEORY **60 Hrs**

1	**Targeted Drug Delivery Systems:** concepts, events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.	12 Hrs
2	**Targeting Methods:** Introduction preparation and evaluation. Nanoparticles & Liposomes: Types, preparation and evaluation.	12 Hrs
3	**Microcapsules/ Microspheres:** Types, preparation and evaluation , Monoclonal Antibodies ; preparation and applications, preparation and applications of Niosomes, Aquasomes, Phytosomes, Electrosomes.	12 Hrs
4	**Pulmonary Drug Delivery Systems :** Aerosols, propellents, containers, types, preparation and evaluation, Intra Nasal Route Delivery systems; types, preparation and evaluation.	12 Hrs
5	**Nucleic acid based therapeutic delivery system :** Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of future.	12 Hrs

REFERENCES:

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

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 202T)

Scope:

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

Objectives:

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

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

THEORY **60 Hrs**

1 **Drug Absorption from the Gastrointestinal Tract:**

Gastrointestinal tract, mechanism of drug absorption, factors affecting drug absorption, pH–partition theory of drug absorption. Formulation and physicochemical factors effecting absorption, 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.

12 Hrs

2	**Biopharmaceutic considerations in drug product design and *In-Vitro* drug product performance:** Introduction, biopharmaceutic factors affecting drug bioavailability, rate limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. *In-vitro in-vivo* correlation, dissolution profile comparisons, drug product stability considerations in the design of a drug product.	12 Hrs
3	**Pharmacokinetics:** Basic considerations, pharmacokinetic models. Compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model:two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of K_{max} and V_{max}. **Drug interactions:** introduction, the effect of proteinbinding interactions,the effect of tissue-binding interactions,cytochrome P450-based drug interactions,drug interactions linked to transporters.	12 Hrs
4	**Drug Product Performance, *In Vivo*:** Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutical classification system, methods. Permeability: *In-vitro*, *in-situ* and *In-vivo* methods.generic biologics (biosimilar drug products),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.	12 Hrs
5	Application of Pharmacokinetics: Modified-Release Drug Products, targeted drug delivery systems and biotechnological products. Introduction to pharmacokinetics and pharmacodynamic drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, proteins and peptides, monoclonal antibodies, oligonucleotides, Vaccines (immunotherapy), Gene therapies.	12 Hrs

REFERENCES:

1. Milo Gibaldi, Biopharmaceutics and Clinical Pharmacokinetics, 4th edition,Lea and Febiger, Philadelphia, 1991
2. D.M. Brahmankarand Sunil B. Jaiswal.,Biopharmaceutics and Pharmacokinetics a Treatise, VallabPrakashan, Pitampura, Delhi.
3. Leon Shargel, Susanna Wu-Pong, Andrew B.C. Yu, Applied Biopharmaceutics and Pharmacokinetics, 5 thedition, The McGraw Hill companies, 2004.
4. Dr. Shoba Rani R Hiremath, Textbook of Biopharmaceutics and Pharmacokinetics, Prism Publications, 2012.
5. Milo Gibaldi, Donald Perrier, Pharmacokinetics, 2nd edition,Taylor & Francis, 1982.
6. Swarbrick. J,Current Concepts in Pharmaceutical Sciences: Biopharmaceutics,LeaandFebiger, Philadelphia, 1970.
7. Malcolm Rowland, Thomas N. Tozer, Clinical Pharmacokinetics: Concepts and Applications, 4th edition, Wolters Kluwer Health, Lippincott William & Wilkins, 2011.
8. Abdou. H.M, Dissolution, Bioavailability and Bioequivalence, MackPublishingCompany, Pennsylvania 1989
9. Robert. E. Notari, Biopharmaceutics and Clinical PharmacokineticsAn Introduction, 4th edition, Marcel Dekker Inc, NewYork and Basel,1987.
10. JhonG Wagner andM.Pemarowski, Biopharmaceutics and Relevant Pharmacokinetics,, 1st edition, Drug Intelligence Publications, Hamilton,Illinois, 1971.
11. James Swarbrick, James C. Boylan, Encyclopedia of Pharmaceutical Technology, Vol 13, Marcel Dekker Inc, New York, 1996.
12. Sunil S Jambhekar, Philip J Breen, Basic Pharmacokinetics, 1st edition, Pharmaceutical press, RPS Publishing,2009
13. Alex Avdeef, Absorption and Drug Development- Solubility, Permeability, and ChargeState,2nd Edition, John Wiley & Sons Inc,2012.

COMPUTER AIDED DRUG DEVELOPMENT
(MPH 203T)

Scope:

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

Objectives:

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

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

THEORY **60 Hrs**

1 **a. Computers in Pharmaceutical Research and Development:** A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling — 12 Hrs

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

2 **Computational Modeling of Drug Disposition:** Introduction to Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter. — 12 Hrs

3	**Computer-aided Formulation Development:** Concept of optimization, optimization parameters, factorial design, optimization technology & screening design. **Computers in pharmaceutical formulation:** Development of pharmaceutical emulsions, microemulsion drug carriers. Legal Protection of innovative uses of computers in R & D, the ethics of computing in pharmaceutical research, computers in market analysis	12 Hrs
4	**a. 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 (IVIVC), biowaiver considerations **b. Computer simulations in pharmacokinetics and pharmacodynamics:** introduction, computer simulation whole organism, isolated tissues, organs, cell, proteins and genes. **c. Computers in clinical development:** Clinical data collection and management, regulation of computer systems	12 Hrs
5	**Artificial intelligence (AI), robotics and computational fluid dynamics:** General overview, pharmaceutical automation, pharmaceutical applications, advantages and disadvantages. current challenges and future directions.	12 Hrs

REFERENCES:

1. Sean Ekins., Computer Applications in Pharmaceutical Research and Development, John Wiley & Sons, New Jersey, 2006.

2. Jelena Djuris. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Woodhead Publishing company, USA 2013.

3. James Swarbrick, James. G.Boylan. Encyclopedia of Pharmaceutical Technology, Vol 13, Marcel Dekker Inc, New York, 1996.

COSMETICS AND COSMECEUTICALS
(MPH 204T)

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

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

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

THEORY **60 Hrs**

1	**Cosmetics – Regulatory aspects:** Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics, Regulatory provisions relating to import of cosmetics, Misbranded and Spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, Loan license, Offences and Penalties.	12 Hrs
2	**Cosmetics - Biological aspects :** Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odour. Structure of hair and its growth cycle. Common problems associated with oral cavity. Cleansing and care needs for Face, Eye lids, Lips, Hands, Feet, Nail, Scalp, Neck, Body and Under-arm.	12 Hrs
3	**Formulation Building blocks:** Building blocks for different product formulations of cosmetics/cosmeceuticals. Classification and application. Surfactants, Emollients, rheological additives. Antimicrobial used as preservatives, their merits and demerits, Factors affecting microbial preservative efficacy. Building blocks for formulation of a Moisturizing cream, Vanishing cream, Cold cream, Shampoo and Toothpaste, Soaps and syndetbars. Perfumes: Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.	12 Hrs

Controversial ingredients: Parabens, Formaldehyde liberators, Dioxane.

4	**Design of cosmeceutical products:** Sun protection, sunscreens classification and regulatory aspects. Addressing Dry Skin, Acne, Sun-protection, Pigmentation, Prickly heat, Wrinkles, Body odor, Dandruff, Dental cavities, Bleeding gums, Mouth odour and Sensitive teeth through cosmeceutical formulations.	12 Hrs
5	**Herbal Cosmetics :** Herbal ingredients used in Hair care, Skin care and Oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, Emollients, Foaming agents, Emulsifiers and Rheology modifiers. Challenges in formulating Herbal cosmetics.	12 Hrs

REFERENCES:

1. Norman F. Estrin. CTFA. Cosmetic Ingredient Dictionary. Second edition. Washington DC: The cosmetic, toiletery and fragrance association. Inc; 1976.
2. A. O. Barel. M. Paye. H. I. Maibach. Handbook of Cosmetic Science and Technology. Fourth edition. Newyork: CRC Press work; 2014.
3. P.P. Sharma. Formulation, Manufacture and Quality Control. Fourth edition. Noida: CBS Publishers and distributors; 2008.
4. Hilda Butler. Poucher's Perfumes, Cosmetics and Soaps. Tenth edition. New Delhi: Springer (India) Private Limited; 1997. 782 p.
5. Sanju Nanda. Arun Nanda. Roop K. Khar. Cosmetics Technology. Firstedition. New Delhi: Birla publication private limited; 2007. 479p.
6. B. M. Mithal. R.N. Saha. A Handbook of cosmetics. First edition. New Delhi: Vallabh Prakashan; 2007. 258 p.

PHARMACEUTICS PRACTICALS - II
(MPH 205P)

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

Semester III

MRM301T - Research Methodology & Biostatistics

UNIT – I

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

UNIT – II

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

UNIT – III

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

UNIT – IV

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

UNIT – V

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

M.PHARMACY

PHARMACEUTICAL ANALYSIS (MPA)

PHARMACEUTICAL ANALYSIS (MPA)
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA 101T)

Scope:

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

Objectives:

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

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

THEORY **60 Hrs**

1 **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 — 10 Hrs

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 a **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

2 b **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

3 **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: 10 Hrs
a) Paper chromatography
b) Thin Layer chromatography
c) Ion exchange chromatography d) Column chromatography
e) Gas chromatography f) High Performance Liquid chromatography
g) Affinity chromatography

4 a **Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: 10 Hrs
a) Paper electrophoresis b) Gel electrophoresis
c) Capillary electrophoresis d) Zone electrophoresis
e) Moving boundary electrophoresis f) Iso electric focusing

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

4 c **Immunological Assays:** Radioimmunology assay (RIA), ELISA (Theory & practical) and knowledge on Bioluminescence assays.

5 a **Potentiometry :** Principle, working, Ion selective Electrodes and Application of potentiometry. 10 Hrs

5 b **Thermal Techniques:**Principle,thermal transitions and Instrumentation (Heat flux and power-compensation designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal **Analysis (DTA):** Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGC: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES:

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

ADVANCED PHARMACEUTICAL ANALYSIS
(MPA 102T)

Scope:

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

Objective:

After completion of the course students shall able to know,

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

THEORY **60 Hrs**

1 **Impurity and stability studies:**

Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines — 10 Hrs

Impurities in new drug products:

Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products

Impurities in residual solvents:

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

2 **Elemental impurities:**

Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis — 10 Hrs

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

3 **Impurity profiling and degradent characterization:** Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradent characterization with special emphasis on photostability testing guidelines, ICH stability guidelines for biological products — 10 Hrs

4 **Stability testing of phytopharmaceuticals:**
Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity. — 10 Hrs

5 a **Biological tests and assays of the following:** — 10 Hrs
a. Adsorbed Tetanus vaccine
b. Adsorbed Diphtheria vaccine
c. Human anti haemophilic vaccine d. Rabies vaccine
e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin
h.Heparin sodium IP i. Antivenom. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)

5 b Immunoassays (IA) — 10 Hrs
Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.

REFERENCES:

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

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

PHARMACEUTICAL VALIDATION
(MPA 103T)

Scope:

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

Objectives:

Upon completion of the subject student shall be able to

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

THEORY **60 Hrs**

1	**Introduction:** Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan. **Qualification:** User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status-Calibration Preventive Maintenance, Change management),Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments.	12 Hrs
2	**Qualification of analytical instruments:** Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.	12 Hrs
3	**Validation of Utility systems:** Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen. Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities and Cleaning in place (CIP).	12 Hrs
4	**Analytical method validation:** General principles, Validation of analytical method as per ICH guidelines and USP. Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP 5.	12 Hrs

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

REFERENCES:

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

FOOD ANALYSIS
(MPA 104T)

Scope:

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

Objectives:

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

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

THEORY **60 Hrs**

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

4 General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk. Analysis of fermentation products like wine, spirits, beer and vinegar. 12 Hrs

5 **Pesticide analysis:** Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products. Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA. 12 Hrs

REFERENCES:

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

PHARMACEUTICAL ANALYSIS PRACTICALS - I
(MPA 105P)

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

ADVANCED INSTRUMENTAL ANALYSIS
(MPA 201T)

Scope:

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

Objectives:

After completion of course student is able to know,

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

THEORY **60 Hrs**

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

4	**Mass spectrometry:** Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrpole, Time of flight, FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF;Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap.	12 Hrs
5	**NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR with reference to ^{13}CNMR: Spin spin and spin lattice relaxation phenomenon. ^{13}C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations.	12 Hrs

REFERENCES:

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

MODERN BIO-ANALYTICAL TECHNIQUES
(MPA 202T)

Scope:

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

Objectives:

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

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

THEORY **60 Hrs**

1 **Extraction of drugs and metabolites from biological matrices:** General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid - Liquid extraction and Solid phase extraction and other novel sample preparation approach. Bioanalytical method validation: USFDA and EMEA guidelines. — 12 Hrs

2 **Biopharmaceutical Consideration:** Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, *In-Vitro* dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: *in-vitro*, *in-situ* and *isn-vivo* methods. — 12 Hrs

3 **Pharmacokinetics and Toxicokinetics:** Basic consideration, Drug interaction (PK-PD interactions), The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics-Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics. — 12 Hrs

4 **Cell culture techniques** Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry. — 12 Hrs

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

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

REFERENCES:

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

QUALITY CONTROL AND QUALITY ASSURANCE
(MPA 203T)

Scope:

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

Objectives:

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

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

THEORY **60 Hrs**

1	**Concept and Evolution of Quality Control and Quality Assurance: 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.	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. CPCSEA guidelines.	12 Hrs
3	**Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3)** Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials.	12 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 Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data. 12 Hrs

5 **Manufacturing operations and controls:** Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging. 12 Hrs

REFERENCES:

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

HERBAL AND COSMETIC ANALYSIS
(MPA 204T)

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

Objectives:
At completion of this course student shall be able to understand
* Determination of herbal remedies and regulations
* Analysis of natural products and monographs
* Determination of Herbal drug-drug interaction
*Principles of performance evaluation of cosmetic products.

THEORY **60 Hrs**

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

5 **Evaluation of cosmetic products:** Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS. 12 Hrs

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

REFERENCES:

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

PHARMACEUT ICAL ANALYSIS PRACTICAL - II
(MPA 205P)

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

Semester III

(MRM 301T) - Research Methodology & Biostatistics

UNIT – I

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

UNIT – II

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

UNIT – III

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

UNIT – IV

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

UNIT – V

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

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

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

Objectives:
After completion of course student is able to know about,
* Chemicals and Excipients
* The analysis of various drugs in single and combination dosage forms
* Theoretical and practical skills of the instruments

THEORY **60 Hrs**

1 **UV-Visible spectroscopy:** Introduction, Theory, Laws, 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 — 10 Hrs

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 a **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

REFERENCES:

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

3	Systemic Pharmacology A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems, Autonomic Pharmacology Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction Central nervous system Pharmacology General and local anesthetics Sedatives and hypnotics, drugs used to treat anxiety. Depression, psychosis, mania, epilepsy, neurodegenerative diseases. Narcotic and non-narcotic analgesics.	12 Hrs
4	Cardiovascular Pharmacology Diuretics, antihypertensives, antiischemics, anti-arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants, anticoagulants, fibrinolytics and antiplatelet drugs	12 Hrs
5	Autocoid Pharmacology The physiological and pathological role of Histamine, Serotonin, Kinins, Prostaglandins, Opioid, Autocoids. Pharmacology of antihistamines, 5HT antagonists.	12 Hrs

REFEERENCES:

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

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

Scope:

This subject is designed to impart the knowledge on pre-clinical 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* pre-clinical 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 pre-clinical data to humans

THEORY **60 Hrs**

1 Laboratory Animals

Common laboratory animals: Description, handling and applications of different species and strains of animals. 12 Hrs

Transgenic animals: Production, maintenance and applications Anaesthesia and euthanasia of experimental animals. Maintenance and breeding of laboratory animals. CPCSEA guidelines to conduct experiments on animals

Good laboratory practice.
Bioassay-Principle, scope and limitations and methods

2 Pre-clinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. General principles of pre-clinical screening. CNS Pharmacology: behavioral and muscle co ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System. 12 Hrs

CELLULAR AND MOLECULAR PHARMACOLOGY
(MPL 104T)

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

Objectives:
Upon completion of the course, the student shall be able to,
* Explain the receptor signal transduction processes.
* Explain the molecular pathways affected by drugs.
* Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
* Demonstrate molecular biology techniques as applicable for pharmacology

THEORY **60 Hrs**

1 Cell biology

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

Cell cycles and its regulation.

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

Necrosis and autophagy.

12 Hrs

2 Cell signalling

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

12 Hrs

PHARMACOLOGY PRACTICAL - I
(MPL 105P)

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

Handling of laboratory animals.

1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by 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, ± amylase, ± 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)

ADVANCED PHARMACOLOGY - II
(MPL 201T)

Scope

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

Objectives

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

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

	THEORY	**60 Hrs**
1	Endocrine Pharmacology Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation	12 Hrs
2	Chemotherapy Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.	12 Hrs
3	Chemotherapy Drugs used in Protozoal Infections Drugs used in the treatment of Helminthiasis Chemotherapy of cancer Immunopharmacology Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD. Immunosuppressants and Immunostimulants	12 Hrs

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

Scope:

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

Objectives:

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

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

	THEORY	**60 Hrs**
1	Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice (GLP) History, concept and its importance in drug development	12 Hrs
2	Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization- importance and methods in regulatory toxicology studies	12 Hrs
3	Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II) Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies	12 Hrs
4	IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. Safety pharmacology studies- origin, concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies	12 Hrs

PRINCIPLES OF DRUG DISCOVERY
(MPL 203T)

Scope:

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

Objectives:

Upon completion of the course the student shall be able to

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

THEORY **60 Hrs**

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

CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL 204T)

Scope:

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

Objectives:

Upon completion of the course the student shall be able to

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

THEORY **60 Hrs**

1	Regulatory Perspectives of Clinical Trials: 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	12 Hrs
2	Clinical Trials: Types and Design Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management	12 Hrs

PHARMACOLOGY PRACTICAL - II
(MPL 205P)

1. To record the DRC of agonist using suitable isolated tissues preparation
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine the strength of unknown sample by interpolation bioassay by using suitable tissue preparation
5. To determine the strength of unknown sample by bracketing bioassay by using suitable tissue preparation
6. To determine the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of PA2 values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial.(3 Nos.)
17. Design of ADR monitoring protocol.
18. In-silico docking studies. (2 Nos.)
19. In-silico pharmacophore based screening.
20. In-silico QSAR studies.
21. ADR reporting

REFERENCES:

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

M.PHARMACY

PHARMACEUTICAL REGULATORY AFFAIRS (MRA)

PHARMACEUTICAL MANAGEMENT & REGULATORY AFFAIRS (MRA)

GOOD REGULATORY PRACTICES (MRA 101T)

Scope:

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

Objectives:

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

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

THEORY **60 Hrs**

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

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

REFERENCES:

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

DOCUMENTATION AND REGULATORY WRITING
(MRA 102T)

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

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

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

THEORY **60 Hrs**

1	**Documentation in pharmaceutical industry:** Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF).	12 Hrs
2	**Dossier preparation and submission:** Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions; Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non eCTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission. Submission in Sugam system of CDSCO.	12 Hrs

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

REFERENCES:

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C.Singer, Raluca-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
13. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP)

CLINICAL RESEARCH REGULATIONS
(MRA 103T)

Scope:

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

Objectives:

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

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

THEORY **60 Hrs**

1. Clinical Drug Development Process

12 Hrs

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

Clinical Investigation and Evaluation of Medical Devices & IVDs
Different Types of Studies
Key Concepts of Medical Device Clinical Evaluation
Key concepts of Clinical Investigation

2 **Ethics in Clinical Research:**

* Historical Perspectives: Nuremberg Code, Thalidomide study, Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki
* Origin of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines.
* The ethics of randomized clinical trials
* The role of placebo in clinical trials
* Ethics of clinical research in special population
* Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data
* Data safety monitoring boards.
* Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research
* Ethical principles governing informed consent process
* Patient Information Sheet and Informed Consent Form
* The informed consent process and documentation

12 Hrs

3 **Regulations governing Clinical Trials India:** Clinical Research regulations in India – Schedule Y & Medical Device Guidance

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

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

EU: Clinical Research regulations in European Union (EMA)

12 Hrs

4 Clinical Research Related Guidelines

* Good Clinical Practice Guidelines (ICH GCP E6) 12 Hrs
* Indian GCP Guidelines
* ICMR Ethical Guidelines for Biomedical Research
* CDSCO guidelines

GHTF study group 5 guidance documents
Regulatory Guidance on Efficacy and Safety ICH Guidance's

* E4 – Dose Response 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,
* E11 – Clinical Investigation of Medicinal Products in the Pediatric Population
* General biostatics principle applied in clinical research

5 USA & EU Guidance
USA: FDA Guidance 12 Hrs
* 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
* EU MDD with respect to clinical research
* ISO 14155

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.
9. Drugs & Cosmetics Act & Rules and Amendments

RECOMMENDED WEBSITES:

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

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

Scope:

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

Objectives:

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

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

THEORY **60 Hrs**

1. Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules (with latest amendments): 12 Hrs

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

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

2	Regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals CDSCO (Central Drug Standard Control Organization) and State **Licensing Authority:** Organization, Responsibilities * Rules, regulations, guidelines and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals * Format and contents of Regulatory dossier filing Clinical trial/ investigations	12 Hrs
3	Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards	12 Hrs
4	Bioavailability and Bioequivalence data (BA &BE), BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study 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
5	**Intellectual Property Rights:** Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. IPR vs Regulatory Affairs	12 Hrs

REFERENCES:

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

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

6. ICH E6 Guideline Good Clinical Practice by ICH Harmonised Tripartite

7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation)

8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO

9. Guidelines for Import and Manufacture of Medical Devices by CDSCO

10. Guidelines from official website of CDSCO

REGULATORY AFFAIRS PRACTICAL - I
(MRA 105P)

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

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

Scope:

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

Objectives:

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

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

THEORY **60 Hrs**

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

Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union & Australia.

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

REFERENCES :

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

REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS (MRA 202T)

Scope:

This course is designed to impart fundamental knowledge on Regulatory Requirements, Licensing and Registration, Regulation on Labelling of Biologics in India, USA and Europe It prepares the students to learn in detail on Regulatory Requirements for biologics, Vaccines and Blood Products

Objectives:

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

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

THEORY **60 Hrs**

1	**India :** Introduction, Applicable Regulations and Guidelines , 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
2	**USA:** Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, development and approval of biologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics	12 Hrs
3	**European Union:** Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ biosimilarity assessment, Plasma master file, TSE/ BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars), pre-clinical and clinical development considerations; stability, safety, advertising, labelling and packing of biologics in EU	12 Hrs

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

REFERENCES:

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano , David S. Mantus ; Informa ,2008
2. Biological Drug Products: Development and Strategies; Wei Wang , Manmohan Singh ; wiley ,2013
3. Development of Vaccines: From Discovery to Clinical Testing; Manmohan Singh , Indresh K. Srivastava ;Wiley, 2011
4. www.who.int/biologicals/en
5. www.fda.gov/BiologicsBloodVaccines Guidance Compliance Regulatory Information/
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)

REGULATORY ASPECTS OF MEDICAL DEVICES
(MRA 203T)

Scope:

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

Objectives:

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

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

THEORY **60 Hrs**

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

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

REFERENCES:

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

REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS (MRA 204T)

Scope:

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

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

Objectives:

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

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

THEORY **60 Hrs**

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

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

REFERENCES:

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

REGULATORY AFFAIRS PRACTICAL - II
(MRA 205P)

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

Semester III

MRM301T - Research Methodology & Biostatistics

UNIT – I

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

UNIT – II

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

UNIT – III

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

UNIT – IV

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

UNIT – V

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

M.PHARMACY

INDUSTRIAL PHARMACY (MIP)

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

Scope:

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

Objectives:

After completion of course student is able to know,

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

THEORY **60 Hrs**

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 — 10 Hrs

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 a 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

2 b **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.**

3 **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:
a) Paper chromatography b) Thin Layer chromatography
c) Ion exchange chromatography d) Column chromatography
e) Gas chromatography f) High Performance Liquid chromatography
g) Affinity chromatography **10 Hrs.**

4 a **Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
a) Paper electrophoresis b) Gel electrophoresis
c) Capillary electrophoresis d) Zone electrophoresis
e) Moving boundary electrophoresis f) Iso electric focusing **10 Hrs.**

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

4 c **Immunological Assays:** Radioimmunology assay (RIA), ELISA (Theory & practical) and knowledge on Bioluminescence assays.

5 **Potentiometry :** Principle, working, Ion selective Electrodes and Application of potentiometry. **10 Hrs.**

Thermal Techniques: Principle,thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGC: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES:

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

PHARMACEUTICAL FORMULATION DEVELOPMENT (MIP 102T)

Scope:

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

Objectives:

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

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

	THEORY	**60 Hrs**
1	Preformulation Studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.	12 Hrs
2	Formulation Additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. Design of experiments – factorial design for product and process development.	12 Hrs
3	Solubility: Importance, experimental determination, phasesolubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy.	12 Hrs
4	Dissolution: Theories, mechanisms of dissolution, in-vitro dissolution testing models – sink and non-sink. Factors influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Biorelevent media, in-vitro and in-vivo correlations, levels of correlations.	12 Hrs

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

REFERENCES:

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

NOVEL DRUG DELIVERY SYSTEMS
(MIP 103T)

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

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

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

	THEORY	**60 Hrs**
1	Concept & Models for NDDS: Classification of rate controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release. Carriers for Drug Delivery: Polymers / co-polymers introduction, classification, characterization, polymerization techniques, application in CDDS / NDDS, biodegradable & natural polymers	10 Hrs
2	Study of Various DDS: Concepts, design, formulation & evaluation of controlled release oral DDS, Mucoadhesive DDS (buccal, nasal, pulmonary) Pulsatile, colon specific, liquid sustained release systems, Ocular delivery systems	10 Hrs
3	Transdermal Drug Delivery Systems: Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems.	08 Hrs
4	Sub Micron Cosmeceuticals: Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, eye etc and it's regulatory aspects.	04 Hrs

	Targeted Drug Delivery Systems: Importance, concept, biological process and events involved in drug targeting, design, formulation & evaluation, methods in drug targeting –nanoparticles, liposomes, niosomes, pharmacosomes, resealed erythrocytes, microspheres, magnetic microspheres. Specialized pharmaceutical emulsions – multiple emulsions, micro emulsions.	10 Hrs
5	Protein / Peptide Drug Delivery Systems: Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stabilization methods.	06 Hrs
	Biotechnology in Drug Delivery Systems: Brief review of major areas-recombinant DNA technology, monoclonal antibodies, gene therapy.	06 Hrs
	New trends for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.	06 Hrs

REFERENCES:

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

INTELLECTUAL PROPERTY RIGHTS
(MIP 104T)

Scope:

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

Objectives:

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

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

THEORY **60 Hrs**

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

REFERENCES :

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

INDUSTRIAL PHARMACY PRACTICAL - I
(MIP 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC / GC
4. Estimation of riboflavin/quinine sulphate by fluorimetry
5. Estimation of sodium/potassium by flame photometry
6. Effect of surfactants on the solubility of drugs.
7. Effect of pH on the solubility of drugs.
8. Stability testing of solution and solid dosage forms for photo degradation..
9. Stability studies of drugs in dosage forms at 25^0C, 60% RH and 40^0C, 75% RH
10. Compatibility evaluation of drugs and excipients (DSC & FTIR).
11. Preparation and evaluation of different polymeric membranes.
12. Formulation and evaluation of sustained release oral matrix tablet/ oral reservoir system.
13. Formulation and evaluation of microspheres / microcapsules.
14. Formulation and evaluation of transdermal drug delivery systems.
15. Design and evaluation of face wash, body- wash, creams, lotions, shampoo, toothpaste, lipstick.
16. Electrophoresis of protein solution.
17. Preparation and evaluation of Liposome delivery system.

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MIP 201T)

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

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

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

THEORY **60 Hrs**

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

2	Biopharmaceutic Considerations in Drug Product Design and *in-vitro* Drug Product Performance: Introduction. Biopharmaceutic Factors Affecting Drug Bioavailability, Rate-Limiting Steps in Drug Absortion, Physicochemical Nature of the Drug Formulation Factors Affecting Drug Product Performance, In Vitro: Dissolution and Drug Release Testing, Compendial Methods of Dissolution, Alternative Methods of Dissolution Testing, Meeting Dissolution Requirements, Problems of Variable Control in Dissolution Testing Performance of Drug Products: In Vitro–In Vivo Correlation, Dissolution Profile Comparisons, Drug Product Stability, Considerations in the Design of a Drug Product.	12 Hrs
3	Pharmacokinetics: Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model- IV bolus, IV infusion, Extra-vascular; Multi Compartment model: Two compartment - model in brief, Non-Linear Pharmacokinetics: Causes of non-linearity, Michaelis – Menten equation, Estimation K_{max} and V_{max}. Drug interactions: Introduction, The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters.	12 Hrs
4	Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability, , Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Evaluation of the Data, Bioequivalence Example, Study Submission and Drug Review Process, The Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products),Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution.	12 Hrs
5	Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Relationship between Pharmacokinetics including Pharmacodynamics: Generation of a pharmacokinetic–pharmacodynamic (PKPD) equation, Pharmacokinetic and pharmacodynamic, interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs: Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy),Gene therapies.	12 Hrs

REFERENCES:

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

SCALE UP AND TECHNOLOGY TRANSFER
(MIP 202T)

Scope

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

Objectives:

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

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

THEORY **60 Hrs**

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

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

REFERENCES:

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

PHARMACEUTICAL PRODUCTION TECHNOLOGY
(MIP 203T)

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

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

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

THEORY **60 Hrs**

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

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

REFERENCES:

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

ENTREPRENEURSHIP MANAGEMENT
(MIP 204T)

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

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

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

	THEORY	**60 Hrs**
1	Conceptual Frame Work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management.	12 Hrs
2	Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.	12 Hrs
3	Launching And Organising An Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilisation - finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.	12 Hrs
4	Growth Strategies And Networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study.	12 Hrs

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

REFERENCES:

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

INDUSTRIAL PHARMACY PRACTICAL - II
(MIP 205P)

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

Semester III

(MRM 301T) - Research Methodology & Biostatistics

UNIT – I

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

UNIT – II

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

UNIT – III

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

UNIT – IV

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

UNIT – V

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