Lachoo Memorial College of Science & Technology
(Autonomous)

Faculty of Pharmacy

Masters Degree in Pharmacy

(Pharmaceutics, Pharmaceutical Chemistry, Quality Assurance, Pharmaceutical Management and Regulatory Affairs, Pharmacognosy, Pharmacology)

Syllabus

- Academic Regulations
- Teaching & Examination Scheme
- Course Content

M.Pharm. (2017-2019)

Semester I examination, 2017
Semester II examination, 2018
Semester III examination, 2018
Semester IV examination, 2019

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 ofB.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/extra-curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/peractivity.

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 of2.

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 10. 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.	Pharmaceutical Chemistry	MPC
3.	Pharmaceutical Quality Assurance	MQA
4.	Pharmaceutical Regulatory Affairs	MRA
5.	Pharmacology	MPL
6.	Pharmacognosy	MPG

The course of study for M.Pharm specializations shall include Semester wise Theory & Practical as given in Table – 2 to 7. 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 7.

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

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

Table – 3: Course of study for M. Pharm. (Pharmaceutical Chemistry)

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

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MQA101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MQA102T	Quality Management System	4	4	4	100
MQA103T	Quality Control and Quality Assurance	4	4	4	100
MQA104T	Product Development and Technology Transfer	4	4	4	100
MQA105P	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 – 5: Course of study for M. Pharm. (Regulatory Affairs)

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

Table – 6: Course of study for (Pharmacology)

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

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

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

Table – 8: Course of study for M. Pharm. III Semester
(Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
MRM301T	Research Methodology and Biostatistics*	4	4
-	Journal club	1	1
-	Discussion / Presentation (Proposal Presentation)	2	2
-	Research Work	28	14
Total		35	21

*Non University Exam

Table – 9: Course of study for M. Pharm. IV Semester
(Common for All Specializations)

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

Table – 10: Semester wise credits distribution

Semester	CreditPoints
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 – 11: Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	Maximum Credit Points
Participation in National Level Seminar/Conference/Workshop/Symposium/Training Programs(related to the specializationofthestudent)	01
Participation in international Level Seminar/Conference/Workshop/Symposium/Training Programs(related to the specializationofthestudent)	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 totime.

10. Program Committee

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

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

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

3. Duties of the Programme Committee:

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

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

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table – 12-18.

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.

Tables – 12: Schemes for internal assessments and end semester examinations (Pharmaceutics- MPH)

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

204T	and Cosmeceuticals							
MPH 205P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 13: Schemes for internal assessments and end semester examinations (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 Practicall	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPC201T	Advanced Spectral Analysis	10	15	1 Hr	25	75	3 Hrs	100
MPC202T	Advanced Organic Chemistry -II	10	15	1 Hr	25	75	3 Hrs	100
MPC203T	Computer Aided Drug Design	10	15	1 Hr	25	75	3 Hrs	100
MPC204T	Pharmaceutical Process Chemistry	10	15	1 Hr	25	75	3 Hrs	100
MPC205P	Pharmaceutic	20	30	6 Hrs	50	100	6	150

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

Tables – 14: Schemes for internal assessments and end semester examinations (Pharmaceutical Quality Assurance-MQA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
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 and Quality Assurance	10	15	1 Hr	25	75	3 Hrs	100
MQA104T	Product Development and 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 – 15: Schemes for internal assessments and end semester examinations (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 & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights	10	15	1 Hr	25	75	3 Hrs	100
MRA105T	Pharmaceutical Regulatory Affairs Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MRA201T	Regulatory Aspects of Drugs & Cosmetics	10	15	1 Hr	25	75	3 Hrs	100

MRA202T	Regulatory Aspects of Herbal & 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 & 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 – 16: Schemes for internal assessments and end semester examinations (Pharmacology-MPL)

Course Code	Course	Internal Assessment				End Semester		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			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	Experimental Pharmacology - I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650
SEMESTER II								
MPL201T	Advanced Pharmacology II	10	15	1 Hr	25	75	3 Hrs	100
MPL102T	Pharmacological and Toxicological Screening Methods-II	10	15	1 Hr	25	75	3 Hrs	100
MPL203T	Principles of Drug Discovery	10	15	1 Hr	25	75	3 Hrs	100
MPL204T	Clinical research and pharmacovigilance	10	15	1 Hr	25	75	3 Hrs	100
MPL205P	Experimental Pharmacology - II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
Total								650

Tables – 17: Schemes for internal assessments and end semester examinations (Pharmacognosy-MPG)

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

Tables – 18: 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				
SEMESTERIII								
MRM301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
-	Research work*	-	-	-	-	350	1 Hr	350
Total								525
SEMESTERIV								
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75
-	Research work and Colloquium	-	-	-	-	400	1 Hr	400
Total								500

*Non University Examination

11.2. Internal assessment: Continuous mode

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

Table – 19: 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 – 20: 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 21. The exact dates of examinations shall be notified from time to time.

Table – 21: Tentative schedule of end semester examinations

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

16. Allowed to keep terms(ATKT):

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

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

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

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

17. Grading of performances

17.1. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – 22.

Table–22: 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
Lessthan50	F	0	Fail
Absent	AB	0	Fail

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

18. The Semester grade point average(SGPA)

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

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

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

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

19. Cumulative Grade Point Average(CGPA)

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

is/are passed by obtaining a pass grade on subsequent examination(s) the CGPA

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

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

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

20. Declaration of class

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

First Class with Distinction = CGPA of. 7.50 and above
First Class = CGPA of 6.00 to7.49
Second Class = CGPA of 5.00 to5.99

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 givenbelow.

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	500Marks

Evaluation of Presentation:

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

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 programofstudy

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

25. Revaluation I Retotaling of answer papers

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

26. Re-admission after break of study

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

PHARMACEUTICS(MPH)

MODERNPHARMACEUTICALANALYTICALTECHNIQUES (MPH101T)

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 **60HOURS**

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

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

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

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

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

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

REFERENCES

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

DRUGDELIVERYSYSTEMS
(MPH102T)

SCOPE

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

OBJECTIVES

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

The various approaches for development of novel drug delivery systems.

The criteria for selection of drugs and polymers for the development of delivering system

The formulation and evaluation of Novel drug delivery systems.

THEORY 60Hrs

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

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

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded,
Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York,1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in2001).
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition2002

JOURNALS

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

MODERNPHARMACEUTICS
(MPH103T)

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 preformulationstudies.
- The Active Pharmaceutical Ingredients and Generic drug Product development
- Industrial Management and GMPConsiderations.
- Optimization Techniques & Pilot Plant Scale UpTechniques
- Stability Testing, sterilization process & packaging of dosageforms.

THEORY		**60HRS**
1.a.	**Preformation Concepts**–DrugExcipientinteractions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.	10 Hrs
	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**:IntroductiontoPharmaceuticalValidation,Scope&merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. offacilities.	10 Hrs
3	c**GMP&IndustrialManagement**:Objectives andpolicies 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 QualityManagement.	10 Hrs

4	Compressionandcompaction:Physics oftabletcompression, compression, consolidation, effect of friction, distribution of forces, compaction profiles.Solubility.	10 Hrs
5	Studyofconsolidationparameters;Diffusionparameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVAtest.	10 Hrs

REFERENCES

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

REGULATORYAFFAIRS
(MPH104T)

Scope

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

- To know the approval processof
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirementsfor
- To learn the importanceand

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 developmentprocess
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in differentcountries
- Post approval regulatory requirements for actives and drugproducts
- Submission of global documents in CTD/ eCTDformats
- Clinical trials requirements for approvals for conducting clinicaltrials
- Pharmacovigilence and process of monitoring in clinicaltrials.

THEORY **60Hrs**

1.a. DocumentationinPharmaceuticalindustry:Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. **12 Hrs**

b. Regulatoryrequirementforproductapproval:API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreigndrugs

2	CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROWcountries.	12 Hrs
3	Nonclinicaldrugdevelopment:GlobalsubmissionofIND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure(IB).	12 Hrs
4	Clinicaltrials:Developingclinicaltrialprotocols.Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA-new, requirement to clinical study process, pharmacovigilance safety monitoring in clinicaltrials.	12 Hrs

REFERENCES

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

PHARMACEUTICSPRACTICALS-I

(MPH105P)

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 onHPLC
4. Experiments based on GasChromatography
5. Estimation of riboflavin/quinine sulphate byfluorimetry
6. Estimation of sodium/potassium by flamephotometry
7. To perform In-vitro dissolution profile of CR/ SR marketedformulation
8. Formulation and evaluation of sustained release matrixtablets
9. Formulation and evaluation osmotically controlledDDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Muco adhesivetablets.
12. Formulation and evaluation of trans dermalpatches.
13. To carry out preformulation studies oftablets.
14. To study the effect of compressional force on tablets disintegrationtime.
15. To study Micromeritic properties of powders andgranulation.
16. To study the effect of particle size on dissolution of atablet.
17. To study the effect of binders on dissolution of atablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

MOLECULARPHARMACEUTICS(NANOTECHNOLOGY&TARGETEDDDS)(NTDS)
(MPH201T)

Scope

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

Objectives

Upon completion of the course student shall be able to understand

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

THEORY 60Hrs

1.	TargetedDrugDeliverySystems:Concepts,Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.	12 Hrs
2	TargetingMethods:introductionpreparationandevaluation. Nano Particles & Liposomes: Types, preparation andevaluation.	12 Hrs
3	MicroCapsules/MicroSpheres:Types,preparationand evaluation , Monoclonal Antibodies ; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes,Electrosomes.	12 Hrs
4	PulmonaryDrugDeliverySystems:Aerosols,propellents, ContainersTypes, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation andevaluation.	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 deliverysystems. Biodistribution and Pharmacokinetics.knowledge of therapeutic antisense molecules and aptamers as drugs of future.	12 Hrs

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded,Marcel Dekker, Inc., New York,1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, VallabhPrakashan, New Delhi, First edition2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in2001).

ADVANCEDBIOPHARMACEUTICS&PHARMACOKINETICS
(MPH202T)

Scope

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

Objectives

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

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

THEORY **60Hrs**

1. **Drug Absorption from the Gastrointestinal Tract:** Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formuulation 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. **12 Hrs**

2	Biopharmaceuticconsiderationsindrugproductdesign andInVitroDrugProductPerformance: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 testingperformance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability,considerations in the design of a drugproduct.	12 Hrs
3	Pharmacokinetics:Basic considerations,pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model:two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of k_{max} and v_{max}. Drug interactions: introduction, the effect of protein-binding interactions,the effect of tissue-binding interactions,cytochrome p450-based drug interactions,drug interactions linked totransporters.	12 Hrs
4	DrugProductPerformance,InVivo:Bioavailabilityand Bioequivalence:drugproductperformance,purposeof bioavailability studies, relative and absolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods.generic biologics (biosimilar drug products),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.	12 Hrs
5	ApplicationofPharmacokinetics:Modified-ReleaseDrug 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), Genetherapies.	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., VallabPrakashan, Pitampura,Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts,1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,PrismBook
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York,1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia,1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany, Pennsylvania1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York andBasel,1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois,1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York,1996.
12. Basic Pharmacokinetics,1 st edition,Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPSPublishing,2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons,Inc,2003.

COMPUTERAIDEDDRUGDEVELOPMENT

(MPH203T)

Scope

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

Objectives

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

- History of Computers in Pharmaceutical Research andDevelopment
- Computational Modeling of DrugDisposition
- Computers in PreclinicalDevelopment
- Optimization Techniques in PharmaceuticalFormulation
- Computers in MarketAnalysis
- Computers in ClinicalDevelopment
- Artificial Intelligence (AI) andRobotics
- Computational fluiddynamics(CFD)

	THEORY	60Hrs
1.a.	ComputersinPharmaceuticalResearchand Development:AGeneralOverview:History ofComputers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling b.Quality-by-DesignInPharmaceuticalDevelopment: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.	12 Hrs
2	Computational Modeling Of Drug Disposition: Introduction ,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.	12 Hrs

3	Computer-aidedformulationdevelopment::Conceptof 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 Marketanalysis	12 Hrs
4	a.Computer-aidedbiopharmaceuticalcharacterization: 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, Biowaiverconsiderations b. ComputerSimulationsinPharmacokineticsand Pharmacodynamics:Introduction,ComputerSimulation:Whole Organism, Isolated Tissues, Organs, Cell, Proteins andGenes. c. ComputersinClinicalDevelopment:ClinicalDataCollection and Management, Regulation of ComputerSystems	12 Hrs
5	ArtificialIntelligence(AI),RoboticsandComputationalfluid dynamics:Generaloverview,PharmaceuticalAutomation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and FutureDirections.	12 Hrs

REFERENCES

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

COSMETICSANDCOSMECEUTICALS
(MPH204T)

Scope

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

Objectives

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

- Key ingredients used in cosmetics andcosmeceuticals.
- Key building blocks for variousformulations.
- Current technologies in themarket
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, andefficacy.

THEORY		60Hrs
1.	**Cosmetics–Regulatory:** Definitionof 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-Biologicalaspects:** Structureofskinrelatingto problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.	12 Hrs
3	**FormulationBuildingblocks:** Buildingblocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps andsyndetbars. **Perfumes;** Classificationofperfumes.Perfumeingredients listed as allergens in EU regulation.	12 Hrs

	Controversialingredients:Parabens,formaldehydeliberators, dioxane.	
4	Designofcosmeceuticalproducts:Sunprotection,sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceuticalformulations.	12 Hrs
5	HerbalCosmetics:Herbalingredients usedinHair 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 herbalcosmetics.	12 Hrs

REFERENCES

1. Harry's Cosmeticology. 8th edition.
2. Poucher'sperfumecosmeticsandSoaps,10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4th edition
4. HandbookofcosmeticscienceandTechnologyA.O.Barel,M.Payeand H.I. Maibach. 3 rd edition
5. Cosmetic and Toiletries recent supplierscatalogue.
6. CTFAdirectory.

PHARMACEUTICSPRACTICALS-II

(MPH205P)

1. To study the effect of temperature change , non solventaddition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginatebeads
3. Formulation and evaluation of gelatin /albuminmicrospheres
4. Formulation and evaluation ofliposomes/niosomes
5. Formulation and evaluation ofspherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersiontechnique.
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 inanimals.
10. Pharmacokinetic and IVIVC data analysis by Winnoline^{R}software
11. In vitro cell studies for permeability andmetabolism
12. DoE Using Design Expert$^{®}$Software
13. Formulation data analysis Using Design Expert$^{®}$Software
14. Quality-by-Design in PharmaceuticalDevelopment
15. Computer Simulations in Pharmacokinetics andPharmacodynamics
16. Computational Modeling Of DrugDisposition
17. To develop Clinical Data Collectionmanual
18. To carry out Sensitivity Analysis, and PopulationModeling.
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpastebase
21. To incorporate herbal and chemical actives to developproducts
22. To address Dryskin, acne,blemish,Wrinkles, bleedinggumsanddandruff

PHARMACEUTICALCHEMISTRY(MPC)

MODERNPHARMACEUTICALANALYTICALTECHNIQUES (MPC101T)

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 dosageforms
- Theoretical and practical skills of theinstruments

	THEORY	**60Hrs**
1.a.	**UV-Visiblespectroscopy**:Introduction,Theory,Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. b. **IRspectroscopy**:Theory,Modes ofMolecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. c. **Spectroflourimetry**:TheoryofFluorescence,Factorsaffecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescencespectrophotometer. d. **Flameemissionspectroscopy**and**Atomicabsorption spectroscopy**: Principle, Instrumentation, Interferences and Applications.	10 Hrs
2	**NMR spectroscopy**: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMRspectroscopy.	10 Hrs

3	**M**ass**S**pectroscopy:Principle,Theory,InstrumentationofMass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	10 Hrs
4	**C**hro**m**atography:Principle,apparatus,instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a) Thin Layerchromatography b) High Performance Thin LayerChromatography c) Ion exchangechromatography d) Columnchromatography e) Gaschromatography f) High Performance Liquidchromatography g) Ultra High Performance Liquidchromatography h) Affinitychromatography i) Gel Chromatography	10 Hrs
5	a.**E**lectrophoresis: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 electricfocusing b.X**r**ay**C**rystallography:ProductionofXrays,DifferentXray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-raydiffraction.	10 Hrs
6	a.Potentio**m**etry:Principle,working,IonselectiveElectrodes and Application ofpotentiometry. b.Ther**m**alTechniques:Principle,thermaltransitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation	10 Hrs

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

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons,2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore,1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBSpublishers.
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. DekkerSeries
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.

ADVANCEDORGANICCHEMISTRY-I
(MPC102T)

Scope

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

Objectives

Upon completion of course, the student shall be to understand

- The principles and applications ofreterosynthesis
- The mechanism & applications of various namedreactions
- The concept of disconnection to develop synthetic routes for small target molecule.
- The various catalysts used in organicreactions
- The chemistry of heterocycliccompounds

THEORY **60Hrs**

1. **BasicAspectsofOrganicChemistry:** **12 Hrs**
    1. Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and syntheticapplications.
    2. Types of reaction mechanisms and methods of determiningthem,
    3. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity andorientations.

    Additionreactions

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

2 **Studyofmechanismandsyntheticapplicationsoffollowing namedReactions:** **12 Hrs**

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

3 SyntheticReagents&Applications: 12 Hrs

Aluminiumisopropoxide, N-bromosuccinamide, diazomethane, dicyclohexylcarbodimide, Wilkinson reagent, Witting reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, Triphenylphosphine, Benzotriazol-1-yloxy) tris (dimethylamino) phosphonium hexafluoro-phosphate (BOP).

Protectinggroups

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

4 HeterocyclicChemistry: 12 Hrs

Organic Name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six membered and fused hetrocyclics such as Debus-Radziszewski imidazole synthesis, Knorr Pyrazole Synthesis Pinner Pyrimidine Synthesis, Combes Quinoline Synthesis, Bernthsen Acridine Synthesis, Smiles rearrangement and Traube purine synthesis.

Synthesis of few representative drugs containing these hetrocyclic nucleus such as Ketoconazole, Metronidazole, Miconazole, celecoxib, antipyrin, Metamizole sodium, Terconazole, Alprazolam, Triamterene, Sulfamerazine, Trimethoprim, Hydroxychloroquine, Quinine, Chloroquine, Quinacrine, Amsacrine, Prochlorpherazine, Promazine, Chlorpromazine,Theophylline , Mercaptopurine andThioguanine.

5 Synthonapproachandretrosynthesisapplications 12 Hrs

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

REFERENCES

1. “Advanced Organic chemistry, Reaction, Mechanisms and Structure”, J March, John Wiley and Sons, NewYork.
2. “Mechanism and Structure in Organic Chemistry”, ES Gould, Hold Rinchart and Winston, NewYork.
3. “Organic Chemistry” Clayden, Greeves, Warren and Woihers., Oxford University Press2001.
4. “Organic Chemistry” Vol I and II. I.L. Finar. ELBS, Pearson Education Lts, Dorling Kindersley 9India) Pvt.Ltd.,.
5. A guide to mechanisms in Organic Chemistry, Peter Skyes (Orient Longman, NewDelhi).
6. Reactive Intermediates in Organic Chemistry, Tandom and Gowel, Oxford & IBHPublishers.
7. Combinational Chemistry – Synthesis and applications – Stephen R Wilson& Anthony W Czarnik, Wiley –Blackwell.
8. Carey, Organic Chemistry, 5th Edition (Viva Books Pvt.Ltd.)
9. Organic Synthesis - The Disconnection Approach, S. Warren, WilyIndia
10. Principles of Organic Synthesis, ROC Norman and JM Coxan, Nelson Thorns.
11. Organic Synthesis - Special Techniques. VK Ahluwalia and R Agarwal, NarosaPublishers.
12. Organic Reaction Mechanisms IVth Edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.

ADVANCEDMEDICINALCHEMISTRY
(MPC103T)

Scope

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

Objectives

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

- Different stages of drugdiscovery
- Role of medicinal chemistry in drugresearch
- Different techniques for drugdiscovery
- Various strategies to design and develop new drug like molecules for biologicaltargets
- Peptidomimetics

THEORY **60Hrs**

1. **Drugdiscovery:** Stages ofdrugdiscovery,leaddiscovery; identification, validation and diversity of drugtargets. **12 Hrs**

   Biologicaldrugtargets: Receptors,types,bindingand activation, theories of drug receptor interaction, drug receptor interactions, agonists vs antagonists, artificialenzymes.

2. **ProdrugDesignandAnalogdesign:** **12 Hrs**

   a. **Prodrugdesign:** Basicconcept,Carrierlinkedprodrugs/ Bioprecursors, Prodrugs of functional group, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrugdesign.

   b. **Combatingdrugresistance:** Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drugresistance.

   c. **AnalogDesign:** Introduction,Classical&Nonclassical, Bioisosteric replacement strategies, rigid analogs,

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

3 a) Medicinal chemistry aspects of the following class ofdrugs — 12 Hrs

Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class ofdrugs:

- Anti-hypertensive drugs, Psychoactive drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors, Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents.

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

4 RationalDesignofEnzymeInhibitors — 12 Hrs

Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.

5 Peptidomimetics — 12 Hrs

Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally. Chemistry of prostaglandins, leukotrienes and thromboxones.

REFERENCES

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

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

CHEMISTRYOFNATURALPRODUCTS
(MPC104T)

Scope

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

Objectives

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

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

THEORY **60Hrs**

1. StudyofNaturalproductsasleadsfornewpharmaceuticals forthefollowingclassofdrugs — 12 Hrs
   a) Drugs Affecting the Central Nervous System: Morphine Alkaloids
   b) Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide
   c) Cardiovascular Drugs: Lovastatin, Teprotide andDicoumarol
   d) Neuromuscular Blocking Drugs: Curarealkaloids
   e) Anti-malarial drugs andAnalogues
   f) Chemistry of macrolid antibiotics (Erythromycin, Azithromycin, Roxithromycin, and Clarithromycin) and β - Lactam antibiotics (Cephalosporins andCarbapenem)
2. a)Alkaloids — 12 Hrs

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

b) Flavonoids

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

c) Steroids

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

3	a)Terpenoids Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono (citral, menthol, camphor), di(retinol, Phytol, taxol) and tri terpenoids (Squalene,Ginsenoside) carotinoids (βcarotene). b)Vitamins Chemistry and Physiological significance of Vitamin A, B1, B2, B12, C, E, Folic acid and Niacin.	12 Hrs
4	a). Recombinant DNA technology and drug discovery rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation b). Active constituent of certain crude drugs used in Indigenous system Diabetic therapy–Gymnema sylvestre, Salacia reticulate, Pterocarpus marsupiam, Swertia chirata, Trigonella foenum graccum; Liver dysfunction – Phyllanthus niruri; Antitumor – Curcuma longa Linn.	12 Hrs
5	Structural Characterization of natural compounds Structural characterization of natural compounds using IR, 1HNMR, 13CNMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit-D, Quercetin and Digitalis glycosides.	12 Hrs

REFERENCES

1. Modern Methods of Plant Analysis, Peech and M.V.Tracey, Springer – Verlag, Berlin,Heidelberg.
2. Phytochemistry Vol. I and II by Miller, Jan Nostrant ReinHld.
3. Recent advances in Phytochemistry Vol. I to IV – Scikel Runeckles, Springer Science & BusinessMedia.
4. Chemistry of natural products Vol I onwardsIWPAC.
5. Natural Product Chemistry Nakanishi Gggolo, University Science Books, California.
6. Natural Product Chemistry “A laboratory guide” – RaphealKhan.
7. The Alkaloid Chemistry and Physiology by RHF Manske, AcademicPress.
8. Introduction to molecular Phytochemistry – CHJ Wells,Chapmannstall.
9. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall, Himalaya PublishingHouse.
10. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal, KrishanPrakashan.
11. Organic Chemistry Vol I and II by I.L. Finar, Pearsoneducation.
12. Elements of Biotechnology by P.K. Gupta, RastogiPublishers.
13. Pharmaceutical Biotechnology by S.P.Vyas and V.K.Dixit, CBSPublishers.
14. Biotechnology by Purohit and Mathur, Agro-Bios, 13th edition.
15. Phytochemical methods of Harborne, Springer,Netherlands.
16. Burger’s MedicinalChemistry.

PHARMACEUTICALCHEMISTRYPRACTICAL-I
(MPC105P)

1. AnalysisofPharmacopoeialcompoundsandtheirformulationsbyUVVis spectrophotometer, RNA & DNA estimation
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on Columnchromatography
4. Experiments based onHPLC
5. Experiments based on GasChromatography
6. Estimation of riboflavin/quinine sulphate byfluorimetry
7. Estimation of sodium/potassium by flamephotometry

Toperform thefollowingreactionsofsynthetic importance

1. Purification of organic solvents, columnchromatography
2. Claisen-schimidtreaction.
3. Benzyllic acidrearrangement.
4. Beckmannrearrangement.
5. Hoffmannrearrangement
6. Mannichreaction
7. Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4experiments)
8. Estimation of elements and functional groups in organic naturalcompounds
9. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, co-chromatographic technique for identification of isolated compounds and interpretation of UV and IRdata.
10. Some typical degradation reactions to be carried on selected plant constituents

ADVANCEDSPECTRALANALYSIS
(MPC201T)

Scope

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

Objectives

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

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

THEORY		**60Hrs**
1.	**UVandIRspectroscopy:** Wood ward – Fieser rule for 1,3- butadienes, cyclic dienes and α, β-carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds.	12 Hrs
2	**NMRspectroscopy:** 1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds.	12 Hrs
3	**MassSpectroscopy** Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds.	12 Hrs
4	**Chromatography:** Principle, Instrumentation and Applications of the following : a) GC-MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CE-MS g) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I-EC (Ion-Exclusion Chromatography) k) Flashchromatography	12 Hrs

5 a). Thermal methods of analysis 12 Hrs

Introduction, principle, instrumentation and application of DSC, DTA and TGA.

b). Raman Spectroscopy

Introduction, Principle, Instrumentation and Applications.

c). Radioimmunoassay

Biological standardization , bioassay, ELISA, Radioimmuno assay of digitalis and insulin.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons,2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore,1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBSpublishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS,1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, NewDelhi.
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 DekkerSeries

ADVANCEDORGANICCHEMISTRY-II
(MPC202T)

Scope

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

Objectives

Upon completion of course, the student shall able to understand

- The principles and applications of Greenchemistry
- The concept of peptidechemistry.
- The various catalysts used in organicreactions
- The concept of stereochemistry and asymmetricsynthesis.

THEORY **60Hrs**

1. **GreenChemistry:** **12 Hrs**
   a. Introduction, principles of greenchemistry
   b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis
   c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, syntheticapplications
   d. Continuous flow reactors: Working principle, advantages and syntheticapplications.
2. **Chemistryofpeptides** **12 Hrs**
   a. Coupling reactions in peptidesynthesis
   b. Principles of solid phase peptide synthesis, t-BOC and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications ofpeptides
   c. Segment and sequential strategies for solution phase peptide synthesis with any two casestudies
   d. Side reactions in peptide synthesis: Deletion peptides, side

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

3 PhotochemicalReactions 12 Hrs

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

Pericyclicreactions

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

4 Catalysis: 12 Hrs

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

5 Stereochemistry&AsymmetricSynthesis 12 Hrs

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

REFERENCES

1. “Advanced Organic chemistry, Reaction, mechanisms and structure”, J March, John Wiley and sons, NewYork.
2. “Mechanism and structure in organic chemistry”, ES Gould, Hold Rinchart andWinston,NewYork.
3. “Organic Chemistry” Clayden, Greeves, Warren and Woihers., Oxford University Press2001.
4. “Organic Chemistry” Vol I and II. I.L. Finar. ELBS, Sixth ed.,1995.
5. Carey, Organic chemistry, 5th edition (Viva Books Pvt.Ltd.)
6. Organic synthesis-the disconnection approach, S. Warren, WilyIndia
7. Principles of organic synthesis, ROCNorman and JMCoxan, Nelsonthorns
8. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal, NarosaPublishers.
9. Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar, NarosaPublishers.

COMPUTERAIDEDDRUGDESIGN
(MPC203T)

Scope

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

Objectives

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

- Role of CADD in drugdiscovery
- Different CADD techniques and theirapplications
- Various strategies to design and develop new drug likemolecules.
- Working with molecular modeling softwares to design new drug molecules
- The in silico virtual screeningprotocols

Theory 60Hrs

1. **IntroductiontoComputerAidedDrugDesign(CADD)** 12 Hrs

   History, different techniques and applications.

   QuantitativeStructureActivityRelationships:Basics

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

2 **QuantitativeStructureActivityRelationships:Applications** 12 Hrs

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

   3D-QSAR approaches and contour map analysis.

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

3 **MolecularModelingandDocking** 12 Hrs

   a) Molecular and Quantum Mechanics in drugdesign.

   b) Energy Minimization Methods: comparison betweenglobal

minimum conformation and bioactive conformation

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

4 MolecularPropertiesandDrugDesign 12 Hrs

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

5 PharmacophoreMappingandVirtualScreening 12 Hrs

Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping.

In Silico Drug Design and Virtual Screening Techniques
Similarity based methods and Pharmacophore based screening, structure based In-silico virtual screening protocols.

REFERENCES

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

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

PHARMACEUTICALPROCESSCHEMISTRY
(MPC204T)

Scope

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

Objectives

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

- The strategies of scale up process of apis andintermediates
- The various unit operations and various reactions in processchemistry

THEORY		60Hrs
1.	Processchemistry Introduction, Synthetic strategy Stages of scale up process: Bench, pilot and large scale process. In-process control and validation of large scale process. Case studies of some scale up process of APIs. Impurities in API, types and their sources including genotoxic impurities	12 Hrs
2	Unitoperations a) Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter currentextraction. b) Filtration: Theory of filtration, pressure and vacuum filtration, centrifugalfiltration, c) Distillation: azeotropic and steamdistillation d) Evaporation: Types of evaporators, factors affecting evaporation. e) Crystallization: Crystallization from aqueous, non-aqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphousAPIs.	12 Hrs

3	**U**nit**P**rocesses-I a) **N**itration:Nitratingagents,Aromatic nitration,kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid fornitration, b) **H**alogenation:Kinetics ofhalogenations,types of halogenations, catalytic halogenations. Case study on industrial halogenationprocess. c) **O**xidation:Introduction,typesofoxidativereactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H_2O_2, sodium hypochlorite, Oxygen gas,ozonolysis.	12 Hrs
4	**U**nit**P**rocesses-II a) **R**eduction:Catalytic hydrogenation,Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process. b) Fer**m**entation:Aerobic andanaerobic fermentation. Production of i. Antibiotics; Penicillin andStreptomycin, ii. Vitamins: B2 andB12 iii. Statins: Lovastatin,Simvastatin c) **R**eactionprogresskineticanalysis i. Streamlining reaction steps, routeselection, ii. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful forscale-up.	12 Hrs
5	**I**ndustrial**S**afety a) MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment(PPE) b) Fire hazards, types of fire & fireextinguishers c) Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001(Environmental Management System), Effluents and itsmanagement	12 Hrs

REFERENCES

1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever-Changing Climate-An Overview; K. Gadamasetti, CRCPress.
2. Pharmaceutical Manufacturing Encyclopedia, 3rd edition, Volume2.
3. Medicinal Chemistry by Burger, 6th edition, Volume1-8.
4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7th edition, McGrawHill
5. Polymorphism in Pharmaceutical Solids .Dekker Series Volume 95 Ed: H G Brittain(1999)
6. Regina M. Murphy: Introduction to Chemical Processes: Principles, Analysis,Synthesis
7. Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes toScale-Up
8. P.H.Groggins: Unit processes in organic synthesis(MGH)
9. F.A.Henglein: Chemical Technology(Pergamon)
10. M.Gopal: Dryden's Outlines of Chemical Technology, WEP East-West Press
11. Clausen,Mattson: Principle of Industrial Chemistry, Wiley PublishingCo.,
12. Lowenheim & M.K. Moran: IndustrialChemicals
13. S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II, Vikas PublishingHouse
14. J.K. Stille: Industrial Organic Chemistry(PH)
15. Shreve: Chemical Process, McGrawhill.
16. B.K.Sharma: Industrial Chemistry, Goel PublishingHouse
17. ICHGuidelines
18. United States Food and Drug Administration official websitewww.fda.gov

PHARMACEUTICALCHEMISTRYPRACTICALS-II

(MPC205P)

1. Synthesis of organic compounds by adapting different approaches involving (3 experiments)
   a) Oxidation
   b) Reduction/hydrogenation
   c) Nitration
2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2experiments)
3. Assignments on regulatory requirements in API (2experiments)
4. Comparison of absorption spectra by UV and Wood ward – Fieserrule
5. Interpretation of organic compounds byFT-IR
6. Interpretation of organic compounds byNMR
7. Interpretation of organic compounds byMS
8. Determination of purity by DSC inpharmaceuticals
9. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
10. To carry out the preparation of following organiccompounds
11. Preparation of 4-chlorobenzhydrylpiperazine. (an intermediate for cetirizine HCl).
12. Preparation of 4-iodotolene fromp-toluidine.
13. $NaBH_4$ reduction of vanillin to vanillylalcohol
14. Preparation of umbelliferone by Pechhmanreaction
15. Preparation of triphenylimidazole
16. To perform the Microwave irradiated reactions of synthetic importance (Anytwo)
17. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs usingsoftwares
18. Calculation of ADMET properties of drug molecules and its analysis using softwares
    Pharmacophore modeling
19. 2D-QSAR basedexperiments
20. 3D-QSAR basedexperiments
21. Docking study basedexperiment
22. Virtual screening basedexperiment

PHARMACEUTICALQUALITYASSURANCE(MQA)

MODERNPHARMACEUTICALANALYTICALTECHNIQUES (MQA101T)

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 dosageforms
- Theoretical and practical skills of theinstruments

	THEORY	**60Hrs**
1.	a. **UV-Visiblespectroscopy**:Introduction,Theory,Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivativespectroscopy. b. **IRspectroscopy**:Theory,Modes ofMolecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. c. **Spectroflourimetry**:Theory ofFluorescence,Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescencespectrophotometer. d. **Flameemissionspectroscopyand Atomicabsorption spectroscopy**: Principle, Instrumentation, Interferences and Applications.	12 Hrs
2	**NMR spectroscopy**: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMRspectroscopy.	12 Hrs

3	**M**ass**S**pectr**o**scopy:Principle,Theory,InstrumentationofMass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	12 Hrs
4	**C**hro**m**atography:Principle,apparatus,instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: • Thin Layerchromatography • High Performance Thin LayerChromatography • Ion exchangechromatography • Columnchromatography • Gaschromatography • High Performance Liquidchromatography • Ultra High Performance Liquidchromatography • Affinitychromatography • GelChromatography	12 Hrs
5	a.Electrophoresis:Principle,Instrumentation,Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b.XrayCrystallography:ProductionofX rays,DifferentX ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.	12 Hrs
6	a.Potentio**m**etry:Principle,working,IonselectiveElectrodes and Application ofpotentiometry. b.Ther**m**alTechniques:Principle,thermaltransitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation	12 Hrs

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

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons,2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore,1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBSpublishers.
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. DekkerSeries
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons,1982.
10. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, JohnWiley & Sons, 1982.

QUALITYMANAGEMENTSYSTEMS
(MQA102T)

Scope

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

Objectives

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

- The importance ofquality
- ISO managementsystems
- Tools for qualityimprovement
- Analysis of issues inquality
- Quality evaluation ofpharmaceuticals
- Stability testing of drug and drugsubstances
- Statistical approaches forquality

THEORY 60Hrs

1. **Introduction to Quality:** Evolution of Quality, Definition of Quality, Dimensions of Quality — 12 Hrs

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

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

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

2	Pharmaceuticalquality**M**anage**m**ent:Basics ofQuality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMPrequirements.	12 Hrs
3	SixSyste**m**Inspection**m**odel:Quality Managementsystem, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system. Concept of selfinspection. **Q**uality syste**m**s:ChangeManagement/Changecontrol. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Lineclearance.	12 Hrs
4	DrugStability:ICHguidelines for stability testingofdrug substances and drugproducts. StudyofI**CH**Q8,**Q**ualitybyDesignandProcess develop**m**entreport **Q**ualityrisk**m**anage**m**ent:Introduction, riskassessment,risk control, risk review, risk management tools, HACCP, risk ranking andfilteringaccordingtoICHQ9guidelines.	12 Hrs
5	StatisticalProcesscontrol(**SPC**):DefinitionandImportanceof SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased processvariability.	8 Hrs
6	Regulatory Compliance through Quality Managementanddevelopment of QualityCulture Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.	4 Hrs

REFERENCES

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

QUALITYCONTROLANDQUALITYASSURANCE
(MQA103T)

Scope

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

Objectives

Upon completion of this course the student should be able to

- Understand the cGMP aspects in a pharmaceuticalindustry
- To appreciate the importance ofdocumentation
- To understand the scope of quality certifications applicable to Pharmaceuticalindustries
- To understand the responsibilities of QA & QCdepartments.

THEORY		60Hrs
1.	**Introduction:** Conceptandevolutionand scopes ofQuality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q- series guidelines. **GoodLaboratoryPractices:** ScopeofGLP,Definitions,Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. CPCSEAguidelines.	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 WarehousingPractice.	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 rawmaterials.	12 Hrs

	In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to referpharmacopoeias).	
4	Documentationinpharmaceuticalindustry:Threetier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolleddocuments. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non regulated markets.	12 Hrs
5	Manufacturingoperationsandcontrols:Sanitationof manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrapdisposal. Introduction, scope and importance of intellectual property rights.Concept of trade mark, copyright and patents.	12 Hrs

REFERENCES

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

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

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (MQA104T)

Scope

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

Objectives

Upon completion of this course the student should be able to

- To understand the new product developmentprocess
- To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained duringR&D
- To elucidate necessary information to transfer technology of existing products between various manufacturingplaces

THEORY		60Hrs
1.	Principles of Drug discovery and development: Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO,USFDA.	12 Hrs
2	Pre-formulation studies: Introduction/concept,organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol, Stability testing during productdevelopment.	12 Hrs
3	Pilot plant scale up: Concept,Significance,design,layoutof pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities andchallenges.	12 Hrs

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

REFERENCES

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

QUALITYASSURANCEPRACTICAL-I
(MQA105P)

PRACTICALS

1. Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet/ capsules/ semisolids) by UV Visspectrophotometer
2. Simultaneous estimation of multi-drug component containing formulations by UVspectrophotometry
3. Experiments based onHPLC
4. Experiments based on GasChromatography
5. Estimation of riboflavin/quinine sulphate byfluorimetry
6. Estimation of sodium/potassium by flame photometry orAAS
7. Case studieson
   - Total QualityManagement
   - SixSigma
   - Change Management/ Change control.Deviations,
   - Out of Specifications(OOS)
   - Out of Trend(OOT)
   - Corrective & Preventive Actions(CAPA)
   - Deviations
8. Development of Stability studyprotocol
9. Estimation of processcapability
10. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosageforms.
11. Assay of raw materials as per officialmonographs
12. Testing of related and foreign substances in drugs and rawmaterials
13. To carry out pre formulation study for tablets, parenterals (2experiment).
14. To study the effect of pH on the solubility of drugs, (1experiment)
15. Quality control tests for Primary and secondary packagingmaterials
16. Accelerated stability studies (1experiment)
17. Improved solubility of drugs using surfactant systems (1experiment)
18. Improved solubility of drugs using co-solvency method (1experiment)
19. Determination of Pka and Log p ofdrugs.

HAZARDS AND SAFETY MANAGEMENT
(MQA201T)

Scope

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

Objectives

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

- Understand about environmental problems amonglearners.
- Impart basic knowledge about the environment and its alliedproblems.
- Develop an attitude of concern for the industryenvironment.
- Ensure safety standards in pharmaceuticalindustry
- Provide comprehensive knowledge on the safetymanagement
- Empower an ideas to clear mechanism and management in different kinds of hazard managementsystem
- Teach the method of Hazard assessment, procedure, methodology for provide safe industrialatmosphere.

THEORY		60Hrs
1.	Multidisciplinarynatureofenvironmentalstudies:Natural Resources, Renewable and non-renewable resources, Natural resources and associatedproblems, a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Landresources Ecosystems:Conceptofanecosystem andStructureand function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil andRadioisotopes.	12 Hrs
2	Airbasedhazards:Sources,TypesofHazards,Air circulation maintenance industry for sterile area and non sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard managementsystem.	12 Hrs
3	Chemicalbasedhazards:Sources ofchemicalhazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards,	12 Hrs

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

4	Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion-electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares,scrubbers.	12 Hrs
5	Hazard and risk management: Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services.	12 Hrs

REFERENCES

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

PHARMACEUTICALVALIDATION
(MQA202T)

Scope

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

Objectives

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

- The concepts of calibration, qualification andvalidation
- The qualification of various equipments andinstruments
- Process validation of different dosageforms
- Validation of analytical method for estimation ofdrugs
- Cleaning validation of equipments employed in the manufacture of pharmaceuticals

THEORY		60Hrs
1.	Introductiontovalidation:DefinitionofCalibration,Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation.Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan. **Q**ualification:User requirementspecification,Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status-Calibration Preventive Maintenance, Changemanagement).	10 Hrs
2	**Q**ualificationof**m**anufacturingequip**m**ent:Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule fillingmachine. **Q**ualification of analytical instru**m**ents: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC,LC-MS.	10 Hrs

3	**Q**ualificationof**l**aboratory**e**qui**p**ments:Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution testapparatus Validationof**U**tilitysyste**m**s:Pharmaceuticalwatersystem &pure steam, HVAC system, Compressed air andnitrogen.	10 Hrs
4	ProcessValidation:Concept,Processanddocumentationof Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach. Analytical**m**ethodvalidation:Generalprinciples,Validationof analytical method as per ICH guidelines andUSP.	10 Hrs
5	**C**leaning**V**alidation:CleaningMethoddevelopment,Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place(CIP). Validationoffacilitiesinsterileandnon-sterileplant.**C**om**p**uterizedsyste**m**validation:Electronicrecordsa nddigital signature - 21 CFR Part 11 and GAMP	10 Hrs
6	**G**eneral**P**rinciplesof**I**ntellectual**P**roperty:Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.	10 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,
5. (MarcelDekker).
6. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc.,N.Y.
7. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed ImtiazHaider
8. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, InterpharmPress
9. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), MarcelDekker
10. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, WileyInterscience.
11. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
12. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. InterpharmPress
13. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. InterpharmPress

AUDITSANDREGULATORYCOMPLIANCE
(MPA203T)

Scope

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

Objectives

Upon completion of this course the student should be able to

- To understand the importance ofauditing
- To understand the methodology ofauditing
- To carry out the auditprocess
- To prepare the auditingreport
- To prepare the check list forauditing

THEORY		60Hrs
1.	Introduction:Objectives,Managementofaudit,Responsibilities, Planning process, information gathering, administration, Classifications ofdeficiencies	12 Hrs
2	Roleofqualitysystemsandauditsinpharmaceutical manufacturingenvironment:cGMPRegulations,Quality assurance functions, Quality systems approach, Management responsibilities,Resource,Manufacturingoperations,Evaluation activities, Transitioning to quality system approach, Audit checklist for drugindustries.	12 Hrs
3	Auditingofvendorsandproductiondepartment:Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production andpackaging.	12 Hrs
4	AuditingofMicrobiologicallaboratory:Auditingthe manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.	12 Hrs

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

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, WashingtonD.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).

PHARMACEUTICALMANUFACTURINGTECHNOLOGY
(MQA204T)

Scope

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

Objectives

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

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

THEORY	60Hrs
1.Pharmaceuticalindustrydevelopments:Legal requirements and Licenses for API and formulation industry, Plant location- Factors influencing. Plantlayout:Factors influencing,Specialprovisions,Storage space requirements, sterile and aseptic area layout. Productionplanning:Generalprinciples,productionsystems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.	12 Hrs
2 Asepticprocesstechnology:Manufacturing,manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution(SmallVolume&largeVolume). Advancedsterileproductmanufacturingtechnology:Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities &utilities equipmentlocation,engineeringandmaintenance. ProcessAutomationinPharmaceuticalIndustry:Withspecific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP),	12 Hrs

	Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS). Lyophilizationtechnology:Principles,process,equipment.	
3	Nonsterilemanufacturingprocesstechnology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard &Soft). Advancenon-sterilesolidproductmanufacturing technology:ProcessAutomationinPharmaceuticalIndustrywith specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problemsencountered. Coatingtechnology:Process,equipments,particlecoating, fluidized bed coating, application techniques. Problems encountered.	12 Hrs
4	Containersandclosuresforpharmaceuticals:Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packagingmaterial.	12 Hrs
5	Qualitybydesign(QbD)andprocessanalyticaltechnology (PAT):Currentapproachanditslimitations.WhyQbDisrequired, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatoryrequirements.	12 Hrs

REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida,2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York,2005.
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing houseMumbai.
6. Indian Pharmacopoeia. Controller of Publication. Delhi,1996.
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London,2008.
8. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA,2003.
9. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor & Francis, 1st Edition.UK.
10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA Inc. Newyork.
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey,2008.

QUALITYASSURANCEPRACTICAL–IIPRACTICALS (MQA205P)

1. Organic contaminants residue analysis byHPLC
2. Estimation of Metallic contaminants by Flamephotometer
3. Identification of antibiotic residue byTLC
4. Estimation of Hydrogen Sulphide inAir.
5. Estimation of Chlorine in WorkEnvironment.
6. Sampling and analysis of SO_2 using Colorimetricmethod
7. Qualification of following Pharma equipment
   a. Autoclave
   b. Hot airoven
   c. Powder Mixer(Dry)
   d. Tablet CompressionMachine
8. Validation of an analytical method for adrug
9. Validation of a processingarea
10. Qualification of at least two analyticalinstruments
11. Cleaning validation of oneequipment
12. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, DisintegrationTester)
13. Check list for Bulk Pharmaceutical Chemicalsvendors
14. Check list for tabletingproduction.
15. Check list for sterile productionarea
16. Check list for Water forinjection.
17. Design of plant layout: Sterile andnon-sterile
18. Case study on application ofQbD
19. Case study on application ofPAT

PHARMACEUTICALREGULATORYAFFAIRS(MRA)

GOODREGULATORYPRACTICES(MRA101T)

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 DocumentationPractices.
- Prepare and implement the check lists and SOPs for various Good RegulatoryPractices
- Implement Good Regulatory Practices in the Healthcare and related Industries
- Prepare for the readiness and conduct of audits andinspections.

	THEORY	60Hrs
1.	CurrentGoodManufacturingPractices:Introduction,UScGMP 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 LaboratoryPractices: 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	GoodAutomatedLaboratoryPractices:IntroductiontoGALP, 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 QCIStandards.	12 Hrs

4	**G**ood**D**istri**b**uti**o**n**P**ract**i**ces:IntroductiontoGDP,LegalGDP 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 ISOstandards	12 Hrs
5	**Q**ual**i**ty**m**anage**m**entsyste**m**s:ConceptofQuality,TotalQuality 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, CRCPress
3. Establishing a cGMP Laboratory Audit System, A practical Guide by David M.Bleisner, WileyPublication.
4. How to practice GLP by PP Sharma, VandanaPublications.
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

DOCUMENTATIONANDREGULATORYWRITING
(MRA102T)

Scope

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

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 regulatorycompilation
- Create and assemble the regulation submission as per the requirements ofagencies
- Follow up the submissions and post approval documentrequirements

THEORY		**60Hrs**
1.	**Documentationinpharmaceuticalindustry:**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	**Dossierpreparationandsubmission:**Introductionand 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 ofCDSCO.	12 Hrs

3	Audits:Introduction,Definition,Summary,Typesofaudits,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. ISO13485.	12 Hrs
4	Inspections:Pre-approvalinspections,Inspectionof 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	Productlifecyclemanagement:Prior ApprovalSupplement (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 ManagementStandard	12 Hrs

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, WashingtonD.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, ASQPublications
12. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQPublications
13. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program(MDSAP)

CLINICALRESEARCHREGULATIONS
(MRA103T)

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 clinicalresearch.

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 clinicaltrials
- Regulatory requirements and guidance for conduct of clinical trials and research

Theory **60Hrs**

1. **ClinicalDrugDevelopmentProcess** 12 Hrs
   - Different types of ClinicalStudies
   - Phases of clinical trials, Clinical Trialprotocol
   - Phase 0studies
   - Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK endpoints
   - Phase II studies (proof of concept or principle studies to establishefficacy)
   - Phase III studies (Multi ethnicity, global clinical trial, registrationstudies)
   - Phase IV studies (Post Marketing Studies;PSUR)

   ClinicalInvestigationandEvaluationofMedicalDevices&IVDs

   Different Types of Studies

   Key Concepts of Medical Device Clinical Evaluation

   Key concepts of Clinical Investigation

2 EthicsinClinicalResearch: 12 Hrs

- Historical Perspectives: Nuremberg Code, Thalidomidestudy , 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 clinicaltrials
- The role of placebo in clinicaltrials
- Ethics of clinical research in specialpopulation
- Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safetydata
- Data safety monitoringboards.
- Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinicalresearch
    - Ethical principles governing informed consentprocess
    - Patient Information Sheet and Informed ConsentForm
    - The informed consent process anddocumentation

3 RegulationsgoverningClinicalTrials 12 Hrs

India:ClinicalResearch regulations inIndia–ScheduleY&Medical Device Guidance

USA:Regulationstoconductdrugstudies inUSA(FDA)

- NDA 505(b)(1) of the FD&C Act (Application for approval of a newdrug)
- 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 theapplicant)
- ANDA 505(j) of the FD&C Act (Application for approval of a generic drugproduct)
- FDA Guidance for Industry - Acceptance of Foreign Clinical Studies
- FDA Clinical Trials Guidance Document: Good Clinical Practice

EU:ClinicalResearchregulationsinEuropeanUnion(EMA)

4	**ClinicalResearchRelatedGuidelines** • Good Clinical Practice Guidelines (ICH GCPE6) • Indian GCPGuidelines • ICMR Ethical Guidelines for BiomedicalResearch • CDSCOguidelines GHTF study group 5 guidance documents **RegulatoryGuidanceonEfficacyandSafetyICHGuidance's** • E4 – Dose Response Information to support Drug Registration • E7 – Studies in support of General Population:Geriatrics • E8 – General Considerations of ClinicalTrials • E10 – Choice of Control Groups and Related Issues in ClinicalTrials, • E 11 – Clinical Investigation of Medicinal Products in the PediatricPopulation • General biostatics principle applied in clinicalresearch	12 Hrs
5	**USA&EUGuidance** **USA:FDAGuidance** • CFR 21Part 50: Protection of HumanSubjects • CFR 21Part 54: Financial Disclosure by ClinicalInvestigators • CFR 21Part 312: INDApplication • CFR 21Part 314: Application for FDA Approval to Market a NewDrug • CFR 21Part 320: Bioavailability and bioequivalence requirements • CFR 21Part 812: Investigational DeviceExemptions • CFR 21Part 822: Post-marketsurveillance • FDA Safety Reporting Requirements for INDs and BA/BE Studies • FDA MedWatch • Guidance for Industry: Good Pharmacovigilance Practices and PharmacoepidemiologicAssessment **EuropeanUnion:EMAGuidance** • EU Directives2001 • EudraLex (EMEA) Volume 3 – Scientific guidelines for medicinal products for humanuse • EU Annual Safety Report(ASR) • Volume 9A – Pharmacovigilance for Medicinal Products for HumanUse • EU MDD with respect to clinicalresearch • ISO14155	12 Hrs

REFERENCES

1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K.Adams
2. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, 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 officialwebsites.
9. Drugs & Cosmetics Act & Rules andAmendments

RECOMMENDEDWEBSITES:

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 DrugApplication:
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

REGULATIONSANDLEGISLATIONFORDRUGS&COSMETICS, MEDICALDEVICES,BIOLOGICALS&HERBALS,ANDFOOD& NUTRACEUTICALSININDIAANDINTELLECTUALPROPERTY RIGHTS (MRA104T)

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 propertyrights.

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 inIndia.
- Understand the approval process and regulatory requirements for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals

THEORY **60Hrs**

1. **Biologicals&Herbals,andFood&Nutraceuticals ActsandRules(withlatestamendments):** **12 Hrs**
    1. Drugs and Cosmetics Act 1940 and Rules 1945: DPCO andNPPA
    2. Other relevant provisions (rules schedules and guidelines for approval of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals inIndia

    OtherrelevantActs:Narcotics Drugs andPsychotropic 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 AnimalsAct.

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 delhi2006.
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 Practicell by ICH HarmonisedTripartite
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 byCDSCO
9. Guidelines for Import and Manufacture of Medical Devices byCDSCO
10. Guidelines from official website ofCDSCO

REGULATORYAFFAIRSPRACTICAL-I

(MRA105P)

1. Case studies (4 Nos.) of each of Good PharmaceuticalPractices.
2. Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterilepreparations.
3. Preparation of SOPs, Analytical reports (Stability andvalidation)
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 inIndia
7. Registration for conducting BA/ BE studies inIndia
8. Import of drugs for research and developmentalactivities
9. Preparation of regulatory dossier as per Indian CTD format and submission inSUGAM
10. Registering for different Intellectual Property Rights inIndia
11. GMP Audit Requirements as perCDSCO
12. Preparation and documentation for Indian Patentapplication.
13. Preparation of checklist for registration of IND as per ICH CTDformat.
14. Preparation of checklist for registration of NDA as per ICH CTDformat.
15. Preparation of checklist for registration of ANDA as per ICH CTDformat.
16. Case studies on response with scientific rationale to USFDA WarningLetter
17. Preparation of submission checklist of IMPD for EUsubmission.
18. Comparison study of marketing authorization procedures inEU.
19. Comparative study of DMF system in US, EU andJapan
20. Preparation of regulatory submission using eCTDsoftware
21. Preparation of Clinical Trial Application (CTA) for USsubmission
22. Preparation of Clinical Trial Application (CTA) for EUsubmission
23. Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosageform.
24. Regulatory requirements checklist for conducting clinical trials inIndia.
25. Regulatory requirements checklist for conducting clinical trials inEurope.
26. Regulatory requirements checklist for conducting clinical trials inUSA

SEMESTER II
REGULATORYASPECTSOFDRUGS&COSMETICS
(MRA201T)

Scope

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

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-regulatedcountries
- A comparative study of India with other global regulatedmarkets

Theory **60Hrs**

1. **USA&CANADA:**Organizationstructureandfunctions ofFDA. 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 andCanada. — 12 Hrs

2 **EuropeanUnion&Australia:**OrganizationandstructureofEMA & 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 inJapan	12 Hrs
4	**EmergingMarket:**Introduction,Countriescovered,Studyofthe world map,study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH,SADC) **WHO:**WHO,GMP,Regulatory Requirements for registrationof 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 andBotswana)	12 Hrs
5	**Brazil,ASEAN,CISandGCCCountries:** **ASIANCountries:**IntroductiontoACTD,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(CommonwealthIndependentStates):**Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine GCC (Gulf Cooperation Council) for Arab states: Regulatory pre-requisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia andUAE Legislation and regulations for import, manufacture, distribution	and sale of cos

metics 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 carePublishers.
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 RickNg
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 officialwebsites.
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, ISBN978-981-230-750-7
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, LevFreinkman,
16. The world Bank, Washington, DC, ISBN:0-8212-5896-0
17. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World ByFrederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes 139
18. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low and Lorraine Carlos Salazar (Nov 22,2010)
19. Doing Business in the Asean Countries, Balbir Bhasin, Business Expert PressISBN: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

REGULATORYASPECTSOFHERBALANDBIOLOGICALS
(MRA202T)

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 andVaccines
- 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 labelrequirements

Theory **60Hrs**

1.	India:Introduction,ApplicableRegulations andGuidelines , 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:IntroductiontoBiologics;biologics,biologicaland 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	EuropeanUnion:IntroductiontoBiologics;directives,scientific guidelines and guidance related to biologics in EU, comparability/ biosimilarity assessment, Plasma master file, TSE/ BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars),pre-clinical	12 Hrs

	and clinical development considerations; stability, safety, advertising, labelling and packing of biologics inEU	
4	VaccineregulationsinIndia,USandEuropeanUnion: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 HaemovigilenceNetwork)	12 Hrs
5	HerbalProducts:Quality,safety andlegislationfor herbal products in India, USA and EuropeanUnion.	12 Hrs

REFERENCES

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano , David S. Mantus ; Informa,2008
2. Biological Drug Products: Development and Strategies; Wei Wang , Manmohan Singh ; wiley,2013
3. Development of Vaccines: From Discovery to Clinical Testing; Manmohan Singh , Indresh K. Srivastava ;Wiley,2011
4. www.who.int/biologicals/en
5. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/
6. www.ihn-org.com
7. www.isbtweb.org
8. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization inIndia
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
(MRA203T)

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: ISO14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device	12 Hrs

3	USA:Introduction,Classification,Regulatory approvalprocessfor 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 approvalprocess.	12 Hrs
4	European Union: Introduction, Classification, Regulatory approval process for MedicalDevices (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:MedicalDevicesandIVDs,Regulatory registration procedures, Quality System requirements and clinical evaluation andinvestigation. 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, DavidMantus.
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 GaryWalsh
4. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics by CarmenMedina
5. Country Specific Guidelines from officialwebsites.

REGULATORYASPECTSOFFOOD&NUTRACEUTICALS
(MRA204T)

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 fornutraceuticals
- Understand the regulation for registration and labeling of nutraceuticals and food supplements in India, USA andEurope.

Theory **60Hrs**

1.	Nutraceuticals:Introduction,History ofFoodandNutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market.	12 Hrs
2	GlobalAspects:WHOguidelines onnutrition.NSFInternational: 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:FoodSafety andStandards Act,FoodSafety 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:USFDAFoodSafety ModernizationAct,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.

REGULATORYAFFAIRSPRACTICAL-II
(MRA205P)

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

PHARMACOLOGY(MPL)

MODERNPHARMACEUTICALANALYTICALTECHNIQUES (MPL101T)

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 andExcipients
- The analysis of various drugs in single and combination dosageforms
- Theoretical and practical skills of theinstruments

THEORY 60Hrs

1.	UV-Visiblespectroscopy:Introduction,Theory,Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. IRspectroscopy:Theory,Modes ofMolecularvibrations,Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, DataInterpretation. Spectroflourimetry:Theory ofFluorescence,Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescencespectrophotometer. FlameemissionspectroscopyandAtomicabsorption spectroscopy: Principle, Instrumentation, Interferences and Applications.	10 Hrs
2	NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMRspectroscopy.	10 Hrs

3	**M**ass**S**pectroscopy:Principle,Theory,InstrumentationofMass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	10 Hrs
4	**C**hro**m**atography:Principle,apparatus,instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: j) Thin Layerchromatography k) High Performance Thin LayerChromatography l) Ion exchangechromatography m) Columnchromatography n) Gaschromatography o) High Performance Liquidchromatography p) Ultra High Performance Liquidchromatography q) Affinitychromatography r) Gel Chromatography	10 Hrs
5	**E**lectrophoresis:Principle,Instrumentation,Workingconditions, factors affecting separation and applications of thefollowing: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electricfocusing X**r**ay**C**rystallography:ProductionofXrays,DifferentXray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-raydiffraction.	10 Hrs
6	Potentio**m**etry:Principle,working,IonselectiveElectrodes and Application ofpotentiometry. Ther**m**alTechniques:Principle,thermaltransitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceuticalapplications.	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, CBSpublishers.
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. DekkerSeries
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons,1982.

ADVANCED PHARMACOLOGY - I
(MPL102T)

Scope

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

Objectives

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

- Discuss the pathophysiology and pharmacotherapy of certaindiseases
- Explain the mechanism of drug actions at cellular and molecularlevel
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment ofdiseases

THEORY		**60Hrs**
1.	**General Pharmacology** a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding. b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicitedeffects.	12 Hrs
2	**Neurotransmission** a. General aspects and steps involved inneurotransmission. b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline). c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate andglycine]. d. Non adrenergic non cholinergic transmission (NANC). Co-transmission	12 Hrs

	SystemicPharmacology 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 AutonomicPharmacology Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction	
3	Centralnervoussystem 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	CardiovascularPharmacology Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants , anticoagulants, fibrinolytics and anti-platelet drugs	12 Hrs
5	AutocoidPharmacology 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 andGillman'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 & WilkinsPublishers.
3. Basic and Clinical Pharmacology by B.GKatzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi andPrescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and AndrewB.C.Yu.
6. Graham Smith. Oxford textbook of ClinicalPharmacology.
7. Avery DrugTreatment
8. Dipiro Pharmacology, Pathophysiologicalapproach.
9. Green Pathophysiology forPharmacists.

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

PHARMACOLOGICALANDTOXICOLOGICALSCREENING METHODS- I

(MPL103T)

Scope

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

Objectives

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

- Appraise the regulations and ethical requirement for the usage of experimentalanimals.
- 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 discoveryprocess
- Appreciate and correlate the preclinical data tohumans

THEORY 60Hrs

1. LaboratoryAnimals 12 Hrs

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

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 Preclinicalscreeningofnewsubstancesforthe pharmacologicalactivityusinginvivo,invitro,andother possibleanimalalternativemodels. 12 Hrs

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

	depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.	
3	Preclinicalscreeningofnewsubstancesforthe pharmacologicalactivityusinginvivo,invitro,andother possibleanimalalternativemodels. Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti -emetic, anti-diarrheal and laxatives.	12 Hrs
4	Preclinicalscreeningofnewsubstancesforthe pharmacologicalactivityusinginvivo,invitro,andother possibleanimalalternativemodels. Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents.Anti cancer agents.Hepatoprotective screeningmethods.	12 Hrs
5	Preclinicalscreeningofnewsubstancesforthe pharmacologicalactivityusinginvivo,invitro,andother possibleanimalalternativemodels. Iimmunomodulators, Immunosuppressants and immunostimulants Generalprinciplesofimmunoassay:theoreticalbasis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin Limitations of animal experimentation and alternate animal experiments. Extrapolation of in vitro data to preclinical and preclinical to humans	12 Hrs

REFERENCES

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

CELLULAR AND MOLECULAR PHARMACOLOGY
(MPL104T)

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 transductionprocesses.
- Explain the molecular pathways affected bydrugs.
- Appreciate the applicability of molecular pharmacology and biomarkers in drug discoveryprocess.
- Demonstrate molecular biology techniques as applicable for pharmacology

THEORY		**60Hrs**
1.	**Cellbiology** 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	**Cellsignaling** Intercellular and intracellular signaling pathways. Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors. Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol. Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.	12 Hrs

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

REFERENCES:

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

PHARMACOLOGICALPRACTICAL-I

(MPL105P)

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 onHPLC
4. Experiments based on GasChromatography
5. Estimation of riboflavin/quinine sulphate byfluorimetry
6. Estimation of sodium/potassium by flamephotometry

Handlingoflaboratoryanimals.

1. Various routes of drugadministration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwintest)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsantactivity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and mioticactivity.
6. Evaluation of diureticactivity.
7. Evaluation of antiulcer activity by pylorus ligationmethod.
8. Oral glucose tolerancetest.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goatliver).
10. Isolation of RNA fromyeast
11. Estimation of proteins by Braford/Lowry's in biologicalsamples.
12. Estimation of RNA/DNA by UVSpectroscopy
13. Gene amplification byPCR.
14. Protein quantification WesternBlotting.
15. Enzyme based in-vitro assays (MPO, AChEs, α amylase, αglucosidase).
16. Cell viability assays (MTT/Trypanblue/SRB).
17. DNA fragmentation assay by agarose gelelectrophoresis.
18. DNA damage study by Cometassay.
19. Apoptosis determination by fluorescent imagingstudies.
20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration usingsoftwares
21. Enzyme inhibition and inductionactivity
22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques(UV)
23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques(HPLC)

REFERENCES

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

ADVANCED PHARMACOLOGY - II
(MPL201T)

Scope

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

Objectives

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

- Explain the mechanism of drug actions at cellular and molecularlevel
- Discuss the Pathophysiology and pharmacotherapy of certaindiseases
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment ofdiseases

THEORY		**60Hrs**
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

4	**GITPharmacology** Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs forconstipation and irritable bowel syndrome. **Chronopharmacology** Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer	12 Hrs
5	**FreeradicalsPharmacology** Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidant **RecentAdvancesinTreatment:** Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus	12 Hrs

REFERENCES

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

PHARMACOLOGICALANDTOXICOLOGICALSCREENING METHODS-II

(MPL202T)

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

	THEORY	60Hrs
1.	Basic definition and types of toxicology(general,mechanistic,regulatory anddescriptive) 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 OECDguidelines. 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 (segmentII) 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.	12 Hrs

	Safety pharmacology studies- origin, concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies	
5	Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.	12 Hrs

REFERENCES

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

PRINCIPLESOFDRUGDISCOVERY
(MPL203T)

Scope:

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

Objectives:

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

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

THEORY **60Hrs**

1.	An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drugdiscovery. 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 hitidentification. 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 DrugDesign Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches	12 Hrs

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

REFERENCES

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

CLINICALRESEARCHANDPHARMACOVIGILANCE
(MPL204T)

Scope:

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

Objectives:

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

- Explain the regulatory requirements for conducting clinicaltrial
- Demonstrate the types of clinical trialdesigns
- Explain the responsibilities of key players involved in clinicaltrials
- Execute safety monitoring, reporting and close-outactivities
- Explain the principles ofPharmacovigilance
- Detect new adverse drug reactions and theirassessment
- Perform the adverse drug reaction reporting systems and communication inPharmacovigilance

THEORY		60Hrs
1.	**RegulatoryPerspectivesofClinicalTrials:** 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 **InformedConsentProcess:**Structureand contentofan Informed Consent Process Ethical principles governing informed consent process	12 Hrs
2	**ClinicalTrials:**TypesandDesign Experimental Study- RCT and NonRCT, Observation Study: Cohort, Case Control, Cross sectional **ClinicalTrialStudyTeam** Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management	12 Hrs

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

REFERENCES

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry ofHealth;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May1996.

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

PHARMACOLOGICALPRACTICAL-II

(MPL205P)

1. To record the DRC of agonist using suitable isolated tissuespreparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissuepreparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitable tissuepreparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissuepreparation
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissuepreparation
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissuepreparation.
7. Estimation of PA_2 values of various antagonists using suitable isolated tissuepreparations.
8. To study the effects of various drugs on isolated heartpreparations
9. Recording of rat BP, heart rate andECG.
10. Recording of ratECG
11. Drug absorption studies by averted rat ileumpreparation.
12. Acute oral toxicity studies as per OECDguidelines.
13. Acute dermal toxicity studies as per OECDguidelines.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histologicalstudies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial.(3Nos.)
17. Design of ADR monitoringprotocol.
18. In-silico docking studies. (2Nos.)
19. In-silico pharmacophore basedscreening.
20. In-silico QSARstudies.
21. ADRreporting

REFERENCES

1. Fundamentals of experimental Pharmacology-byM.N.Ghosh
2. Hand book of ExperimentalPharmacology-S.K.Kulakarni
3. Text book of in-vitro practical Pharmacology by IanKitchen
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and WilliamThomsen
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and AndrewB.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for IndustrialScientists.

PHARMACOGNOSY(MPG)

MODERNPHARMACEUTICALANALYTICALTECHNIQUES (MPG101T)

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 dosageforms
- Theoretical and practical skills of theinstruments

	THEORY	**60Hrs**
1.	**UV-Visiblespectroscopy:**Introduction,Theory,Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy. **IRspectroscopy:**Theory,Modes ofMolecularvibrations,Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IRspectroscopy **Spectrofluorimetry:**Theory ofFluorescence,Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescencespectrophotometer. **FlameemissionspectroscopyandAtomicabsorption spectroscopy**: Principle, Instrumentation, Interferences and Applications.	**12 Hrs**
2	**NMR spectroscopy**: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMRspectroscopy.1	**12 Hrs**

3	**M**ass**S**pectroscopy:Principle,Theory,InstrumentationofMass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	10 Hrs
4	**C**hr**om**atography:Principle,apparatus,instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a) Thin Layerchromatography b) High Performance Thin LayerChromatography c) Ion exchangechromatography d) Columnchromatography e) Gaschromatography f) High Performance Liquidchromatography g) Ultra High Performance Liquidchromatography h) Affinitychromatography i) Gel Chromatography	10 Hrs
5	**E**lectrophoresis:Principle,Instrumentation,Workingconditions, factors affecting separation and applications of thefollowing: a) Paperelectrophoresis b) Gelelectrophoresis c) Capillaryelectrophoresis d) Zoneelectrophoresis e) Moving boundaryelectrophoresis f) Iso electricfocusing X**r**ay**C**rystallography:ProductionofXrays,DifferentXray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-raydiffraction.	10 Hrs
6	P**o**tenti**om**etry:Principle,working,IonselectiveElectrodes and Application ofpotentiometry. Ther**m**alTechniques: Principle,thermaltransitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and	10 Hrs

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

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

ADVANCED PHARMACOGNOSY -I
(MPG102T)

SCOPE

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

OBJECTIVES

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

- advances in the cultivation and production ofdrugs
- various phyto-pharmaceuticals and their source, its utilization and medicinalvalue.
- various nutraceuticals/herbs and their healthbenefits
- Drugs of marineorigin
- Pharmacovigilance of drugs of naturalorigin

THEORY		60Hrs
1.	Plantdrugcultivation:Generalintroductiontotheimportanceof Pharmacognosy in herbal drug industry, Indian Council of Agricultural Research, Current Good Agricultural Practices, Current Good Cultivation Practices, Current Good Collection Practices, Conservation of medicinal plants- Ex-situ and In-situ conservation of medicinalplants.	12 Hrs
2	Marinenaturalproducts:Generalmethods ofisolationand purification, Study of Marine toxins, Recent advances in research in marine drugs, Problems faced in research on marine drugs such as taxonomical identification, chemical screening and their solution.	12 Hrs
3	Nutraceuticals:Currenttrends andfuturescope,Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibres, Cereals and grains, Health drinks of natural origin, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods, Formulation and standardization of neutraceuticals, Regulatory aspects, FSSAI guidelines, Sources, name of marker compounds and their chemical nature, medicinal uses and health benefits offollowing i) Spirulina ii) Soya bean iii) Ginseng iv) Garlic v) Broccoli vi) Green and Herbal Tea vii) Flax seeds viii) Black cohosh ix) Turmeric.	12 Hrs

4	Phytopharmaceuticals:Occurrence,isolationandcharacteristic features (Chemical nature, uses in pharmacy, medicinal and health benefits) offollowing. a) Carotenoids – i) α and β - Carotene ii) Xanthophyll(Lutein) b) Limonoids – i) d-Limonene ii) α –Terpineol c) Saponins – i)Shatavarins d) Flavonoids – i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin e) Phenolic acids- Ellagicacid f) Vitamins g) Tocotrienols andTocopherols h) Andrographolide, Glycolipids, Gugulipids,Withanolides, Vascine, Taxol i) Miscellaneous	12 Hrs
5	Pharmacovigilanceofdrugsofnaturalorigin:WHOand AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for biodrug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples.	12 Hrs

REFERENCES (Latest Editions of)

1. Pharmacognosy - G. E. Trease and W.C. Evans. Saunders Edinburgh, NewYork.
2. Pharmacognosy-Tyler, Brady,Robbers
3. Modem Methods of Plant Analysis- Peach & M.V. Tracey, Vol.I&II
4. Text Book of Pharmacognosy by T.E.Wallis
5. Marine Natural Products-Vol.I toIV.
6. Natural products: A lab guide by Raphael Ikan , Academic Press1991.
7. Glimpses of Indian Ethano Pharmacology, P. Pushpangadam. Ulf Nyman. V.George Tropical Botanic Garden & Research Institute,1995.
8. Medicinal natural products (a biosynthetic approach), Paul M. Dewick, John Wiley & Sons Ltd., England,1998.
9. Chemistry of Marine Natural Products- Paul J. Schewer1973.
10. Herbal Drug Industry by RD. Choudhary, Eastern Publisher, New Delhi, 1996.
11. Cultivation of Medicinal Plants by C.K. Atal & B.M.Kapoor.
12. Cultivation and Utilization of Aromatic Plants, C.K. Atal & B.M.Kapoor
13. Cultivation of medicinal and aromatic crops, AA Farooqui and B.S. Sreeramu. University Press,2001.

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

PHYTOCHEMISTRY
(MPG103T)

SCOPE

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

OBJECTIVES

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

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

	THEORY	60Hrs
1.	Biosynthetic pathways and Radiotracing techniques: Constituents & their Biosynthesis, Isolation, Characterization and purification with a special reference to their importance in herbal industries of following phyto-pharmaceuticals containing drugs: a) Alkaloids: Ephedrine, Quinine, Strychynine, Piperine, Berberine, Taxol, Vincaalkoloids. b) Glycosides: Digitoxin, Glycyrrhizin, Sennosides, Bacosides, Quercitin. c) Steroids: Hecogenin, guggulosterone and withanolides d) Coumarin: Umbelliferone. e) Terpenoids: Cucurbitacins	12 Hrs
2	Drug discovery and development: History of herbs as source of drugs and drug discovery, the lead structure selection process, structure development, product discovery process and drug registration, Selection and optimization of lead compounds with suitable examples from the following source : artemesin, andrographolides. Clinical studies emphasising on phases of clinical trials, protocol design for lead molecules.	12 Hrs
3	Extraction and Phytochemical studies: Recent advances in extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used like microwave	12 Hrs

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

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

REFERENCES (Latest Editions of)

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

INDUSTRIALPHARMACOGNOSTICALTECHNOLOGY
(MPG104T)

SCOPE

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

OBJECTIVES

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

- the requirements for setting up the herbal/natural drugindustry.
- the guidelines for quality of herbal/natural medicines and regulatory issues.
- the patenting/IPR of herbals/natural drugs and trade of raw and finishedmaterials.

THEORY 60Hrs

1. **Herbaldrugindustry:** Infrastructureofherbaldrugindustry involved in production of standardized extracts and various dosage forms. Current challenges in upgrading and modernization of herbal formulations. Entrepreneurship Development, Project selection, project report, technical knowledge, Capital venture, plant design, layout and construction. Pilot plant scale –up techniques, case studies of herbal extracts. Formulation and production management ofherbals. — 12 Hrs

2. **Regulatoryrequirementsforsettingherbaldrugindustry:** Global marketing management. Indian and international patent law as applicable herbal drugs and natural products. Export - Import (EXIM) policy,TRIPS.
   Quality assurance in herbal/natural drug products.Concepts of TQM, GMP, GLP, ISO-9000. — 12 Hrs

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

4	Testingofnaturalproductsanddrugs:Herbalmedicines- clinical laboratory testing. Stability testing of natural products, protocols.	12 Hrs
5	Patents:Indianandinternationalpatentlaws,proposed amendments as applicable to herbal/natural products and process. Geographical indication, Copyright, Patentable subject maters, novelty, non obviousness, utility, enablement and best mode, procedure for Indian patent filing, patent processing, grant of patents, rights of patents, cases of patents, opposition and revocation of patents, patent search and literature, Controllers of patents.	12 Hrs

REFERENCES (Latest Editions of)

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

PHARMACOGNOSYPRACTICAL-I

(MPGI05P)

1. Analysis of Pharmacopoeial compounds of natural origin andtheir formulations by UV Vis spectrophotometer
2. Analysis of recorded spectra of simplephytoconstituents
3. Experiments based on GasChromatography
4. Estimation of sodium/potassium by flamephotometry
5. Development of fingerprint of selected medicinal plant extracts commonly used in herbal drug industry viz. Ashwagandha, Tulsi, Bael, Amla, Ginger, Aloe, Vidang, Senna, Lawsonia by TLC/HPTLCmethod.
6. Methods ofextraction
7. Phytochemicalscreening
8. Demonstration of HPLC- estimation ofglycerrhizin
9. Monograph analysis of cloveoil
10. Monograph analysis of castoroil.
11. Identification of bioactive constituents from plantextracts
12. Formulation of different dosage forms and theirstandardisation.

MEDICINALPLANTBIOTECHNOLOGY
(MPG201T)

SCOPE

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

OBJECTIVES

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

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

THEORY 60Hrs

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

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

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

REFERENCES (Latest Editions of)

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

ADVANCED PHARMACOGNOSY- II
(MPG202T)

SCOPE

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

OBJECTIVES

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

- validation of herbalremedies
- methods of detection of adulteration and evaluation techniques for the herbaldrugs
- methods of screening of herbals for various biologicalproperties

THEORY 60Hrs

1.	Herbalremedies–ToxicityandRegulations:Herbals vs Conventional drugs, Efficacy of Herbal medicine products, Validation of herbal therapies, Pharmacodynamic and Pharmacokinetic issues.	12 Hrs
2	AdulterationandDeterioration:Introduction,Types of Adulteration/ Substitution of Herbal drugs, Causes and Measures of Adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, detection of heavy metals, pesticide residues, phytotoxin, microbial contamination in herbs and their formulations.	12 Hrs
3	EthnobotanyandEthnopharmacology:Ethnobotany inherbal drug evaluation, Impact of Ethnobotany in traditional medicine, New development in herbals, Bio-prospecting tools for drug discovery, Role of Ethnopharmacology in drug evaluation, ReversePharmacology.	12 Hrs
4	AnalyticalProfilesofherbaldrugs:Andrographis paniculata, Boswellia serata, Coleus forskholii, Curcuma longa, Embelica officinalis, Psoraleacorylifolia.	12 Hrs
5	Biologicalscreeningofherbaldrugs:IntroductionandNeedfor Phyto-Pharmacological Screening, New Strategies for evaluating	12 Hrs

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

REFERENCES (Latest Editions of)

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

INDIANSYSTEMSOFMEDICINE
(MPG203T)

SCOPE

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

OBJECTIVES

After completion of the course, student is able to

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

THEORY 60Hrs

1.	Fundamental concepts of Ayurveda, Siddha, Unani andHomoeopathy systems ofmedicine Different dosage forms of the ISM. Ayurveda:Ayurvedic Pharmacopoeia,Analysis offormulations and bio crude drugs with references to: Identity, purity and quality. Siddha:Gunapadam (SiddhaPharmacology),raw drugs/Dhatu/Jeevam in Siddha system of medicine, Purification process(Suddhi).	12 Hrs
2	Naturopathy,YogaandAro**m**atherapypractices a) Naturopathy - Introduction, basic principles and treatment modalities. b) Yoga - Introduction and Streams of Yoga. Asanas, Pranayama, Meditations and Relaxationtechniques. c) Aromatherapy – Introduction, aroma oils for common problems, carrieroils.	12 Hrs
3	For**m**ulationdevelop**m**entofvarioussyste**m**sof**m**edicine Salient features of the techniques of preparation of some of the important class of Formulations as per Ayurveda, Siddha, Homeopathy and Unani Pharmacopoeia and texts.Standardization, Shelf life and Stability studies of ISM formulations.	12 Hrs

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

REFERENCES(Latest Editions of)

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

HERBALCOSMETICS
(MPG204T)

SCOPE

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

OBJECTIVES

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

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

THEORY		60Hrs
1.	Introduction: Herbal/natural cosmetics, Classification &Economicaspects. Regulatory Provisions relation to manufacture of cosmetics: - License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics.	12 Hrs
2	Commonly used herbal cosmetics, raw materials, preservatives, surfactants, humectants, oils, colors, and some functional herbs, preformulation studies, compatibility studies, possible interactions between chemicals and herbs, design of herbal cosmetic formulation.	12 Hrs
3	HerbalCosmetics:Physiology andchemistry ofskinand pigmentation, hairs, scalp, lips and nail, Cleansing cream, Lotions, Face powders, Face packs, Lipsticks, Bath products, soaps and baby product, Preparation and standardisation of the following: Tonic, Bleaches, Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails.	12 Hrs
4	Cosmeceuticalsofherbalandnaturalorigin:Hair growth formulations, Shampoos, Conditioners, Colorants & hair oils, Fairness formulations, vanishing & foundation creams, anti-sun burn preparations, moisturizing creams, deodorants.	12 Hrs

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

REFERENCES (Latest Editions of)

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

HERBALCOSMETICSPRACTICALS
(MPG205P)

1. Isolation of nucleic acid from cauliflowerheads
2. Isolation of RNA fromyeast
3. Quantitative estimation ofDNA
4. Immobilizationtechnique
5. Establishment of callusculture
6. Establishment of suspensionculture
7. Estimation of aldehyde contents of volatileoils
8. Estimation of total phenolic content in herbal rawmaterials
9. Estimation of total alkaloid content in herbal rawmaterials
10. Estimation of total flavonoid content in herbal rawmaterials
11. Preparation and standardization of various simple dosage forms from Ayurvedic, Siddha, Homoeopathy and Unaniformulary
12. Preparation of certain Aromatherapyformulations
13. Preparation of herbal cosmetic formulation such as lip balm, lipstick, facial cream, herbal hair and nail careproducts
14. Evaluation of herbal tablets andcapsules
15. Preparation of sunscreen, UV protection cream, skin careformulations.
16. Formulation & standardization of herbal coughsyrup.

SemesterIII

MRM301T-ResearchMethodology&Biostatistics

UNIT–I

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

***UNIT–II**

Biostatistics: Definition,application,sample size,importanceofsamplesize, 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

MedicalResearch: History,valuesinmedicalethics,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

CPCSEAguidelinesforlaboratoryanimalfacility: Goals,veterinarycare, 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 labanimals.

UNIT–V

DeclarationofHelsinki: History,introduction,basicprinciplesforallmedical research, and additional principles for medical research combined with medicalcare.