PROGRESSIVE EDUCATION SOCIETY'S MODERN COLLEGE OF PHARMACY, NIGDI, PUNE

(AUTONOMOUS)

AFFILIATED TO

SAVITRIBAI PHULE PUNE UNIVERSITY

FACULTY OF SCIENCE AND TECHNOLOGY

RULES & SYLLABUS

FIRST YEAR & SECOND YEAR MASTER OF PHARMACY (M. Pharm.) COURSE – 2019 pattern

(EFFECTIVE FROM ACADEMIC YEAR 2025-2026)

PROGRESSIVE EDUCATION SOCIETY'S MODERN COLLEGE OF PHARMACY, NIGDI, PUNE

(AUTONOMOUS)

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CHAPTER - I: REGULATIONS

1. Short Title and Commencement

These regulations shall be called as "The Revised Regulations for the Master of Pharmacy (M. Pharm.) Degree Program – Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 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) Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B.Pharm.)

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

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

3. Duration of the program

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

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

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

6. Attendance and progress

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

7. Program / Course credit structure

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

7.1 Credit assignment

Theory and Laboratory courses

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

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

Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co– curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co–Curricular activities over the duration of four semesters. The credits are distributed semester–wise as shown in Table 14. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester–wise schedule of courses given in the syllabus.

8. Academic work

A regular record of attendance both in Theory, Practical, Seminar and Assignment and 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

Sr. No.	Specialization	Code
1.	Pharmaceutics	MPH
2.	Pharmaceutical Chemistry	MPC
3.	Pharmaceutical Quality Assurance	MQA
4.	Pharmacology	MPL

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

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SEMESTER I					
MPAT101T	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 Development	4	4	4	100
MPH204T	Cosmetic & 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					
MPAT101T	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					
MPAT101T	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 (Pharmacology)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SEMESTER I					
MPAT101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPL102T	Advanced Pharmacology - I	4	4	4	100
MPL 103T	Pharmacological and Toxicological Screening Methods–I	4	4	4	100
MPL104T	Cellular and Molecular Pharmacology	4	4	4	100
MPL105P	Pharmacology Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
SEMESTER II					
MPL201T	Advanced Pharmacology II	4	4	4	100
MPL 202T	Pharmacological and Toxicological Screening Methods–II	4	4	4	100
MPL203T	Principles of Drug Discovery	4	4	4	100
MPL204T	Clinical Research and Pharmacovigilance	4	4	4	100
MPL205P	Pharmacology Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table - 6: Course of study for M. Pharm. III Semester
(Common for All Specializations)

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

* *Non University Exam*

	Introduction to Constitution*	2	2

Table - 7: 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 - 8: Semester wise credits distribution

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

**Credit Points for Co–curricular Activities*

Table – 9: Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	Maximum Credit Point eligible/ Activity*
NPTEL courses (**1 course duration 8 weeks/ 2 courses duration 4 weeks**)	02
Presentation in State Level/ National Level/ International Level Seminar/Conference **(Oral/ Poster)**	01
Research / Review Publication in National Journals/ International Journals (**Indexed in Scopus / Web of Science)**/ Book Chapter/ Book Publication (ISSN/ ISBN)	01
Performance in SEM IV Colloquium	02
Extracurricular and Co-curricular Achievement **(College Level/ Intercollegiate/ University level/ State/ National Level)**	01

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

10. Program Committee

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

2. The composition of the Programme Committee shall be as follows:
   A teacher at the cadre of Professor shall be the Chairperson; One Teacher from 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 - 16.

11.1 End semester examinations

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

Question paper pattern for end semester theory examination

I.	Long answer questions (solve 1 out of 2)	1 X 15=15
II.	Medium Length answers (Solve 2 out of 4)	2 X 7.5=15
III.	Short answer questions (solve 3 out of 5)	3 X 05=15
IV.	Long answer questions (solve 1 out of 2)	1 X 15=15
V.	Short notes (Solve 3 out of 5)	3 X 05= 15
		Total Marks= 75

Question paper pattern for end semester practical examination

I.	Synopsis	15
II.	Experiment(s)	70
III.	Viva voce	15
		Total Marks = 100

Tables - 10: Schemes for internal assessments and end semester (Pharmaceutics - MPH)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPAT101T	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
MPH104T	Regulatory Affair	10	15	1 Hr	25	75	3 Hrs	100
MPH105P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	–	–	–	–	–	–	100
							Total	**650**
SEMESTER II								
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 Development	10	15	1 Hr	25	75	3 Hrs	100
MPH204T	Cosmetic and Cosmeceuticals	10	15	1 Hr	25	75	3 Hrs	100
MPH205P	Pharmaceutics Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar Assignment	–	–	–	–	–	–	100
							Total	**650**

Tables - 11: Schemes for internal assessments and end semester (Pharmaceutical Chemistry–MPC)

Course Code	Course	Internal Assessment				End Semester Exams		Total Mark
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPAT101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3Hrs	100
MPC102T	Advanced Organic Chemistry –I	10	15	1 Hr	25	75	3Hrs	100
MPC103T	Advanced Medicinal chemistry	10	15	1 Hr	25	75	3Hrs	100
MPC104T	Chemistry of Natural Products	10	15	1 Hr	25	75	3Hrs	100
MPC105P	Pharmaceutic al Chemistry Practical I	20	30	6 Hrs	50	100	6Hrs	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 AidedDrug Design	10	15	1 Hr	25	75	3 Hrs	100
MPC204T	Pharmaceutic alProcess Chemistry	10	15	1 Hr	25	75	3 Hrs	100
MPC205P	Pharmaceutic alChemistry Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	–	–	–	–	–	–	100
							Total	**650**

Tables - 12: Schemes for internal assessments and end semester examinations (Pharmaceutical Quality Assurance–MQA)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous	Sessional Exams		Total	Marks	Duration	
		Mode	Marks	Duration				
SEMESTER I								
MPAT101T	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
MQA1 04T	Product Developmentand Technology Transfer	10	15	1 Hr	25	75	3 Hrs	100
MQA1 05P	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
MQA2 03T	Auditsand Regulatory Compliance	10	15	1 Hr	25	75	3 Hrs	100
MQA2 04T	Pharmaceutical Manufacturing Technology	10	15	1 Hr	25	75	3 Hrs	100
MQA2 05P	Pharmaceutical QualityAssurance Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

Tables - 13: Schemes for internal assessments and end semester examinations (Pharmacology–MPL)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Session Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER I								
MPAT101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3Hrs	100
MPL102T	Advanced Pharmacology–I	10	15	1 Hr	25	75	3Hrs	100
MPL10 3T	Pharmacological and Toxicological Screening Methods–I	10	15	1 Hr	25	75	3Hrs	100
MPL10 4T	Cellular and Molecular Pharmacology	10	15	1 Hr	25	75	3Hrs	100
MPL105P	Experimental Pharmacology – I	20	30	6 Hrs	50	100	6Hrs	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

Seminar/Assignment

1. **Seminar:** The evaluation of seminar for semester I & II shall be carried out as per following scheme.
   a. Reference work and scientific contents ---------- 10 marks
   b. Communication skill ---------- 05 marks
   c. Discussion/defense ---------- 05 marks
   d. Presentation ---------- 30 marks
   Total ---------- 50 marks

2. **Assignment:** one assignment related to any topic from the specialization shall be conducted in semester I and II.
   Evaluation criteria for assignment are as follows:

   a. Structure, organization and content ---------- 20 marks
   b. Creativity and originality ---------- 05 marks
   c. Compilation of information ---------- 10 marks
   d. Literature resources ---------- 10 marks
   e. Reference style ---------- 05 marks
   Total ---------- 50 marks

Tables - 14: Schemes for internal assessments and end semester examinations (Semester III& IV)

Course Code	Course	Internal Assessment				End SemesterExams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
MRM 301T	Research methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
-	Journal club	–	–	–	25	–	–	25
-	Discussion / Presentation (Proposal Presentation)	–	–	–	50	–	–	50
-	Research work*	–	–	–	–	350	1 Hr	350
							Total	**525**
SEMESTER IV								
-	Journal club	–	–	–	25	–	–	25
-	Discussion / Presentation (Proposal Presentation)	–	–	–	75	–	–	75
-	Research work and Colloquium	–	–	–	–	400	1 Hr	450
							Total	**550**

*Non University Examination

	Introduction to Constitution*	10	15	2 Hr	25	25	2 Hrs	50

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 - 15: 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 - 16: 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

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 sessional exam will be conducted for 30 marks and computed for 15 marks. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables.

Scheme for theory Sessional examination

I. Objective Type questions (solve 5 out of 7) 5 X 2=10
II. Short answer questions (solve 2 out of 3) 2 X 5=10
III. Long answer questions (solve 1 out of 2) 1 X 10=10

Total Marks= 30

Scheme for Practical Sessional examination

I. Synopsis 05
II. Experiment(s) 20
III. Viva voce 05

Total Marks= 30

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 in each semester sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of end semester theory examinations.

15. Re examination of end semester examinations

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

Table - 17: 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

Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table - 30.

Table – 18: Letter grades and grade points equivalent to Percentage of marks and performances

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

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

18. The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called „Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester.

For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 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:

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

19. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed 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 to 7.49
Second Class	= CGPA of 5.00 to 5.99

21. Project work

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages).The internal and external exainer appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

- Objective(s) of the work done 25 Marks
- Methodology adopted 75 Marks
- Results and Discussions 125 Marks
- Conclusions and Outcomes 25 Marks

Total 250 Marks

Evaluation of Presentation:

- Presentation of work 75 Marks
- Communication skills 50 Marks
- Question and answer skills 25 Marks

Total 150 Marks

22. Award of Ranks

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

23. Award of degree

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

24. Duration for completion of the program of study

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

25. Revaluation and retotaling of answer papers

There is provision for re-totaling and revaluation of the answer papers in any examination. The candidates can apply for revaluation/ re-totaling 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.

Common subjects for all specializations
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPAT101T)
60 hours

SCOPE

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are UV, IR, NMR, Mass spectrometer, HPLC, GC etc. Simple structure elucidation problems may be included based on UV-IR-NMR data.

OBJECTIVES

Upon completion of the course the student shall be able to · Analytical techniques for identification, characterization and quantification of drugs · Theoretical and practical skills of instrument handling and use. · Structural Elucidation of organic compounds using spectroscopic tools

Upon completion of the course the student shall be able to

1. Quality Assurance:

- Ensuring purity and potency:

Modern analytical techniques are crucial for determining the purity and potency of drug substances and formulations, ensuring they meet required standards.

- Detecting and quantifying impurities:

These techniques help in identifying and quantifying impurities in drug products, including degradation products and genotoxic impurities, which is essential for safety.

- Assessing stability:

Analytical methods are used to evaluate the stability of drug substances and products under various conditions, ensuring their effectiveness over time.

- Validating analytical methods:

Developing and validating robust analytical methods is vital to ensure the reliability and accuracy of quality control measurements.

2. Drug Development:

- Drug discovery and design:

Analytical techniques play a significant role in the early stages of drug development, helping in the identification and characterization of potential drug candidates.

- Formulation development:

These techniques aid in the development of stable and effective drug formulations, including the selection of appropriate excipients and dosage forms.

- Preclinical and clinical studies:

Analytical methods are used to monitor drug levels in biological samples during preclinical and clinical trials, providing valuable data on drug absorption, distribution, metabolism, and excretion (ADME).

3. Regulatory Compliance:

- Meeting regulatory requirements:

Pharmaceutical companies must adhere to strict regulatory guidelines for drug development, manufacturing, and quality control, which heavily rely on analytical data.

- Ensuring compliance with pharmacopeias:

Analytical techniques are used to demonstrate compliance with the standards set by pharmacopeias like the United States Pharmacopeia (USP) and the European Pharmacopoeia (Ph. Eur.).

4. Advancing Analytical Science:

- Developing new analytical methods:

Continuous research and development of new and improved analytical techniques are essential for addressing emerging challenges in pharmaceutical analysis.

- Improving sensitivity and selectivity:

Advanced techniques offer higher sensitivity and selectivity, enabling the detection and quantification of trace amounts of substances and the separation of complex mixtures.

- Applying analytical techniques to new areas:

Modern analytical techniques are being applied to new areas, such as biopharmaceutical analysis, personalized medicine, and process analytical technology (PAT).

In essence, modern pharmaceutical analytical techniques are fundamental to ensuring the quality, safety, and efficacy of drugs, ultimately benefiting patients by providing access to effective and reliable medications.

THEORY

Sr. No.	Topic	Hrs
1	**UNIT-1** a) UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV Visible spectroscopy. b) IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. c) Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectroscopy. d) Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.	(10)
2	**UNIT-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.	(10)
3	**UNIT-3** **Mass Spectrometry:** Principle, Theory, Instrumentation of Mass Spectrometry, Different types of ionization like electron impact, chemical field, Including hard and soft ionization techniques (FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its	(12)

	rules, Meta stable ions, Isotopic peaks and Applications of Mass spectrometry). Simple structure elucidation problems based on UV, IR, NMR and Mass data.	
4	**UNIT-4** **Chromatography:** Principle, instrumentation, chromatographic parameters, factors affecting resolution and applications, recent advancements of the following: a) High Performance Liquid chromatography b) High Performance Thin Layer Chromatography c) Ion exchange chromatography d) Gas chromatography e) Ultra High Performance Liquid chromatography f) Affinity chromatography g) Gel Chromatography h) Introduction to hyphenated techniques (e.g.LC-MS, GC-MS etc.) i)ICPMS (Inductively Coupled Plasma Mass Spectrometry): Elemental Analysis j) NDSRI (Nitrosamine Drug Substance Related Impurities): quantification of impurities k) Introduction to Method Development	(10)
5	**UNIT-5** **Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing g) X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X ray diffraction.	(10)
6	**UNIT-6** **Thermal Techniques:** **a**) Thermogravimetric analysis (TGA): Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications. b) Differential scanning calorimetry (DSC): Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. c) Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA)	(08)

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 A and B - J W Munson, Volume 11, Marcel Dekker Series
8. Introduction to Spectroscopy, Donald L. Pavia, Gary M. Lampman, George S. Kriz, James A. Vyvyan, Cengage Learning, 2008.
9. Solving spectroscopy problems: A basic approach by Nazma Inamdar (Career publications).

PHARMACEUTICS (MPH)

DRUG DELIVERY SYSTEM (MPH 102T)
60 hours

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

THEORY

The formulation and evaluation of Novel drug delivery systems.

Sr. No.	Topic	Hrs
1.	**Sustained Release (SR) and Controlled Release (CR) formulations:** Introduction & basic concepts, advantages / disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, and Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy. Introduction to application of AI in drug delivery	**(10)**
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)**
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)**
4.	**Ocular Drug Delivery Systems:** Ocular Anatomy and Barriers, Methods to overcome barriers, Routes of Administration, Conventional and Novel Drug Delivery Systems, Factors Influencing Drug Delivery, Characterization and Evaluation, Specific Diseases and Treatments.	**(06)**
5.	**Transdermal Drug Delivery Systems:** Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.	**(10)**

6.	**Protein and Peptide Delivery: Barriers for protein delivery**. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	**(08)**
7	**Vaccine delivery systems:** Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	**(06)**

REFERENCES

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

JOURNALS

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

MODERN PHARMACEUTICS (MPH 103T)

60 hours

SCOPE:

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts of formulation development used in pharmaceutical industries.

OBJECTIVES:

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

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

THEORY

Sr. No.	Topic	Hrs
1.	**Preformulation Concepts and Objectives:** Drug Excipient interactions, different methods, kinetics in stability testing, Preparation, stability and theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) Manufacturing and Evaluation aspects of Large and small volume parental formulation. Introduction to Preformulation of phytopharmaceutical	(14)
2.	**Optimization techniques in Pharmaceutical Formulation Development:** Concept and need of optimization, Optimization techniques in pharmaceutical processing and formulation development. Statistical design, Response surface method, Contour plots. Applications of factorial design in product development. QbD approach. Case studies.	(10)
3.	**Pharmaceutical Validation**: Introduction, Scope & Merits of Validation, ICH & WHO guidelines for validation of equipment's, Validation of Double Cone Blender, RMG, and Tablet Compression Machine. DQ, IQ, OQ & P.Q. of facilities, Types of process validation. Process validation of any one dosage form. Technology transfer from R & D to pilot plant and plant scale.	(10)
4.	**GMP and Industrial Management**: Objectives, Policies and guidelines of current Good Manufacturing Practices. Layout of buildings, services, equipment's and their maintenance Production management, Materials management, Inventory management and control, Sales forecasting, Budget and cost control, Industrial and Personal Management Concept of Total Quality Management.	(14)
5.	**Compression and compaction:** Physics of tablet compression, compression and consolidation, Effect of friction, distribution of forces. Compaction profiles, Consolidation parameters, Application of Heckel plot	(08)

6.	**Diffusion, Dissolution** and Pharmacokinetic parameters, Use of Similarity factors – f_1 and f_2, Dissolution models and kinetics of drug release. .	**(04)**

REFERENCES

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

REGULATORY AFFAIRS (MPH104T)
60 hours

SCOPE

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

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance and

OBJECTIVES

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

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilence and process of monitoring in clinical trials.

THEORY

Sr. No.	Topic	Hrs
1.	**Documentation in Pharmaceutical industry:** Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch– Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in - vivo, scale up process approval changes, post marketing surveillance.	(12)
2.	**Regulatory requirement for product approval:** API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs.	(12)
3.	**CMC, post approval regulatory affairs.** Regulation for combination products and medical devices. CTD and ECTD format, ICH – Guidelines of ICH–Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.	(12)
4.	**Non clinical drug development:** Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB). Introduction for Regulatory requirement of cosmeceutical & nutraceutical	(12)

5.	**Clinical trials:** HIPAA – new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials. Clinical Trial Application (CTA) for US submission, EU submission. Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form. Regulatory requirements for conducting clinical trials in India, Europe &USA**.** Regulatory requirement Medical Devices	**(12)**

REFERENCES

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

PHARMACEUTICS PRACTICALS – I (MPH 105P)

(12 hours/ week)

Sr. No.	Topic
1	Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2	Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3	Experiments based on HPLC
4	Experiments based on Gas Chromatography
5	Estimation of riboflavin/quinine sulphate by fluorimetry
6	Estimation of sodium/potassium by flame photometry
7	To perform In-vitro dissolution profile of CR/ SR marketed formulation
8	Formulation and evaluation of sustained release matrix tablets
9	Formulation and evaluation osmotically controlled DDS
10	Preparation and evaluation of Floating DDS– hydro dynamically balanced DDS
11	Formulation and evaluation of Muco adhesive tablets.
12	Formulation and evaluation of Transdermal patches.
13	To carry out preformulation studies of tablets.
14	To study the effect of compressional force on tablets disintegration time.
15	To study Micromeritic properties of powders and granulation.
16	To study the effect of particle size on dissolution of a tablet.
17	To study the effect of binders on dissolution of a tablet.
18	To perform Heckel plot analysis of the sample

REFERENCES

1. A.H. Beckett and J.B.Stenlake. Practical Pharmaceutical Chemistry. Volume -2. Fourth edition. Page no.284-286.
2. P. D. Sethi, "High Performance Liquid Chromatography", CBS Publications, 1st edition, 2001, Page No. -13-115.
3. 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.
4. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
5. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
6. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.

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

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

THEORY

The formulation and evaluation of novel drug delivery systems.

Sr. No.	Topic	60 Hrs
1.	**Targeted Drug Delivery Systems:** Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.	12
2.	**Targeting Methods:** Introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.	12
3.	**Micro Capsules / Micro Spheres:** Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes	12
4.	**Pulmonary Drug Delivery Systems:** Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.	12
5.	**Nucleic acid based therapeutic delivery system:** Gene therapy, introduction (ex–vivo & in–vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Recent advancements in gene separation and gene augmentation, Biodistribution and pharmacokinetic in gene delivery systems	12

REFERENCES

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

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 202T)

(60 hours)

SCOPE

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

OBJECTIVES

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

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

THEORY

Sr. No.	Topic	Hrs
1	**Drug Absorption from the Gastrointestinal Tract:** Properties of Gastrointestinal tract, pH Microclimate Intracellular pH Environment, Mechanism of drug absorption, Transport model: Permeability–Solubility–Charge State. Factors affecting drug absorption and pH-partition theory of drug absorption. Drug dissolution and extent of absorption, Factors affecting the dissolution rate. Gastrointestinal absorption from various dosage forms of drug.	(14)
2	**Biopharmaceutic considerations in drug product design**: Introduction, biopharmaceutic factors affecting drug bioavailability, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, Drug product stability. In vitro-in vivo correlation IVIVC, dissolution profile comparisons, BCS and Biowaiver.	(12)
3	**Pharmacokinetics:** Basic considerations, pharmacokinetic models, compartment modelling: 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 to transporters.	(14)
4	**Bioavailability and Bioequivalence:** drug product performance, Purpose of bioavailability studies, Relative and Absolute availability. Methods for assessing bioavailability, Bioequivalence studies, Study designs,	(10)

	evaluation of the data, Regulatory requirements, study submission and drug review process. Application of Biopharmaceutics Classification System, Permeability Methods: In–vitro, in–situ and In–vivo, Generic biologics (biosimilar drug products), Clinical significance of bioequivalence studies.	
5	**Application of Pharmacokinetics:** Pharmacokinetics of Modified–Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Pharmacokinetics and Pharmacodynamic Drug Interactions. Biopharmaceutical considerations in Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.	(10)

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

COMPUTER AIDED DRUG DEVELOPMENT (MPH 203T)

(60 hours)

SCOPE

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

OBJECTIVES

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

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

THEORY

Sr. No.	Topic	Hrs
1	a) **Computers in Pharmaceutical Research and Development:** A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modelling in pharmaceutical research and development: Descriptive versus Mechanistic Modelling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modelling **b) Quality-by-Design In Pharmaceutical Development**: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, scientifically based QbD – examples of application.	**(12)**
2	Computational Modelling 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)**
3	**Computer-aided formulation development:** Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in	**(12)**

	Pharmaceutical Research, Computers in Market analysis	
4	a) **Computer-aided biopharmaceutical characterization:** Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro- in vivo correlation, Biowaiver considerations b) **Computer Simulations in Pharmacokinetics and Pharmacodynamics:** Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. **c) Computers in Clinical Development:** Clinical Data Collection and Management, Regulation of Computer Systems	**(12)**
5	**Artificial Intelligence (AI), Robotics and Computational fluid dynamics:** General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.	**(12)**

REFERENCES

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

COSMETICS AND COSMECEUTICALS (MPH 204T)

(60 Hours)

SCOPE

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

OBJECTIVES

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

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

THEORY

Sr. No.	Topic	Hrs
1	**Cosmetics Regulatory:** Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labelling of cosmetics, Regulatory provisions relating to import of cosmetics, Misbranded and spurious cosmetics. Regulatory provisions relating to the manufacture of cosmetics - Conditions for obtaining a license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.	**(12)**
2	**Cosmetics - Biological aspects**: Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. role of skin microbiome in formulation strategies, Age-related skin and hair changes & ethnic differences in skin	**(10)**
3	**Formulation Building blocks:** Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants - Classification and application. Emollients, rheological additives: classification and application. Antimicrobials used as preservatives: their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of **basic emulsion-based systems** shampoo, and toothpaste. Soaps and syndet bars. Perfumes: Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane. Nanotechnological Applications in cosmetics (nanoemulsions, liposomes), clean beauty trends; role of ingredient safety assessments (IFRA, EWG).	**(14)**

4	**Design of cosmeceutical products:** Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun–protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.	**(12)**
5	**Herbal Cosmetics**: Herbal ingredients used in Hair care, skin care, and oral care. Overview of certification systems (e.g., COSMOS, NATRUE etc.) with respect to preservatives, emollients, foaming agents, emulsifiers, and rheology modifiers. Challenges in formulating herbal cosmetics. Standardization and quality control of herbal cosmetics; regulatory expectations for herbal cosmetics.	**(12)**

REFERENCES

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

PHARMACEUTICS PRACTICALS - II (MPH 205P)
(12 hours/ week)
(To conduct 20 Experiments from the following list)

Sr. No.	Topic
1	To study the effect of temperature change, non-solvent addition, incompatible polymer addition in microcapsules preparation
2	Preparation and evaluation of Alginate beads
3	Formulation and evaluation of gelatin /albumin microspheres
4	Formulation and evaluation of liposomes/niosomes
5	Formulation and evaluation of spherules/microparticles
6	Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7	Comparison of dissolution of two different marketed products /brands
8	Protein binding studies of a highly protein bound drug & poorly protein bound drug
9	Case studies of Bioavailability studies of Paracetamol in animals.
10	Case studies of Pharmacokinetic and IVIVC data analysis
11	Case studies of In vitro cell studies for permeability and metabolism
12	Design of Experiment for any formulation using Design Expert® Software (Only formulation DOE is expected)
13	Formulation data analysis Using Design Expert® Software (Data analysis and interpretation of the previous experiment is expected)
14	Quality-by-Design in Pharmaceutical Development
15	Case studies of Computer Simulations in Pharmacokinetics and Pharmacodynamics
16	Case studies of Computational Modeling of Drug Disposition
17	Case studies of Developing Clinical Data Collection manual
18	Case studies of Sensitivity Analysis, and Population Modeling
19	Development and evaluation of Creams
20	Development and evaluation of Shampoo and Toothpaste base
21	To incorporate herbal and chemical actives to develop products to address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff
22	To determine the particle size , particle size distribution and zeta potential of given sample using zetasizer

REFERENCES

1. A.H. Beckett and J.B.Stenlake. Practical Pharmaceutical Chemistry. Volume -2. Fourth edition. Page no.284-286.
2. P. D. Sethi, "High Performance Liquid Chromatography", CBS Publications, 1st edition, 2001, Page No. -13-115.
3. 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.
4. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
5. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
6. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.

PHARMACEUTICAL CHEMISTRY (MPC)

ADVANCED ORGANIC CHEMISTRY - I (MPC 102T)

60 hours

SCOPE

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

OBJECTIVES

Upon completion of course, the student shall be to understand

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

THEORY

Sr. No.	Topic	Hrs
1	**a) Basic Aspects of Organic Chemistry** 1. Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes, their method of formation, stability and synthetic applications. Green Chemistry Principles and how they relate to intermediates and reaction choice. 2. Types of reaction mechanisms and methods of determining them: reactions, mechanisms and their relative reactivity and orientations. Modern Reaction Kinetics & Thermodynamics tools in organic chemistry (e.g., use of computational modeling to predict intermediate stability). b) **Addition reactions** Nucleophilic uni– and bimolecular reactions (SN1 and SN2) Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule) Rearrangement reactions Electro organic synthesis as a sustainable approach.	**(10)**
2	**UNIT-II** **Study of mechanism and synthetic applications of following name reactions (perspective from lab scale to industry scale.)** a) **Important Name reactions:** Ullmann coupling reactions, Dieckmann reaction, Doebner-Miller reaction, Sandmeyer reaction, Mitsunobu reaction, Mannich reaction, Vilsmeyer-Haack reaction, Sharpless asymmetric epoxidation, Shapiro & Suzuki reaction, Ozonolysis, Michael addition reaction, Buchwald–Hartwig amination, C–H activation reactions, Photoredox catalysis (e.g., MacMillan-type), b) Flow chemistry adaptations of named reactions used in continuous manufacturing like Haber-Bosch Process (Ammonia Synthesis), Grignard Reaction, Buchwald-Hartwig Coupling, Friedel-Crafts Alkylation, Aldol	**(12)**

	Condensation, Diels-Alder Reaction, Hydrogenation Reactions c) Multi-component synthesis: Ugi reaction, Biginelli reaction, Hantzsch reaction, Passerini reaction and Strecker synthesis. d) 3. Click Chemistry (Copper-Catalyzed Azide-Alkyne Cycloaddition)	
3	a) Synthetic Reagents & Applications 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). Reagents for Green and Scalable Synthesis, such as: Organocatalysts, Enzymatic reagents. b) Protecting groups-Role of protection in organic synthesis, Protection for the hydroxyl group, including 1,2–and1,3–diols: ethers, esters, carbonates, cyclic acetals & ketals, Protection for the Carbonyl Group: Acetals and Ketals, Protection for the Carboxyl Group: amides and hydrazides, esters, Protection for the Amino Group and Amino acids: carbamates and amides, Protecting Group Strategies for peptide synthesis and oligonucleotides. c) Role of solid-phase synthesis in reagent selection.	**12 Hrs**
4	a. 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. b. AI-aided heterocycle design in drug discovery c. Synthesis of few representative drugs containing these heterocyclic nucleus such as Ketoconazole, Metronidazole, Celecoxib, Metamizole sodium, Antipyrine, Alprazolam, Triamterene, Sulfamerazine, Hydroxychloroquine, Quinacrine, Amsacrine, Prochlorpherazine, Promazine, Theophylline, Mercaptopurine. d. Process development of currently marketed drugs and Alternate Synthetic Method for Imatinib, Oseltamivir, Dolutegravir, Remdesivir (relevant examples from recent pharmacopeias).	**14 Hrs**
5	**UNIT-V Synthon approach and retrosynthesis applications** a. Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconvertion and addition (FGI and FGA), Application of retrosynthesis in green and economical routes. b. C-X disconnections; C-C disconnections - alcohols and carbonyl compounds; 1,2-, 1,3-,1,4-, 1,5-, 1,6-difunctionalized compounds c. Strategies for synthesis of three, four, five and six-membered ring. d. Computer-aided retrosynthesis tools (e.g., Chematica, AI-based retrosynthesis platforms). e. Case studies from industry, e.g., Pfizer's COVID-19 drug or Gilead's antiviral synthesis planning.	**12 Hrs**

REFERENCES

1. Advanced Organic chemistry, Reaction, Mechanisms and Structure", J March, John Wiley and Sons, New York.
2. "Mechanism and Structure in Organic Chemistry", ES Gould, Hold Rinchart and Winston, New York.
3. "Organic Chemistry" Clayden, Greeves, Warren and Woihers. Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Pearson Education Lts, Dorling Kindersley 9India) Pvt. Ltd.
5. A guide to mechanisms in Organic Chemistry, Peter Skyes (Orient Longman, New Delhi).
6. Reactive Intermediates in Organic Chemistry, Tandom and Gowel, Oxford & IBH Publishers.
7. 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, Wily India
10. Principles of Organic Synthesis, ROC Norman and JM Coxan, Nelson Thorns.
11. Organic Synthesis - Special Techniques. VK Ahluwalia and R Agarwal, Narosa Publishers.
12. Organic Reaction Mechanisms IVth Edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.
13. Clayden, Greeves, Warren, and Wothers – Organic Chemistry, 2nd Ed., Oxford University Press. (Foundational, deep mechanistic insight.)
14. Jonathan Clayden & Nick Greeves – Organic Chemistry: Structure and Function. (Mechanism-heavy, modern structure.)
15. Peter Sykes – A Guidebook to Mechanism in Organic Chemistry, 6th Ed. (Concise mechanism review.)
16. Jerry March – Advanced Organic Chemistry: Reactions, Mechanisms, and Structure, 6th Ed., Wiley.
17. Named Reactions & Synthesis
18. Michael B. Smith – March's Advanced Organic Chemistry: Reactions, Mechanisms, and Structure, 7th Ed. (Expanded reaction profiles.)
19. Li, Jie Jack – Name Reactions: A Collection of Detailed Reaction Mechanisms, Springer.
20. Laszlo Kurti, Barbara Czako – Strategic Applications of Named Reactions in Organic Synthesis. Elsevier.
21. Andreas Kirschning (Ed.) – Modern Methods in Synthesis and Catalysis, Wiley-VCH. (Green & catalytic synthesis.)
22. V.K. Ahluwalia & R. Aggarwal – Organic Synthesis: Special Techniques, Narosa. (Lab-scale and modern tools.)
23. Paul Anastas & John Warner – Green Chemistry: Theory and Practice. Oxford University Press. (Must-read for green aspects.)
24. Heterocyclic Chemistry & Drug Molecules
25. John Joule & Keith Mills – Heterocyclic Chemistry, 5th Ed., Wiley-Blackwell.
26. R.K. Bansal – Heterocyclic Chemistry, 5th Ed., New Age International.

27. G.L. Patrick – An Introduction to Medicinal Chemistry, Oxford University Press. (For application to drugs.)
28. Stuart Warren & Paul Wyatt – Organic Synthesis: The Disconnection Approach, 2nd Ed., Wiley.
29. Erick M. Carreira & Karl Heinz Dötz – Classics in Total Synthesis. Wiley-VCH.
30. Corey, E.J. – The Logic of Chemical Synthesis. Wiley. (Retrosynthesis classic.)
31. Digital Tools & Industry Trends (optional for faculty/researchers)
32. Software and online resources:
33. Reaxys® and SciFinder® for retrosynthetic planning.
34. Chematica (Synthia) retrosynthesis AI tools.
35. PubChem & DrugBank for modern heterocyclic drugs.

ADVANCED MEDICINAL CHEMISTRY (MPC 103T)

60 hours

SCOPE

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

OBJECTIVES

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

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

THEORY

Sr. No.	Topics	Hrs
1	**a) Drug discovery**: Stages of drug discovery, lead discovery, identification, validation and diversity of drug targets. Recent advances- Artificial intelligence, Machine learning in drug discovery. b) **Biological drug targets:** Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs antagonists, and Artificial enzymes, Drug targets- proteins (case studies of new molecules) c) **Introduction to Biosimilars and Vaccines:** Basics concept of immunology in biosimilar and biologics, vaccines; Introduction to biosimilars and vaccines	**(05)** **(04)** **(03)**
2	**Medicinal Chemistry Aspects of following classes of drugs** **Systematic study of new generation molecules of the following class of drugs:** **a)** Anti–hypertensive drugs, psychoactive drugs, Anticonvulsant drugs, H1 & H2 receptor antagonists, COX-1 & COX-2 inhibitors, Antineoplastic and Antiviral agents(SAR, Mechanism of action and synthesis of new drug). Alzheimer's and Parkinson's disease (case studies of new molecules targeting protein disorders). **b) Stereochemistry and Drug action:** Stereo selectivity as a pre–requisite for evolution, role of chirality in selective and specific therapeutic agents, Enantioselectivity in drug adsorption, metabolism, distribution and elimination with Case studies.	**(10)** **(04)**
3	**Peptidomimetics** Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally. Chemistry of prostaglandins, leukotrienes and thromboxones.	**(10)**

4	**Rational Design of Enzyme Inhibitors** Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.	**(10)**
5	**Prodrug Design and Analog Design** **a) Prodrug design**: Basic concept, Carrier-linked prodrugs/ 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 considerations of prodrug design. Recently added Pro-drugs (Case Study). **b) Combating drug resistance**: Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance. **c) Analog Design**: Introduction, Classical & Non-classical, 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 interatomic distance.	**(05)** **(05)** **(04)**

REFERENCES

1. Medicinal Chemistry by Burger, Vol I -VI.
2. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry, 12th Edition, Lippincott Williams & Wilkins, Wolters Kluwer (India) Pvt.Ltd, New Delhi.
3. Comprehensive Medicinal Chemistry - Corwin and Hansch.
4. Computational and structural approaches to drug design, edited by Robert M Stroud and Janet. F Moore
5. Introduction to Quantitative Drug Design by Y.C. Martin.
6. Principles of Medicinal Chemistry by William Foye, 7th Edition, Lippincott Williams & Wilkins, Wolters Kluwer (India) Pvt. Ltd, New Delhi.
7. Drug Design Volumes by Arienes, Academic Press, Elsevier Publishers, Noida, Uttar Pradesh.
8. Principles of Drug Design by Smith.
9. The Organic Chemistry of the Drug Design and Drug action by Richard B.Silverman, II Edition, Elsevier Publishers, New Delhi.
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, New Delhi.
12. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, First edition, Wiley publishers.
13. Mahroza Kanwal Khan, Mohsin Raza, Muhammad Shahbaz, Iftikhar Hussain, Muhammad Farooq Khan, Zhongjian Xie, Syed Shoaib Ahmad Shah, Ayesha Khan Tareen, Zoobia Bashir and Karim Khan, The recent advances in the approach of artificial intelligence (AI) towards drug discovery. Front. Chem. 12:1408740. doi:10.3389/fchem.2024.1408740.
14. Dr. Akarapu Premalatha, Dr Manisha Atul Bora, Dr.Srinu Bhoomandla, Dr Aruna Kumari Nakkella, Recent Advances in Drug Discovery: Innovative Approaches and Targeted Therapeutics, Eur. Chem. Bull. 2023,12(Special Issue 12), 2068 – 2074.

15. Felcia Lai, Bryson A. Hawkins, Esteban Cruz, Jane R. Hanrahan, Paul W. Groundwater, and David E. Hibbs. Drug Targets for Biologics. Iqbal Ramzan. In: Biologics, Biosimilars, and Biobetters: An Introduction for Pharmacists, Physicians, and Other Health Practitioners, 5th ed. John Wiley & Sons, Inc;2021. P. 71-88.

CHEMISTRY OF NATURAL PRODUCTS (MPC 104T)

60 hours

SCOPE

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

OBJECTIVES

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

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

THEORY

Sr. No.	Topic	Hrs
1	**Unit I** **Study of Natural products as leads for new pharmaceuticals for the following class of drugs**	**(12)**
	a. Drugs Affecting the Central Nervous System: Morphine Alkaloids	**2**
	b. Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide	**2**
	c. Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol	**2**
	d. Neuromuscular Blocking Drugs: Curare alkaloids	**2**
	e. Anti-malarial drugs and Analogues	**2**
	f. Chemistry of macrolide antibiotics (Erythromycin, Azithromycin, Roxithromycin, and Clarithromycin) and β-Lactam antibiotics (Cephalosporins and Carbapenem)	**2**

2	**Unit II** a. **Alkaloids**: 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).	**(12)** **4** **4** **4**
3	**Unit III** 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 (β carotene). b. **Vitamins** : Chemistry and Physiological significance of Vitamin A, B1, B2, B12, C, E, Folic acid and Niacin.	**(10)** **5** **5**
4	**Unit IV** 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.*	**(10)** **5** **5**
5	**UNIT-V** Structural Characterization of natural compounds Structural characterization of natural compounds using IR, 1H-NMR, 13C-NMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit–D, Quercetin and Digitalis glycosides.	**(10)**

6	**UNIT-VI** Standardization, QC monitoring and efficacy evaluation of natural Products. Standardization of herbal medicinal products. QC monitoring of available marketed herbal products. Preclinical and clinical efficacy study of natural products.	**(06)** **2** **2** **2**

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 Rein Hld.
3. Recent advances in Phytochemistry Vol. I to IV - Scikel Runeckles, Springer Science & Business Media.
4. Chemistry of natural products Vol I onwards IWPAC.
5. Natural Product Chemistry Nakanishi Gggolo, University Science Books, California.
6. Natural Product Chemistry "A laboratory guide" - Rapheal Khan.
7. The Alkaloid Chemistry and Physiology by RHF Manske, Academic Press.
8. Introduction to molecular Phytochemistry - CHJ Wells, Chapmannstall.
9. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall, Himalaya Publishing House.
10. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal, Krishan Prakashan.
11. Organic Chemistry Vol I and II by I.L. Finar, Pearson education.
12. Elements of Biotechnology by P.K. Gupta, Rastogi Publishers.
13. Pharmaceutical Biotechnology by S. P. Vyas and V. K. Dixit, CBS Publishers.
14. Biotechnology by Purohit and Mathur, Agro–Bios, 13th edition.
15. Phytochemical methods of Harborne, Springer, Netherlands.
16. Burger's Medicinal Chemistry.
17. Analytical Profiles of Drug Substances: v. 1-19 by Klaus Florey
18. Chemistry of Natural Products by Jaswant Kour, Pee Vee Publication, Edition 2018.
19. Chemistry of Natural Products by Sunil Jalalpure, Nirali Prakashan, First Edition 2019.
20. Chemistry of Natural Products by H V Shahare, Nirali Prakashan, First Edition 2025.
21. Chemistry of Natural Products by M K Gupta, Pragati Prakashan, First Edition 2009.
22. Pharmacology and Pharmacotherapeutics Kindle Edition by RS Satoskar, Nirmala Rege, SD Bhandarkar, 25th Edition, 2017.

PHARMACEUTICAL CHEMISTRY PRACTICAL – I (MPC 105P)
(12 hours/ week)

Sr. No.	Topics
1	Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer, RNA & DNA estimation
2	Simultaneous estimation of multi-component containing formulations by UV spectrophotometry
3	Experiments based on Column chromatography
4	Experiments based on HPLC
5	Experiments based on Gas Chromatography
6	Estimation of riboflavin/quinine sulphate by fluorimetry
7	Estimation of sodium/potassium by flame photometry
	To perform the following reactions of synthetic importance
1	Purification of organic solvents, column chromatography
2	Claisen–Schimidt reaction.
3	Benzyllic acid rearrangement.
4	Beckmann rearrangement.
5	Hoffmann rearrangement
6	Mannich reaction
7	Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4 experiments)
8	Estimation of elements and functional groups in organic natural compounds
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 IR data.
10	Some typical degradation reactions to be carried on selected plant constituents
11	Hands on Training: TLC Method Development (Plate Preparation & Activation, Mobile Phase Development, Reaction Monitoring by TLC)
12	Flash Chromatography: Virtual Demonstration / Industrial Visit
13	Validation of Analytical Method Parameter: (including Accuracy, Precision etc)
14	Alternate Synthetic Method for currently marketed drugs

REFERENCES

1. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
2. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
3. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative Analysis of Drugs in Pharmaceutical Formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods – Part A and B - J W Munson, Volume 11, Marcel Dekker Series
7. Introduction to Spectroscopy, Donald L. Pavia, Gary M. Lampman, George S. Kriz, James A. Vyvyan, Cengage Learning, 2008.
8. Principal of organic synthesis Norman,R O C & Coxon, J M ELBS

ADVANCED SPECTRAL ANALYSIS (MPC 201T)
60 hours

SCOPE

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

OBJECTIVES

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

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

THEORY

Sr. No.	Topic	Hrs
1	**UNIT-I** **UV and IR spectroscopy** • Wood ward - Fieser rule for 1,3– butadienes, cyclic dienes and α, β–carbonyl compounds, aromatic compounds and interpretation compounds of enones. • ATR–IR, Interpretation of IR Spectra of Organic Compound	**(12)**
2	**UNIT-II** **NMR spectroscopy** • 1–D and 2–D NMR (NOESY and COSY, HECTOR, INADEQUATE techniques), Interpretation of NMR spectra of organic compounds.	**(12)**
3	**UNIT-III** **Mass Spectroscopy** • Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds.	**(12)**
4	**UNIT-IV** • **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) Super critical fluid chromatography h) Flash chromatography i.) LC-MS/MS	**(16)**
5	**UNIT-V** a) **Thermal methods of analysis** Interpretation of TGA, DTA and DSC spectra of drug and excipients Bioassay, ELISA, and Radioimmunoassay of digitalis and insulin. b) Elemental analysis of organic compound.	**(8)**

REFERENCES

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

ADVANCED ORGANIC CHEMISTRY – II (MPC 202T)

60 hours

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 able to understand

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

THEORY

Sr. No.	Topics	Hrs
1	**UNIT-I** **Green Chemistry** **a)** Introduction, principles of green Chemistry (brief review), Comparison of Synthesis by Green Chemistry Approach with Conventional Method. **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 (short overview, focus on modern synthetic applications). **c)** Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid–liquid and liquid–solid reactions, synthetic applications **d)** Continuous flow reactors: Working principle, advantages and synthetic applications. **e)** Automated/AI-optimized flow synthesis; 3D-printed reactors. **f)** Ionic liquids, and solvent free reactions **g)** Electrochemical and Photoredox Organic Synthesis (key methods for drug synthesis). **h)** CO_2 utilization and bio-based feedstocks in sustainable chemistry. **i)** Mechanochemistry **j)** Synthesis Including Enzyme as Catalyst	**(12)**
2	**UNIT-II** **Stereochemistry & Asymmetric Synthesis** **a)** Basic concepts in stereochemistry - optical activity, specific rotation, racemates and resolution of racemates techniques, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis–trans	**(12)**

	isomerism, E and Z notation. **b)** Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples. Chiral Catalysts (N-Heterocyclic Carbenes, Organocatalysts), Biocatalysis in Enantioselective Reactions, Dual Catalysis (Photoredox + Transition Metal), Applications in drug synthesis (case studies), Computational Chemistry (DFT) for predicting stereochemical outcomes.	
3	**UNIT-III** **Chemistry of peptides** a) Peptide & Biomolecular Chemistry, Coupling reactions in peptide synthesis (concise classical coverage). b) Solid Phase Peptide Synthesis (SPPS): Principles of solid phase peptide synthesis, t–BOC and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site–specific chemical modifications of peptides. Automated techniques, orthogonal protecting group strategies. c) Segment and sequential strategies for solution phase peptide synthesis with any two case studies d) Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, over– activation and side reactions of individual amino acids. e) Click Chemistry & Bio-orthogonal Ligations (bcz got Nobel in 2022). f) Peptidomimetics, Stapled Peptides, and Macrocycles, Case studies: Therapeutic peptides & peptidomimetic drugs.	**(12)**
4	**UNIT-IV** a) **Photochemical Reactions** Basic principles of photochemical reactions. Photo–oxidation, photo–addition and photo–fragmentation. b) **Pericyclic reactions** Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatrophic rearrangement reactions with examples	**(12)**
5	**UNIT-V** **Catalysis** a) Types of catalysis, heterogeneous and homogenous catalysis, (brief overview), advantages and disadvantages b) Heterogeneous catalysis - preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs. c) Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs d) Transition–metal and Organo–catalysis in organic synthesis: (late-stage functionalization).Metal–catalyzed reactions.	**(12)**

	e) Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction. f) Phase transfer catalysis - theory and applications. **g)** Industrial Case Studies: Flow-synthesis of APIs (e.g., Remdesivir, Sotorasib), Sustainable catalytic routes in modern pharma.	

REFERENCES

1) "Advanced Organic chemistry, Reaction, mechanisms and structure", J March, John Wiley and sons, New York.
2) "Mechanism and structure in organic chemistry", ES Gould, Hold Rinchart and Winston, NewYork.
3) "Organic Chemistry" Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.
4) "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5) Carey, Organic Chemistry, 5th edition (Viva Books Pvt. Ltd.)
6) Organic synthesis–the disconnection approach, S. Warren, Wiley India
7) Principles of organic synthesis, ROC Norman and J M Coxan, Nelson thorns
8) Organic synthesis– Special techniques VK Ahluwalia and R Aggarwal, Narosa Publishers.
9) Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.
10) Clayden et al., Organic Chemistry, 2nd Edition (Updated).
11) Nicholas G. Richmond, "Green and Sustainable Medicinal Chemistry," RSC (2023).
12) Baran & MacMillan's work on Photoredox Catalysis (Nature Reviews).
13) MIT Open Course Ware: 5.47 and 5.52 (Advanced Organic Synthesis) for reference material.

COMPUTER AIDED DRUG DESIGN (MPC 203T)

60 hours

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 courseit is expected that students will be able to understand

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

THEORY

Sr. No.	Topics	Hrs
1	**UNIT-I Introduction to CADD** a) History, different techniques and applications of computer aided drug design b) Molecular Properties and Drug Design c) Prediction and analysis of AI-assisted ADMET properties of new molecules and its importance in drug design. (Using DeepChem, Chemprop). d) Integration of multi-omics data (genomics, proteomics, e) Metabolomics) for target and lead identification. f) De novo drug design: with AI/Generative Models (e.g., reinforcement learning for novel molecules). Modern fragment-based and covalent drug design strategies. g) Receptor/enzyme–interaction and its analysis, h) Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design. i) Homology modeling and generation of 3D–structure of protein. Link with AI-based structure prediction tools (AlphaFold2, RoseTTAFold). Descriptor-based automated pipelines (RDKit/Mordred).	**(12)**
2	**UNIT-II** • **Pharmacophore Mapping and Virtual Screening** Concept of pharmacophore, pharmacophore mapping, and identification of Pharmacophore features and Pharmacophore modeling; Conformational search connect to ensemble docking and AI-based conformer generation used in pharmacophore mapping. In Silico Drug Design and Virtual Screening Techniques AI-driven virtual screening (cloud and GPU-accelerated pipelines).	**(12)**

	• Similarity based methods and Pharmacophore based screening, structure based In-silico virtual screening protocols. • High-throughput screening (HTVS) using platforms like AutoDock-GPU, Schrödinger Glide, and Atomwise. • Pharmacophore generation using machine learning and automated workflows (MOE, LigandScout). • Cryo-EM-derived structures for pharmacophore mapping.	
3	**UNIT-III** **Molecular Modeling and Docking** **a)** Molecular and Quantum Mechanics in drug design. **b)** Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation **c)** Molecular docking and drug receptor interactions: Flexible and ensemble docking 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) AI-accelerated docking (DiffDock, Gnina). **d)** DFT **e)** Molecular Dynamics (MD): **f)** Enhanced sampling methods (Metadynamics, Umbrella Sampling). **g)** Free Energy Perturbation (FEP+) for binding affinity predictions. Application to modern drug targets (KRAS, GPCRs, PROTACs) alongside classical enzymes.	**(12)**
4	**UNIT-IV** • Quantitative Structure Activity Relationships: Basics History and development of QSAR: Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equation and electronic parameters (sigma), lipophilicity effects and parameters (log P, pi–substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters. AI/ML in drug design: • Deep learning for QSAR (graph neural networks, random forests). • Generative AI for molecular design (e.g., variational autoencoders, diffusion models). • Automated descriptor calculation with RDKit, PaDEL, Mordred. • Use of cloud and big-data platforms for scalable analysis.	**(12)**
5	**UNIT-V** Quantitative Structure Activity Relationships: • Data-driven lead optimization pipelines (Active learning, Bayesian optimization). • Industry Applications: Hansch analysis, Free Wilson analysis and relationship between them, case studies on AI-guided drug discovery (Atomwise, BenevolentAI, Schrödinger). • Advantages and disadvantages; Deriving 2D-QSAR equations. • 3D–QSAR approaches and contour map analysis with modern AI tools. • Statistical methods used in QSAR analysis and importance of statistical parameters. Classical statistical methods (Hansch regression) integrated	**(12)**

	with ML validation metrics (ROC-AUC, RMSE, cross-validation).	

REFERENCES

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2. Introduction to Quantitative Drug Design by Y.C. Martin, CRC Press, Taylor & Francis group.
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975, 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, Elsevier Publishers.
6. Medicinal Chemistry by Burger, Wiley Publishing Co.
7. An Introduction to Medicinal Chemistry-Graham L. Patrick, Oxford University Press.
8. Wilson and Gisvold's Textbook 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. F Moore
11. Deep Learning for the Life Sciences – Bharath Ramsundar et al. (O'Reilly, 2019)
12. Machine Learning in Chemistry – Hugh M. Cartwright (Springer, 2021)
13. Computational Drug Discovery and Design – Riccardo Baron (Springer, 2020)
14. AlphaFold and Next-Generation Structure Prediction – Nature Reviews (latest editions)
15. Recent papers from Journal of Chemical Information and Modeling (JCIM) and Journal of Cheminformatics.

PHARMACEUTICAL PROCESS CHEMISTRY (MPC 204T)
60 hours

SCOPE

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

OBJECTIVES

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

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

THEORY

Sr. No.	Topic	Hrs
1	**UNIT-I** **Industrial Safety** **a)** MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE) **b)** Fire hazards, types of fire & fire extinguishers, Occupational Health & Safety Assessment Series 1800 (OHSAS–1800) and ISO–14001(Environmental Management System), Effluents and its management **c)** Good Laboratory Practices **d)** Different Types of Symbols (Example: Corrosive, Flammable etc.) **e)** Hazards at Industrial Scale (Case Study) **f)** Terminologies in IPC Validation Batches	**(12)**
2	**UNIT-II** **Process chemistry** • Introduction, Synthetic strategy • **Stages of scale-up process**: Bench, pilot and large-scale process. In–process control and validation of large-scale processes. • Case studies of some scale-up processes of APIs. • Impurities in API, types and their sources, including genotoxic impurities	**(12)**

3	**UNIT-III** **Unit operations** **a. Extraction**: Liquid equilibria, extraction with reflux, extraction with agitation, counter-current extraction. **b. Filtration**: Theory of filtration, pressure and vacuum filtration, centrifugal filtration, **c. Distillation**: azeotropic and steam distillation **d. Evaporation**: Types of evaporators, factors affecting evaporation. **e. Crystallization**: Crystallization from aqueous, non–aqueous solutions, factors affecting crystallization, nucleation. Principles and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.	**(12)**
4	**UNIT-IV** **Unit Processes – I** a) **Nitration**: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration, **b) Halogenation**: Kinetics of halogenations, types of halogenations, and catalytic halogenations. Case study on industrial halogenation **c) Oxidation**: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H2O2, sodium hypochlorite, Oxygen gas, ozonolysis	**(12)**
5	**UNIT-V** **Unit Processes – II** a) **Reduction**: Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process. b) **Fermentation**: Aerobic and anaerobic fermentation. Production of - i. Antibiotics; Penicillin and Streptomycin, ii. Vitamins: B2 and B12 iii. Statins: Lovastatin, Simvastatin c) **Reaction progress kinetic analysis** i. Streamlining reaction steps, route selection, ii. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale–up.	**(12)**

REFERENCES

1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever– Changing Climate-An Overview; K. Gadamasetti, CRC Press.
2. Pharmaceutical Manufacturing Encyclopedia, 3rd edition, Volume 2.
3. Medicinal Chemistry by Burger, 6th edition, Volume 1–8.
4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7th edition, McGraw Hill
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 to Scale–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 Tech., WEP East–West Press Clausen, Mattson: Principle of Industrial Chemistry, Wiley Publishing Co.,
11. Lowenheim & M.K. Moran: Industrial Chemicals
12. S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II, Vikas Publishing House
13. J.K. Stille: Industrial Organic Chemistry (PH)
14. Shreve: Chemical Process, Mc Grawhill.

PHARMACEUTICAL CHEMISTRY PRACTICALS – II (MPC 205P)

(12 hours/ week)

Sr. No.	Topics
1	Synthesis of organic compounds by adapting different approaches involving (3 experiments) • Oxidation • Reduction/hydrogenation • Nitration
2	Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)
3	Assignments on regulatory requirements in API (2 experiments)
4	Comparison of absorption spectra by UV and the Woodward-Fieser rule
5	Interpretation of organic compounds by FT–IR
6	Interpretation of organic compounds by NMR
7	Interpretation of organic compounds by MS
8	Determination of purity by DSC in pharmaceuticals
9	Identification of organic compounds using FT–IR, NMR, CNMR and Mass spectra
10	To carry out the preparation of following organic compounds
11	Preparation of 4–chlorobenzhydrylpiperazine. (An intermediate for cetirizine HCl).
12	Preparation of 4–iodotolene from p–toluidine.
13	NaBH4 reduction of vanillin to vanillyl alcohol
14	Preparation of umbelliferone by Pechhman reaction
15	Preparation of triphenyl imidazole
16	To perform the Microwave irradiated reactions of synthetic importance (Any two)
17	Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using software.
18	Calculation of ADMET properties of drug molecules and its analysis using software Pharmacophore modelling

19	2D–QSAR based experiments
20	3D–QSAR based experiments
21	Docking study-based experiment
22	Virtual screening-based experiment
23	Virtual demonstration of accident & first aid in chemistry laboratory (Accident of Bromine, Accident of Acids, Na metal Handling etc)
24	Racemic mixture separation Experiment
25	Determination of QSAR Parameters like Log P, HBD, HBA Practically and comparison with that of software determination results.

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.

PHARMACEUTICAL QUALITY ASSURANCE (MQA)

QUALITY MANAGEMENT SYSTEMS (MQA 102T)

60 hours

SCOPE

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

OBJECTIVES

Upon completion of the course the student shall be able to

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

THEORY

Sr. No.	Topic	Hrs
1	**UNIT-I** • **Introduction to Quality: Evolution of Quality** • **Definition of Introduction to Quality**: Evolution of Quality, Definition of Quality, Dimensions of Quality • **Quality as a Strategic Decision**: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behavior, concept of internal and external customers. Case studies. • **Cost of Quality**: Cost of quality, Categories of cost of Quality, Models of cost of quality, optimizing costs, preventing cost of quality.	**(08)**

2	**UNIT-II** • **Pharmaceutical quality Management**: Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management-ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, Introduction to 21 CFR	**(16)**
3	**UNIT-III** • **Six System Inspection model:** Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labelling system. Concept of self-inspection. • **Quality systems**: Change Management / Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), • **Complaints** - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance	**(12)**
4	**UNIT-IV** • **Drug Stability**: ICH Q1 guidelines for stability testing of drug substances and drug products. • Study of ICH Q8, Quality by Design and Process development report • **Quality risk management**: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.	**(12)**
5	**UNIT-V** • **Statistical Process control (SPC)**: Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.	**(08)**
6	**UNIT-VI** • **Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking**: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.	**(04)**

REFERENCES

1. Al Endres, Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, Wiley, 2000.
2. Jiju Antony; David Preece, Routledge, Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, 2002.

3. Edward E. Lawler, Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report, 2001.
4. James W. Fairfield-Sonn, Corporate Culture and the Quality Organization, Quorum Books, 2001.
5. Christine Avery; Diane Zabel, Routledge, the Quality Management Sourcebook: An International Guide to Materials and Resources 1997.
6. Nancy R. Tague, the Quality Toolbox, Second Edition, ASQ Publications.
7. Joseph M. Juran and Joseph A., De Feo, Juran's Quality Handbook, Sixth Edition, ASQ Publications.
8. Duke Okes, Root Cause Analysis, the Core of Problem Solving and Corrective Action, 2009, ASQ Publications.

QUALITY CONTROL AND QUALITY ASSURANCE (MQA 103T)

60 hours

SCOPE

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

OBJECTIVES

Upon completion of this course the student should be able to

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

THEORY

Sr. No.	Topic	Hrs
1	**UNIT-I** **Introduction**: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Qseries guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. Digital transformation in Pharma industry for regulatory compliance, integrated Quality 4.0 frame work for Quality improvement	**(12)**
2	**UNIT-II** **cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering**: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.	**(12)**
3	**UNIT-III** Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. 126 In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).	**(12)**

4	**UNIT-IV** **Documentation in pharmaceutical industry**: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non regulated markets. Audit readiness & Regulatory intelligence- mock regulatory inspection, Preparing for pre-approval inspection	**(16)**
5	**UNIT-V** **Manufacturing operations and controls**: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal. Defects in Packaging, Classification of defects & detection system. Sustainability & Environment Social Governance in QA	**(08)**

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Sandy Weinberg, Good Laboratory Practice Regulations, 2nd Edition, Vol. 69, Marcel Dekker Series, 1995.
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& Francis; 2003.

12. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
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14. Pravin Ullagaddi, Digital Transformation in the Pharmaceutical Industry: Enhancing Quality Management Systems and Regulatory Compliance, International Journal of Health Sciences June 2024, Vol. 12, No. 1, pp. 31-43.
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19. https://www.thefdagroup.com/services/mock-pai
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21. Anuja Sengupta, International Journal for Research in Management & Pharmacy (IJRMP) DOI: https://doi.org/10.63345/ijrmp.v11.i11.1
22. Sustainability in Pharmaceutical Packaging, American Pharmaceutical Review.

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (MQA 104T)

60 Hours

SCOPE

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

OBJECTIVES

Upon completion of this course the student should be able to

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

THEORY

Sr. No.	Topics	Hrs
1	**Unit I** • **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)**
2	**Unit II** • **Preformulation studies and biopharmaceutics:** Physicochemical characterization of drug substances; polymorphism and solid-state analysis (XRPD, DSC, NIR); solubility enhancement strategies (co-solvency, surfactants, complexation); Biopharmaceutical Classification System (BCS); Pre-formulation protocol, stability testing and compatibility studies.	**(12)**
3	**Unit III** • **Pilot plant scale up** : Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges.	**(12)**

4	**Unit IV** • **Pharmaceutical packaging**: Pharmaceutical dosage form and their packaging requirements, 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. Innovative packaging technologies (RFID, QR codes); serialization and traceability systems (DSCSA-Drug Supply Chain Security Act (USA), FMD-Falsified Medicines Directive (EU) • **Regulatory requirement for packaging** • **Quality control test**: Containers, closures and secondary packing materials.	**(12)**
5	**Unit V** • **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)**

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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 E/d Bhalani publishing house Mumbai.
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9. D. A Sawant, The Pharmaceutical Sciences; the Pharma Path way Pure and applied Pharmacy, Pragathi Books Pvt. Ltd.
10. D.A. Dean. E.R. Evans, Pharmaceutical Packaging technology, I.H. Hall. 1st E/d (Reprint 2006). Taylor and Francis. London and New York. 130

QUALITY ASSURANCE PRACTICAL – I (MQA 105P)

(12 hours/ week)

(20 Experiments To be Conducted)

Sr. No.	Topics
1	Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet / capsules / semisolids) by UV Vis spectrophotometer
2	Simultaneous estimation of multi-drug component containing formulations by UV spectrophotometry
3	Experiments based on HPLC
4	Experiments based on Gas Chromatography
5	Estimation of riboflavin/quinine sulphate by fluorimetry
6	Estimation of sodium/potassium by flame photometry or AAS
7	Case studies on – • Total Quality Management • Six Sigma • Change Management/ Change control. Deviations • Out of Specifications (OOS) • Out of Trend (OOT) • Corrective & Preventive Actions (CAPA) • Deviations
8	Development of Stability study protocol
9	Estimation of process capability
10	In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
11	Assay of raw materials as per official monographs
12	Testing of related and foreign substances in drugs and raw materials.
13	To carry out pre formulation study for tablets,
14	To carry out pre formulation study for parenterals
15	To study the effect of pH on the solubility of drugs, (1 experiment)
16	Quality control tests for Primary and secondary packaging materials
17	Accelerated stability studies (1 experiment)
18	Improved solubility of drugs using surfactant systems (1 experiment)
19	Improved solubility of drugs using co-solvency method (1 experiment)

20	Determination of Pka and Log p of drugs.
21	To perform IPQC & QC tests for Liquid Orals (Suspension, Emulsion).
22	To perform FTIR spectroscopy for the given pure drug.

REFERENCES

1. Md. Sahab Uddin, Abdullah Al Mamun, Nahia Akter, Md. Shahid Sarwar, Mamunur Rashid and Md. Shah Amran Pharmacopoeial Standards and Specifications for Pharmaceutical Oral Liquid Preparations Archives of Current Research International 3(2): 1-12, 2016, Article no.ACRI.22675
2. https://pharmastate.academy/in-process-control-of-liquid-orals/
3. T.S.S. Dikshith, Hazardous Chemicals: Safety Management and Global Regulations, CRC press
4. C.S.Rao, Environmental Pollution Control Engineering, New Age international publisher
5. Charles G. Smith, James T and O. Donnell, The process of new drug discovery and development. I and II Edition (2006) CRC Press, Group of Taylor and Francis.
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8. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and related materials Vol I & II, 2nd edition, WHO Publications, 1999.
9. 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.
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11. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
12. D&C Act 1940 and Rules 1945.
13. ICH guidelines.

HAZARDS AND SAFETY MANAGEMENT (MQA 201T)

60 hours

SCOPE

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

OBJECTIVES

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

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

THEORY

Sr No.	Topics	Hrs
1	**UNIT-I** • **Multidisciplinary nature of environmental studies:** Natural Resources and associated problems, Renewable and non-renewable resources, a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources • **Ecosystems**: Concept of an ecosystem, Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes. • Impact of hazards on Industrial Safety Planning	**(12)**
2	**UNIT-II** • Indoor air Quality Standards according to ISO, ASHRAE,WHO Standards, Types of Hazards, Air circulation, Air handling system, HVAC system, air maintenance in industry for sterile area and non-sterile area.	**(12)**

3	**UNIT-III** • **Chemical based hazards**: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard. Control measures for chemical hazards. Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, MSDS, Labelling guidelines, Management of over- Exposure to chemicals and TLV concept, Disposal of hazardous material.	**(12)**
4	**UNIT-IV** • **Fire and Explosion**: Introduction, Industrial processes and hazards potential, Mechanical, electrical, thermal and process hazards, mechanical and chemical explosion, multiphase reactions. Safety and hazards regulations • **Fire protection system**: Fire prevention, types of fire extinguishers and critical Hazard management system, Preventive and protective management from fires and explosion- electricity passivation, ventilation, and sprinkling, proofing, fire walls, bunds, relief systems - relief valves, flares, scrubbers. Smart Fire detection & Supression Systems.	**(12)**
5	**UNIT-V** • **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, Preliminary hazard analysis • 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)**

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1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. Quantitative Risk Assessment in Chemical Process Industries, American Institute of Chemical Industries, Centre for Chemical Process safety.
3. T.S.S. Dikshith, Hazardous Chemicals: Safety Management and Global Regulations, CRC press
4. M. N. Vyas, Safety and hazard management in chemical industries, Atlantic Publisher
5. Daniel A. Crowl, Joseph F. Louvar, Chemical Process Safety: Fundamentals with Applications, 3rd Edition, Prentice Hall, 2011
6. H. H. Fawcett and W.S. Wood, Safety and Accident Prevention in Chemical Operations, 2nd E/d, John Wiley & Sons, New York 1982.
7. C.S.Rao, Environmental Pollution Control Engineering, New Age international publisher
8. Phillip Carson, Clive Mumford, Butterworth-Heinemann, Hazardous Chemicals Handbook, Second edition, An imprint of Elsevier Science.

PHARMACEUTICAL VALIDATION (MQA202T)

60 hours

SCOPE

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

OBJECTIVES

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

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

THEORY

Sr. No.	Topic	Hrs
1	**UNIT-I** • **Introduction to validation**: Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan. • **Qualification**: User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status-Calibration Preventive Maintenance, Change management).	**(08)**
2	**UNIT-II** • **Qualification of manufacturing equipment**: Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization / Tunnels, Autoclaves, Membrane filtration, Capsule filling machine. • **Qualification of analytical instruments**: UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC.	**(10)**
3	**UNIT-III** • **Qualification of laboratory equipments**: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus • **Validation of Utility systems**: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.	**(10)**

4	**UNIT-IV** • **Process Validation**: Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach. • **ICH Q14:** Analytical Method Development • **Analytical method validation Q2**: General principles, Validation of analytical method as per ICH guidelines and USP.	**(12)**
5	• **UNIT-V** Cleaning Validation: Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP). Validation of facilities in sterile and non-sterile plant. **Computerized system validation**: Electronic records and digital signature - 21 CFR Part 11 and GAMP	**(10)**
6	**UNIT-VI** • **General Principles of Intellectual Property:** Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property–patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.	**(10)**

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. Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, The Theory & Practice of Industrial Pharmacy, 3rd edition, Varghese Publishing House, Bombay.
3. Terveeks , Validation Master plan Davis Harwood International publishing.
4. Carleton & Agalloco, Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by
5. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
6. Syed Imtiaz Haider.Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries,
7. Phillip A. Cloud, Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, , Interpharm Press.

8. Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Validation of Pharmaceutical Processes: Sterile Products, Marcel Dekker.
9. Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Analytical Method validation and Instrument Performance Verification, Wiley Interscience.
10. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
11. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press.

AUDITS AND REGULATORY COMPLIANCE (MPA 203T)

60 hours

SCOPE

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

OBJECTIVES

Upon completion of this course the student should be able to

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

THEORY

Sr. No.	Topics	Hrs
1	**UNIT-I** • **INTRODUCTION**: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies.	**(12)**
2	**UNIT-II** • **Role of quality systems and audits in pharmaceutical manufacturing environment**: cGMP Regulations, Quality systems approach, Resource, Manufacturing operations, Evaluation activities, transitioning to quality system approach, Audit checklist for drug industries. (GLP ,GCP,GDP Audits)	**(12)**
3	**UNIT-III** • Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.	**(12)**
4	**UNIT-IV** • **Auditing of Microbiological laboratory**: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water (WFI ,SWFI ,BWFI), Packaging materials.	**(12)**
5	**UNIT-V** • **Auditing of Quality Assurance and engineering department**: Quality Assurance Maintenance, Critical systems: HVAC, Water System , Water for Injection systems, ETP, HEPA, AHU.	**(12)**

REFERENCES

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

PHARMACEUTICAL MANUFACTURING TECHNOLOGY (MQA 204T)

60 hours

SCOPE

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

OBJECTIVES

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

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

THEORY

Sr. No.	Topics	Hrs
1	**UNIT-I** • **Pharmaceutical industry developments**: Legal requirements and Licenses for API and formulation industry, Plant location- Factors influencing. • **Plant layout**: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout. • **Production planning**: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.	**(12)**
2	**UNIT-II** • **Aseptic process technology**: Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume). • **Advanced sterile product manufacturing technology** : Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance. • **Process Automation in Pharmaceutical Industry**: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS). Lyophilization technology: Principles, process, equipment.	**(12)**

3	**UNIT-III** • **Non sterile manufacturing process technology**: Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft). • Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, **Improved Tablet Production**: Tablet production process, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. • **Problems encountered. Coating technology**: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.	**(12)**
4	**UNIT-IV** • **Containers and closures for pharmaceuticals**: Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Innovative packaging material & container designed for novel formulations **Green manufacturing & Solvent Recovery:-** Sustainable Reducing Waste Carcinogenic Solvents etc.	**(12)**
5	**UNIT-V** • **Quality by design (QbD) and process analytical technology (PAT)**: Current approach and its limitations. Why QbD is required, Advantages, • **Elements of QbD, Terminology**: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation / minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. Introduction to ICH Q11, Q12 & Q13 Guidelines • **FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs**: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements. **Case studies:** Regular Agency Letters, Warning Letters against failure of Manufacturing.	**(12)**

REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I- III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
6. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
8. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
9. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor & Francis, 1st Edition. UK.
10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA Inc. New york.
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey, 2008.

QUALITY ASSURANCE PRACTICAL – II PRACTICALS (MQA 205P)

(12 hours/ week)

(To conduct any 20 Experiments)

Sr. No.	Topics
1	Organic contaminants residue analysis by HPLC
2	Identification of antibiotic residue by TLC
3	Estimation of Chlorine in Work Environment.
4	To perform optimization utilizing Design of experiment (DOE)
5	Sampling and analysis of SO_2 using Colorimetric method
6	HACCP Case Study (Include)
7	Qualification of following Pharma equipment (Any Two)
	a) Autoclave b) Hot air oven
	c) Powder Mixer (Dry) d) Tablet Compression Machine
8	Validation of an analytical method for a drug
9	Process validation of any non-sterile or sterile dosage form
10	Validation of a processing area
11	Qualification of at least two analytical instruments
12	Cleaning validation of one equipment
13	Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
14	Check list for Bulk Pharmaceutical Chemicals vendors
15	Check list for tableting production.
16	Check list for sterile production area
17	Check list for Water for injection.
18	Design of plant layout: Sterile and non-sterile
19	Case study on application of QbD
20	Case study on application of PAT
21	To identify & Differentiate Antibiotics in tablet Dosage form using TLC.
22	To carry out Case Study on: HVAC System.

REFERENCES

1. Hubicka Et Al.: Journal Of AOAC International Vol. 92, No. 4, 2009
2. https://www.cedengineering.com/userfiles/M05-006%20%20HVAC%20Design%20for%20Pharmaceutical%20Facilities%20-%20US.pdf
3. Parth Patel, IJPSR, 2013; Vol. 4(9): 3347-3356
4. Leonard Sunny Peris, Performance Evaluation of a HVAC system in a pharmaceutical Plant, Lambert Academic Publishing.
5. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
6. Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, The Theory & Practice of Industrial Pharmacy, 3rd edition, Varghese Publishing House, Bombay.
7. ICH guidelines
8. Syed Imtiaz Haider.Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries,
9. Phillip A. Cloud, Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, , Interpharm Press.
10. Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Validation of Pharmaceutical Processes: Sterile Products, Marcel Dekker.
11. Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Analytical Method validation and Instrument Performance Verification, Wiley Interscience.
12. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
13. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press.

PHARMACOLOGY (MPL)

ADVANCED PHARMACOLOGY – I (MPL 102T)

60 hours

SCOPE

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

OBJECTIVES

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

• Discuss the pathophysiology and pharmacotherapy of certain diseases

• Explain the mechanism of drug actions at cellular and molecular level

• Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

THEORY

Sr. No.	Topics	Hrs
1	**Unit-I** **General Pharmacology** Pharmacokinetics: Pharmacokinetics: Concepts of linear and non–linear compartment models. Significance of Protein binding. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.	**(12)**
2	**Unit -II** General aspects and steps involved in neurotransmission. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters– Adrenaline and Acetyl choline). Neurohumoral transmission in central nervous system (Detailed study about neurotransmitter Histamine, serotonin, dopamine, GABA, glutamate and glycine). Non adrenergic non cholinergic transmission (NANC). Co–transmission **Systemic Pharmacology** A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems. **Autonomic Pharmacology** Parasympathomimetics and Parasympatholytics, Sympathomimetics and Sympatholytics, agents affecting Neuromuscular Junction.	**(12)**

3	**Central nervous system Pharmacology** General Anesthetics Sedatives and Hypnotics, Anti-anxiety drugs. Depression, Psychosis, Mania, Epilepsy, Neurodegenerative diseases (Parkinsonism and Alzheimer's). Narcotic and Non–narcotic analgesics.	**(12)**
4	**Cardiovascular Pharmacology** Diuretics, Anti-hypertensives, Anti-ischemic drugs, Anti-arrhythmic drugs, drugs for Heart failure and Hyperlipidemia. **Blood Disorders** Hematinics, Coagulants and Anticoagulants, Fibrinolytics and Anti–platelet drugs.	**(12)**
5	**Autocoid Pharmacology** The physiological and pathological role of Histamine, Serotonin, Bradykinins, Prostaglandins and Opioid. Pharmacology of antihistamines, Serotonin antagonists.	**(12)**

REFEERENCES

1. Goodman & Gilman's: The Pharmacological Basis of Therapeutics, by Louis S. Goodman and Alfred Gilman, New York: McGraw-Hill.
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer–Lippincott Williams & Wilkins Publishers.
3. Katzung's Basic and Clinical Pharmacology by B.G Katzung. McGraw-Hill.
4. Hand book of Clinical Pharmacokinetics by Gibaldi, Milo and Prescott, L. F, New-York; Sydney: ADIS Health Science Press.
5. Shargel & Yu's Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu. McGraw-Hill.
6. Oxford textbook of Clinical Pharmacology by D G Grahame-Smith, J K Aronson, Oxford: Oxford University Press
7. Avery Drug Treatment by Trevor M. Speight, Nicholas H.G. Holford, Wiley India Pvt Ltd
8. Dipiro's Pharmacotherapy: A pathophysiological approach by Joseph T. DiPiro and Robert L. Talbert. McGraw Hill
9. Pathology and Therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice by Russell J. Greene, Norman D. Harris. Pharmaceutical Press.

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

(60 hours)

SCOPE:

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

OBJECTIVES:

Upon completion the course the student shall be able to:

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

THEORY

Sr. No.	Topics	Hrs
1	**Unit-I** **Laboratory Animals** Common Laboratory Animals: Description, handling and applications of different species and strains of animals Transgenic Animals: Production, maintenance and applications **CCSEA** Guidelines for Experimental Animals. Anaesthesia and Euthanasia of experimental animals Maintenance and Breeding of Laboratory Animals Good Laboratory Practice	**(12)**
2	**Unit-II** Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro* and other possible alternative methods in animals **CNS Pharmacology** General Principles of Preclinical Screening, Screening of Behavioural Activity and Muscle Coordination- Skeletal muscle relaxants, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti-epileptics, nootropics, parkinsonism and alzheimer's disease. **ANS Pharmacology** Drugs Acting on Autonomic Nervous System: Adrenergics & Antiadrenergics, Cholinergics & Anticholinergics	**(12)**

3	**Unit III** Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro* and other possible alternative methods in animals **Respiratory Pharmacology:** Anti-asthmatics, drugs for COPD and anti-allergic drugs **Reproductive Pharmacology:** Aphrodisiacs and ant-fertility agents **Gastrointestinal drugs:** Anti-ulcer, Anti-emetic, Anti-diarrheal and Laxatives **Analgesics & Anti-inflammatory drugs:** Analgesic, Anti-inflammatory and anti-pyretic drugs, Drugs for gout and rheumatoid arthritis	**(12)**
4	**Unit-IV** Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro* and other possible alternative methods in animals **Cardiovascular Pharmacology:** Anti-hypertensive, Anti-arrhythmic, Anti-anginals, and Diuretics **Drugs for metabolic disorders:** Anti-diabetic, Anti-hyperlipidemic and Anti-cancer drugs. Methods for screening of hepatoprotective drugs, Alcoholic liver disease, Non-alcoholic fatty liver disease	**(12)**
5	**Unit-V** Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro* and other possible alternative methods in animals. **General principles of immunoassay:** Theoretical basis and optimization of immunoassay, Heterogeneous and homogenous immunoassay system, Immunoassay methods evaluation; protocol outline, objectives and preparation, Immunoassay for digoxin and insulin	**(12)**

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 and Bachrach.
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M. N. Ghosh.
6. Pharmacological experiment on intact preparations by Churchill Livingstone.
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R. K. Goyal.

9. Preclinical evaluation of new drugs by S. K. Gupta.
10. Handbook of Experimental Pharmacology by S. K. Kulkarni.
11. Practical Pharmacology and Clinical Pharmacy by S. K. Kulkarni
12. Animal Models in Cardiovascular Research by David R. Gross., Kluwer Academic Publishers, London, UK.
13. Rodents for Pharmacological Experiments by Tapan Kumar Chatterjee.
14. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi, Ajay Prakash.

CELLULAR AND MOLECULAR PHARMACOLOGY (MPL 104T)

60 hours

SCOPE

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

OBJECTIVES

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

THEORY

Sr. No.	Topics	Hrs
1	**Unit-I Cell biology** Structure and function of the cell and its organelles. Genome organization. Gene expression and its regulation. Importance of siRNA and microRNA, gene mapping and gene sequencing. Cell cycle and its regulation. Role of telomeres in aging and cancer Cell death events, regulators of intrinsic and extrinsic pathways of apoptosis. Necrosis and autophagy	**(12)**
2	**Unit-II Cell signalling** Intercellular and intracellular signaling pathways. Classification of receptor family and molecular structure of: ligand-gated ion channels, G-protein coupled receptors, tyrosine kinase recept, and nuclear receptor **Secondary messengers** Cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-triphosphate (IP3), nitric oxide (NO) and diacylglycerol (DAG). **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)**

3	**Unit-III Principles and applications of genomic and proteomic tools** DNA electrophoresis, PCR (reverse transcriptase and real time), gene sequencing, microarray technique, SDS page, ELISA and western blotting. **Basic principles of recombinant DNA technology** Restriction enzymes, various types of vectors, various applications of recombinant DNA technology. **Gene therapy** Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.	**(12)**
4	**Unit-IV Pharmacogenomics** Gene mapping and cloning of disease gene. Gene variation and its role in health / pharmacology. Polymorphism affecting drug metabolism. Genetic variation in drug transporters & in G-protein coupled receptors. **Application of proteomic science** Genomics, proteomics, metabolomics, functionomics, nutrigenomics. **Immunotherapeutic** Types of immunotherapeutics, humanisation, antibody therapy, Immunotherapeutics in clinical practice.	**(12)**
5	**Unit-V Cell culture techniques** Basic equipment's used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell culture, 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 application of flow cytometry. Importance of pH Indicators in Culture Media. Introduction and applications of biosimilars	**(12)**

REFERENCES

1. Animal Cell Culture: A Practical Approach by John R. Masters, Oxford University Press.
2. Basic Cell Culture (A Practical Approach) by J. M. Davis, Oxford University Press.
3. Basic Cell Culture Protocols by Cheril D. Helgason, Cindy L. Miller, Humana Press.
4. Current Protocols in Molecular Biology by Frederick M. Ausubel et al., Wiley.
5. Handbook of Cell Signaling (Second Edition) by Ralph A. Bradshaw et al., Academic Press.
6. Molecular Pharmacology: From DNA to Drug Discovery by John Dickenson et al., Wiley.
7. Pharmacogenomics: The Search for Individualized Therapies by Julio Licinio, Ma-Li Wong, Wiley-VCH.
8. The Cell: A Molecular Approach by Geoffrey M. Cooper, Sinauer Associates.

PHARMACOLOGICAL PRACTICAL I (MPL 105P)
(12 hours/ week)

Sr. No.	Topics
1	Analysis of pharmacopeial compound and their formulations by UV method.
2	Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
3	Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)
	LABORATORY ANIMAL EXPERIMENTS
1	Study of various routes of drug administration.
2	Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3	Functional observation battery tests (modified Irwin test)
4	Evaluation of CNS stimulant activity
5	Evaluation of CNS depressant activity,
6	Evaluation of anxiolytic activity.
7	Evaluation of anticonvulsant activity.
8	Evaluation of analgesic activity
9	Evaluation of anti–inflammatory activity using plethysmometer
10	Enzyme based in-vitro assays (AChEs, a -amylase, a- glucosidase)
11	Estimation of proteins by Braford/Lowry's in biological samples
12	Evaluation of local anesthetic, mydriatic and miotic activity using suitable software.
13	Evaluation of diuretic activity.
14	Evaluation of antiulcer activity by pylorus ligation method
15	Oral glucose tolerance test
16	DNA fragmentation assay by agarose gel electrophoresis.
17	Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver)
18	Isolation of RNA from yeast
19	Cell viability assays (MTT/Trypan blue/SRB)

20	DNA damage study by Comet assay
21	Gene amplification by PCR.
22	Protein quantification by Western Blotting
23	Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares.
24	Network Pharmacology

REFERENCES

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines.
2. Fundamentals of Experimental Pharmacology by M. N. Ghosh.
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug Discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds –Robert M Silverstein.
6. Principles of Instrumental Analysis by Doglas A Skoog, F. James Holler, Timothy A. Nieman.
7. Vogel's Textbook of Quantitative Chemical Analysis by Jeffery, Basset, Mendham, Denney.
8. Basic Cell Culture Protocols by Cheril D. Helgason and Cindy L. Mille.
9. Basic Cell Culture (Practical Approach) by J. M. Davis.
10. Animal Cell Culture: A Practical Approach by John R. Masters.
11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi, Ajay Prakash Jaypee Brothers' Medical Publishers Pvt. Ltd
12. Experimental Aspects of Cellular and Molecular Pharmacology: a Treatise by N S. Vyawahare
13. Advances in Biomedical Experiments Techniques in Pharmacological Assays by A R. Juvekar
14. Uma Chandran, Neelay Mehendale, Saniya Patil, Rathnam Chaguturu, Bhushan Patwardhan, 2016. Network Pharmacology, Innovative Approaches in Drug Discovery. 14:127-164

ADVANCED PHARMACOLOGY II (MPL201T)

60 hours

SCOPE:

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

OBJECTIVES:

Upon completion the course the student shall be able to:

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

THEORY

Sr. No.	Topics	Hrs
1	**Unit-I** **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 and Drugs affecting calcium regulation	(12)
2	**Unit-II** **Chemotherapy I** Cellular and molecular mechanism of actions and resistance of antimicrobial agents - β-lactams, Sulfonamides, Aminoglycosides, Quinolones, Broad spectrum antibiotics, Macrolides antibiotics, Antifungals, Protozoal infections & Helminthiasis	(12)
3	**Unit-III** **Chemotherapy II** Chemotherapy of Cancer, Antiviral & Anti-TB drugs, Immunosuppressants and Immunomodulators **Inflammation & Drugs for Respiratory Disorders** Cellular and biochemical mediators of inflammation, Allergy or hypersensitivity reactions, Pharmacotherapy of asthma and COPD	(12)
4	**Unit-IV** **GIT Pharmacology** Anti-ulcer drugs, Prokinetics, Antiemetics, Antidiarrheals and Drugs for constipation and irritable bowel syndrome **Chronopharmacology** Biological and circadian rhythms, Applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer	(12)

5	**Unit-V** **Free Radical Pharmacology** Generation of free radicals, Role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer **Antioxidants** Protective activity of certain important antioxidants such as Vitamin E, Vitamin C, Curcumin, CoQ10, Lipoic acid	(12)

REFERENCES

1. The Pharmacological Basis of Therapeutics by Goodman and Gillman
2. Principles of Pharmacology, the Pathophysiologic Basis of Drug Therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G.Katzung.
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Handbook of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Textbook of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.
9. Pathologic Basis of Disease by Robbins and Cortan, 9^{th} Ed. (Robbins Pathology)
10. A Complete Textbook of Medical Pharmacology by S.K Srivastava published by APC Avichal Publishing Company.
11. Essentials of Medical Pharmacology by K. D. Tripathi.
12. Lippincott Illustrated Reviews: Pharmacology by Karen Whalen, Richard Finkel and Thomas A. Panvelil.

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II (MPL202T)
60 hours

SCOPE

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

OBJECTIVES

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

• Explain the various types of toxicity studies.
• Appreciate the importance of ethical and regulatory requirements for toxicity studies.
• Demonstrate the practical skills require conducting the preclinical toxicity studies.

THEORY

Sr. No.	Topics	Hrs
1	**Unit-I** Basic definition and types of toxicology (General, Mechanistic, Regulatory and Descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y, OECD Principles of Good laboratory practice. History, concept and its importance in drug development	(12)
2	**Unit -II** Acute, Sub-acute and chronic-oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization- importance and methods in regulatory toxicity studies.	(12)
3	**Unit-III** Reproductive toxicity studies, Male reproductive toxicity studies, Female reproductive studies (segment I and III), Teratogenicity studies (segment II) Genotoxicity studies (Ames Test, *in vitro* and *in vivo* Micronucleus and Chromosomal aberrations studies) In vivo Carcinogenicity studies	(12)
4	**Unit-IV** IND enabling studies (IND studies): Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. Safety pharmacology studies: origin, concepts and importance of safety pharmacology Tier 1- CVS, CNS and Respiratory safety pharmacology, HERG assay. Tier 2- GI, renal and other studies	(12)

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

REFERENCES

1. Hand book on GLP, Quality practices for regulated non–clinical research and development (http://www.who.int/tdr/publications/documents/glp– handbook.pdf).
2. Schedule Y Guideline: Drugs and Cosmetics (second amendment) rules,2005, Ministry of Health and Family Welfare (Department of Health) New Delhi.
3. Drugs from discovery to approval by Rick NG. Willey Blackwell
4. Animal Models in Toxicology by Shayne C. Gad,Taylor & Francis Group
5. OECD test guidelines.
6. Principles of Toxicology by Karen E. Stine, Thomas M. Brown. CRC Press
7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals, FDA-2008-D-0470, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

PRINCIPLES OF DRUG DISCOVERY (MPL203T)

(60 hours)

SCOPE:

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

OBJECTIVES:

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

- Explain the various stages of drug discovery.
- Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery.
- Explain various targets, biomarkers and *in vitro* screening techniques for drug discovery.
- Explain various lead seeking method and lead optimization.

THEORY

Sr. No.	Topics	Hrs
1	**Unit I** **An overview of modern drug discovery process** Target identification, target validation, lead identification and lead His optimization, and economics of drug discovery. Target discovery and validation- role of genomics, proteomics and bioinformatics. Role of nucleic acid microarrays, protein microarrays, antisense technologies, siRNAs oligonucleotides, zinc finger proteins. Role of transgenic animals in target validation. Importance of drug discovery for rare diseases.	**(12)**
2	**Unit II** **Lead Identification** Combinatorial chemistry & high throughput screening in silico lead discovery techniques, assay development for hit identification. Protein structure, levels of protein structure, domains, motifs, and folds in protein structure. Computational prediction of protein structure. Threading and homology modelling methods, application of NMR and X-ray crystallography in protein structure prediction.	**(12)**
3	**Unit III** **Rational Drug Design** Structure and pharmacophore-based approaches, virtual screening technique, rational approaches for reperfusing of existing molecules for new therapeutic target. Introduction to molecular docking, QSAR statistical methods, and product concept.	**(12)**

4	**Unit IV** **Classical Targets, Translational Medicine and Biomarkers in Drug Discovery** Enzymes inhibition, G-protein-coupled receptors (GPCRs), ion channels, membrane transport proteins (transporters), emerging targets. Definition of a biomarker and their classification, characteristics and impact of biomarkers, biomarkers versus surrogate end points, imaging technologies. Practical applications of biomarkers. Biomarkers for cancer (breast, lung, skin), diabetes, CVs etc.	**(12)**
5	***Unit V*** ***In vitro* screening systems** The language of screening: basic terms, biochemical versus cellular assays, assay systems and methods of detection, radioligand assay systems (RIA), fluorescence-based assay systems, reporter gene assays, kinetic fluorescent measurement systems, label-free assay systems, electrophysiological patch clamp,	**(12)**

REFERENCES

1. Basic Principles of Drug Discovery and Development by Benjamin Blass, Academic Press, 2015.
2. Disease Gene Identification: Methods and Protocols by Johanna K. DiStefano, Springer, New York, Dordrecht, Heidelberg, London.
3. In Silico Technologies in Drug Target Identification and Validation by Darryl León, Scott Markel, Taylor & Francis Group, LLC, 2006.
4. New Drug Development: Design, Methodology, and Analysis by J. Rick Turner, John Wiley & Sons, Inc., New Jersey.
5. QSAR: Hansch Analysis and Related Approaches (Methods and Principles in Medicinal Chemistry) by Hugo Kubinyi, Wiley–VCH.
6. Rational Drug Design: Novel Methodology and Practical Applications by Abby L. Parrill, M. Rami Reddy, American Chemical Society, Washington, DC, 1999.
7. Structure-Based Ligand Design (Methods and Principles in Medicinal Chemistry) by Klaus Gubernator, Hans Joachin Böhm, Wiley–VCH.
8. Target Discovery and Validation: Reviews and Protocols, Emerging Molecular Targets and Treatment Options by Mouldy Sioud, Humana Press Inc., 2007.

CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL204T)

60 hours

SCOPE:

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

OBJECTIVES:

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

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

THEORY

Sr. No.	Topics	Hrs
1	**Unit I** **Regulatory Perspective of Clinical Trials:** Origin and Principles of International Conference on Harmonization-Good Clinical Practice (ICH-GCP) guidelines. Ethical Committee: Institutional Review Board, Ethical guidelines for Biomedical Research and Human Participant, Schedule Y, ICMR. Inform Consent Process: Structure and content of an Inform Consent Process, Ethical principles governing informed consent process.	**(12)**
2	**Unit II** **Clinical Trials: Types and Design** Experimental Study- RCT and Non RCT Observation Study: Cohort, Case control, Cross sectional Clinical trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management	**(12)**

3	**Unit III** **Clinical Trial Documentation**- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report, Clinical Trial Monitoring, Safety monitoring in Clinical Trials.	**(12)**
4	**Unit IV** **Basic aspects, terminologies and establishment of Pharmacovigilance** History and progress of Pharmacovigilance, Significant of safety monitoring, pharmacovigilance in India and international aspects, WHO international drug monitoring programmed, WHO and Regulatory evaluation of medication safety, establishing Pharmacovigilance centers in Hospitals, Industry and National programs related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance.	**(12)**
5	***Unit V*** **Methods, ADR reporting and tools used in Pharmacovigilance** International classification of diseases, List of 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. Methods for ADR reporting (Arugs, Aris G Pharmacovigilance, Vigiflow), Statistical methods for evaluating medication safety data (Disproportionality Analysis, Regression models, and Survival analysis)	**(12)**

REFERENCES

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

PHARMACOLOGICAL PRACTICAL – II (MPL 205P)

(12 hours/ week)

Sr. No.	Topics
1	To record the DRC of agonist using suitable isolated tissues preparation.
2	To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3	To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4	To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation
5	To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation
6	To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7	Estimation of PA_2 values of various antagonists using suitable isolated tissue preparations.
8	To study the effects of various drugs on isolated heart preparations
9	Recording of rat BP, heart rate and ECG.
10	Drug absorption studies by averted rat ileum preparation.
11	Acute oral toxicity studies as per OECD guidelines.
12	Acute dermal toxicity studies as per OECD guidelines.
13	Repeated dose toxicity studies– Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
14	Drug mutagenicity study using mice bone–marrow chromosomal aberration test.
15	Protocol design for clinical trial.(3 Nos.)
16	Design of ADR monitoring protocol.
17	In-silico docking studies. (2 Nos.)
18	In-silico pharmacophore-based screening.
19	ADR reporting

REFERENCES

1. Fundamentals of experimental Pharmacology by M.N.Ghosh
2. Hand book of Experimental Pharmacology by S.K.Kulakarni
3. Text book of in-vitro practical Pharmacology by Ian Kitchen
4. Bioassay Techniques for Drug Development by Atta–ur–Rahman, Iqbal choudhary and William Thomsen 206
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.
7. Experimental aspects of cellular and molecular pharmacology: a Treatise by N S. Vyawahare by Walnut publications
8. Advances in Biomedical Experiments Techniques in Pharmacological Assays by A R. Juvekar by CBS publishers.

SEMESTER III

RESEARCH METHODOLOGY & BIOSTATISTICS (MRM 301T)

60 hours

Scope:

The field of pharmaceutical research is dynamic and constantly growing. It is crucial to understand the procedures required to conduct high-quality research. It is challenging to develop a research strategy without prior understanding of the fundamental ideas of biostatistics and research technique. This course offers a structured framework that directs the planning, designing, executing and assessing of research in order to guarantee accurate and significant results while also adhering to ethical standards concerning the rights of humans and animals. Additionally, it offers the statistical concepts, methods, and resources needed to plan scientific investigations, evaluate complicated data, and correctly interpret findings.

Objectives:

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

- Demonstrate knowledge about basic concepts about research and the methodology to conduct research
- Describe the appropriate statistical methods required for a particular research design
- Explain the rationale, importance and processes for abiding to research ethics in research conducted using humans and animals
- Develop an appropriate framework for research studies including study design, method of data collection, sampling techniques, data analysis, report writing and publication
- Create research proposals, scientific reports, and scientific communications

THEORY

Unit No.	Topics	Hrs
UNIT-I	General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, Introduction to PRISMA, Cochrane & MOOSE guidelines, study design, optimization techniques, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques, data collection techniques, scientific communications, publication ethics. AI tools for research	**(26)**
UNIT-II	Biostatistics: Definition, application, sampling techniques, basics of statistics, statistical distribution, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non–parametric	**(24)**

Unit No.	Topics	Hrs
	tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values. Include case studies.	
UNIT-III	Medical Research: History, values in medical ethics, autonomy, beneficence, non– maleficence, double effect, conflicts between autonomy and beneficence/non– maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.	**(04)**
UNIT-IV	CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals**.**	**(03)**
UNIT-V	Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	**(03)**

REFERENCES:

1. Pagano, M., Gauvreau, K., & Mattie, H. (2022). Principles of Biostatistics (3rd ed.). Chapman and Hall/CRC.
2. BL Agarwal, 2006, Basic Statistics, Revised edition, New Age International Publisher.
3. Alain Li Wan Po, 1998, Statistics for Pharmacists, Blackwell Publishing, Wiley
4. Animesh Kumar Dutta, 2007, Basic Biostatistics and application, New Central Book Agency
5. Ranjit Kumar, Research Methodology: a step-by-step guide for beginners, Sage Publications, 3rd edition, 2011 (e-book)
6. Prabhat Pandey, Meenu Mishra Pandey, Research Methodology: Tools And Techniques, Bridge centre Publishing, 2015 (e-book)
7. Research Methodology Methods and Techniques –Second Revised edition, New Age International Publishers, C.R.Kothari.
8. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton Charles Bon, Marcel Dekker Inc. NewYork., 2010

INTRODUCTION TO CONSTITUTION
30 hours

Scope:

The course introduces students to the constitution of India. The Constitution, being supreme law of the land, must be known to every citizen of India. It begins with the preamble, which indicates the source and object of it. Course has been designed for everyone to make acquaint themselves with their fundamental rights.

Objectives:

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

- To introduce the philosophy of constitution of India.
- To acquaint their freedom and responsibilities.
- To understand basic fundamental rights and duties as per Indian constitution.

THEORY

Unit No.	Topics	Hrs
UNIT - I	**PHILOSOPHY OF THE INDIAN CONSTITUTION** **a)** Constitutional History of India **b)** Role of Dr. B.R. Ambedkar in Constituent Assembly **c)** Preamble – Source and Objects **d)** Sovereign and Republic **e)** Socialist and Secular **f)** Democratic – Social and Economic Democracy **g)** Justice – Social, Economic and Political **h)** Liberty – Thought, Expression, Belief, Faith and Worship **i)** Equality – Status and Opportunity **j)** Fraternity, Human Dignity, Unity and Integrity of the Nation	**(05)**
UNIT-II	**FUNDAMENTAL RIGHTS** **a)** Right to equality **b)** Right to freedoms **c)** Right against exploitation **d)** Right to freedom of religion **e)** Cultural and educational rights **f)** Right to property **g)** Right to constitutional remedies	**(10)**
UNIT-III	**DIRECTIVE PRINCIPLES OF STATE POLICY** **a)** Equal Justice and free legal aid **b)** Right to work and provisions for just and humane conditions of work **c)** Provision for early childhood, Right to education and SC, ST, weaker section **d)** Uniform Civil Code **e)** Standard of Living, nutrition and public health **f)** Protection and improvement of environment **g)** Separation of Judiciary from executive Promotion of International peace and security	**(10)**

UNIT-IV	**FUNDAMENTAL DUTIES** **a)** Duty to abide by the Constitution **b)** Duty to cherish and follow the noble ideals **c)** Duty to defend the country and render national service **d)** Duty to value and preserve the rich heritage of our composite culture **e)** Duty to develop scientific temper, humanism, the spirit of inquiry & reform **f)** Duty to safeguard public property and abjure violence **g)** Duty to strive towards excellence	**(05)**

REFERENCES:

1. The Constitution of India (20th Edition) by P.M. Baksh
2. Indian Constitutional Law (9^{th} Edition) by M.P. Jain