AMRITA THAM | School of Pharmacy

Rules & Syllabus for Master of Pharmacy

M. Pharm

(PCI regulations 2014)

AMRITA VISHWA VIDYAPEETHAM is a multi-campus, multi-disciplinary research academia that is accredited 'A' by NAAC and is ranked as one of the best research institutions in India. Amrita is spread across five campuses in three states of India - Kerala, Tamil Nadu and Karnataka, with the headquarters at Ettimadai, Coimbatore, Tamil Nadu. Amrita Vishwa Vidyapeetham continuously collaborates with top US universities including Ivy league universities and top European universities for regular student exchange programs, and has emerged as one of the fastest growing institutions of higher learning in India. The institution is managed by the Mata Amritanandamayi Math.

AMRITA SCHOOL OF PHARMACY is a constituent Unit of AMRITA VISHWA VIDYAPEETHAM Deemed University established under Section 3 of UGC Act l956. It is located in the Health Sciences Campus of the University at Kochi, Kerala, India. Amrita School of Pharmacy offers training for one of the most sought after professions. The School's commitment to excellence in healthcare is in line with the overall objective of the Kochi - based Health Sciences campus of the University. Amrita School of Pharmacy is recognized by Pharmacy Council of India (PCI) and All India Council for Technical Education (AICTE).

The School of Pharmacy strives not only to provide quality education in pharmaceutical sciences but also to establish itself in research and serves as an ideal platform for the overall development of highly competent pharmacy professionals. The School maintains an exemplary clinical practice and conducts community outreach programmes that address the needs of Kochi and the society at large.

VISION

To develop as a center of excellence in Pharmacy education and research and become one among the distinguished pharma institutions in the country. It envisions to establish effective collaborations with Pharma industries and international pharmacy institutions for mutual benefits.

MISSION

To provide high quality value-based education with high emphasis on research and mould competent and socially committed pharmacy professionals capable of practicing and managing the future of pharmacy profession in the country and abroad.

Programmes Offered:

- BPharm (4 years – 8 semesters)
- MPharm (2 years – 4 semesters)
  - o Pharmacy Practice
  - o Pharmaceutics
  - o Pharmaceutical Chemistry
  - o Pharmacology
- Pharm D Regular (5 years plus 1 year Internship)
- Pharm D Post Baccalaureate (2 years plus 1 year Internship)
- PhD in Pharmaceutical Sciences

M.PHARM

The rules and syllabus of Master of Pharmacy framed under regulation 6, 7, 8 of the Master of Pharmacy (M.Pharm) course regulations 2014 by Pharmacy Council of India has been adopted for the M.Pharm programme of Amrita Vishwa Vidyapeetham from the academic year 2017 - 18 onwards.


भारत का राजपत्र
The Gazette of India

CHAPTER – I:REGULATIONS

1. Short Title and Commencement

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

2. Minimum qualification for admission

A Pass in the following examinations

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

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

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

3. Duration of the program

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

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

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

6. Attendance and progress

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

7. Program/Course credit structure

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

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, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department/ teaching staff of respective courses.

9. Course of study

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

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

1.		
2.	Industrial Pharmacy	
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

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.

The Specializations offered by Amrita School of Pharmacy are denoted in bold in table 1 and the details of the respective Specializations are only included in this book. (Tables 2,4,9 & 10 only are shown below)

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

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]01	Analytica	[illegible]	[illegible]	[illegible]	[illegible]
-	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]1	[illegible]	4	4	4	1[illegible]
MPH202T	Advanced [illegible]	4	4	4	1[illegible]
MPH203T	[illegible]	4	4	4	1[illegible]
MPH204T	Cosmetics [illegible]	4	4	4	1[illegible]
MPH205P	Pharmaceutics [illegible] II	12	6	12	1[illegible]
-	[illegible]	7	4	7	1[illegible]
	[illegible]	35	[illegible]	35	[illegible]

Table – 4: Course of study for M. Pharm.

(Pharmaceutical Chemistry)

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible] I					
[illegible]	[illegible] Pharmace[illegible] Analytical [illegible]n[illegible]um	4	4	4	1[illegible]
[illegible]0[illegible]	[illegible] [illegible] Chemi[illegible] –I	4	4	4	1[illegible]
[illegible]	[illegible] [illegible] Medicinal [illegible]emi[illegible]	4	4	4	1[illegible]
[illegible]	Chemi[illegible] of Natural [illegible]u[illegible]	4	4	4	1[illegible]
[illegible]	Pharmace[illegible] Chemi[illegible] [illegible] I	12	6	12	15[illegible]
-	[illegible]	7	4	7	1[illegible]
	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible] II					
[illegible]	[illegible] [illegible] [illegible]is	4	4	4	1[illegible]
MPC202T	[illegible] [illegible] Chemi[illegible] –II	4	4	4	1[illegible]
MPC203T	[illegible]r [illegible] [illegible]g [illegible]n	4	4	4	1[illegible]
MPC204T	[illegible]l [illegible]s Chemi[illegible]	4	4	4	1[illegible]
MPC205P	Pharmace[illegible] Chemi[illegible] [illegible] II	12	6	12	15[illegible]
-	[illegible]	7	4	7	1[illegible]
	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

Table – 9: Course of study for M. Pharm. (Pharmacy Practice)

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]					
[illegible]	Clinical Pharmacy [illegible]	4	4	4	1[illegible]
[illegible]	[illegible] -I	4	4	4	1[illegible]
[illegible]	[illegible] & Community Pharmacy	4	4	4	1[illegible]
[illegible]	Clinical [illegible]	4	4	4	1[illegible]
[illegible]	Pharmacy [illegible] I	12	6	12	150
-	[illegible]	7	4	7	1[illegible]
[illegible]		[illegible]	[illegible]	[illegible]	[illegible]
[illegible]					
[illegible]	[illegible] Use of [illegible]	4	4	4	1[illegible]
[illegible]	Pharmacotherapeutics II	4	4	4	1[illegible]
[illegible]	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	4	4	1[illegible]
[illegible]	Pharmacoepidemiology & Pharmacoeconomics	4	4	4	1[illegible]
[illegible]	[illegible] III	12	6	12	150
-	[illegible]	7	4	7	1[illegible]
	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

Table – 10: Course of study for (Pharmacology)

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]					
[illegible]	[illegible] Pharmaceutical Analytical [illegible]	4	4	4	1[illegible]
[illegible]	[illegible]-I	4	4	4	1[illegible]
[illegible]	[illegible] Toxicological [illegible] s-I	4	4	4	1[illegible]
[illegible]	[illegible] Pharmacology	4	4	4	1[illegible]
[illegible]	[illegible] II	12	6	12	150
-	[illegible]	7	4	7	1[illegible]
[illegible]		[illegible]	[illegible]	[illegible]	[illegible]
[illegible]					
[illegible]	Advanced Pharmacology II	4	4	4	1[illegible]
[illegible]	[illegible] Toxicological [illegible] s-II	4	4	4	1[illegible]
[illegible]	[illegible] g [illegible]	4	4	4	1[illegible]
[illegible]	Clinical research and pharmacovigilance	4	4	4	1[illegible]
[illegible]	[illegible] II	12	6	12	150
-	[illegible]	7	4	7	1[illegible]
	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

Table – 12: Course of study for M. Pharm. III Semester

(Common for All Specializations)

[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
-	Journal club	1	1
-	[illegible] (Proposal Presentation)	2	2
-	[illegible]	28	14
[illegible]		35	21

* Non University Exam

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

(Common for All Specializations)

[illegible]	[illegible]	[illegible]	[illegible]
-	Journal Club	1	1
-	[illegible]	31	16
-	[illegible]	3	3
[illegible]		35	[illegible]

Table – 14: Semester wise credits distribution

[illegible]	[illegible]
I	26
[illegible]	26
[illegible]	21
[illegible]	20
[illegible] (Attending Conference, Scientific Presentations and other Extra Curricular Activities)	[illegible]
[illegible]	Minimum=35 Maximum=[illegible]

* Credit points for co-curricular activities

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

Name of the Activity	[illegible]
[illegible]	01
[illegible]	☑
[illegible]	01
[illegible]	☑
[illegible]	01
[illegible]	☑

* International conference : Held out side India

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

10. Program Committee

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

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

A teacher at the cadre of Professor shall be the Chairperson; One Teacher from 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 sessionalexam and before the end semester exam.

11. Examinations/Assessments

The schemes for internal assessment and end semester examinations are given in Table (16-25)

Note : Tabels relevant to the available specializations 16, 18, 23 & 24 are only included

End semester examinations

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

Tables – 16: Schemes for internal assessments and end semester examinations

(Pharmaceutics- MPH)

			Sessional					
		ous		on	al		on	
SEMESTER I								
101	Pharmaceuti	10	15	1	25		3H	1
1	s	10	15	1	25		3	1
1	Pharmaceuti	10	15	1	25		3H	1
1	Regulatory s	10	15	1	25		3	1
1	Pharmaceuti -I			6	50	1	6 H	150
-	/Assignment	-	-	-	-	-	-	1
SEMESTER II								
1	Technology &	10	15	1	25		3H	1
	Advanced Pharmacokin	10	15	1	25		3	1
	s	10	15	1	25		3H	1
	s Cosmeceutic	10	15	1	25		3	1
	Pharmaceuti Practical II			6	50	1	6 H	150
-	/Assignment	-	-	-	-	-	-	1

Tables – 18: Schemes for internal assessments and end semester examinations

(Pharmaceutical Chemistry-MPC)

						d ms		
		us e					on	
	Pharmaceutic al	10	15	1 r	25	75	3	1
	Advanced –I	10	15	1 r	25	75	3	1
	Advanced	10	15	1 r	25	75	3	1
		10	15	1 r	25	75	3	1
	Pharmaceutic al I	20	30	6	50	1	6	150
-	n	–	–	–	–	–	–	1

	Advanced is	10	15	1r	25	75	3	1
MPC202T	Advanced –II	10	15	1r	25	75	3	1
MPC203T		10	15	1r	25	75	3	1
MPC204T		10	15	1r	25	75	3	1
		20	30	6r	50	1	6	150
-		–	–	–	–	–	–	1
								650

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

(Pharmacy Practice-MPP)

					al			
	Clin	10	15	1Hr	25		3Hrs	1
	Pharmacotherapeutic	10	15	1Hr	25		3Hrs	1
	mun	10	15	1Hr	25		3Hrs	1
	Clin	10	15	1Hr	25		3Hrs	1
	I			6 Hrs		1	rs	1
-	inar	–	–	–	–	–	–	1
	nes	10	15	1Hr	25		3Hrs	1
	Pharmacotherapeutic s II	10	15	1Hr	25		3Hrs	1
	Clin Therapeutic	10	15	1Hr	25		3Hrs	1
	Pharmacoepidem Pharmacoeconom	10	15	1Hr	25		3Hrs	1
	II			rs		1	rs	1
-	inar	–	–	–	–	–	–	1
								6

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

(Pharmacology-MPL)

		nuous			al			
	Pharmaceutical n	10	15	1	25		3	1
	Pharmacology-I	10	15	1	25		3	1
	Pharmacolog and Toxicolog i	10	15	1	25		3	1
	lu Pharmacology	10	15	1	25		3	1
	Pharmacology Practical – I					1		1
-	inar	–	–	–	–	–	–	1
	Pharmacology II	10	15	1	25		3	1
20 2T	Pharmacolog and Toxicolog i Methods-II	10	15	1	25		3	1
		10	15	1	25		3	1
	Clin and pharmacovigi	10	15	1	25		3	1
	Pharmacology Practical – II					1		1
-	inar	–	–	–	–	–	–	1

Tables – 26: Schemes for internal assessments and end semester examinations

(Semester III& IV)

* Non University Exam

Internal assessment: Continuous mode

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

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

[illegible]	
[illegible]	[illegible]
[illegible] – [illegible]	8
[illegible]	2
[illegible]	10
[illegible]	
[illegible] – [illegible])	10
[illegible]	10
[illegible]	[illegible]

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

[illegible]	[illegible]	Practical
[illegible] – 1[illegible]	8	10
[illegible] – [illegible]	6	7.5
[illegible] – [illegible]	4	5
[illegible] – [illegible]	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 average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables.

12. Promotion and award of grades

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

13. Carry forward of marks

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

14. Improvement of internal assessment

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

15. Reexamination of end semester examinations

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

Table – 29: Tentative schedule of end semester examinations

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

16. Allowed to keep terms (ATKT):

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

A student shall be eligible to carry forward all the courses of I and 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 – 30: Letter grades and grade points equivalent to Percentage of marks and performances

[illegible]	[illegible]	[illegible]	[illegible]
[illegible] – 1[illegible]	[illegible]	10	Outstandi[illegible]
[illegible] – [illegible]	[illegible]	9	[illegible] e[illegible]
[illegible] – [illegible]	[illegible]	8	[illegible]
[illegible] – [illegible]	[illegible]	7	[illegible] r
[illegible] – [illegible]	[illegible]	6	[illegible]
[illegible]	F	0	[illegible]
[illegible]	[illegible]	0	[illegible]

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 AB grade awarded in that semester. For example if a learner has a F or ABS grade in course 4, the SGPA shall then be computed as:

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

19. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course (s) is/are passed. When the course (s) is/are passed by obtaining a pass grade on subsequent examination (s) the CGPA shall only reflect the new grade and not the fail grades earned earlier. The CGPA is calculated as:

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

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

20. Declaration of class

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

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

21. Project work

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

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

Evaluation of Dissertation Book:

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

Evaluation of Presentation:

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

22. Award of Ranks

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

23. Award of degree

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

24. Duration for completion of the program of study

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

25. Revaluation / Retotaling of answer papers

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

26. Re-admission after break of study

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

PHARMACEUTICS (MPH)

Programme Educational Objectives

1. To develop competent pharmacy graduates by structured teaching learning process through dedicated and devoted faculty.
2. To mould professionals with technical skills and inculcate high level of understanding in the area of manufacturing of drugs and pharmaceuticals.
3. To master the students to use modern tools, equipments and softwares necessary to design and develop advanced pharmaceutical formulations.
4. To provide interdisciplinary research and educational opportunities to solve problems that will improve the quality of life for those suffering from health-related diseases and disorders.
5. To inspire the graduates for higher education, research or entrepreneurship and life¬long learning in the context of technological advancement.

SEMESTER I

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)

SCOPE

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

OBJECTIVES

After completion of course student is able to know,

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

THEORY **60 HOURS**

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. 11Hrs

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

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

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

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

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

4. **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: 11Hrs

   a) Paper chromatography b) Thin Layer chromatography

   c) Ion exchange chromatography d) Column chromatography

   e) Gas chromatography f) High Performance Liquid chromatography

   g) Affinity chromatography

5. a. **Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: 11Hrs

a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis

d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

b. 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.

6. **Immunological assays :** RIA (Radio immuno assay), ELISA, Bioluminescence assays. 5Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

DRUG DELIVERY SYSTEMS (MPH 102T)

SCOPE

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

OBJECTIVES

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

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

THEORY **60 HOURS**

1. **Sustained Release (SR) and Controlled Release (CR) formulations:** Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy. 10Hrs

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. 10Hrs

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. 10Hrs

4. **Occular Drug Delivery Systems:** Barriers of drug permeation, Methods to overcome barriers. 6Hrs

5. **Transdermal Drug Delivery Systems:** Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation. 10Hrs

6. **Protein and Peptide Delivery:** Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules. 8Hrs

7. **Vaccine delivery systems:** Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines. 6Hrs

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)

SCOPE

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

OBJECTIVES

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

- The elements of preformulation studies.
- 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 **60 HOURS**

1. a. **Preformulation Concepts** – Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation. 12Hrs

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

2. **Validation:** Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities. 12Hrs

3. **cGMP & Industrial Management:** Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management. 12Hrs

4. **Compression and compaction:** Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility. 12Hrs

5. **Study of consolidation parameters:** Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation, Chi square test, students T-test, ANOVA test. 12Hrs

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 (MPH 104T)

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 **60 HOURS**

1. a. **Documentation in Pharmaceutical Industry:** Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION), drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. 18Hrs

   b. **Regulatory requirement for product approval:** API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs 6Hrs

2. **CMC, post approval regulatory affairs:** Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries. 12Hrs

3. **Non clinical drug development:** Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB). 12Hrs

4. **Clinical trials:** Developing clinical trial protocols. Institutional review board / independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA-new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials. 12Hrs

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 PRACTICAL - I (MPH 105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. To perform In-vitro dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Muco adhesive tablets.
12. Formulation and evaluation of trans dermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

SEMESTER II

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

SCOPE

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

OBJECTIVES

Upon completion of the course student shall be able to understand

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

THEORY **60 HOURS**

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

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, New Delhi, First edition 1997 (reprint in 2001).

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 202T)

SCOPE

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

OBJECTIVES

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

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use 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 biopharma ceutic parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetics.

THEORY **60 HOURS**

1. **Drug Absorption from the Gastrointestinal Tract:** Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formuulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex. 12Hrs
2. **Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance:** Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing,meeting dissolution requirements,problems of variable control in dissolution testingperformance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability,considerations in the design of a drug product. 12Hrs
3. **Pharmacokinetics:** Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model:two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of kmax and vmax. Drug interactions: introduction, the effect of protein-binding interactions,the effect of tissue-binding interactions,cytochrome p 4 5 0 - based drug interactions, drug interactions linked to transporters. 12Hrs
4. **Drug Product Performance, In Vivo: Bioavailability and Bioequivalence:** drug product performance, purpose of bioavailability studies, relative and absolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods.generic biologics (biosimilar drug products),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution. 12Hrs
5. **Application of Pharmacokinetics:** Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacody- 12Hrs

namic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D.M. Brahmankar and Sunil B. Jaiswal., Vallab-Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack 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, 1st edition, Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPS Publishing, 2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

COMPUTER AIDED DRUG DELIVERY SYSTEM (MPH 203T)

SCOPE

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

OBJECTIVES

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

- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition

- Computers in Preclinical Development
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics (CFD)

THEORY **60 HOURS**

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

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

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

3. **Computer-aided formulation development:** Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis 12Hrs

4. 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 12Hrs

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

5. **Artificial Intelligence (AI), Robotics and Computational fluid dynamics:** General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions. 12Hrs

REFERENCES

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

COSMETICS AND COSMECEUTICALS (MPH 204T)

SCOPE

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

OBJECTIVES

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

- Key ingredients used in cosmetics 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 **60 HOURS**

1. **Cosmetics – Regulatory :** Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics., Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties. 12Hrs

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. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm. 12Hrs

3. **Formulation Building blocks:** Building blocks for different product formulations of cosmetics/ cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars. 12Hrs

   Perfumes: Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

4. **Design of cosmeceutical products:** Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations. 12Hrs

5. **Herbal Cosmetics:** Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics. 12 Hrs

REFERENCES

1. 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. 3rd edition

5. Cosmetic and Toiletries recent suppliers catalogue.

6. CTFA directory.

PHARMACEUTICS PRACTICAL - II (MPH 205P)

1. To study the effect of temperature change, non solvent addition, incompatible polymer addition in microcapsules preparation

2. Preparation and evaluation of Alginate beads

3. Formulation and evaluation of gelatin /albumin microspheres

4. Formulation and evaluation of liposomes/niosomes

5. Formulation and evaluation of spherules

6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.

7. Comparison of dissolution of two different marketed products /brands

8. Protein binding studies of a highly protein bound drug & poorly protein bound drug

9. Bioavailability studies of Paracetamol in animals.

10. Pharmacokinetic and IVIVC data analysis by WinnolineR software

11. In vitro cell studies for permeability and metabolism

12. DoE Using Design Expert® Software

13. Formulation data analysis Using Design Expert® Software

14. Quality-by-Design in Pharmaceutical Development

15. Computer Simulations in Pharmacokinetics and Pharmacodynamics

16. Computational Modeling Of Drug Disposition

17. To develop Clinical Data Collection manual

18. To carry out Sensitivity Analysis, and Population Modeling.

19. Development and evaluation of Creams

20. Development and evaluation of Shampoo and Toothpaste base

21. To incorporate herbal and chemical actives to develop products

22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

PHARMACEUTICAL CHEMISTRY (MPC)

Programme Educational Objectives

1. To develop competent pharmacy graduates by structured teaching learning process through dedicated and devoted faculty.
2. To integrate theoretical knowledge and practical skills of synthetic and analytical chemistry to meet the challenges in drug discovery.
3. To develop skills in Computer Aided Drug Design to facilitate outcome oriented research in drug discovery.
4. To provide interdisciplinary research and educational opportunities to solve problems that will improve the quality of life for those suffering from health-related diseases and disorders.
5. To inspire the graduates for higher education, research or entrepreneurship and life¬long learning in the context of technological advancement.

SEMESTER I

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(MPC 101T)

SCOPE

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

OBJECTIVES

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

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

- Theoretical and practical skills of the instruments

THEORY **60 HOURS**

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, Difference/ Derivative spectroscopy. 10 Hrs

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

   c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

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

2. **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. 10 Hrs

3. **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. 10 Hrs

4. **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: 10 Hrs

a) Thin Layer chromatography

b) High Performance Thin Layer Chromatography

c) Ion exchange chromatography

d) Column chromatography

e) Gas chromatography

f) High Performance Liquid chromatography

g) Ultra High Performance Liquid chromatography

h) Affinity chromatography

i) Gel Chromatography

5. **a.Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: 10 Hrs

a. Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresise) Moving boundary electrophoresis f) Iso electric focusing

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

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

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

REFERENCES

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

ADVANCED ORGANIC CHEMISTRY - I
(MPC 102T)

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

THEORY **60 Hrs**

1. Basic Aspects of Organic Chemistry: 12 Hrs

1. Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications.
2. Types of reaction mechanisms and methods of determining them
3. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations.

Addition reactions

a) Nucleophilic uni- and bimolecular reactions (SN1 and SN2)

b) Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule)

c) Rearrangement reaction

2. Study of mechanism and synthetic applications of following named Reactions: 12 Hrs

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

3. 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). 12 Hrs

Protecting groups

a. Role of protection in organic synthesis

b. Protection for the hydroxyl group, including 1,2-and1,3-diols: ethers, esters, carbonates, cyclic acetals & ketals

c. Protection for the Carbonyl Group: Acetals and Ketals

d. Protection for the Carboxyl Group: amides and hydrazides, esters

e. Protection for the Amino Group and Amino acids: carbamates and amides

4. Heterocyclic Chemistry:

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. 12 Hrs

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

5. Synthon approach and retrosynthesis applications: 12 Hrs

i. Basic principles, terminologies and advantages of retrosynthesis; guid lines for dissection of molecules. Functional group interconvertion and addition (FGI and FGA)

ii. C-X disconnections; C-C disconnections – alcohols and carbonyl compounds; 1,2-, 1,3-,1,4-, 1,5-, 1,6-difunctionalized compounds

iii. Strategies for synthesis of three, four, five and six-membered ring.

REFERENCES

1. "Advanced Organic chemistry, Reaction, Mechanisms and Structure", J March, John Wiley and Sons, New York.
2. "Mechanism and Structure in Organic Chemistry", ES Gould, Hold Rinchart and Winston, 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 9 India) 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.

ADVANCED MEDICINAL CHEMISTRY
(MPC 103T)

SCOPE

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

OBJECTIVES

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

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

THEORY **60 Hrs**

1. **Drug discovery:** Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets. 12 Hrs

   Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs antagonists, artificial enzymes.

2. **Prodrug Design and Analog design:** 12 Hrs

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 consideration of prodrug design.

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 inter atomic distance.

3. **a. Medicinal chemistry aspects of the following class of drugs** 12 Hrs

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

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

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

4. Rational Design of Enzyme Inhibitors 12 Hrs

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

5. Peptidomimetics: 12 Hrs

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

REFERENCES

1. Medicinal Chemistry by Burger, Vol I –VI.
2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 12th Edition, Lppincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
3. Comprehensive Medicinal Chemistry – Corwin and Hansch.
4. Computational and structural approaches to drug design edited by Robert M Stroud & Janet. F Moore
5. Introduction to Quantitative Drug Design by Y.C. Martin.
6. Principles of Medicinal Chemistry by William Foye, 7th Edition, Ippincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, 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.

CHEMISTRY OF NATURAL PRODUCTS
(MPC 104T)

SCOPE

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

OBJECTIVES

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

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

THEORY **60 Hrs**

1. Study of Natural products as leads for new pharmaceuticals for the following class of drugs 12 Hrs

a) Drugs Affecting the Central Nervous System: Morphine Alkaloids

b) Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide

c) Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol

d) Neuromuscular Blocking Drugs: Curare alkaloids

e) Anti-malarial drugs and Analogues

f) Chemistry of macrolid antibiotics (Erythromycin, Azithromycin, Roxithromycin, and Clarithromycin) and β - Lactam antibiotics (Cephalosporins and Carbapenem)

2. a) Alkaloids: 12 Hrs

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

b) Flavonoids:

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

c) Steroids:

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

3. a) Terpenoids: 12 Hrs

Classification, isolation, isoprene rule and general methods of structural elucidation of Ter-

penoids; 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.

4. a) Recombinant DNA technology and drug discovery: 12 Hrs

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.

5. Structural Characterization of natural compounds: 12 Hrs

Structural characterization of natural compounds using IR, 1HNMR, 13CNMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit-D, Quercetin and Digitalis glycosides.

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.

PHARMACEUTICAL CHEMISTRY PRACTICAL - I
(MPC 105P)

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

SEMESTER I

ADVANCED SPECTRAL ANALYSIS
(MPC 201T)

SCOPE

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

OBJECTIVES

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

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

THEORY **60Hrs**

1. UV and IR spectroscopy:

Wood ward – Fieser rule for 1,3- butadienes, cyclic dienes and α, β-carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds. 12 Hrs

2. NMR spectroscopy: 12 Hrs

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

3. Mass Spectroscopy: 12 Hrs

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.

4. Chromatography: 12 Hrs

Principle, Instrumentation and Applications of the following :

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

5. a) Thermal methods of analysis Introduction, principle, instrumentation and application of DSC, DTA and TGA. 12 Hrs

b) Raman Spectroscopy Introduction, Principle, Instrumentation and Applications.

c) Radio immuno assay Biological standardization, bioassay, ELISA, Radioimmuno assay of digitalis and insulin.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edi-

tion, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis - Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

ADVANCED ORGANIC CHEMISTRY - II
(MPC 202T)

SCOPE

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

OBJECTIVES

Upon completion of course, the student shall able to understand

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

THEORY **60 Hrs**

1. Green Chemistry: 12 Hrs

a. Introduction, principles of green chemistry

b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis

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.

2. Chemistry of peptides 12 Hrs

a. Coupling reactions in peptide synthesis

b. Principles of solid phase peptide synthesis, t-BOC and FMOC protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides

c. Segment and sequential strategies for solution phase peptide

synthesis with any two case studies

d. Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, over- activation and side reactions of individual amino acids.

3. Photochemical Reactions: Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation. 12 Hrs

Pericyclic reactions

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

4. Catalysis: 12 Hrs

a. Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages

b. Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.

c. Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs

d. Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions

e. Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.

f. Phase transfer catalysis - theory and applications

5. Stereochemistry & Asymmetric Synthesis 12 Hrs

a. Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis-trans isomerism, E and Z notation.

b. Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.

REFERENCES

1. “Advanced Organic chemistry, Reaction, mechanisms and structure”, J March, John Wiley and sons, New York.

2. “Mechanism and structure in organic chemistry”, ES Gould, Hold Rinchart and Winston,NewYork.

3. “Organic Chemistry” Clayden, Greeves, Warren and Woihers., Oxford University Press 2001.

4. “Organic Chemistry” Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.

5. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)

6. Organic synthesis-the disconnection approach, S. Warren, Wily India

7. Principles of organic synthesis, ROCNorman and JMCoxan, Nelson thorns

8. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal, Narosa Publishers.

9. Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.

COMPUTER AIDED DRUG DESIGN
(MPC 203T)

SCOPE

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

OBJECTIVES

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

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

Theory **60 Hrs**

1. Introduction to Computer Aided Drug Design (CADD): 12 Hrs

History, different techniques and applications.

Quantitative Structure Activity Relationships:

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

2. Quantitative Structure Activity Relationships: Applications 12 Hrs

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

3D-QSAR approaches and contour map analysis.

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

3. Molecular Modeling and Docking: 12 Hrs

a) Molecular and Quantum Mechanics in drug design.

b) Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation

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

4. Molecular Properties and Drug Design: 12 Hrs

a) Prediction and analysis of ADMET properties of new molecules and its importance in drug design.

b) *De novo* drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design.

c) Homology modeling and generation of 3D-structure of protein.

5. Pharmacophore Mapping and Virtual Screening: 12 Hrs

Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping. *In Silico* Drug Design and Virtual Screening Techniques Similarity based methods and Pharmacophore based screening, structure based *In-silico* virtual screening protocols.

REFERENCES

1. Computational and structural approaches to drug discovery, Robert M Stroud and Janet. F Moore, RCS Publishers.
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 Text book of Organic Medicinal and Pharmaceutical Chemistry, Ippincott Williams & Wilkins.
9. Comprehensive Medicinal Chemistry – Corwin and Hansch, Pergamon Publishers.
10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

PHARMACEUTICAL PROCESS CHEMISTRY
(MPC 204T)

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 **60 Hrs**

1. Process chemistry: Introduction, Synthetic strategy 12 Hrs

Stages of scale up process: Bench, pilot and large scale process.

In-process control and validation of large scale process. Case studies of some scale up process of APIs.

Impurities in API, types and their sources including genotoxic impurities

2. Unit operations: 12 Hrs

a) Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.

b) Filtration: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,

c) Distillation: azeotropic and steam distillation

d) Evaporation: Types of evaporators, factors affecting evaporation.

e) Crystallization: Crystallization from aqueous, non- aqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.

3. Unit Processes - I 12 Hrs

a) Nitration: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration,

b) Halogenation: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process.

c) Oxidation: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H2O2, sodium hypochlorite, Oxygen gas, ozonolysis.

4. Unit Processes - II 12 Hrs

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.

5. Industrial Safety 12 Hrs

a) MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE)

b) Fire hazards, types of fire & fire extinguishers

c) Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001 (Environmental Management System), Effluents and its management

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 Technology, WEP East-West Press
11. Clausen, Mattson: Principle of Industrial Chemistry, Wiley Publishing Co.,
12. Lowenheim & M.K. Moran: Industrial Chemicals
13. S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II, Vikas Publishing House

14. J.K. Stille: Industrial Organic Chemistry (PH)

15. Shreve: Chemical Process, Mc Grawhill.

16. B.K.Sharma: Industrial Chemistry, Goel Publishing House

17. ICH Guidelines

18. United States Food and Drug Administration official website www.fda.gov

PHARMACEUTICAL CHEMISTRY PRACTICALS – II
(MPC 205P)

1. Synthesis of organic compounds by adapting different approaches involving (3 experiments)

a) Oxidation

b) Reduction/hydrogenation

c) Nitration

2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)
3. Assignments on regulatory requirements in API (2 experiments)
4. Comparison of absorption spectra by UV and Wood ward – 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 Pechmman 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 softwares
18. Calculation of ADMET properties of drug molecules and its analysis using softwares Pharmacophore modeling
19. 2D-QSAR based experiments
20. 3D-QSAR based experiments
21. Docking study based experiment
22. Virtual screening based experiment

PHARMACY PRACTICE
(MPP)

Programme Educational Objectives

1. To develop competent pharmacy graduates by structured teaching learning process through dedicated and devoted faculty.
2. To enable the graduates in practicing patient centered care and involve in the development of practice guidelines and evidence-based practices.
3. To develop responsible clinical pharmacy professionals to practice in collaboration with other healthcare practitioners for the purpose of improving patient care.
4. To develop skills in identifying rational, reasonable and practical solutions to drug related problems for the wellbeing of the patients.
5. To inspire the graduates for higher education, research or entrepreneurship and life long learning in the context of technological advancement.

SEMESTER I

CLINICAL PHARMACY PRACTICE (MPP 101T)

SCOPE

This course is designed to impart the basic knowledge and skills that are required to practice pharmacy including the provision of pharmaceutical care services to both healthcare professionals and patients in clinical settings.

OBJECTIVES

Upon completion of this course it is expected that students shall be able to :

- Understand the elements of pharmaceutical care and provide comprehensive patient care services
- Interpret the laboratory results to aid the clinical diagnosis of various disorders
- Provide integrated, critically analyzed medicine and poison information to enable healthcare professionals in the efficient patient management

THEORY **60 Hrs**

1. Introduction to Clinical Pharmacy: Definition, evolution and scope of clinical pharmacy, International and national scenario of clinical pharmacy practice, Pharmaceutical care 12 Hrs
Clinical Pharmacy Services: Ward round participation, Drug therapy review (Drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions)

2. Clinical Pharmacy Services: Patient medication history interview, Basic concept of medicine and poison information services, Basic concept of pharmacovigilance, Hemovigilance, Materiovigilance and AEFI, Patient medication counselling, Drug utilisation evaluation, Documentation of clinical pharmacy services, Quality assurance of clinical pharmacy services. 12 Hrs

3. Patient Data Analysis:
Patient Data & Practice Skills: Patient's case history - its structure and significances in drug therapy management, Common medical abbreviations and terminologies used in clinical practice. 12 Hrs
Communication skills: verbal and non-verbal communications, its applications in patient care services.
Lab Data Interpretation: Hematological tests, Renal function tests, Liver function tests

4. Lab Data Interpretation: Tests associated with cardiac disorders, Pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, Microbiological culture sensitivity tests 12 Hrs

5. Medicines & Poison Information Services Medicine Information Service: Definition and need for medicine information service, Medicine information resources, Systematic approach in answering medicine information queries, Preparation of verbal and written response, Establishing a drug information centre. 12 Hrs
Poison Information Service: Definition, need, organization and functions of poison information centre.

REFERENCES

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
2. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia
3. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc
4. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS-I (MPP 102T)

SCOPE

This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.

OBJECTIVES

Upon completion of this course it is expected that students shall be able to:

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence based medicine
- Prepare individualized therapeutic plans based on diagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time- course of clinical and laboratory indices of therapeutic response and adverse effect/s)

THEORY **60 Hrs**

Etiopathogenesis and pharmacotherapy of diseases associated with following systems

1. Cardiovascular system: Hypertension, Congestive cardiac failure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias. 12 Hrs

2. Respiratory system: Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases 12 Hrs

Endocrine system: Diabetes, Thyroid diseases

3. Gastrointestinal system: Peptic ulcer diseases, Reflux esophagitis, Inflammatory bowel diseases, Jaundice & hepatitis 12 Hrs

4. Gastrointestinal system: Cirrhosis, Diarrhea and Constipation, Drug-induced liver disease 12 Hrs
Hematological diseases: Anemia, Deep vein thrombosis, Drug induced hematological disorders

5. Bone and joint disorders: Rheumatoid arthritis, Osteoarthritis, Gout, Osteoporosis 12 Hrs
Dermatological Diseases: Psoriasis, Eczema and scabies, impetigo, drug induced skin disorders
Ophthalmology: Conjunctivitis, Glaucoma

REFERENCES

1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

HOSPITAL & COMMUNITY PHARMACY (MPP 103T)

SCOPE

This course is designed to impart basic knowledge and skills that are required to practice pharmacy in both hospital and community settings.

OBJECTIVES

Upon completion of this course it is expected that students shall be able to:

- Understand the organizational structure of hospital pharmacy
- Understand drug policy and drug committees
- Know about procurement & drug distribution practices
- Know the admixtures of radiopharmaceuticals
- Understand the community pharmacy management
- Know about value added services in community pharmacies

THEORY **60 Hrs**

1. Introduction to Hospitals – Definition, classification, organizational structure 12 Hrs
Hospital Pharmacy: Definition, Relationship of hospital pharmacy department with other departments, Organizational structure, legal requirements, work load statistics, Infrastructural requirements, Hospital Pharmacy Budget and Hospital Pharmacy management
Hospital Drug Policy: Pharmacy & Therapeutics Committee, Infection Control committee, Research & Ethics Committee, Management of Medicines as per NABH

2. Hospital Formulary Guidelines and its development, Developing Therapeutic guidelines, Drug procurement process, and methods of Inventory control, Methods of Drug distribution, Intravenous admixtures, Hospital Waste Management 12 Hrs

3. Education and training: Training of technical staff, training and continuing education for pharmacists, Pharmacy students, Medical staff and students, Nursing staff and students, Formal and informal meetings and lectures, Drug and therapeutics newsletter. 12 Hrs
Community Pharmacy Practice: Definition, roles & responsibilities of community pharmacists, and their relationship with other health care providers.
Community Pharmacy management: Legal requirements to start community pharmacy, site selection, lay out & design, drug display, super drug store model, accounts and audits, Good dispensing practices, Different softwares & databases used in community pharmacies. Entrepreneurship in community pharmacy.

4. Prescription – Legal requirements & interpretation, prescription related problems 12 Hrs
Responding to symptoms of minor ailments: Head ache, pyrexia, menstrual pains, food and drug allergy,
OTC medication: Rational use of over the counter medications, Medication counseling and use of patient information leaflets.
Medication adherence – Definition, factors influencing adherence
behavior, strategies to improve medication adherence Patient referrals to the doctors
ADR monitoring in community pharmacies

5. Health Promotion – Definition and health promotion activities, family planning, Health screening services, first aid, prevention of communicable and non-communicable diseases, smoking cessation, Child & mother care 12 Hrs
National Health Programs- Role of Community Pharmacist in Malaria and TB control programs
Home Medicines review program – Definition, objectives, Guidelines, method and outcomes
Research in community pharmacy Practice

REFERENCES

1. Hospital Pharmacy - Hassan WE. Lea and Febiger publication.
2. Textbook of hospital pharmacy - Allwood MC and Blackwell.
3. Avery's Drug Treatment, Adis International Limited.
4. Community Pharmacy Practice – Ramesh Adepu, BSP Publishers, Hyderabad
5. Remington Pharmaceutical Sciences.
6. Relevant review articles from recent medical and pharmaceutical literature

CLINICAL RESEARCH (MPP 104T)

SCOPE

This course aims to provide the students an opportunity to learn drug development process especially the phases of clinical trials and also the ethical issues involved in the conduct of clinical research. Also, it aims to imparts knowledge and develop skills on conceptualizing, designing, conducting and managing clinical trials.

OBJECTIVES

Upon completion of this course it is expected that students shall be able to:

- Know the new drug development process.
- Understand the regulatory and ethical requirements.
- Appreciate and conduct the clinical trials activities
- Know safety monitoring and reporting in clinical trials
- Manage the trial coordination process

THEORY **60 Hrs**

1. **Drug development process:** Introduction, various approaches to drug discovery, Investigational new drug application submission. 12 Hrs

Ethics in Biomedical Research: Ethical Issues in Biomedical Research – Principles of ethics in biomedical research, Ethical committee [institutional review board] - its constitution and functions, Challenges in implementation of ethical guidelines, ICH GCP guidelines and ICMR guidelines in conduct of Clinical trials, Drug Safety Reporting.

2. **Types and Designs used in Clinical Research:** Planning and execution of clinical trials, Various Phases of clinical trials, Bioavailability and Bioequivalence studies, Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification), Types of research designs based on Controlling Method (Experimental, Quasi experimental, and Observational methods) Time Sequences (Prospective and Retrospective), Sampling methods (Cohort study, case Control study and cross sectional study), Health outcome measures (Clinical & Physiological, Humanistic and economic) 12 Hrs

Clinical Trial Study team: Roles and responsibilities of: Investigator, Study Coordinator, Sponsor, Monitor, Contract Research Organization.

3. **Clinical trial Documents:** Guidelines to the preparation of following documents: Protocols, Investigator's Brochure, Informed Consent Form, Case report forms, Contracts and agreements, Dairy Cards . 12 Hrs

Clinical Trial Start up activities: Site Feasibility Studies, Site/Investigator selection, Pre-study visit, Investigator meeting, Clinical trial agreement execution, Ethics committee document preparation and submission

4. **Investigational Product:** Procurement and Storage of investigation product. 12 Hrs

Filing procedures: Essential documents for clinical trial, Trial Master File preparation and maintenance, Investigator Site File, Pharmacy File, Site initiation visit, Conduct, Report and Follow up Clinical Trial Monitoring and Close out: Preparation and conduct of monitoring visit: Review of source documents, CRF, ICF, IP storage, accountability and reconciliation, Study Procedure, EC communications, Safety reporting, Monitoring visit reporting and follow-up Close-Out visit: Study related documents collection, Archival requirement, Investigational Product reconciliation and destruction, Close-Out visit report.

5. Quality Assurance and Quality Control in Clinical Trials: Types of audits, Audit criteria, Audit process, Responsibilities of stakeholders in audit process, Audit follow-up and documentation, Audit resolution and Preparing for FDA inspections, Fraud and misconduct management 12 Hrs

Data Management Infrastructure and System Requirement for Data Management: Electronic data capture systems, Selection and implementation of new systems, System validation and test procedures, Coding dictionaries, Data migration and archival.

Clinical Trial Data Management: Standard Operating Procedures, Data management plan, CRF & Data base design considerations, Study set-up, Data entry, CRF tracking and corrections, Data cleaning, Managing laboratory and ADR data, Data transfer and database lock, Quality Control and Quality Assurance in CDM, Data mining and warehousing.

REFERENCES

1. Principles and practice of pharmaceutical medicine, Second edition.Authors:Lionel. D. Edward, Aadrew.J.Flether Anthony W Fos , Peter D Sloaier Publisher:Wiley;
2. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone
3. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
4. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health.
5. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good ClinicalPractice.E6; May 1996.
6. Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research, New Delhi.
7. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, John Wiley and Sons.
8. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
9. Goodman & Gilman: JG Hardman, LE Limbard, McGraw Hill Publications.
10. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACY PRACTICE PRACTICAL – I (MPP 105P)

Pharmacy Practice practical component includes experiments covering important topics of the courses Clinical Pharmacy Practice, Pharmacotherapeutics-I, Hospital & Community Pharmacy and Clinical Research.

List of Experiments (24)

1. Treatment Chart Review (one)
2. Medication History Interview (one)
3. Patient Medication Counseling (two)
4. Drug Information Query (two)
5. Poison Information Query (one)
6. Lab Data Interpretation (two)
7. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
8. ABC Analysis of a given list of medications (one)
9. Preparation of content of a medicine, with proper justification, for the inclusion in the hospital formulary (one)
10. Formulation and dispensing of a given IV admixtures (one)
11. Preparation of a patient information leaflet (two)
12. Preparation of Study Protocol (one)
13. Preparation of Informed Consent Form (one)

SEMESTER II

PRINCIPLES OF QUALITY USE OF MEDICINES (MPP 201T)

SCOPE:

This course is designed to impart basic knowledge and skills that are required to practice quality use of medicines (QUM) in different healthcare settings and also to promote quality use of medicines, in clinical practice, through evidence-based medicine approach.

OBJECTIVES:

Upon completion of this course it is expected that students shall be able to:

- Understand the principles of quality use of medicines
- Know the benefits and risks associated with use of medicines
- Understand regulatory aspects of quality use of medicines
- Identify and resolve medication related problems
- Promote quality use of medicines
- Practice evidence-based medicines

THEORY **60 Hrs**

1. Introduction to Quality use of medicines (QUM): Definition and Principles of QUM, Key partners and responsibilities of the partners, Building blocks in QMC, Evaluation process in QMC, Communication in QUM, Cost effective prescribing. 12 Hrs

2 Concepts in QUM: Evidence based medicine: Definition, concept of evidence based medicine, Approach and practice of evidence based edicine in clinical settings 12 Hrs

Essential drugs: Definition, need, concept of essential drug, National essential drug policy and list.

Rational drug use: Definition, concept and need for rational drug use, Rational drug prescribing, Role of pharmacist in rational drug use.

3 QUM in various settings: Hospital settings, Ambulatory care/Residential care, Role of health care professionals in promoting the QUM, Strategies to promote the QUM, Impact of QUM on E-health, integrative medicine and multidisciplinary care. QUM in special population: Pediatric prescribing, Geriatric prescribing, Prescribing in pregnancy and lactation, Prescribing in immune compromised and organ failure patients. 12 Hrs

4 Regulatory aspects of QUM in India: Regulation including scheduling, Regulation of complementary medicines, Regulation of OTC medicines, Professional responsibility of pharmacist, Role of industry in QUM in medicine development. 12 Hrs

5 Medication errors: Definition, categorization and causes of medication errors, Detection and prevention of medication errors, Role of pharmacist in monitoring and management of medication errors . 12 Hrs

Pharmacovigilance: Definition, aims and need for pharmacovigilance, Types, predisposing factors and mechanism of adverse drug reactions (ADRs), Detection, reporting and monitoring of ADRs, Causality assessment of ADRs, Management of ADRs, Role of pharmacist in pharmacovigilance.

REFERENCES:

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
2. Andrews EB, Moore N. Mann's Pharmacovigilance
3. Dipiro JT, Talbert RL, Yee GC. Pharmacotherapy: A Pathophysiologic Approach
4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teach it
5. Cohen MR. Medication Errors

6. Online:
•http://medicinesaustralia.com.au/files/2012/05/MA_QUM_External_Reduced.pdf
•http://curriculum.racgp.org.au/statements/quality-use-of-medicines/
•http://www.rug.nl/research/portal/files/14051541/Chapter_2.pdf
7. Relevant review articles from recent medical and pharmaceutical literature.

PHARMACOTHERAPEUTICS - II (MPP 202T)

SCOPE

This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.

OBJECTIVES

Upon completion of this course it is expected that students shall be able to:

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence based medicine
- Prepare individualized therapeutic plans based on diagnosis
- Identify the patient specific parameters relevant in initiating drug therapy and monitoring therapy (including alternatives, time- course of clinical and laboratory indices of therapeutic response and adverse effect/s)

THEORY **60 Hrs**

1. Nervous system: Epilepsy, Parkinson's disease, Stroke, Headache, Alzheimer's disease, Neuralgias and Pain pathways and Pain management. 12 Hrs

2. Psychiatric disorders: Schizophrenia, Depression, Anxiety disorders, Sleep disorders, Drug induced psychiatric disorders. 12 Hrs

Renal system: Acute renal failure, Chronic renal failure, Renal dialysis, Drug induced renal disease

3. Infectious diseases: General guidelines for the rational use of antibiotics and surgical prophylaxis, Urinary tract infections, Respiratory tract infections, Gastroenteritis, Tuberculosis, Malaria, Bacterial endocarditis, Septicemia. 12 Hrs

4. Infectious diseases: Meningitis, HIV and opportunistic infections, Rheumatic fever, Dengue fever, H1N1, Helmenthiasis, Fungal infections 12 Hrs

Gynecological disorders: Dysmenorrhea, Hormone replacement therapy.

5. Oncology: General principles of cancer chemotherapy, pharmacotherapy of breast cancer, lung cancer, head & neck cancer, hematological malignancies, Management of nausea and vomiting, Palliative care 12 Hrs

REFERENCES

1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication.
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach-Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING (MPP 203T)

SCOPE

This course is designed to enable students to understand the basics principles and applications of pharmacokinetics in designing the individualized dosage regimen, to interpret the plasma drug concentration profile in altered pharmacokinetics, drug interactions and in therapeutic drug monitoring processes to optimize the drug dosage regimen. Also, it enables students to understand the basic concepts of pharmacogenetics, pharmacometrics for modeling and simulation of pharmacokinetic data.

OBJECTIVES

Upon completion of this course it is expected that students shall be able to:

- Design the drug dosage regimen for individual patients
- Interpret and correlate the plasma drug concentrations with patients' therapeutic outcomes
- Recommend dosage adjustment for patients with renal/ hepatic impairment
- Recommend dosage adjustment for paediatrics and geriatrics
- Manage pharmacokinetic drug interactions
- Apply pharmacokinetic parameters in clinical settings
- Interpret the impact of genetic polymorphisms of individuals on pharmacokinetics and or pharmacodynamics of drugs
- Do pharmacokinetic modeling for the given data using the principles of pharmacometrics

THEORY **60 Hrs**

1. Introduction to Clinical pharmacokinetics: Compartmental and Non compartmental models, Renal and non-renal clearance, Organ extraction and models of hepatic clearance, Estimation and determinants of bioavailability, Multiple dosing, Calculation of loading and maintenance doses. 12 Hrs

Designing of dosage regimens: Determination of dose and dosing intervals, Conversion from intravenous to oral dosing, Nomograms and Tabulations in designing dosage regimen.

2. Pharmacokinetics of Drug Interaction: Pharmacokinetic drug interactions, Inhibition and Induction of Drug metabolism, Inhibition of Biliary Excretion. 12 Hrs

Pharmacogenetics: Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes, Genetic Polymorphism in Drug Transport and Drug Targets, Pharmacogenetics and Pharmacokinetic / Pharmacodynamic considerations.

Introduction to Pharmacometrics: Introduction to Bayesian Theory, Adaptive method or Dosing with feedback, Analysis of Population pharmacokinetic Data.

3. Non Linear Mixed Effects Modelling: The Structural or Base Model, Modeling Random Effects, Modeling Covariate Relationships, Mixture Model, Estimation Methods, Model Building Techniques, Covariate Screening Methods, Testing the model assumptions, Precision of the parameter estimates and confidence intervals, Model misspecification and violation of the model assumptions, Model Validation, Simulation of dosing regimens and dosing recommendations, Pharmacometrics software. 12 Hrs

4. Altered Pharmacokinetics: Drug dosing in the elderly, Drug dosing in the paediatrics, Drug dosing in the obese patients, Drug dosing in the pregnancy and lactation, Drug dosing in the renal failure and extracorporeal removal of drugs, Drug dosing in the in hepatic failure. 12 Hrs

5. Therapeutic Drug monitoring: Introduction, Individualization of drug dosage regimen (Variability – Genetic, age, weight, disease and Interacting drugs), Indications for TDM, Protocol for TDM, Pharmacokinetic/Pharmacodynamic Correlation in drug therapy. 12 Hrs

TDM of drugs used in the following conditions: Cardiovascular disease: Digoxin, Lidocaine, Amiodarone; Seizure disorders: Phenytoin, Carbamazepine, Sodium Valproate; Psychiatric conditions: Lithium, Fluoxetine, Amitriptyline; Organ transplantations: Cyclosporine; Cytotoxic Agents: Methotrexate, 5-FU, Cisplatin; Antibiotics:Vancomycin, Gentamicin, Meropenem.

REFERENCES

1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics. New York: Mc Graw Hill.
2. Peter L. Bonate. Pharmacokinetic - Pharmacodynamic Modeling and Simulation. Springer Publications.
3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E.Evans. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring. Iippincott Williams & Wilkins.
4. Steven How-Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. CRC Press, USA.
5. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press.
6. Joseph T.Dipiro, William J.Spruill, William E.Wade, Robert A.Blouin and Jane M.Pruemer Concepts in Clinical Pharmacokinetics. American Society of Health-System Pharmacists, USA.
7. Malcolm Rowland, Thomas N. Tozer .Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. Iippincott Williams & Wilkins, USA.
8. Evans, Schentag, Jusko. Applied pharmacokinetics. American Society of Health system Pharmacists, USA.
9. Michael E. Winter. Basic Clinical Pharmacokinetics. Iippincott Williams & Wilkins, USA.
10. Milo Gibaldi. Biopharmaceutics and Clinical Pharmacokinetics. Pharma Book Syndicate, USA.
11. Dhillon and Kostrzewski. Clinical pharmacokinetics. Pharmaceutical Press, London.
12. John E .Murphy. Clinical Pharmacokinetics. 5th edition. US: American Society of Health-System Pharmacist, USA.
13. Relevant review articles from recent medical and pharmaceutical literature

PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (MPP 204T)

SCOPE

This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health care regimen.

OBJECTIVES

Upon completion of this course it is expected that students shall be able to:

- Understand the various epidemiological methods and their applications
- Understand the fundamental principles of Pharmacoeconomics.
- Identify and determine relevant cost and consequences associated with pharmacy products and services.
- Perform the key Pharmacoeconomics analysis methods
- Understand the Pharmacoeconomic decision analysis methods and its applications.
- Describe current Pharmacoeconomic methods and issues.
- Understand the applications of Pharmacoeconomics to various pharmacy settings.

THEORY **60 Hrs**

1. Introduction to Pharmacoepidemiology: Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements. Concept of risk: Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio — 12 Hrs

2. Pharmacoepidemiological Methods: Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds' ratio, Meta analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology — 12 Hrs

3. Introduction to Pharmacoeconomics: Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs. Outcomes and Measurements of Pharmacoeconomics: Typesof outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost Effective Ratio, Average Cost Effective Ratio. Person Time, Willingness To Pay, Time Trade Off and Discounting. — 12 Hrs

4. Pharmacoeconomic evaluations: Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA). — 12 Hrs

5. Definition, Steps involved, Applications, Advantages and disadvantages of the following: Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, Common HRQOL measures. Definition, Steps involved, Applications of the following: Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in pharmacoeconomic analysis, Applications of Pharmacoeconomics. 12 Hrs

REFERENCES

1. Rascati K L. Essentials of Pharmacoeconomics,Woulters Kluwer Lippincott Williams & Wilkins, Philadelphia.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons, USA.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health Economic Evaluation, Oxford University Press, London.
4. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press, London.
5. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics.
6. Graker, Dennis. Pharmacoeconomics and outcomes.
7. Walley, Pharmacoeconomics.
8. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
9. Relevant review articles from recent medical and pharmaceutical literature

PHARMACY PRACTICE PRACTICAL - II (MPP 205P)

Pharmacy Practice practical component includes experiments covering important topics of the courses Principles of Quality Use of Medicines, Pharmacotherapeutics-II, ClinicalPharmacokinetics & Therapeutic Drug Monitoring and Pharmacoepidemiology and Pharmacoeconomics.

List of Experiments (24)

1. Causality assessment of adverse drug reactions (three)
2. Detection and management of medication errors (three)
3. Rational use of medicines in special population (three)
4. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
5. Calculation of Bioavailability and Bioequivalence from the given data (two)
6. Interpretation of Therapeutic Drug Monitoring reports of a given patient (three)
7. Calculation of various Pharmacoeconomic outcome analysis for the given data (two)

SEMESTER III

ANTIMICROBIAL RESISTANCE AND ROLE OF ANTIMICROBIAL STEWARDSHIP IN COMBATING AMR (MPP302C)

15 hours

Definition of AMR

Overview of resistance mechanisms

Antimicrobials based on mechanism of action, examples of bacteria with inherent resistance to different antimicrobials, mechanisms of [illegible]ance including efflux pump effect, modification of drug target, inactivation o[illegible] limiting uptake of a drug.

- AMR surveillance system
  - Types of surveillance including alert organisms tracking, enhanced routine surveillance, targeted surveys , Software for antimicrobial surveillance – WHO NET
  - Introduction to Global Antimicrobial Resistance Surveillance System
- Causes and consequences of AMR
- Situation analysis – Antibiotic use and resistance in India
- Strategies to combat AMR
  - Call for action -GAP, NAP and KARSAP, WHO guidelines on AMR, International measures and national strategies, action at community level, at hospital or health care settings, surveillance strategies, good microbiology practice, at personal or patient level, actions for pharmaceutical promotion, action against antibiotic use as growth promoter in animal husbandry, environment
- Antimicrobial Stewardship
  - Introduction to Antimicrobial Stewardship (ASP), goal, principles of optimal antimicrobial use which includes initiating empiric therapy, “antimicrobial time- out”, IV to oral switch, shortest effective duration of treatment, pharmacokinetic monitoring, core elements of an ASP program, stewardship program interventions including antimicrobial oversight, prospective audit and feedback , pre-authorization, facility specific clinical protocols, point-of- care interventions by pharmacy, prescriber led review of prescriptions, antimicrobial allergy assessments, educating prescribers, reducing the incidence of C.difficile infections, antibiogram, non-culture based diagnostic tools
  - Introduction to antifungal and anti-tubercular stewardship
  - Core elements of outpatient stewardship
  - Commitment, action for policy and practice (identification of high priority conditions, clinician interventions, leadership interventions), tracking and reporting, education and expertise
  - Stewardship practices in special settings (emergency department, outpatient dialysis units, dentist offices etc.)
  - Stewardship program metrics
    - Measuring antimicrobial use and cost savings (DDD, DOT), process measures and outcome measures
- Guidelines for appropriate antimicrobial use based on common focus of infections including UTI, pneumonia, skin and soft tissue infections, CNS infections, abdominal infections, sepsis.

Pharmacology (MPL)

Programme Educational Objectives

1. To develop competent pharmacy graduates by structured teaching learning process through dedicated and devoted faculty.
2. To prepare students for careers of constructive service to society in academia, government, industry and health related fields.
3. To orient students to conduct translational research, from conceptual design through *in vivo* testing with an eye towards clinical implementation.
4. To provide interdisciplinary research and educational opportunities to solve problems that will improve the quality of life for those suffering from health-related diseases and disorders.
5. To inspire the graduates for higher education, research or entrepreneurship and life-long learning in the context of technological advancement.

SEMESTER I

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPL 101T)

SCOPE

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

OBJECTIVES

After completion of course student is able to know about,

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

THEORY **60 Hrs**

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

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

   Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. 10 Hrs

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

2 **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. 10 Hrs

3 **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. 10 Hrs

4 **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: 10 Hrs

   a) Thin Layer chromatography
   b) High Performance Thin Layer Chromatography
   c) Ion exchange chromatography
   d) Column chromatography
   e) Gas chromatography
   f) High Performance Liquid chromatography
   g) Ultra High Performance Liquid chromatography
   h) Affinity chromatography
   i) Gel Chromatography

5 **Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:

a) Paper electrophoresis
b) Gel electrophoresis
c) Capillary electrophoresis
d) Zone electrophoresis
e) Moving boundary electrophoresis
f) Iso electric focusing

X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction. 10 Hrs

6 **Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry. **Thermal Techniques:** Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs),Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

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

10 Hrs

REFERENCES

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

ADVANCED PHARMACOLOGY - I (MPL 102T)

SCOPE

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

OBJECTIVES

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

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

THEORY **60 Hrs**

1. General Pharmacology

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

b. **Pharmacodynamics:** Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects. 12 Hrs

2a. Neurotransmission

a. General aspects and steps involved in neurotransmission.

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

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

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

2b. Systemic Pharmacology

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

Autonomic Pharmacology

Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction 12 Hrs

3 **Central nervous system :** Pharmacology General and local anesthetics Sedatives and hypnotics, drugs used to treat anxiety. Depression, psychosis, mania, epilepsy, neurodegenerative diseases. Narcotic and non-narcotic analgesics. 12 Hrs

4 **Cardiovascular Pharmacology :** Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants, anticoagulants, fibrinolytics and antiplatelet drugs 12 Hrs

5 **Autocoid Pharmacology :** The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists. 12 Hrs

REFERENCES

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman's
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists.
10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company
12. KD.Tripathi. Essentials of Medical Pharmacology.
13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14. Clinical Pharmacokinetics & Pharmacodynamics : Concepts and Applications – Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
15. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

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

SCOPE

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

OBJECTIVES

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

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

THEORY **60 Hrs**

1. **Laboratory Animals**

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

   Transgenic animals: Production, maintenance and applications Anaesthesia and euthanasia of experimental animals. Maintenance and breeding of laboratory animals.

   CPCSEA guidelines to conduct experiments on animals

   Good laboratory practice.

   Bioassay-Principle, scope and limitations and methods 12 Hrs

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

   General principles of preclinical screening.

   CNS Pharmacology: behavioral and muscle co ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System. 12 Hrs

3 **Respiratory Pharmacology:** anti-asthmatics, drugs for COPD and anti allergics.

   Reproductive Pharmacology: Aphrodisiacs and antifertility agents.

   Analgesics, antiinflammatory and antipyretic agents.

   Gastrointestinal drugs: anti ulcer, anti-emetic, anti-diarrheal and laxatives. 12 Hrs

4 **Cardiovascular Pharmacology:** antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods. 12 Hrs

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

   Iimmunomodulators, Immunosuppressants and immunostimulants

   General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin Limitations of animal experimentation and alternate animal experiments. 12 Hrs

   Extrapolation of *in vitro* data to preclinical and preclinical to humans

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. Guta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3rd Edition.
12. David R.Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.
13. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.
14. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)

CELLULAR AND MOLECULAR PHARMACOLOGY (MPL 104T)

SCOPE

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

OBJECTIVES

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

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

THEORY **60 Hrs**

1. Cell biology

Structure and functions of cell and its organelles

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

Cell cycles and its regulation.

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

Necrosis and autophagy. 12 Hrs

2 Cell signaling

Intercellular and intracellular signaling pathways.

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

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

Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway. 12 Hrs

3 Principles and applications of genomic and proteomic tools : DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, Recombinant DNA technology and gene therapy

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

Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy. 12 Hrs

4 Pharmacogenomics

Gene mapping and cloning of disease gene.

Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism

Genetic variation in drug transporters Genetic variation in G protein coupled receptors

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

Immunotherapeutics

Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice 12 Hrs

5 a. Cell culture techniques

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

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

Principles and applications of flow cytometry

b. Biosimilars 12 Hrs

REFERENCES:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al

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

PHARMACOLOGY PRACTICAL - I (MPL 105P)

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

Handling of laboratory animals.

1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Braford/Lowry's in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
16. Cell viability assays (MTT/Trypan blue/SRB).
17. DNA fragmentation assay by agarose gel electrophoresis.
18. DNA damage study by Comet assay.
19. Apoptosis determination by fluorescent imaging studies.
20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares

21. Enzyme inhibition and induction activity
22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

REFERENCES

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

SEMESTER II

ADVANCED PHARMACOLOGY - II (MPL 201T)

SCOPE

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

OBJECTIVES

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

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

THEORY **60 Hrs**

1. Endocrine Pharmacology

Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones Anti-thyroid Drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids. 12 Hrs

Drugs affecting calcium regulation

2 Chemotherapy

Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti- TB drugs. 12 Hrs

3 Chemotherapy

Drugs used in Protozoal Infections

Drugs used in the treatment of Helminthiasis

Chemotherapy of cancer

Immunopharmacology

Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD.

Immunosuppressants and Immunostimulants 12 Hrs

4 GIT Pharmacology

Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals 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 Hrs

5 Free radicals Pharmacology

Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer.

Protective activity of certain important antioxidant

Recent Advances in Treatment: Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus 12 Hrs

REFERENCES

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

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

SCOPE

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

OBJECTIVES

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

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

THEORY **60 Hrs**

1. Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice (GLP) History, concept and its importance in drug development 12 Hrs

2 Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines.

Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. 12 Hrs

Test item characterization- importance and methods in regulatory toxicology studies

3 Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II) 12 Hrs

Genotoxicity studies (Ames Test, *in vitro* and *in vivo* Micronucleus and Chromosomal aberrations studies) *In vivo* carcinogenicity studies

4 IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. 12 Hrs

Safety pharmacology studies- origin, concepts and importance of safety pharmacology.

Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies

5 Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies.

Alternative methods to animal toxicity testing. 12 Hrs

REFERENCES

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

PRINCIPLES OF DRUG DISCOVERY (MPL 203T)

SCOPE

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

OBJECTIVES

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

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

THEORY **60 Hrs**

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

   Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation. 12 Hrs

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

   Protein structure Levels of protein structure, Domains, motifs, and folds in protein structure.

   Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction 12 Hrs

3 Rational Drug Design:Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design

   Rational Drug Design Methods: Structure and Pharmacophore based approaches
   Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening 12 Hrs

4 **Molecular docking:** Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them. 12 Hrs

5 **QSAR Statistical methods**: regression analysis, partial least square analysis (PLS) and other multivariate statistical methods.

   3D-QSAR approaches like COMFA and COMSIA

   Prodrug design : Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design 12 Hrs

REFERENCES

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

CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL 204T)

SCOPE

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

OBJECTIVES

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

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

THEORY **60 Hrs**

1. **Regulatory Perspectives of Clinical Trials:** Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant- Schedule Y, ICMR Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process 12 Hrs

2 Clinical Trials: Types and Design Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team

Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management 12 Hrs

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

Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment.Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR. 12 Hrs

4 Basic aspects, terminologies and establishment of pharmacovigilance

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

5 Methods, ADR reporting and tools used in Pharmacovigilance 12 Hrs
International classification of diseases, International Non- proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

6 Pharmacoepidemiology, pharmacoeconomics, safety pharmacology 12 Hrs

REFERENCES

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

PHARMACOLOGY PRACTICAL - II (MPL 205P)

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine 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 pA2 values of various antagonists using suitable isolatedtissue preparations.
8. To study the effects of various drugs on isolated heart preparations

9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial.(3 Nos.)
17. Design of ADR monitoring protocol.
18. In-silico docking studies. (2 Nos.)
19. In-silico pharmacophore based screening.
20. In-silico QSAR studies.
21. ADR reporting

REFERENCES

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

SEMESTER III

MRM 301T - Research Methodology & Biostatistics

UNIT – I

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

UNIT – II

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

UNIT – III

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

UNIT – IV

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

UNIT – V

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

ADDITIONAL GUIDELINES FOR M.PHARM

The M.Pharm programmes follow the syllabus and course regulations 2014 notified by Pharmacy Council of India. The following shall serve as additional guidelines for M.Pharm of Amrita Vishwa Vidyapeetham.

1. Modern Pharmaceutical Analytical Techniques

The course on Modern Pharmaceutical Analytical Techniques in the 1st sem of M.Pharm for different specializations of M.Pharm have different course codes and there is slight difference in course contents too as per PCI syllabus. Hence, it shall be considered as different courses for evaluation and there shall be different question paper for each specialization. All the common topics shall be handled as combined classes for the different specializations.

2. Practical Examination

As per the PCI regulations, the duration of end semester practical exam is 6 hours, which shall be considered as a full day exam of maximum duration of 7 hours. In both the 1st and 2nd semesters there is only one Practical exam which includes experiments from different courses of that semester. The end semester practical exam shall include all the experiments mentioned under the Practical syllabus for that semester and a student shall be prepared to perform any of these experiments.

3. Seminar/Assignment

As per the PCI regulations, the number of hours allotted to seminar/assignment in the 1st and 2nd semester is 7 hours each. However, each semester has 4 theory courses and so 8 hours for seminar/assignment in the time-table (2 hours for each course) will be noted.

The marks allotted for Seminar/Assignment is 100 per semester. As there are 4 theory courses in each semester (1st and 2nd) each course shall carry 25 marks for seminar/assignment.

The Course codes for Seminar/assignment in the 1st & 2nd sem of various specializations of M. Pharm are as follows.

Specialization	Course code for Seminar/assignment	
	1st Sem	2nd Sem
Pharmaceutics	MPH 106S	MPH 206S
Pharm.Chemistry	MPC 106S	MPC 206S
Pharmacology	MPL 106S	MPL 206S
Pharmacy Practice	MPP 106S	MPP 206S

Course codes for 3rd and 4th semesters

As per PCI regulations 2014, the course "Research Methodology and Biostatistics" in 3rd semester is common for all specializations and hence has the same course code (MRM310T). The course code for the other courses in the third semester for the various specializations shall be as follows.

M.Pharm III Semester Scheme

Course code for various specializations				
Name of the course	Pharmaceutics	Pharmaceutical Chemistry	Pharmacology	Pharmacy Practice
Journal Club	MPH302J	MPC302J	MPL302J	MPP302J
Discussion/Presentation (Proposal Presentation)	MPH303D	MPC303D	MPL303D	MPP303D
Research Work	MPH304R	MPC304R	MPL304R	MPP304R

M.Pharm IV Semester Scheme

Course code for various specializations				
Name of the course	Pharmaceutics	Pharmaceutical Chemistry	Pharmacology	Pharmacy Practice
Journal Club	MPH401J	MPC401J	MPL401J	MPP401J
Research Work	MPH402R	MPC402R	MPL402R	MPP402R
Discussion/ Final Presentation	MPH403D	MPC403D	MPL403D	MPP 403 D

Guidelines for awarding credit points for co-curricular activities

As per the requirements of Amrita Vishwa Vidyapeetham, all M. Pharm students are required to publish a paper in a Scopus indexed journal in order to be eligible for the award of the degree. The award of the credit points for co-curricular activities shall be done at the end of the 4th Semester based on the details and documentary evidences submitted by the students and this shall appear as " Additional credits earned for co curricular activities "in the final marklist or transcript.

A per PCI guidelines there shall be minimum of 2 credits and maximum of 7 credits earned from cocurricular activities (attending conferences/workshops etc).

6. Scheme for internal assessment and end semester examinations of Sem III &IV

As per PCI regulations the mark distribution for 3rd & 4th Semester of M.Pharm is as follows :

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exam		Total	Marks	Duration	
			Marks	Duration				
SEMESTER III								
MRM30 IT	Research Methodology and Biostastics*	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 Colloquim	-	-	-	-	400	1 HR	400
							Total	500

"The 400 marks for Research Work and Colloquium (Semester IV)" shall have the following split up.

1.	Evaluation by Guide	100 marks
2.	Dissertation Book	200 marks
3.	Evaluation of Presentation	100 marks
	Total for Research Work and Colloquium	**400 marks**

Evaluation of Dissertation Book	
Objective (s) of the work done	25 marks
Methodology adopted	75 marks
Results and Discussion	75 marks
Conclusions and Outcomes	25 marks
Total	**200 marks**

Evaluation of Presentation	
Presentation & Communication skills	50 marks
Question and answer skills	50 marks
Total	**100 marks**

The 75 marks assigned for Discussion/Presentation (Proposal Presentation) shall be allotted by the Internal examiner.

7. M.Pharm Thesis submission & evaluation

The M.Pharm project report in the form of thesis shall be submitted as per guidelines.

- Students shall submit one hard copy of the thesis in soft binding on or before the last date notified in the academic calendar.
- Soft bound copy of thesis can be sent to the external examiner before thesis evaluation date
- The page "Evaluated & Approved" can be submitted on the day of thesis evaluation so that it can be signed by the committee
- The final thesis can be submitted after one week of evaluation incorporating the corrections suggested by the panel.

8. Improvement of internal assessments

A student who fails in university exam in the 1st attempt can apply for improvement sessional exam by submitting the duly filled application form when notified by the Principal.

9. Condonation under exceptional cases:

If the attendance of student falls short of 80% in any course, due to continuous absence caused by accident, prolonged illness, or unforeseen circumstances, such case may be considered by the Principal for condonation of absence based on the request of the student supported by recommendation of the respective faculty advisor. However in such cases, the student must have duly applied for leave in time. **The overall attendance of a student in such a case shall not fall below 70%.** Condonation will be considered only in the case of those students who have proved themselves to be otherwise regular, by attending at least 80% of the classes during the semester, excluding the period of long leave. At least 70% physical presence is mandatory in every course even in such exceptional cases and this provision can be exercised by a student, only once in the programme.

Condonation cannot be claimed as a matter of right. It shall be granted at the discretion of the authorities, based on the genuineness and validity of the reasons cited for the absence. A student is not eligible for condonation, if he had any unauthorized absence during the year.

10. Revaluation

A failed student shall have the right to apply for revaluation of the theory paper by filling the application form along with the required fees within the stipulated time after the publication of the result.

11. Question paper pattern for sessional and end semester exams

There shall be no choice of questions for sessional as well as semester examination of M.Pharm

Sessional (30 marks)

Objective type	5 x 2 marks = 10 marks
Long answer type	1 x 10 marks = 10 marks
Short answer type	2 x 5 marks = 10 marks

End Semester Examination (75 marks)

Objective type	10 x 2 marks = 20 marks
Long answer type	2 x 10 marks = 20 marks
Short answer type	7 x 5 marks = 35 marks

12. Eligibility of Examiners & Q.P Setters

i) Internal Examiners:

Teachers of the Amrita School of Pharmacy who are handling the respective courses and are having a minimum of 5 years of teaching experience are eligible to be appointed as internal examiners.

ii) External Examiners:

Teachers having a minimum of 10 years experience (or having Ph D with 5 years experience)in PCI/AICTE approved Pharmacy institutions are eligible to be appointed as external examiners for 1st and 2nd Semester theory and practical examinations. Teachers having PhD with 10 years of experience in pharmacy/research institutions are eligible to be appointed as external examiners in the panel for thesis evaluation.

iii) Q.P.Setter

Faculty who are eligible to be internal & external examiners as per the above criteria are eligible to be Q.P setters too.

13. Every M.Pharm student is required to publish a Scopus indexed paper as mandated by Amrita Vishwa Vidyapeetham in order to be eligible for award of degree.

14. The declaration of class mentioned as point 20 (page no : 24) under PCI regulations require further clarifications from PCI and shall be modified accordingly.