GANDHI INSTITUTE OF TECHNOLOGY AND MANAGEMENT (GITAM)

(Deemed to be University, Estd. u/s 3 of the UGC Act 1956)

VISAKHAPATNAM * HYDERABAD *BENGALURU

Accredited by NAAC with 'A+' Grade

GITAM

(DEEMED TO BE UNIVERSITY)

(Estd. u/s 3 of the UGC Act, 1956)

VISAKHAPATNAM ✺ HYDERABAD ✺ BENGALURU

REGULATIONS & SYLLABUS

Master of Pharmacy

As per the PCI Norm

(w.e.f. 2017-18 admitted batch)

Website: www.gitam.edu

MASTER OF PHARMACY (M. Pharm.)
REGULATIONS as per PCI norms
(w.e.f. 2017-2018 admitted batch)

1.0 ADMISSIONS

1.1 Admissions into M. Pharmacy programme of GITAM University are governed by GITAM University admission regulations.

2.0 MINIMUM QUALIFICATION FOR ADMISSION

A Pass in the following examinations

2.1 B. Pharm. Degree examination of an Indian University established by law in India from an institution approved by Pharmacy Council of India (PCI) and has scored not less than 50 % of the maximum marks (aggregate of 4 years of B. Pharm.)

2.2 Every student, selected for admission to post graduate pharmacy programme 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.

2.3 Admissions into M. Pharm. will be based on All India Entrance Test (GAT - PGP) conducted by GITAM University and the rule of reservation is followed wherever applicable.

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 PROGRAMME

The programme of study for M. Pharm. shall extend over a period of four semesters (two academic years).

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 November/December to April/May 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. PROGRAMME/COURSE CREDIT STRUCTURE

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

7.1. Credit assignment

7.1.1. Theory and Laboratory courses

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

7.2. Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is **95.** These credits are divided into theory courses, practical, seminars, assignments, research work, discussions with the supervisor and journal club over the duration of four semesters. The credits are distributed semester-wise as shown in Table 8. 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. programme are given in Table 1.

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

S. No	Specialization	Code
1	Pharmaceutics	MPH
2	Pharmaceutical Chemistry	MPC
3	Pharmaceutical Analysis	MPA
4	Pharmacology	MPL

The course of study for M. Pharm. specializations shall include semester wise theory & practical as given in Table – 2 to 6. 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 6.

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPH 101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH 102T	Drug Delivery Systems	4	4	4	100
MPH 103T	Modern Pharmaceutics	4	4	4	100
MPH 104T	Regulatory Affairs	4	4	4	100
MPH 105P	Pharmaceutics Practical – I	12	6	12	150
MPH 106P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
MPH 201T	Molecular Pharmaceutics (Nano Technology and Targeted DDS)	4	4	4	100
MPH 202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH 203T	Computer Aided Drug Delivery System	4	4	4	100
MPH 204T	Cosmetic and Cosmeceuticals	4	4	4	100
MPH 205P	Pharmaceutics Practical – II	12	6	12	150
MPH 206P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPC 101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPC 102T	Advanced Organic Chemistry – I	4	4	4	100
MPC 103T	Advanced Medicinal Chemistry	4	4	4	100
MPC 104T	Chemistry of Natural Products	4	4	4	100
MPC 105P	Pharmaceutical Chemistry Practical – I	12	6	12	150
MPC 106P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
MPC 201T	Advanced Spectral Analysis	4	4	4	100
MPC 202T	Advanced Organic Chemistry – II	4	4	4	100
MPC 203T	Computer Aided Drug Design	4	4	4	100
MPC 204T	Pharmaceutical Process Chemistry	4	4	4	100
MPC 205P	Pharmaceutical Chemistry Practical – II	12	6	12	150
MPC 206P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

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

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPA 101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPA 102T	Advanced Pharmaceutical Analysis	4	4	4	100
MPA 103T	Pharmaceutical Validation	4	4	4	100
MPA 104T	Food Analysis	4	4	4	100
MPA 105P	Pharmaceutical Analysis Practical – I	12	6	12	150
MPA 106P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
MPA 201T	Advanced Instrumental Analysis	4	4	4	100
MPA 202T	Modern Bio-Analytical Techniques	4	4	4	100
MPA 203T	Quality Control and Quality Assurance	4	4	4	100
MPA 204T	Herbal and Cosmetic Analysis	4	4	4	100
MPA 205P	Pharmaceutical Analysis Practical – II	12	6	12	150
MPA 206P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Table -5: Course of study for M. Pharm. (Pharmacology)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPL 101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPL 102T	Advanced Pharmacology – I	4	4	4	100
MPL 103T	Pharmacological and Toxicological Screening Methods –I	4	4	4	100
MPL 104T	Cellular and Molecular Pharmacology	4	4	4	100
MPL 105P	Pharmacological Practical – I	12	6	12	150
MPL 106P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
MPL 201T	Advanced Pharmacology – II	4	4	4	100
MPL 202T	Pharmacological and Toxicological Screening Methods – II	4	4	4	100
MPL 203T	Principles of Drug Discovery	4	4	4	100
MPL 204T	Clinical Research and Pharmacovigilance	4	4	4	100
MPL 205P	Pharmacological Practical – II	12	6	12	150
MPL 206P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

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

Course Code	Course	Credit Hours	Credit points
MRM 301T	Research Methodology and Biostatistics*****	4	4
MPR 301T	Journal club	2	2
MPR 302T	Discussion/Presentation (Proposal presentation)	2	2
MPR 303P	Research Work (Proposed project work, Literature survey, Plan of work, Methodology)	28	14
Total		36	22

* Non University Exam

Table – 7: Course of study for M. Pharm. IV Semester (Common for All Specializations)

Course Code	Course	Credit Hours	Credit points
MPR 401T	Discussion/ Final Presentation (Presentation of work, communication skills, question and answers)	3	3
MPR 402P	Research work and colloquium (Objective(s) of the work done, Methodology adopted, Results & Discussions, Conclusions & Outcomes)	36	18
Total		39	21

Table – 8: Semester wise credits distribution

Semester	Credit points
I	26
II	26
III	22
IV	21
Total Credit Points	**95**

10. PROGRAMME COMMITTEE

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

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

3. Duties of the Programme Committee:

i. Periodically reviewing the progress of the classes.

ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.

iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.

iv. Communicating its recommendation to the Head of the institution on academic matters.

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

11. EXAMINATIONS/ASSESSMENTS

The schemes for internal assessment and end semester examinations are given in Table – 9 to 13.

11.1. **End semester examinations**

The End Semester Examinations for each theory and practical course through semesters I to IV shall be conducted by the respective University except for the subject with asterix symbol (*) in table 6 for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the University.

Table – 9: Schemes for internal assessments and end semester (Pharmaceutics – MPH)

Course code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MPH 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hr	100
MPH 102T	Drug Delivery Systems	10	15	1 Hr	25	75	3 Hr	100
MPH 103T	Modern Pharmaceutics	10	15	1 Hr	25	75	3 Hr	100
MPH 104T	Regulatory Affairs	10	15	1 Hr	25	75	3 Hr	100
MPH 105P	Pharmaceutics Practical – I	20	30	6 Hr	50	100	6 Hr	150
MPH 106P	Seminar/Assignment	-	-	-	-	100	-	100
Total								650
Semester II								
MPH 201T	Molecular Pharmaceutics (Nano Technology and Targeted DDS)	10	15	1 Hr	25	75	3 Hr	100
MPH 202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1 Hr	25	75	3 Hr	100
MPH 203T	Computer Aided Drug Delivery System	10	15	1 Hr	25	75	3 Hr	100
MPH 204T	Cosmetic and Cosmeceuticals	10	15	1 Hr	25	75	3 Hr	100
MPH 205P	Pharmaceutics Practical – II	20	30	6 Hr	50	100	6 Hr	150
MPH 206P	Seminar/Assignment	-	-	-	-	100	-	100
Total								650

Table – 10: Schemes for internal assessments and end semester (Pharmaceutical Chemistry – MPC)

Course code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MPC 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hr	100
MPC 102T	Advanced Organic Chemistry - I	10	15	1 Hr	25	75	3 Hr	100
MPC 103T	Advanced Medicinal Chemistry	10	15	1 Hr	25	75	3 Hr	100
MPC 104T	Chemistry of Natural Products	10	15	1 Hr	25	75	3 Hr	100
MPC 105P	Pharmaceutical Chemistry Practical –	20	30	6 Hr	50	100	6 Hr	150
MPC 106P	Seminar/Assignment	-	-	-	-	100	-	100
Total								650
Semester II								
MPC 201T	Advanced Spectral Analysis	10	15	1 Hr	25	75	3 Hr	100
MPC 202T	Advanced Organic Chemistry – II	10	15	1 Hr	25	75	3 Hr	100
MPC 203T	Computer Aided Drug Design	10	15	1 Hr	25	75	3 Hr	100
MPC 204T	Pharmaceutical Process Chemistry	10	15	1 Hr	25	75	3 Hr	100
MPC 205P	Pharmaceutical Chemistry Practical – II	20	30	6 Hr	50	100	6 Hr	150
MPC 206P	Seminar/Assignment	-	-	-	-	100	-	100
Total								650

Table – 11: Schemes for internal assessments and end semester (Pharmaceutical Analysis – MPA)

Course code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MPA 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hr	100
MPA 102T	Advanced Pharmaceutical Analysis	10	15	1 Hr	25	75	3 Hr	100
MPA 103T	Pharmaceutical Validation	10	15	1 Hr	25	75	3 Hr	100
MPA 104T	Food Analysis	10	15	1 Hr	25	75	3 Hr	100
MPA 105P	Pharmaceutical Analysis Practical – I	20	30	6 Hr	50	100	6 Hr	150
MPA 106P	Seminar/Assignment	-	-	-	-	100	-	100
Total								650
Semester II								
MPA 201T	Advanced Instrumental Analysis	10	15	1 Hr	25	75	3 Hr	100
MPA 202T	Modern Bio-Analytical Techniques	10	15	1 Hr	25	75	3 Hr	100
MPA 203T	Quality Control and Quality Assurance	10	15	1 Hr	25	75	3 Hr	100
MPA 204T	Herbal and Cosmetic Analysis	10	15	1 Hr	25	75	3 Hr	100
MPA 205P	Pharmaceutical Analysis Practical – II	20	30	6 Hr	50	100	6 Hr	150
MPA 206P	Seminar/Assignment	-	-	-	-	100	-	100
Total								650

Table – 12: Schemes for internal assessments and end semester (Pharmacology – MPL)

Course code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MPL 101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hr	100
MPL 102T	Advanced Pharmacology – I	10	15	1 Hr	25	75	3 Hr	100
MPL 103T	Pharmacological and Toxicological Screening Methods –I	10	15	1 Hr	25	75	3 Hr	100
MPL 104T	Cellular and Molecular Pharmacology	10	15	1 Hr	25	75	3 Hr	100
MPL 105P	Pharmacological Practical – I	20	30	6 Hr	50	100	6 Hr	150
MPL 106P	Seminar/Assignment	-	-	-	-	100	-	100
Total								650
Semester II								
MPL 201T	Advanced Pharmacology – II	10	15	1 Hr	25	75	3 Hr	100
MPL 202T	Pharmacological and Toxicological Screening Methods – II	10	15	1 Hr	25	75	3 Hr	100
MPL 203T	Principles of Drug Discovery	10	15	1 Hr	25	75	3 Hr	100
MPL 204T	Clinical Research and Pharmacovigilance	10	15	1 Hr	25	75	3 Hr	100
MPL 205P	Pharmacological Practical – II	20	30	6 Hr	50	100	6 Hr	150
MPL 206P	Seminar/Assignment	-	-	-	-	100	-	100
Total								650

Table – 13: Schemes for internal assessments and end semester examinations

(Semester III & IV)

Course code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester III								
MRM 301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hr	100
MPR 301T	Journal club	-	-	-	100	-	-	100
MPR 302T	Discussion/Presentation (Proposal presentation)	-	-	-	100	-	-	100
MPR 303P	Research Work (proposed project work, Literature survey, Plan of work, Methodology)	-	-	-	-	100	1 Hr	100
Total								400
Semester IV								
MPR 401T	Discussion/ Presentation (Presentation of work, communication skills, question and answers)	-	-	-	100	-	-	100
MPR 402P	Research Work and colloquium (Objective(s) of the work done, Methodology adopted, Results & Discussions, Conclusions & Outcomes)	-	-	-	-	100	1 Hr	100
Total								200

* Non University Examination

11.2. **Internal assessment: Continuous mode**

The marks allocated for Continuous mode of Internal Assessment shall be awarded as follows.

Table – 14: Scheme for awarding internal assessment: Continuous mode

Criteria	Maximum Marks
Theory	
Attendance (Refer Table – 15)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – 15)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

Table – 15: Guidelines for allotment of marks for attendance

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

11.2 **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 tables 9 – 13. 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 16. The exact dates of examinations shall be notified from time to time.

Table – 16: Tentative schedule of end semester examinations

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

16. ALLOWED TO KEEP TERMS (ATKT):

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

A student shall be eligible to carry forward all the courses of I and II semesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed. A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

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

17. GRADING OF PERFORMANCES

17.1. Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – 17.

Table – 17: Letter grades and grade points equivalent to Percentage of marks and performances

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

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

18. THE SEMESTER GRADE POINT AVERAGE (SGPA)

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

$$\mathbf{SGPA} = \frac{\mathbf{C_1 G_1 + C_2 G_2 + C_3 G_3 + C_4 G_4}}{\mathbf{C_1 + C_2 + C_3 + C_4}}$$

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 AB grade in course 4, the SGPA shall then be computed as:

$$\mathbf{SGPA} = \frac{\mathbf{C_1 G_1 + C_2 G_2 + C_3 G_3 + C_4 \times ZERO}}{\mathbf{C_1 + C_2 + C_3 + C_4}}$$

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:

$$\mathbf{CGPA} = \frac{\mathbf{C_1 S_1 + C_2 S_2 + C_3 S_3 + C_4 S_4}}{\mathbf{C_1 + C_2 + C_3 + C_4}}$$

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

20. DECLARATION OF CLASS

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

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

21. PROJECT WORK

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

The internal and external examiner appointed by the University shall evaluate the project at the time of the practical examinations of other semester(s).

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. programme shall not be eligible for award of ranks. Moreover, the candidates should have completed the M. Pharm. programme 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 PROGRAMME OF STUDY

The duration for the completion of the programme shall be fixed as double the actual duration of the programme 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 programme after break of study has to get the approval from the University by paying a condonation fee.

SEMESTER – I

PHARMACEUTICS (MPH)

MPH 101T. MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

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

Objectives: After completion of course student is able to know,

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

UNIT – I **12 Hrs**

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.
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. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analyzed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

UNIT – II **12 Hrs**

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

UNIT – III **12 Hrs**

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.

UNIT – IV **12 Hrs**

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

a. Thin Layer chromatography
b. High Performance Thin Layer Chromatography
c. Ion exchange chromatography

d. Column chromatography
e. Gas chromatography
f. High Performance Liquid chromatography
g. Ultra High Performance Liquid chromatography
h. Affinity chromatography
i. Gel Chromatography

UNIT – V **12 Hrs**

a. Principle, instrumentation and applications of Gel electrophoresis and Moving boundary electrophoresis

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

c. Thermal Techniques:

Differential Scanning Calorimetry (DSC): Principle, thermal transitions and instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

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

Thermogravimetric Analysis (TGA): Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

References

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – A. H. Beckett and J. B. 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 edition, P. S. Kalsi, Wiley Eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, K. A. Connors, 3rd edition, John Wiley & Sons, 1982.

MPH 102T. DRUG DELIVERY SYSTEMS

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

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.

UNIT – I **12 Hrs**

SR/CR formulation: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. 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.

UNIT – II **12 Hrs**

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.

Polymers: Introduction, definition, classification, properties and application

UNIT – III **12 Hrs**

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.

UNIT – IV **12 Hrs**

Occular Drug Delivery Systems: Barriers of drug permeation,

Methods to overcome barriers.

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

UNIT – V **12 Hrs**

Protein and Peptide Delivery: Barriers for protein delivery.

Formulation and Evaluation of delivery systems of proteins and other macromolecules.

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

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 Wiley Interscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4. N. K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, 1st edition 1997 (reprint in 2001).
5. S. P. Vyas and R. K. Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, 1st 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

MPH 103T. MODERN PHARMACEUTICS

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

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.

UNIT – I **12 Hrs**

Preformation Concepts – Drug Excipient interactions - different methods, Kinetics of stability, stability testing.

Dissolution: Dissolution mechanisms, kinetic models for drug release - Zero order, First order, Hixson Crowell's, Higuchi, Peppas, Various compendial dissolution apparatus, Dissolution profiles comparison- difference factor (f_1), similarity factor (f_2).

UNIT – II **12 Hrs**

Theories of dispersion and pharmaceutical dispersion (Emulsion and Suspension, SMEDDS) preparation and stability.

Large and small volume parenterals – physiological and formulation consideration, Manufacturing and evaluation.

UNIT – III **12 Hrs**

Compression and Consolidation: Physics of tablet compression, Consolidation, effect of friction, Force distribution, Force – volume distribution, Heckel plots, Decompression, Energy involved in compression

UNIT – IV **12 Hrs**

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.

UNIT – V **12 Hrs**

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.

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.

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, 2nd 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.

MPH 104T. REGULATORY AFFAIRS

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

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
- Pharmacovigilance and process of monitoring in clinical trials.

UNIT – I **12 Hrs**

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 FEDERALREGULATION), 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.

UNIT – II **12 Hrs**

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

UNIT – III **12 Hrs**

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.

UNIT – IV **12 Hrs**

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

UNIT – V **12 Hrs**

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.

References

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, 2nd 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

MPH 105P. PHARMACEUTICS PRACTICALS – I

Hours per week: 12 End Examination: 100 Marks
Credit: 6 Midsem: 50 Marks

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

MPH 201T. MOLECULAR PHARMACEUTICS

(NANO TECHNOLOGY & TARGETED DDS) (NTDS)

Hours per week: 4L End Examination: 75 Marks
Credit: 4 Midsem: 25 Marks

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.

UNIT – I **12 Hrs**

Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.

UNIT – II **12 Hrs**

Targeting Methods: Introduction, preparation and evaluation.
Nano Particles & Liposomes: Types, preparation and evaluation.

UNIT – III **12 Hrs**

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

UNIT – IV **12 Hrs**

Pulmonary Drug Delivery Systems: Aerosols, propellents, container types, preparation and evaluation

Intra Nasal Route Delivery systems; Types, preparation and evaluation.

UNIT –V **12 Hrs**

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.

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, 1st edition 2002.
3. N. K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, 1st edition 1997 (reprint in 2001).

MPH 202T. ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

Hours per week: 4L End Examination: 75 Marks

Credit: 4 Midsem: 25 Marks

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 biopharmaceutical studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

UNIT – I **12 Hrs**

Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formulation and physicochemical factors: 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.

UNIT – II **12 Hrs**

Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.

UNIT – III **12 Hrs**

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 p450-based drug interactions, drug interactions linked to transporters.

UNIT – IV **12 Hrs**

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, 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.

UNIT – V **12 Hrs**

Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.

References

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

MPH 203T. COMPUTER AIDED DRUG DEVELOPMENT

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

Scope: This course is designed to impart knowledge and skills necessary for computer Applications inpharmaceutical 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)

UNIT – I **12 Hrs**

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.

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

UNIT – II **12 Hrs**

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.

UNIT – III **12 Hrs**

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.

UNIT – IV **12 Hrs**

a.Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro- in vivo correlation, Biowaiver considerations.

b.Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.

c.Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems

UNIT – V **12 Hrs**

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

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.

MPH 204T. COSMETICS AND COSMECEUTICALS

Hours per week: 4L | End Examination: 75 Marks
Credit: 4 | Midsem: 25 Marks

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

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

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

UNIT – I **12 Hrs**

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.

UNIT – II **12 Hrs**

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.

UNIT – III **12 Hrs**

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 syndet bars.

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

Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

UNIT – IV **12 Hrs**

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

UNIT – V **12 Hrs**

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.

References

1. Harry's Cosmeticology. 8th edition.
2. Poucher'sperfume cosmetics and soaps, 10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, P. P. 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.

MPH 205P. PHARMACEUTICS PRACTICALS – II

Hours per week: 12 End Examination: 100 Marks
Credit: 6 Midsem: 50 Marks

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 Winnoline® software.
11. In vitro cell studies for permeability and metabolism
12. DoE Using Design Expert® Software
13. Formulation data analysis Using Design Expert® Software
14. Quality-by-Design in Pharmaceutical Development
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Computational Modeling of Drug Disposition
17. To develop Clinical Data Collection manual
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams.
20. Development and evaluation of Shampoo and Toothpaste base.
21. To incorporate herbal and chemical actives to develop products.
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff.

SEMESTER – I

PHARMACEUTICAL CHEMISTRY (MPC)

MPC 101T. MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Hours per week: 4L | End Examination: 75 Marks
Credit: 4 | Midsem: 25 Marks

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

Objectives: After completion of course student is able to know,

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

UNIT – I **12 Hrs**

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.
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. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analyzed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

UNIT – II **12 Hrs**

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

UNIT – III **12 Hrs**

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.

UNIT – IV **12 Hrs**

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

a. Thin Layer chromatography
b. High Performance Thin Layer Chromatography
c. Ion exchange chromatography

d. Column chromatography
e. Gas chromatography
f. High Performance Liquid chromatography
g. Ultra High Performance Liquid chromatography
h. Affinity chromatography
i. Gel Chromatography

UNIT – V **12 Hrs**

a. Principle, instrumentation and applications of Gel electrophoresis and Moving boundary electrophoresis

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

c. Thermal Techniques:

Differential Scanning Calorimetry (DSC): Principle, thermal transitions and instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

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

Thermogravimetric Analysis (TGA): Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

References

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – A. H. Beckett and J. B. 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 edition, P. S. Kalsi, Wiley Eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, K. A. Connors, 3rd edition, John Wiley & Sons, 1982.

MPC 102T. ADVANCED ORGANIC CHEMISTRY – I

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

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

UNIT – I **12 Hrs**

Basic Aspects of Organic Chemistry:

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

1. Nucleophilic uni- and bimolecular reactions (SN_1 and SN_2)
2. Elimination reactions (E_1 & E_2; Hoffman & Saytzeff's rule)
3. Rearrangement reaction

UNIT – II **12 Hrs**

Study of mechanism and synthetic applications of following named Reactions: 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

UNIT – III **12 Hrs**

1. 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).

2. Protecting groups

a. Role of protection in organic synthesis
b. Protection for the hydroxyl group, including 1, 2- and 1, 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

UNIT – IV **12 Hrs**

Heterocyclic Chemistry:

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

Synthesis of few representative drugs containing these heterocyclic 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.

UNIT – V **12 Hrs**

Synthon approach and retrosynthesis applications

(i) Basic principles, terminologies and advantages of retrosynthesis; guidelines 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 9India) Pvt. Ltd.,.
5. A guide to mechanisms in Organic Chemistry, Peter Skyes (Orient Longman, New Delhi).
6. Reactive Intermediates in Organic Chemistry, Tandom and Gowel, Oxford & IBH Publishers.
7. Combinational Chemistry – Synthesis and applications – Stephen R Wilson & Anthony W Czarnik, Wiley – Blackwell.
8. Carey, Organic Chemistry, 5th edition (Viva Books Pvt. Ltd.)
9. Organic Synthesis - The Disconnection Approach, S. Warren, Wily India
10. Principles of Organic Synthesis, ROC Norman and JM Coxan, Nelson Thorns
11. Organic Synthesis - Special Techniques. VK Ahluwalia and R Agarwal, Narosa Publishers.
12. Organic Reaction Mechanisms 4th edition, VK Ahluwalia and RK Parashar, Narosa Publishers.

MPC 103T. ADVANCED MEDICINAL CHEMISTRY

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

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

UNIT – I **12 Hrs**

Drug discovery: Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets.

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

UNIT – II **12 Hrs**

Prodrug Design and Analog design:

(a) Prodrug design: Basic concept, Carrier linked prodrugs/Bioprecursors, Prodrugs of functional group, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.

(b) Combating drug resistance: Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy,

(**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.

UNIT – III **12 Hrs**

Medicinal chemistry aspects of the following class of drugs: 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, COX-1 & COX-2 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.

UNIT – IV **12 Hrs**

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

UNIT – V **12 Hrs**

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

References

1. Medicinal Chemistry by Burger, Vol I –VI.
2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 12th edition, Lippincott 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 and 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, 2nd edition, Elsevier Publishers, New Delhi.
10. An Introduction to Medicinal Chemistry, Graham L. Patrick, 3rd edition, Oxford University Press, USA.
11. Biopharmaceutics and pharmacokinetics, D M. Brahmankar, Sunil B. Jaiswal 2nd edition, 2014, Vallabh Prakashan, New Delhi.
12. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, 1st edition, Wiley publishers.

MPC 104T. CHEMISTRY OF NATURAL PRODUCTS

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

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 of simple chemical constituents from natural source

UNIT – I **12 Hrs**

Study of Natural products as leads for new pharmaceuticals for the following class of drugs

(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)

UNIT – II **12 Hrs**

(a) Alkaloids

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

(b) Flavonoids

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

(c) Steroids

General introduction, chemistry of sterols, sapogenin and cardiac glycosides.

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

UNIT – III

(a) Terpenoids: Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono (citral, menthol, camphor), di(retinol, Phytol, taxol) and tri terpenoids (Squalene, Ginsenoside) carotinoids (β carotene).

(b) Vitamins: Chemistry and Physiological significance of Vitamin A, B1, B2, B12, C, E, Folic acid and Niacin.

UNIT – IV **12 Hrs**

(a) Recombinant DNA technology and drug discovery

rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation.

b) Active constituent of certain crude drugs used in Indigenous system Diabetic therapy – Gymnema sylvestre, Salacia reticulate, Pterocarpus marsupiam, Swertia chirata, Trigonella foenum graccum; Liver dysfunction – Phyllanthus niruri; Antitumor – Curcuma longa Linn.

UNIT – V **12 Hrs**

Structural Characterization of natural compounds

Structural characterization of natural compounds using IR, ^{1}H NMR, ^{13}C NMR 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

MPC 105P. PHARMACEUTICAL CHEMISTRY PRACTICAL – I

Hours per week: 12 End Examination: 100 Marks
Credit: 6 Midsem: 50 Marks

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 – II

MPC 201T. ADVANCED SPECTRAL ANALYSIS

Hours per week: 4L End Examination: 75 Marks
Credit: 4 Midsem: 25 Marks

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

UNIT – I **12 Hrs**

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.

UNIT – II **12 Hrs**

NMR spectroscopy:

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

UNIT – III **12 Hrs**

Mass Spectroscopy

Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds.

UNIT – IV **12 Hrs**

Chromatography:

Principle, Instrumentation and Applications of the following:

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

UNIT – V **12 Hrs**

(a) Thermal methods of analysis: Introduction, principle, instrumentation and application of DSC, DTA and TGA.

(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, 6th edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A.

Nieman, 5th edition, Eastern press, Bangalore, 1998
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. 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

MPC 202T. ADVANCED ORGANIC CHEMISTRY – II

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

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.

UNIT – I **12 Hrs**

Green Chemistry:

(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.

UNIT – II **12 Hrs**

Chemistry of peptides

(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.

UNIT – III **12 Hrs**

(a) Photochemical reactions

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

(b) Pericyclic reactions: Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatrophic rearrangement reactions with examples.

UNIT – IV **12 Hrs**

Catalysis:

(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

UNIT – V **12 Hrs**

Stereochemistry & Asymmetric Synthesis

(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", E. S 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, R. O. C. Norman and J M Coxan, Nelson thorns
8. Organic synthesis- Special techniques V. K. Ahluwalia and R Aggarwal, Narosa Publishers.
9. Organic reaction mechanisms, 4th edition, V. K. Ahluwalia and R. K. Parashar, Narosa Publishers.

MPC 203T. COMPUTER AIDED DRUG DESIGN

Hours per week: 4L | End Examination: 75 Marks
Credit: 4 | Midsem: 25 Marks

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

UNIT – I **12 Hrs**

Introduction to Computer Aided Drug Design (CADD) - 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.

UNIT – II **12 Hrs**

Quantitative Structure Activity Relationships: Applications: 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.

UNIT – III **12 Hrs**

Molecular Modeling and Docking

(a) Molecular and Quantum Mechanics in drug design.
(b) Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation**.**
(c) Molecular docking and drug receptor interactions: 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)

UNIT – IV **12 Hrs**

Molecular Properties and Drug Design

(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.

UNIT – V **12 Hrs**

(a) Pharmacophore Mapping and Virtual Screening

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

(b) 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

MPC 204T. PHARMACEUTICAL PROCESS CHEMISTRY

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

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

UNIT – I **12 Hrs**

Process chemistry

Introduction, Synthetic strategy. Stages of scale up process: Bench, pilot and large scale process. In-process control and validation of large scale process. Case studies of some scale up process of APIs. Impurities in API, types and their sources including genotoxic impurities.

UNIT – II **12 Hrs**

Unit operations

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

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

(c) Distillation: Azeotropic and steam distillation

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

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

UNIT – III **12 Hrs**

Unit Processes - I

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

(b) Halogenation: Kinetics of halogenations, types of halogenations, 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 H_2O_2, sodium hypochlorite, Oxygen gas, ozonolysis.

UNIT – IV **12 Hrs**

Unit Processes - II

(a) **Reduction**: Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.

(b) **Fermentation**: Aerobic and anaerobic fermentation. Production of

i. Antibiotics; Penicillin and Streptomycin,
ii. Vitamins: B2 and B12
iii. Statins: Lovastatin, Simvastatin

(c) Reaction progress kinetic analysis

i. Streamlining reaction steps, route selection,
ii. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.

UNIT – V **12 Hrs**

Industrial Safety

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

(b) Fire hazards, types of fire & fire extinguishers

(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

MPC 205P. PHARMACEUTICAL CHEMISTRY PRACTICALS – II

Hours per week: 12 End Examination: 100 Marks
Credit: 6 Midsem: 50 Marks

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. $NaBH_4$ reduction of vanillin to vanillyl alcohol
14. Preparation of umbelliferone by Pechhman reaction
15. Preparation of triphenyl imidazole
16. To perform the Microwave irradiated reactions of synthetic importance (Any two)
17. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using 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

SEMESTER – I

PHARMACEUTICAL ANALYSIS (MPA)

MPA 101T. MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

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

Objectives: After completion of course student is able to know,

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

UNIT – I **12 Hrs**

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.
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. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analyzed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

UNIT – II **12 Hrs**

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

UNIT – III **12 Hrs**

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.

UNIT – IV **12 Hrs**

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

a. Thin Layer chromatography
b. High Performance Thin Layer Chromatography
c. Ion exchange chromatography

d. Column chromatography
e. Gas chromatography
f. High Performance Liquid chromatography
g. Ultra High Performance Liquid chromatography
h. Affinity chromatography
i. Gel Chromatography

UNIT – V **12 Hrs**

a. Principle, instrumentation and applications of Gel electrophoresis and Moving boundary electrophoresis

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

c. Thermal Techniques:

Differential Scanning Calorimetry (DSC): Principle, thermal transitions and instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

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

Thermogravimetric Analysis (TGA): Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications

References

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – A. H. Beckett and J. B. 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 edition, P. S. Kalsi, Wiley Eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, K. A. Connors, 3rd edition, John Wiley & Sons, 1982.

MPA 102T. ADVANCED PHARMACEUTICAL ANALYSIS

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

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

Objective: After completion of the course students shall able to know,

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

UNIT – I **12 Hrs**

Impurity and stability studies:

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

Impurities in new drug products:

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

Impurities in residual solvents:

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

UNIT – II **12 Hrs**

Elemental impurities:

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

Stability testing protocols:

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

UNIT – III **12 Hrs**

Impurity profiling and degradant characterization: Method development, Stability studies and concepts of validation, accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradant characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products.

UNIT – IV **12 Hrs**

a. Stability testing of phytopharmaceuticals:

Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.

b. Immunoassays (IA) Basic principles, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.

UNIT –V **12 Hrs**

Biological tests and assays of the following:

a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)

References

1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th edition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis – K. A. Connors, 3rd edition, John Wiley & Sons, 1982.
4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd edition, Wiley – Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P. D. Sethi, 3rd edition, CBS Publishers New Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods – J. W. Munson – Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs – D. C. Garratt, 3rd edition, CBS Publishers, New Delhi, 1964.
8. Indian Pharmacopoeia Vol. I, II & III 2007, 2010, 2014.
9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005
12. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.
13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

MPA 103T. PHARMACEUTICAL VALIDATION

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

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

Objectives: Upon completion of the subject student shall be able to

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

UNIT – I **12 Hrs**

Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.

Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re-Qualification (Maintaining status Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments.

UNIT – II **12 Hrs**

Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

UNIT – III **12 Hrs**

Validation of Utility systems: Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen.

Cleaning Validation: Cleaning Method development, Validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).

UNIT – IV **12 Hrs**

Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.

Computerized system validation: Electronic records and digital significance - 21 CFR part 11 and GAMP 5.

UNIT – V **12 Hrs**

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

References

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd edition., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci. Series, Vol. 157, 2nd edition., Marcel Dekker Inc., N.Y.

6. Validation of Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd edition.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

MPA 104T. FOOD ANALYSIS

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

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

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

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

UNIT – I **12 Hrs**

Carbohydrates: classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, Crude fibre and application of food carbohydrates

Proteins: Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins.

UNIT – II **12 Hrs**

Lipids: Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, various methods used for measurement of spoilage of fats and fatty foods.

Vitamins: classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series.

UNIT – III **12 Hrs**

Food additives: Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents.

Pigments and synthetic dyes: Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes.

UNIT – IV **12 Hrs**

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

UNIT – V **12 Hrs**

Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products.

Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA.

References

1. The chemical analysis of foods – David Pearson, 7th edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, 6th edition, Vol. I & II, 1997.
4. Analysis of Food constituents – Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005.

MPA 105P. PHARMACEUTICAL ANALYSIS PRACTICALS – I

Hours per week: 12 End Examination: 100 Marks
Credit: 6 Midsem: 50 Marks

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Assay of official compounds by different titrations
8. Assay of official compounds by instrumental techniques.
9. Quantitative determination of hydroxyl group.
10. Quantitative determination of amino group
11. Colorimetric determination of drugs by using different reagents
12. Impurity profiling of drugs
13. Calibration of glasswares
14. Calibration of pH meter
15. Calibration of UV-Visible spectrophotometer

16. Calibration of FTIR spectrophotometer
17. Calibration of GC instrument
18. Calibration of HPLC instrument
19. Cleaning validation of any one equipment
20. Determination of total reducing sugar
21. Determination of proteins
22. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
23. Determination of fat content and rancidity in food products
24. Analysis of natural and synthetic colors in food
25. Determination of preservatives in food
26. Determination of pesticide residue in food products
27. Analysis of vitamin content in food products
28. Determination of density and specific gravity of foods
29. Determination of food additives

SEMESTER – II

MPA 201T. ADVANCED INSTRUMENTAL ANALYSIS

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

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

Objectives: After completion of course student is able to know,

- interpretation of the NMR, Mass and IR spectra of various organic compounds
- theoretical and practical skills of the hyphenated instruments
- identification of organic compounds

UNIT – I **12 Hrs**

HPLC: Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC-role and principles of ultra, nano liquid chromatography in pharmaceutical analysis.
Immobilized polysaccharide CSP's: Advancement in enantiomeric separations, revised phase Chiral method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC.

UNIT – II **12 Hrs**

Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.
Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification.

High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications.

UNIT – III **12 Hrs**

Super critical fluid chromatography: Principles, instrumentation, pharmaceutical applications. Capillary electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method development in CE, Crown ethers as buffer additives in capillary electrophoresis. CE-MS hyphenation.

UNIT – IV **12 Hrs**

Mass spectrometry: Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrpole, Time of flight, FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF;Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap.

UNIT – V **12 Hrs**

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR with reference to ^{13}C NMR: Spin spin and spin lattice relaxation phenomenon. ^{13}C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations.

References

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. 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 II, Marcel Dekker Series.
8. Organic Spectroscopy by Donald L. Paviya, 5th edition.

MPA 202T. MODERN BIO-ANALYTICAL TECHNIQUES

Hours per week: 4L End Examination: 75 Marks
Credit: 4 Midsem: 25 Marks

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

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

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

UNIT – I **12 Hrs**

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

UNIT – II **12 Hrs**

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

UNIT – III **12 Hrs**

Pharmacokinetics and Toxicokinetics: Basic consideration, Drug interaction (PK-PD interactions), The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. Microsomal assays

Toxicokinetics - Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics.

UNIT – IV **12 Hrs**

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

UNIT – V **12 Hrs**

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

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

References

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd edition. CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd edition, Wiley – Interscience Publications, 1961.

4. Pharmaceutical Analysis- Modern methods – Part B – J. W. Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd edition, John Wiley & Sons, New Jersy. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd edition, Marcel Dekker, New York, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercy, USA. 2007.
8. Good Laboratory Practice Regulations, 2nd edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
10. ICH, USFDA & CDSCO Guidelines.
11. Palmer

MPA 203T QUALITY CONTROL AND QUALITY ASSURANCE

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

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

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

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

UNIT – I **12 Hrs**

Concept and Evolution of Quality Control and Quality Assurance Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines.
Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation.

UNIT – II **12 Hrs**

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

UNIT – III **12 Hrs**

Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3) Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products, Quality control test for containers, closures and secondary packing materials.

UNIT – IV **12 Hrs**

Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures, Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data.

UNIT – V **12 Hrs**

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

References

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – Vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, 6th edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.

MPA 204T. HERBAL AND COSMETIC ANALYSIS

Hours per week: 4L | End Examination: 75 Marks
Credit: 4 | Midsem: 25 Marks

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

Objectives: At completion of this course student shall be able to understand

- Determination of herbal remedies and regulations
- Analysis of natural products and monographs
- Determination of Herbal drug-drug interaction
- Principles of performance evaluation of cosmetic products.

UNIT – I **12 Hrs**

Herbal remedies- Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines.

UNIT – II **12 Hrs**

Adulteration and Deterioration: Introduction, types of adulteration/substitution of herbal drugs, Causes and Measure of adulteration, Sampling Procedures, Determination of Foreign Matter, and DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations. Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patent law as applicable to herbal drugs and natural products and its protocol.

UNIT – III **12 Hrs**

Testing of natural products and drugs: Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products, protocol. Monographs of Herbal drugs: Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

UNIT – IV **12 Hrs**

Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines.

UNIT – V **12 Hrs**

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

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

References

1. Pharmacognosy by Trease and Evans.
2. Pharmacognosy by Kokate, Purohit and Gokhale.
3. Quality Control Methods for Medicinal Plant, WHO, Geneva.
4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar.
5. Essential of Pharmacognosy by Dr. S. H. Ansari
6. Cosmetics – Formulation, Manufacturing and Quality Control, P. P. Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi.
7. Indian Standard specification, for raw materials, BIS, New Delhi.
8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi.
9. Harry's Cosmeticology 8th edition.
10. Suppliers catalogue on specialized cosmetic excipients.
11. Wilkinson, Moore, 7th edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps.
12. Hilda Butler, 10th edition, Poucher's Perfumes, Cosmetics and Soaps, Kluwer Academic Publishers.
13. A O Barel, M Paye, H I Maibach, Handbook of Cosmetic Science and Technology, 3rd edition, CRC Press, 2009.

MPA 205P. PHARMACEUTICAL ANALYSIS PRACTICALS – II

Hours per week: 12 End Examination: 100 Marks
Credit: 6 Midsem: 50 Marks

1. Comparison of absorption spectra by UV and Wood ward – Fieser rule
2. Interpretation of organic compounds by FT-IR
3. Interpretation of organic compounds by NMR
4. Interpretation of organic compounds by MS
5. Determination of purity by DSC in pharmaceuticals
6. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
7. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis.
8. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques.
9. Isolation of analgesics from biological fluids (Blood serum and urine).
10. Protocol preparation and performance of analytical/bioanalytical method validation.
11. Protocol preparation for the conduct of BA/BE studies according to guidelines.
12. In process and finished product quality control tests for tablets, capsules, parenterals and creams
13. Quality control tests for Primary and secondary packing materials
14. Assay of raw materials as per official monographs
15. Testing of related and foreign substances in drugs and raw materials
16. Preparation of Master Formula Record.

17. Preparation of Batch Manufacturing Record.
18. Quantitative analysis of rancidity in lipsticks and hair oil
19. Determination of aryl amine content and Developer in hair dye
20. Determination of foam height and SLS content of Shampoo.
21. Determination of total fatty matter in creams (Soap, skin and hair creams)
22. Determination of acid value and saponification value.
23. Determination of calcium thioglycolate in depilatories

SEMESTER – I

PHARMACOLOGY (MPL)

MPL 101T. MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

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

Objectives: After completion of course student is able to know,

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

UNIT – I **12 Hrs**

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.
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. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analyzed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

UNIT – II **12 Hrs**

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

UNIT – III **12 Hrs**

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.

UNIT – IV **12 Hrs**

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

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

UNIT – V **12 Hrs**

a. Principle, instrumentation and applications of Gel electrophoresis and Moving boundary electrophoresis

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

c. Thermal Techniques:

Differential Scanning Calorimetry (DSC): Principle, thermal transitions and instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

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

Thermogravimetric Analysis (TGA): Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications

References

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6th edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – A. H. Beckett and J. B. 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 edition, P. S. Kalsi, Wiley Eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, K. A. Connors, 3rd edition, John Wiley & Sons, 1982.

MPL 102T. ADVANCED PHARMACOLOGY – I

Hours per week: 4L End Examination: 75 Marks

Credit: 4 Midsem: 25 Marks

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

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

UNIT – I **12 Hrs**

General Pharmacology a. Pharmacokinetics:
a.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.

UNIT – II **12 Hrs**

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.
e. 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

UNIT – III **12 Hrs**

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.

UNIT – IV **12 Hrs**

Cardiovascular Pharmacology Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants, anticoagulants, fibrinolytics and anti- platelet drugs

UNIT – V **12 Hrs**

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

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, 9^{th} edition. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S. K. Srivastava published by APC Avichal Publishing Company
12. K. D. 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 C. R. & Stitzel R. E, Little Brown & Company**.**

MPL 103T. PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – I

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

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
- Describe the various newer screening methods involved in the drug discovery process
- Appreciate and correlate the preclinical data to humans

UNIT– I **12 Hrs**

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

UNIT – II **12 Hrs**

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

UNIT – III **12 Hrs**

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics.

Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti -emetic, anti-diarrheal and laxatives.

UNIT – IV **12 Hrs**

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro and other possible animal alternative models. Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods.

UNIT – V **12 Hrs**

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. 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. Screening Methods in Pharmacology, Robert A.Turner.
14. Rodents for Pharmacological Experiments, Dr. Tapan Kumar Chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)

MPL 104T. CELLULAR AND MOLECULAR PHARMACOLOGY

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

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

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

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

UNIT – I **12 Hrs**

Cell biology Structure and functions of cell and its organelles Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing Cell cycles and its regulation. Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis. Necrosis and autophagy.

UNIT – II **12 Hrs**

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

UNIT – III **12 Hrs**

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.

UNIT – IV **12 Hrs**

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.

UNIT – V **12 Hrs**

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

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 (2nd 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 protocols in molecular biology vol I to VI edited by Frederick M. Ausuvel et la.

MPL 105P. PHARMACOLOGICAL PRACTICAL – I

Hours per week: 12 End Examination: 100 Marks
Credit: 6 Midsem: 50 Marks

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

MPL 201T. ADVANCED PHARMACOLOGY – II

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

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

- 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

UNIT – I **12 Hrs**

Endocrine Pharmacology Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation

UNIT – II **12 Hrs**

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.

UNIT – III **12 Hrs**

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

UNIT – IV **12 Hrs**

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

UNIT – V **12 Hrs**

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

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, 9^{th} edition. (Robbins Pathology)

10. A Complete Textbook of Medical Pharmacology by Dr. S. K Srivastava published by APC Avichal Publishing Company.
11. K. D. 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

MPL 202T. PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – II

Hours per week: 4L | End Examination: 75 Marks
Credit: 4 | Midsem: 25 Marks

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.

UNIT – I **12 Hrs**

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

UNIT – II **12 Hrs**

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

UNIT – III **12 Hrs**

Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II) Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies

UNIT – IV **12 Hrs**

IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. Safety pharmacology studies- origin, concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies

UNIT – V **12 Hrs**

Toxicokinetics – Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing. 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 N. G.
4. Animal Models in Toxicology, 3rd edition, Lower and Bryan
5. OECD test guidelines.
6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
7. Guidance for Industry M3 (R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals. (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

MPL 203T. PRINCIPLES OF DRUG DISCOVERY

Hours per week: 4L | End Examination: 75 Marks
Credit: 4 | Midsem: 25 Marks

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,

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

UNIT – 1 **12 Hrs**

An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

UNIT – II **12 Hrs**

Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification. Protein structure Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction

UNIT – III **12 Hrs**

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

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

UNIT – IV **12 Hrs**

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

UNIT – V **12 Hrs**

QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.

References

1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targets and Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott Markel In. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. Di Stefano. 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.

MPL 204T. CLINICAL RESEARCH AND PHARMACOVIGILANCE

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

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 marketing surveillance.

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

- Explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities

- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance

UNIT – I **12 Hrs**

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

UNIT – II **12 Hrs**

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

UNIT – III **12 Hrs**

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. 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.

UNIT – IV **12 Hrs**

Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance. Methods, ADR reporting and tools used in Pharmacovigilance. International classification of diseases, International Non- proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance.

UNIT – V **12 Hrs**

Spontaneous reporting system and Reporting to reglatory authorities, Guidelines for ADRs reporting. Argus, Aris G Phamacovigilance, Vigi Flow, Statistical methods for evaluating medication safety data.

Pharmacoepidemiology, pharmacoeconomics and safety pharmacology.

References

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.

3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R. K. Rondels, S. A. Varley, C. F. Webbs. 2nd 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.

MPL 205P. PHARMACOLOGICAL PRACTICAL – II

Hours per week: 12 End Examination: 100 Marks
Credit: 6 Midsem: 50 Marks

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 isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, hematological, 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

Hours per week: 4L — End Examination: 75 Marks
Credit: 4 — Midsem: 25 Marks

UNIT – I **12 Hrs**

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 **12 Hrs**

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts.

Measures of central tendency: Computation of means, median and mode from grouped and ungrouped data. Measure of dispersion: Computation of variance, standard deviation, standard error and their coefficients.

UNIT – III **12 Hrs**

Regression and correlation: Method of least squares, Correlation Coefficient, rank correlation and multiple regressions.

Probability rules: Binomial, Poison and Normal distribution.

UNIT – IV **12 Hrs**

Tests of significance: Testing hypotheses- principle and applications of Z, t-, F- ratio and chi-square tests in pharmaceutical and medical research. Analysis of Variance: 1-way, 2-way and 3-way classification. Non-parametric tests: Sign test, Wilcoxon signed rank test, Wilcoxon rank sum test, Kruskal Wallis test, Run test and Median tests.

UNIT – V **12 Hrs**

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.

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

References

1. Santosh Gupta: "Research Methodology and Statistical Techniques", Deep & Deep Publication, 2001
2. C. R. Kothari: "Research Methodology – Methods & Techniques", 2nd edition, Wishwa Prakashan, 2000.
3. K. P. C. Swain: "A Text book of Research Methodology", 1st edition, Kalyani Publishers, 2007.
4. "Research Methodology and Statistical Techniques" Indira Gandhi National Open University.

5. M. N. Ghosh: “Fundamentals of Experimental Pharmacology”, 2nd edition, Scientific Book Agency, Calcutta, India, 1984.
6. H. G. Vogel: “Drug Discovery and Evaluation-Pharmacological Assays”, 2nd edition, Springer Verlag, Berlin, Germany, 2002.