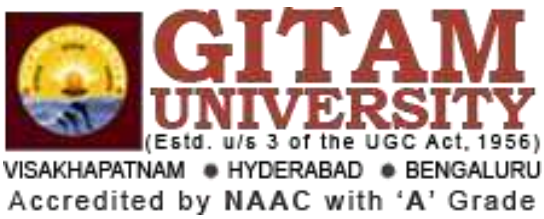
GANDHI INSTITUTE OF TECHNOLOGY AND MANAGEMENT
(GITAM)
(Deemed to be University, Estd. u/s 3 of the UGC Act 1956)
*VISAKHAPATNAM * HYDERABAD *BENGALURU*
Accredited by NAAC with 'A' Grade



REGULATIONS & SYLLABUS

MASTER OF PHARMACY
(M. Pharm. Pharmacology)
(W.e.f. 2017-18 admitted batch)

Website: www.gitam.edu

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

1.0 ADMISSIONS

1.1 Admissions into M. Pharmacy programmeof 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 course of study for M. Pharm. specialization shall include semester wise theory & practical as given in Table –1 to 3. 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 –1 to 3.

Table – 1: 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 – 2: Course of study for M. Pharm. III Semester

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	28	14

	(Proposed project work, Literature survey, Plan of work, Methodology)		
Total		36	22

* Non University Exam

Table – 3: Course of study for M. Pharm. IVSemester

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 – 4: 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 –5 to 6.

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 – 5: 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 – 6: 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 – 7: Scheme for awarding internal assessment: Continuous mode

Criteria	Maximum Marks
Theory	
Attendance (Refer Table -5)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – 5)	10
Based on Practical Records, Regular viva voce, etc.	10

Total	20

Table – 8: 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 5 – 6. 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 9. The exact dates of examinations shall be notified from time to time.

Table – 9: 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 – 10.

Table – 10: 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:

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

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:

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

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:

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

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.

27. PROGRAM OUTCOMES (PO)

PO1-Advanced Pharmacology knowledge: Possess comprehension knowledge and basic principles regarding the advancement in phramcology and toxicology, screening techniques and advanced knowledge on molecular and cellular basis drug mechanism of action and clinical uses.

PO2-In vivo and In vitro research Practice: Utilize skills for designing appropriate protocol for preclinical screening of diverse compounds and analysing them for suitability in clinical management of disorders.

PO3-Problem Analysis : Develop ability to utilise the principles of scientific enquiry and Outline critically appraise the principal steps involved in advancement of Pharmacology.

PO4-Modern tool Usage : Learn, select and apply appropriate techniques, and efficient utilization of resources, softwares for overcoming the limitations of conventional practices.

PO5-Research Communication skills : Ability to document all the research outcomes in terms of reports for Communicating effectively to journals, proceedings or conferences for sharing their experience with other scientific fraternity.

PO6-Professional Identity : Act in consultative position and abiding with all the regulatory guidelines of governing bodies. Further demonstrate scientific practice to o pharmacy students and contribute to the training of the growth and success of pharmacy profession.

PO7-Pharmaceutical Ethics : Honour personal values and apply ethical values in professional and social context. Demonstrate high degree of professional, ethical and legal manners, conforming with all national, state and local rules and regulations related to pharmacy practice.

PO8-Planning Abilities : Develop and apply skills for time management and utilization of resources and implement them to complete the task to meet deadlines. critically appraise the principal steps involved in practice of clinical Pharmacology.

PO9-Leadership skills : Inculcate leadership abilities for competent team-centric approaches to improve and facilitate the health and well-being of society.

PO10-Environment and sustainability : Understand the impact of the professional pharmacy solution in societal and environmental perspectives, and demonstrate the knowledge for sustainable development.

PO11-Life-long learning : Recognize the need to develop independent ideas to solve the community issues and critically review the outcomes for further interest. Understand the importance of attending the participation in scientific seminars/ conferences/workshops for life-long learning.

28. Programme Specific Outcome (PSO)

PSO1: Work in different divisions of pharmaceutical industry like manufacturing, quality assurance, analytical, preclinical research, pharmacovigilance and regulatory affairs.

PSO2: Become an entrepreneur in the areas of clinical research, preclinical development, pharmaceutical consultancy services, drug sales and distribution.

PSO3: Explore opportunities in different government and non-government organizations as clinical research associate, academician, research scientist and drug inspector.

SEMESTER – I

PHARMACOLOGY (MPL)

MPL 101T. MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

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

Course Description: This course is designed to provide the student with basic information about various instrumental techniques covering spectroscopy, chromatography and thermal analysis. During the course the student will be learning the concepts and applications of various absorption (UV-Visible, IR) and emission (Spectrofluorimetry, Flame photometry) spectroscopic techniques along with X-ray crystallography, NMR and Mass spectroscopy. The student will also gain knowledge on the significance of various basic to complex chromatographic (TLC, HPLC, GC, Affinity chromatography) and electrophoresis (Gel, Moving boundary) techniques.

Course objectives: 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.

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 13C 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.

Course Outcomes: 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

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

Course Description: In this course, the student can learn the concept of fate of drugs after administration, influence of permeability of biological membranes on efficacy and bioavailability of drugs, Mechanism of drug action with special emphasis on affinity of drugs towards different receptor families. The course also emphasizes the role of several neurotransmitters in both CNS & PNS with a detailed study on drugs influencing the central and peripheral transmission. The student can also learn in detail the pharmacology of various categories of drugs acting on CNS, CVS and endogenous peptides including the physiological role & significance of autacoids in the human body.

Course objectives: 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.

UNIT – I **12 Hrs**

General Pharmacology

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

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

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.

Course Outcomes: 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

References

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

MPL 103T. PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS – I

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

Course Description: This course describes the standard protocols and procedures to be followed in case of laboratory animals regarding their maintenance, handling and usage. The content in this course provides various preclinical animal models to assess the pharmacological activities of drugs, which are helpful in pharmacological & toxicological research in the drug discovery process. It clearly describes the preclinical screening models and also alternative

models for CNS pharmacology, Respiratory pharmacology, Reproductive pharmacology, GI pharmacology and CVS pharmacology with special focus on Immunopharmacology.

Course objectives: 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.

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. Anesthesia 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, anti-inflammatory 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: antihypertensive, 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

Course Outcomes: 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

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

Course Description: This course describes the molecular aspects involved in the cellular function and sequence of reactions that occur in a cell. It describes the genomic and proteomic tools, their applications in gene therapy and gives insight into the personalized drug therapy. The course also describes Cell based assays which are applicable in cancer studies to assess the cellular changes in cancer cell lines.

Course objectives: 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.

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

Course Outcomes: 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

References

1. The Cell, A Molecular Approach. Geoffrey M Cooper.

2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L. Miller
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current 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

Course Description:

Within each class of therapeutic drugs, the course examines endocrine pharmacology, GIT Pharmacology, Free radical pharmacology and chemotherapy, in which it explains the pharmacodynamics, pharmacokinetics and clinical application, drug actions, interactions, reactions, and contraindications

Course objectives: 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.

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

Course Outcomes: 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

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 Ed. (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

Course Description:

Introduce toxicology's fundamental principles and practice, including dose-response and

toxicokinetic analysis. It will also cover reproductive toxicology, Toxicokinetic evaluation in preclinical studies. IND enabling studies (IND studies) emphasise understanding mechanisms for these responses.

Course objectives: 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.

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

Course Outcomes: : 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

References

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glp- handbook.pdf).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd edition, Lower and Bryan
5. OECD test guidelines.

6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
7. Guidance for Industry M3 (R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals. (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

MPL 203T. PRINCIPLES OF DRUG DISCOVERY

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

Course Description:
The course covers the basic principles of how new drugs are discovered, emphasising lead identification, lead optimization, Lead Identification- Rational Drug Design, and Traditional vs rational drug design. And also covers molecular docking and QSAR Statistical methods

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

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.

Course Outcomes: 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.

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

Course Description: The course covers the regulatory requirements for conducting a clinical trial, responsibilities of key players involved in clinical trials, documentation requirements for clinical trials. Moreover, it covers Adverse drug reactions and their management and ADR reporting, methods and tools used in Pharmacovigilance. It will give basic information on Pharmacoepidemiology, pharmacoeconomics and safety pharmacology.

Course objectives: 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.

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 centers 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 regulatory authorities, guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, Vigi flow, statistical methods for evaluating medication safety data.

Pharmacoepidemiology, pharmacoeconomics and safety pharmacology.

Course Outcomes: 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

References

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

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 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 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.Kulkarni
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

Course Description: This introductory course of research methodologies and biostatistics will give students an overview of the many study designs and statistical tests that are used in the medical industry to answer research issues. This course focuses on the CPCSEA guidelines and prerequisites for performing animal experiments, categorising research projects, developing a study, experimental design, measuring and interpreting data, and conducting ethical research.

Course objectives: Impart knowledge on statistical principles that can be applied to design experiments and help in the interpretation of the results.

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.

Course Outcomes: Upon completion of the course the student is able to select appropriate statistical methods required for a particular research design and develop appropriate research hypothesis for a research project. Develop appropriate framework for research studies. Gain knowledge regarding CPCSEA guidelines and prerequisites for conducting animal experiments

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.