ANDHRA UNIVERSITY

MASTER OF PHARMACY

(2020)

Regulations and Syllabus

Four semester pattern

With effect from 2020-21

M.PHARM (2020) REGULATIONS AND SYLLABUS

INDEX:

1. Admission, instruction and attendance

The degree of Master of Pharmacy of the Andhra University will be conferred on a candidate who has satisfied the following conditions:

1.1. The candidate must have passed the B.Pharm. Degree examination of this University or B.Pharm. Degree examinations of any other University recognized by the Academic Council as equivalent thereto in First or Second class; and must have qualified in any entrance examination, if prescribed.

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

1.3. The candidate should have undergone a regular course of study as prescribed hereunder extending over a period of four semesters, ordinarily consecutive, and satisfied the academic requirements as prescribed hereinafter. The course of instruction and periods of study shall be as given in the scheme of instruction and in the syllabus.

1.4. The subjects of specializations for Master of Pharmacy Course shall be as follows:

1. Pharmaceutical Analysis
2. Pharmaceutical Chemistry
3. Pharmaceutics
4. Pharmaceutical Biotechnology
5. Pharmacology
6. Pharmacognosy
7. Pharmaceutical Regulatory Affairs
8. Pharmaceutical Quality Assurance
9. Industrial Pharmacy
10. Pharmacy Practice

1.5. Instruction and examination in each academic year is spread over two semesters with a minimum of 96 working days in each semester (192 in any given academic year). The odd semesters shall be conducted from the month of July to November and the even semesters shall be conducted from the month of December to April.

1.6. Each period of instruction is of 45 minutes duration. Eight periods of instruction are provided on each day and there are six working days in a week (Monday to Saturday).

1.7. Attendance Requirements: A regular course of study during an academic semester means a minimum of average attendance of 80% of all the courses of the semester computed by totaling the number of periods of lectures and practicals, as the case may be, held in every course. In special cases where sufficient causes were shown, the Vice-

Chancellor may on the recommendation of the Principal concerned condone the deficiency in the average attendance to an extent of 9% for reasons such as ill health, if the application for condonation is submitted at the time of actual illness and is supported by certificate of; authorized Medical officer approved by the Principal. However, in the case of students, who participate in activities like N.S.S., N.C.C., Inter-Collegiate tournaments conducted by Andhra University, Inter-University tournaments conducted by Inter-university Board and any such other activities involving the representation of the College/University with the prior approval of the principal, the candidate may be deemed to have attended the college during the period solely for the purpose of the examination.

1.7. A candidate who cannot satisfy the attendance requirements in clause 1.5 because of late admission under special circumstances reasonable and acceptable to the University on the basis of document, shall fulfill the following conditions; Average attendance: A candidate shall have attended at least a total of 90% of the periods-lectures/practicals as the case may be held from the date of admission and also shall attend at least 50% of the total working days during that academic semester (Late admission means, admissions made after 45 days from date of commencement of the academic semester for the course).

1.8. If any candidate fails to satisfy the regulation under 1.5 or 1.6 she/he shall not be allowed for the University Examinations at the end of the semester, and he/she shall not be allowed for promotion to the next higher class of study. He/she shall be required to repeat the regular course of study of that academic semester along with the next regular batch.

1.9. A regular record of attendance 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.

2. Examinations – Internal assessment and Semester-end

2.1. Assessment for the award of degree shall consists of (a) internal assessment for 30 marks in each of the theory and practical courses separately. (b) Semester-end examination as detailed in the scheme of examination for 70 marks in each of the theory and practical separately.

2.2. Regulations concerning internal assessment: Internal assessment consist of continuous mode (10 marks for theory and 15 marks for practical) and sessional examinations (20 marks for theory and 15 marks for practical)

2.2.1. Scheme for awarding continuous mode marks for theory and practical

Theory-Criteria	**Marks**
Attendance	5
Student-Teacher Interaction	5
Theory sessional examination	20
Total theory internal assessment	**30**
Practical-Criteria	
Attendance	5
Record + Viva-voce	10
Practical sessional examination	15
Total practical internal assessment	**30**

2.2.1.1. Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory/Practical
95 -100	5
90-94	4
85-89	3
80-84	2
Less than 80	0

2.2.1.2. Guidelines for allotment of marks for Student-Teacher interaction

The teacher shall create some interactive sessions for theory topics and every student shall interact on the given topic relating to its application in pharmacy. The teacher should assess the student capacity for understanding of the concept taught. It shall not be like seminars.

2.2.1.3. Guidelines for allotment of marks Record + Viva-voce

The teacher should conduct viva-voce at the end of each practical and evaluate the record on continuous mode and shall award these marks.

2.2.4. Guidelines for sessional examinations

Two sessional examinations shall be conducted for each theory/practical course. The average marks of the two shall be computed.

The teacher who teaches the subject shall ordinarily to be the internal examiner.

There shall be no provision for the improvement of the sessional marks.

There is no minimum mark prescribed for sessional examination for pass in the end semester examination.

If any student is absent for a single or both sessional examinations, the candidate will be awarded "ZERO" in the respective examination.

The theory average sessional mark shall be finally computed for 20 marks and average practical sessional mark shall be finally computed for 15 marks.

2.3. Regulations concerning M.Pharm I and II semester evaluation pattern:

2.3.1. There shall be one semester end examination in each theory course based on the question paper set by an external paper setter and there shall be single valuation. There shall be one semester end examination in each practical course as per the scheme of examination and valuation shall be done by examiner. The duration of the practical examination is of 6 hours as prescribed.

2.3.2. However the student may apply for revaluation of any subject in theory papers after declaring the results as per University examination guide lines.

2.3.3. Seminar

A seminar at the end of first and second semesters is separately conducted keeping in view of the enrichment of required communication, presentation and explanatory skills. A minimum of four seminars shall be given during the semester before the Program Committee and other students and documented separately for record in a Semester Seminar Register.

2.3.4. Comprehensive viva

At the end of II Semester comprehensive viva will be conducted for all the subjects

covering the theory subjects of I & II semesters by the external examiner and eligible internal examiners (at least two from the college) who taught these subjects. The candidate should obtain minimum of 50% marks for passing the examination.

2.3.4. Journal Club

In case of Journal Club, based on the research proposal, each student shall collect a minimum of 5 research papers (published in a reputed journal with impact factor of Thomson & Reuters of not less than 1.0) and should discuss in a Programme Committee (consisting of Head of the Department, Research Supervisor and other Senior faculty members) and documented separately for record in a Journal Club Register.

2.3.5. A student shall be eligible to carry forward all the courses of I, II semesters. However, he/she shall not be eligible to attend the courses of IV semester until the candidate clears III semester Midterm Project Review.

2.4. Regulations concerning M. Pharm. III and IV Semester evaluation pattern:

2.4.1. Evaluation of the seminar on the objectives and work plan of the proposed project is to be completed within one month from the commencement of the project date with three examiners from the same college consisting of research guide, another teacher in the concerned specialization and third teacher from different specialization. These teachers must fulfill the eligibility criteria laid down in Section 3.

2.4.2. Evaluation of the M.Pharm III Semester Mid-term project review and seminar on selected topic will be done by the research guide and external examiner. The seminar on the selected topic shall not be the one connected with the topic of the thesis work but should be related to concerned specialization.

2.4.3. A candidate shall submit four copies of his/her thesis either printed or typed, embodying the results of research work done by him under direction of an approved research director following the specific guidelines as stipulated under Section 5. All the candidates must submit their thesis within the prescribed date as per the academic calendar.

2.4.4. The thesis submitted by the candidate shall be examined by a Board of Examiners consisting of an External Examiner and the research director and shall have to be approved after holding a viva voce examination to test the knowledge of the candidate in the subject. The thesis will be evaluated independently by the external examiner and research director and in case the difference between examiners is more than 20%, the thesis shall be sent to a second external examiner whose award shall be the final. The viva-voce examination will be jointly conducted both by the external examiner and research director. A candidate can re-submit the thesis in a revised form after further work, if required to do so.

2.4.5. A candidate desires of improving his/her class shall take either or both of the first two semesters as a whole.

2.5. Guidelines for writing the thesis

The thesis should have the following pages in order:

1. Title page highlighting the title, name of the candidate, reg. no., guide name, college name and month and year of submission.
2. The inner title page containing the same details on white background.
3. Certificate from the Head of the institution
4. Certificate from the Research Director
5. Certificate from the ethical committees for approval of study, if any

6. Declaration by the student
7. Acknowledgements
8. Index highlighting chapter titles and sections titles
9. Index for tables, figures and plates, if any
10. Abbreviations and symbols
11. Materials used in the investigation with their procurement details like name of the company, batch number etc.
12. Equipment used in the study with the model number and other details
13. The thesis should contain the following chapters:
    a) Aim and objectives of the investigation
    b) Introduction and literature survey
    c) Description: Methods and Materials, etc.
    d) Experimental work
    e) Results and discussion
    f) Summary and conclusions
    g) References (The references may be included at the end of each chapter or at the end of the thesis according to the convenience)

2.5.1. The thesis should be typed in times new roman in 12 font size with 1.5 line spacing from the beginning of the thesis including titles to the chapters and sections. Bold font may be used wherever necessary. The students are expected to follow scientific grammar for writing *in vivo* etc. which should be in italics.

2.5.2. The citation of references should be done carefully by citing the complete reference i.e. name of all the authors. Usage of et al. is not allowed in the citation of reference. The students are expected to give the primary references rather than secondary or higher levels of references. The presentation of reference must be in Vancouver style.

2.5.3. No code names or numbers are allowed to be written in the thesis for the materials used in the project.

2.5.4. The examiners of thesis evaluation are expected to verify all this and appropriate corrections are to be made before conducting the viva-voce examination.

2.5.5 Project Work/IV Semester Assessment – Division of Marks:

Course 402 -Thesis Evaluation (Max. Marks – 150)

Criteria of Evaluation	**Marks**
Seminar/Presentation of work	20
Objective(s) of the work done	20
Methodology adopted	40
Results and Discussion	40
Conclusions and Outcomes	30
Total	**150**

The division of marks shall be clearly indicated for every candidate in the marks statement being sent to the University.

2.6. End Semester examinations

The End Semester examination for each theory, practical and other courses through

semesters I to IV shall be conducted by the University except for the subject with asterisk symbol (*) in the tables of the each specialization courses (Non University Examinations) for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the University. In case of theory examinations, the question paper of the corresponding subject shall be mailed (Official mail id) to the Controller of Examinations and Chairman, BOS with signature of the Head of the Institute in PDF format within twenty four hours after completion of the examination.

3. Eligibility criteria for appointment as examiner for M.Pharm examination

3.1. In order to eligible to be appointed as an internal examiner for the semester end examination in the respective specialization, a teacher shall have M. Pharm. or Ph.D. in the respective specialization with at least three years of M.Pharm teaching experience for the course concerned.

3.2. The eligibility of a teacher for guiding the M.Pharm III and IV semester project is as follows:

3.2.1. The teacher must have M.Pharm/Ph.D. in the respective specialization with an experience of minimum 3 years of Post Graduate teaching in the respective specialization.

3.2.2. The eligibility of such teachers qualified for guiding M.Pharm projects must be ratified by the Board of Studies before commencement of M.Pharm guidance.

3.2.3. The recognized M.Pharm guides are not eligible to guide more than **6** students in one academic year including joint guidance.

4. Regulations for pursuing M.Pharm III and IV Semester project

4.1. Students desirous of pursuing M.Pharm III and IV semester projects outside college are required to get the approval from the college before one month from the commencement of the project work. The research work can be carried out in a GMP compliant industry (as approved by WHO, USFDA etc.) and Central research laboratories like IICT, CDRI, NIH etc. or DSIR and Drug Control Administration recognized laboratories. A certificate to that effect must be incorporated in the M.Pharm thesis indicating the duration of stay. If the duration of stay is less than nine months the remaining period of stay in the college should be certified by the research supervisor and the Principal.

4.2. All the students should present a seminar on the objectives of their work, work plan, etc. within one month from the commencement of the project. The students should attend a mid-term review seminar in the presence of a committee consisting of one external examiner, research director. The suggestions made by the committee are to be taken into consideration for further work and should be presented in the thesis.

5. Declaration of results and classification:

5.1. A candidate shall be declared to have passed the examination held at the end of each semester if obtains i) not less than 40% in the each theory and 50% in each practical, seminar, comprehensive viva, thesis and thesis viva-voce at the end of each semester end examination and ii) an aggregate of 50% of all examinations of that semester including sessoinals. There are no minimum marks prescribed for sessional examination.

5.2. A candidate who has successfully completed the examination in a course by securing not less than 50% of marks shall not be permitted to retake the examination in that course.

5.3. A candidate who fails to secure 50% of marks on the aggregate but secures 50% or

more in some courses and between 40-49% in the other courses, he/she shall be required to retake the semester and supplementary examination in one or more of the courses in which he/she secures less than 50% of marks as per his/her choice to satisfy the requirement of 50% aggregate.

5.4. Declaration of class

The classes 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

6. Grading system:

6.1. Appropriate letter grades are awarded in each theory and practical subject to only such candidates who have passed in the university examinations. Internal assessment marks and university examination marks put together will be taken into account for the letter grading system in each subject separately.

6.2. A candidate registered for the university examination but fails to appear or fails to score the minimum required 40% marks in the university examination will get a grade 'F', indicating failure or grade of incompletion.

6.3. A subject successfully completed cannot be repeated. Final evaluation of each subject (theory and practical separately) will be carried out on a 10- point grading system corresponding to the marks obtained in that subject. Each subject letter grade is converted into a specific grade value associated with the letter grade as given below (Table).

6.4. Grading of performances

Based on the performance, 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 below.

10-Point grading system

Percentage of marks	Grade	Grade points
90.00 - 100	O	10.0
80.00 - 89.99	A	9.0
70.00 – 79.99	B	8.0
60.00 – 69.99	C	7.0
50.00 – 59.99	D	6.0
40.00 – 49.99	E	5.0
< 40.00	F (Fail)	0.0
The grade W represents failure due to insufficient attendance in the semester or year	W	0.0
Incomplete (subsequently to be changed into pass or E or O or F grade in the same semester)	I	0.0

6.5 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:

$$\textbf{SGPA} = \frac{C1G1+C2G2+C3G3+C4G4}{C1+C2+C3+C4}$$

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

$$\textbf{SGPA} = \frac{C1G1+C2G2+C3G3+C4*ZERO}{C1+C2+C3+C4}$$

The credits allotted to each course are given in the respective specialization **Tables 1-10**.

6.6. 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:

$$\textbf{CGPA} = \frac{C1S1+C2S2+C3S3+C4S4}{C1+C2+C3+C4}$$

Where C_1,C_2,C_3, C4…is the total number of credits for semester I, II, III and IV and S1, S2, S3 and S4 are the SGPA of semester I, II, III and IV.

7. Guidelines for paper setting and model papers.

7.1. Guidelines for theory paper setting for semester end examinations

7.1.1. The semester end question paper in each theory course is to be set for a total of 70 marks by an external paper setter as per the general model given below.

7.1.2. Question paper consists of 5 questions each carrying 5 marks out of which 4 questions are to be answered by the candidate and 7 questions each carrying 10 marks out of which 5 questions are to be answered by the candidate for a total of 70 marks. Each main question may contain subsections like a, b, c etc.

7.1.3. The questions given should be spread over the entire syllabus in an even manner covering all the units as per the pattern of the question paper given below.

7.1.4. Model question paper for theory course:

Course No.

Specialization Name:

Title of the course:

Time: 3 Hours **Max. Marks: 70**

Part A (Question Numbers 1-5)

Answer any **four** questions out of five questions 4X5=20

One question has to be set from each unit.

Part B

Answer any **five** questions out of **seven** questions (Question Numbers 6-12) 5X10=50

Five questions are to be set from five units and the remaining two should cover at least four out of five units. The main questions may contain sub question like 6(a), 6(b) etc.

7.2. Guidelines for practical paper setting for semester end examination

7.2.1. The question paper in each semester end practical examination is to be set jointly by two examiners and evaluated, one external and one internal as per the general model provided below.

7.2.2. Model question paper for practical course:

Course No.

Title of the course

Time: 6 hrs.

1. Synopsis	10 marks
2. Major experiment	30 marks
3. Minor experiment	20 marks
4. Viva voce	10 marks
Total:	**70 marks**

7.3. Guidelines for theory/practical sessional examination paper setting:

Question paper pattern for theory Sessional examinations

Max. Marks: 30

Time: 2 Hours

Part A

Answer any **two** questions out of three questions 2X5=10

Part B

Answer any **two** questions out of three questions 2X10=20

Each of the sessional examination question paper should cover at least half the units of the syllabus.

Question paper pattern for practical sessional examinations

Max. Marks: 30

Time: 4 hours

1. Synopsis	5 Marks
2. Experiment	20 Marks
3. Viva	5 Marks
Total:	**30 Marks**

Table 5: Pharmacology (MPL)

Code	Course	Credits	Hours/ week	Internal Assessment			Semester End Exam	Total
				Continuous mode	Sessional Exam	Total		
I Semester								
MPL 101T	Modern Pharmaceutical Analytical Techniques	4	4	10	20	30	70	100
MPL 102T	Advanced Pharmacology – I	4	4	10	20	30	70	100
MPL 103T	Pharmacokinetics and Drug Metabolism	4	4	10	20	30	70	100
MPL 104T	Cellular and Molecular Pharmacology	4	4	10	20	30	70	100
MPL 105P	Pharmacology Practical - I	2	6	15	15	30	70	100
MPL 106P	Pharmacology Practical – II	2	6	15	15	30	70	100
MPL 107	Seminar*	2	4	50	---	---	---	50
	Total	**22**	**32**	**---**	**---**	**---**	**---**	**650**
II Semester								
MPL 201T	Advanced Pharmacology - II	4	4	10	20	30	70	100
MPL 202T	Pharmacological and Toxicological Screening Methods	4	4	10	20	30	70	100
MPL 203T	Principles of Drug Discovery	4	4	10	20	30	70	100
MPL 204T	Clinical Research and Pharmacovigilance	4	4	10	20	30	70	100
MPL 205P	Pharmacology Practical – III	2	6	15	15	30	70	100
MPL 206	Comprehensive Viva	2	---	---	---	---	---	50
MPL 207	Seminar*	2	2	50	---	---	---	50
	Total	**22**	**26**	**---**	**---**	**---**	**---**	**600**

Table 5: Pharmacology (MPL) continued

III Semester								
MRM 301T	Research Methodology and Biostatistics*	2	4	10	20	30	70	100
MPL 302	Journal Club*	2	2	50	---	---	---	50
MPL 303	Discussion /Presentation (Dissertation Title & Project Proposal)*	2	---	50	---	---	---	50
MPL 304	Seminar on selected topic	4	4	---	---	---	100	100
MPL 305	Research Work Progress (Mid Term Report)	10	20	---			200	100
	Total:	**20**	**30**	**---**	**---**	**---**	---	**400**
IV Semester								
MPL 401	Journal Club*	2	2	50	**---**	**---**	---	50
MPL 402	Thesis evaluation	12	20	---	**---**	**---**	150	150
MPL 403	Thesis viva	4	---	---	**---**	**---**	50	50
	Total:	**20**	**22**	**---**	**---**	**---**	---	**250**

* Non-University Examination

PHARMACOLOGY

PROGRAM OUTCOMES

Following the completion of this course,

PO1: Students can have an in-depth knowledge on the concepts and practices of general chemotherapy

PO2: Students can understand the pharmacology of individual drugs, their spectrum of activity, microbial mechanisms for resistance, and their pharmacodynamic aspects in detail would be understood by the students in due course of time

PO3: Students will be enriched with the concept of Chronopharmacology, circadian rhythm and its applications

PO4: Students will be enabled with an in depth knowledge on handling and applications of different species and strains of animals, maintenance and breeding of laboratory animals Use of Transgenic animals in preclinical research their production, maintenance and applications

PO5: Students will gain knowledge on the guidelines imparted by agencies like CPCSEA, OECD, ICH, EPA to conduct experiments on animals and will learn GLP standards

PO6: Students will also gain knowledge on bioassay - principles, scope and limitations and methods of immunoassays

PO7: Students will be enabled with knowledge on FDA and FDA associated drug filings including IND applications

PO8: Students will be enabled with the understanding and approach towards new drug Development design, methodology and analysis

PO9: Students can have a detailed knowledge on gene mapping and gene sequencing

PO10: Students will gain understanding on target identification, target validation, lead identification and lead Optimization along with target discovery and validation, giving importance to understand the economics involved in drug discovery

PO11: Students can have complete understanding on role of Genomics, proteomics and bioinformatics, nucleic acid microarrays, protein microarrays, antisense technologies, siRNAs, antisense oligonucleotides, zinc finger proteins

PO12: Students will gain knowledge on rational drug design, concepts of traditional vs. rational drug design, methods followed in traditional drug design

PO13: Students can achieve distinct knowledge on 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

PROGRAM SPECIFIC OUTCOMES

The outcome of this program will be able

PSO1: To educate the students about toxicity and toxicological measures in preclinical evaluation of drugs and chemical substances.

PSO2: To understand the protocols for new drug applications specific to investigational drugs

PSO3: To understand various pharmacological activities related to different classes of drugs

PROGRAM EDUCATIONAL OBJECTIVES

Upon completion of the program, the student will be able

1. To understand the concept of infections and the principles of chemotherapyfor bacterial infections, viral and fungal infections.
2. To understand the important concepts of cancer therapy and immunosuppression
3. To also understand the preclinical screening of respiratory pharmacology, reproductive pharmacology and gastrointestinal pharmacology associated with in vivo, in vitro and alternative methods.
4. To enable the students with deep and proper understanding on the preclinical screening models of cardiovascular agents and cancer drugs
5. To educate the students about toxicity and toxicological measures in preclinical evaluation of drugs and chemical substances
6. To understand the protocols for new drug applications specific to investigational drugs
7. To make the student understand the modern drug discovery process

I/II M. PHARMACY

ADVANCED PHARMACOLOGY – I (MPL102T)

Course Objectives:

The educational objectives of the program is to provide comprehensive knowledge to the students and enable them

1. To understand the concepts and practices of general pharmacology with respect to basic drug receptor concepts.
2. To educate the students about the pharmacokinetics, pharmacodynamics of drugs along with a vigilant approach towards the adverse reactions associated with drugs.
3. To let them be mindful on the neurohumoral transmission accompanying autonomic nervous system and the drugs used in its disease management.
4. To also let them understand the neurohumoral transmission accompanying autonomic nervous system and the drugs used in its disease management.
5. To understand the important concepts of diseases involved in cardiovascular pharmacology.
6. To enable them understand the importance of neurodegeneration in disease and also the knowledge on different neurodegenerative diseases.
7. To educate the students with a deep insight on the free radical induced diseases.

Course Outcomes:

Following the completion of this course,

- Students can have an in depth knowledge on the concepts and practices of general pharmacology.
- Students will be enabled with complete understanding towards drug receptor concepts like receptor binding, receptor interactions, structural and functional families of the receptors, quantification of drug receptor interactions.
- Students will gain knowledge on pharmacokinetic approaches of ADME and pharmacodynamic profiling of drugs with respect to adverse effects, adverse reactions, contraindications, drug interactions, warnings and precautions associated with drugs.
- Students will also gain knowledge on different categorical drugs associated with drugs acting on the autonomicsystem that is drugs acting of parasympathetic and sympathetic nervous systems in detail.
- Students can achieve distinct knowledge on different central nervous disorders and the drugs used in their therapy.
- Students will gain knowledge on specific cardiovascular disorders and an insightful understanding on cardiovascular pharmacology.
- Students will understand the concepts of neurodegeneration, diseases associated with neurodegeneration.
- Students will be enabled with knowledge on free radicals, antioxidants cellular and molecular level pathophysiology of free radical induced disorders.

PHARMACOKINETICS AND DRUG METABOLISM (MPL 103T)

Course Objectives:

The educational objectives of the program is to provide comprehensive knowledge to the students and enable them

1. To understand the biological membranes, different routes of absorption in detail namely gastrointestinal, percutaneous and rectal absorption, role of ion pumps and ion channels in drug absorption, factors affecting drug absorption, and absorption kinetics.
2. To educate the students regarding binding of drugs to plasma proteins and tissue proteins and distribution kinetics.
3. To educate the students about the concepts of biotransformation, factors affecting drug metabolism and *in vitro* drug metabolism.
4. To understand the routes of drug excretion, factors affecting drug excretion, enterohepatic recirculation, significance of elimination rate constant, elimination half-life.
5. To also let them understand the clinical pharmacokinetics, population pharmacokinetics.
6. To understand the important concepts of PK-PD modelling and therapeutic drug monitoring.
7. To enable them with deep and proper understanding on the importance of drug interactions in today's health and disease.
8. To educate the students about toxicity, drug toxicity, toxicokinetics, and evaluation of toxicokinetics in pre-clinical studies.
9. To understand the importance of alterative research methods and protocols to animal toxicity studies.

Course Outcomes:

Following the completion of this course,

- Students will be enabled with an in depth knowledge on the concepts of drug absorption, importance of absorption in pharmacology, kinetic mechanisms associated with absorption.
- Students can have complete understanding on drug distribution patterns, protein binding concepts and their relevance in patient centric treatment.
- Students will gain knowledge on microsomal and non-microsomal biotransformation, importance of drug metabolic pathways in the body and their understanding through *in vitro* assays.
- Students will also gain knowledge on drug excretion and elimination rate kinetics with essentially important methodological approaches in practice.
- Students can achieve distinct knowledge on the detailed scientific measures of pharmacokinetics at clinical setting and their usefulness in health management.
- Students will gain knowledge on specificities of PK-PD drug modelling concepts, important methods and relevant approaches at industrial as well as hospital practices.

- Students will understand the importance of therapeutic drug monitoring in individualizing drug therapies, precision medicine and its advanced relevance in treating debilitating diseases.
- Students will be enabled with knowledge on drug interactions, types of drug interactions, impact of drug interactions in mediating ADRs.
- Students will be equipped with practical and theoretical approaches associated with toxicokinetics, preclinical evaluations in toxicokinetics and also the alternative toxicity studies in protecting and safeguarding animal research.

CELLULAR AND MOLECULAR PHARMACOLOGY (MPL 104T)

Course Objectives:

The educational objectives of the program is to consummate the students in

1. Understanding cell biology
2. Elaborating the knowledge on cell signalling mechanisms
3. Providing an understanding on the principles of molecular biology
4. Enabling the knowledge related to genes and gene mapping and sequencing.
5. Understanding genetic variations and polymorphisms as hallmarks in disease pathologies.
6. Understanding pharmacogenomics, genes associated with drug transporters.
7. Understanding cell culture techniques.

Course Outcomes:

The completion of this course provides the following outcomes where,

- Students will be enabled with an in depth knowledge on structure and functions of cell and its organelles, genome organization, gene expression and its regulation.
- Students can have a detailed knowledge on gene mapping and gene sequencing.
- Students will gain understanding on cell cycle and its regulation along with cell death mechanisms like apoptosis. Necrosis and autophagy.
- Students can have complete understanding on cell signaling, intercellular and intracellular signaling pathways, classification of receptor family and their molecular structures, secondary messengers like cyclic AMP, cyclic GMP, IP3, NO and DAG.
- Students will gain knowledge on principles and applications of recombinant DNA technology - restriction enzymes, various types of vectors.
- Students will be furnished with the concepts of gene therapy, types of gene transfer techniques, clinical applications and recent advances in gene therapy.
- Students will also gain knowledge on gene mapping and cloning of disease gene as well as genetic variations and genetic polymorphisms in health and pharmacology.
- Students can achieve distinct knowledge on basic equipment used in cell culture lab, cell culture procedures, sub-culturing.
- Students will understand the principles and applications of cell viability assays and flow cytometry.

- Students will be enabled with knowledge and importance on Biosimilars.

I/II M. PHARMACY – II Semester

ADVANCED PHARMACOLOGY – II (MPL201T)

Course Objectives:

The educational objectives of the program is to provide comprehensive knowledge to the students and enable them

1. To understand the concept of infections and the principles of chemotherapy.
2. To let them be mindful on the chemotherapy for bacterial infections.
3. To also let them understand the chemotherapy of viral and fungal infections.
4. To understand the important concepts of cancer therapy and immunosuppression.
5. To enable them understand the insights on endocrinal pharmacology along with calcium regulation in the body.
6. To educate the students with a deep insight on respiratory and gastrointestinal pharmacology.
7. To understand the importance of autacoids in pathophysiology of any disease and their associative pharmacology.
8. To enable them with knowledge on the concepts of Chronopharmacology.

Course Outcomes:

Following the completion of this course,

- Students can have an in depth knowledge on the concepts and practices of general chemotherapy. An understanding that enables the knowledge with respect to powerful and familiar antibiotics like cell wall synthesis inhibitor drugs (penicillins, cephalosporins), protein synthesis inhibitors (tetracyclins, chloramphenicol, macrolides), drugs interfering with mRNA proofreading (aminoglycosides), DNA gyrase inhibitors (fluoroquinolones).
- Students can achieve distinct knowledge on the drugs associated with tuberculosis, leprosy, fungal infections, viral infections, protozoal infections, nematode infections and malaria.
- Students can understand the pharmacology of individual drugs, their spectrum of activity, microbial mechanisms for resistance, and their pharmacodynamic aspects in detail would be understood by the students in due course of time.
- In general, drugs used in the management of malignancy have selective toxicity for malignant cells. These drugs have action specificities in particular. So, students would attain the knowledge on the idea of malignancy, therapeutic strategies available for malignancy, mechanisms of individual drugs, their pharmacokinetics and dynamic aspects, along with systemic toxicities, drug interactions and contraindications.
- Students will attain a deep understanding on different immunostimulants like vaccines, protein drugs, biosimilars as well as immunosuppressants.
- Students will gain knowledge on the pharmacology of hormones (hormones of hypothalamic pituitary axis), pancreatic hormones, pharmacology of antithyroid drugs, oral contraceptives, oral hypoglycemic drugs, corticosteroids and drugs affecting calcium regulation.

- Students will be enabled with complete understanding towards gastrointestinal diseases and drugs acting against those diseases with a detailed focus on antiulcer agents, drugs for constipation and diarrhea, appetite stimulants and suppressants, digestants and carminatives, emetics and anti-emetics.
- Students can have an in depth knowledge on the drugs acting on the respiratory system and their pharmacological details with respect to disease conditions like asthma, COPD and other drugs beneficial for clinical outcomes namely expectorants, antitussives, nasal decongestants, and respiratory stimulants
- Students can achieve distinct knowledge on physiological and pathological role of histamines, serotonin, prostaglandins, kinins, interleukins, substance P, neuropeptides, NFkβ along with pharmacology of antihistamines, 5 HT antagonists.
- Students will be enriched with the concept of Chronopharmacology, circadian rhythm and its applications.

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS (MPL 202T)

Course Objectives:

The educational objectives of the program is to provide comprehensive knowledge to the students and enable them

1. To understand the description, handling and other applications of laboratory animals research.
2. To educate the students regarding the importance of anesthesia and euthanasia in preclinical research.
3. To educate the students about the importance of regulatory bodies namely CPCSEA, OECD, ICH, EPA and their guidelines in conducting animal experimentation.
4. To understand the preclinical screening of CNS pharmacology associated with in vivo, in vitro and alternative methods.
5. To also understand thepreclinical screening of respiratory pharmacology, reproductive pharmacology and gastrointestinal pharmacology associated with in vivo, in vitro and alternative methods.
6. To enable the students with deep and proper understanding on the preclinical screening models of cardiovascular agents and cancer drugs
7. To educate the students about toxicity and toxicological measures in preclinical evaluation of drugs and chemical substances.
8. To understand the protocols for new drug applications specific to investigational drugs.

Course Outcomes:

Following the completion of this course,

- Students will be enabled with an in depth knowledge on handling and applications of different species and strains of animals, maintenance and breeding of laboratory

animals Use of Transgenic animals in preclinical research their production, maintenance and applications.

- Students can have complete understanding on Anesthesia and euthanasia of experimental animals.
- Students will gain knowledge on the guidelines imparted by agencies like CPCSEA, OECD, ICH, EPA to conduct experiments on animals and will learn GLP standards.
- Students will also gain knowledge on bioassay - principles, scope and limitations and methods of immunoassays.
- Students will also gain knowledge on the preclinical screening models for behavioral and muscle coordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti-epileptics and nootropics, drugs for neurodegenerative diseases like Parkinsonism, Alzheimer's and multiple sclerosis. Screening of drugs acting on Autonomic Nervous System.
- Students can achieve distinct knowledge on anti-asthmatics, drugs for COPD and anti-allergics, aphrodisiacs, antifertility agents, analgesics, anti-inflammatory and antipyretic agents, anti-ulcer, anti-emetic, anti-diarrheal and laxative drugs.
- Students will gain knowledge on cardiovascular screening of Antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics; metabolic disease screening of disorders like anti-diabetic, anti-dyslipidemia agents; screening of hepatoprotectants and agents used in cancer.
- Students will understand the importance of toxicity studies (acute, sub-acute and chronic) oral, inhalation and dermal toxicity studies, reproductive toxicity, teratogenicity, genotoxicity (Ames test, in vitro, in vivo micronucleus, chromosomal aberrations) carcinogenicity.
- Students will be enabled with knowledge on FDA and FDA associated drug filings including IND applications.

PRINCIPLES OF DRUG DISCOVERY (MPL 203T)

Course Objectives:

The educational objectives of the program are

1. To make the student understand the modern drug discovery process.
2. To acquire knowledge on genomics, proteomics and bioinformatics.
3. To elaborate the importance of combinatorial chemistry & high throughput screening, in silico lead discovery techniques.
4. To provide an understanding on rational drug design, the concepts and methods associated with rational drug design.
5. To understand molecular docking, docking based screening and QSAR study designs.
6. To understand the concept and rationale for prodrug design.

Course Outcomes:

The completion of this course provides the following outcomes where,

- Students will be enabled with the understanding and approach towardsnew drug Development design, methodology and analysis
- Students can have a detailed knowledge on gene mapping and gene sequencing.
- Students will gain understanding on target identification, target validation, lead identification and lead Optimization along with target discovery and validation, giving importance to understand the economics involved in drug discovery.
- Students can have complete understanding on role of Genomics, proteomics and bioinformatics, nucleic acid microarrays, protein microarrays, antisense technologies, siRNAs, antisense oligonucleotides, zinc finger proteins.
- Students are allowed to acquire the importance on the role of transgenic animals in target validation, lead identification associated with combinatorial chemistry & high throughput screening, in silico lead discovery techniques as well as assay development for hit identification.
- Students will gain knowledge on rational drug design, concepts of traditional vs. rational drug design, methods followed in traditional drug design.
- Students will be furnished with the concepts of Molecular docking - rigid docking, flexible docking, manual docking; Docking based screening.
- Students will gain knowledge on *de novo* drug design and quantitative analysis of structure activity relationship by QSAR study methods.
- Students can achieve distinct knowledge on 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.

PHARMACOLOGY (MPL)

First Semester

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)

(Note: Common paper for MPA, MPC, MPH, MPB, MPL, MPG, MQA, & MIP, specializations)

Unit 1:

a. UV-visible spectroscopy: Introduction, theory, laws and instrumentation associated with UV-visible spectroscopy, choice of solvents and solvent effect and applications of UV-visible spectroscopy.

b. IR spectroscopy: Theory, modes of molecular vibrations, sample handling, instrumentation of dispersive and Fourier-Transform IR Spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopy, data interpretation.

c. Spectroflourimetry: Theory of fluorescence, factors affecting fluorescence (characteristics of drugs that can be analyzed by flourimetry), quenchers, instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, instrumentation, interferences and applications. **12 Hours**

Unit 2:

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

Unit 3:

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. 1**0 Hours**

Unit 4:

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. **14 Hours**

Unit 5:

a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing.

b. 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: Principle, instrumentation, advantage and disadvantages, Pharmaceutical applications of DSC, DTA & TGA.

d. Microscopic techniques: Principles and applications of Scanning Electron Microscopy

and Transmission Electron Microscopy analysis. **14 Hours**

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein. 6th ed. John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler & Timothy A. Nieman. 5th ed. Eastern Press, Bangalore, 1998.
3. Instrumental Methods of Analysis – Willards. 7th ed. CBS Publishers, New Delhi.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake. Vol 2. 4th ed. CBS Publishers, New Delhi
5. Organic Spectroscopy - William Kemp. 3rd ed. ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical Formulation – P.D. Sethi. 3rd ed. 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 - P.S. Kalsi. 2nd ed. Wiley Estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis - K.A. Connors. 3rd ed. John Wiley & Sons.

ADVANCED PHARMACOLOGY – I ((MPL 102T)

Unit 1:

General pharmacology: Drug receptor concepts, relationship between drug concentration and effect, Structural and functional families of the receptors, quantification of drug receptor interaction. Basic concepts of pharmacokinetics. Types of adverse effects. **12 Hours**

Unit 2:

Neurohumoral transmission in peripheral nervous system: Neurotransmitters of autonomic nervous system, nonadrenergic and noncholinergic transmitters. Pharmacology of autonomous nervous system, parasympathomimetics, parsympatholytics, sympathomimetics, sympatholytics. Pharmacology of local anaesthetics. **12 Hours**

Unit 3:

Neurohumoral transmission of central nervous system- neurotransmitters of central nervous system (Detailed study of dopaminergic, serotonergic, GABA, adrenergic, glutamate, cholinergic pathways). Pharmacology of drugs acting on central nervous system- general anaesthetics, sedatives, hypnotics, antianxiety, antidepressants, antipsychotics, antiepileptics, antimaniacs, opioid and non-opioid analgesics. **12 Hours**

Unit 4:

Cardiovascular pharmacology: Diuretics, antihypertensives, antianginal drugs, antiarrythmics, antihyperlipidemics, cardiotonics, coagulants, anticoagulants, fibrinolytics, antiplatelet agents, hematinics. **12 Hours**

Unit 5:

Neurodegenerative disorders: Parkinsonism, Alzheimer's disease, Huntington's disease, concepts of free radical generation. Introduction to free radical induced disorders (diabetes, asthma, gastric ulcer, cardiovascular disorder). **12 Hours**

REFERENCES

1. Goodman and Gillman's: The Pharmacological Basis of Therapeutics - Laurence L Brunton, Randa Hilal-Dandan & Björn C Knollmann. 13th ed. Mc Graw Hill Education.
2. Principles of Pharmacology: The Pathophysiologic Basis of Drug Therapy - David E Golan, Armen H Tashjian Jr, Ehrin J Armstrong & April W Armstrong. Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.

3. Oxford Textbook of Clinical Pharmacology - Graham Smith.
4. Avery Drug Treatment - Trevor M Speight & Nicholas H G Holford.
5. Dipiro Pharmacology, Pathophysiological approach.
6. Robbins & Cortan Pathologic Basis of Disease. 9th ed. (Robbins Pathology)
7. Essentials of Medical Pharmacology – K.D. Tripathi.
8. Modern Pharmacology with Clinical Applications - R. Craig Charles & E. Stitzel Robert. Lippincott.
9. Modern Pharmacology – C.R. Craig & R.E. Stitzel. Little Brown & Company.
10. Green Pathophysiology for Pharmacists.
11. A Complete Text Book of Medical Pharmacology - S.K. Srivastava. APC Avichal Publishing.

PHARMACOKINETICS AND DRUG METABOLISM (MPL 103T)

Unit 1:

ADME: Transfer of drugs through biological membranes (BBB, placental barrier), role of P-glycoprotein in drug absorption. Gastrointestinal, percutaneous and rectal absorption, factors affecting drug absorption, absorption kinetics, distribution kinetics (plasma protein binding, tissue binding). **12 Hours**

Unit 2:

Drug metabolism: Microsomal and non-microsomal biotransformation of drugs (liver, kidney and intestine), human cytochrome P450 enzymes, substrates, inducers and inhibitors. In vitro drug metabolism (liver microsomes, liver S9 fraction and hepatocytes). Physiological, pathological and genetic factors affecting drug metabolism. **12 Hours**

Unit 3:

Routes of drug excretion, factors affecting drug excretion, enterohepatic recirculation, significance of elimination rate constant, elimination half-life. **12 Hours**

Unit 4:

Clinical pharmacokinetics, population pharmacokinetic, PK-PD modeling, therapeutic drug monitoring (TDM), and dug-drug interactions, drug food and predictions of drug-drug interactions. **12 Hours**

Unit 5:

Toxicokinetics: Toxicokinetic evaluation in pre-clinical studies, importance and applications of toxicokinetic studies, alternative methods to animal toxicity studies. **12 Hours**

REFERENCES

1. Biopharmaceutics and Pharmacokinetics - An Introduction - Robert E Notari.
2. Drug metabolism - Bernard Testa & Peter Jenner.
3. Selected Chapters from: Principles of Drug Action - Gldstein, Aranow & Kalman.
4. Drug Interaction - D.G. Grahme Smith
5. Remington – The Science and Practice of Pharmacy – Loyd V Allen. 22nd ed.
6. Goodman and Gillman's The Pharmacological Basis of Therapeutics. 10th ed.
7. Hand book of Clinical Pharmacokinetics - Gibaldi and Prescott.
8. Applied Biopharmaceutics and Pharmacokinetics - Leon Shargel & Andrew B C Yu.
9. Clinical Pharmacokinetics & Pharmacodynamics - Malcolm Rowland & Tozer. 4th ed. Lippincott Publications.
10. Applied Biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug

Metabolism for Industrial Scientists.

11. Hand Book of Essential Pharmacokinetics, Pharmacodynamics & Drug Metabolism for Industrial Scientists.

CELLULAR AND MOLECULAR PHARMACOLOGY (MPL 104T)

Unit 1:

Cell biology: Structure and functions of cell and its organelles, Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing, Cell cycles and its regulation. Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis. Necrosis and autophagy. **12 Hours**.

Unit 2:

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

Unit 3:

Principles of recombinant DNA technology - restriction enzymes, various types of vectors. Applications of recombinant DNA technology. ELISA and Western blotting Gene therapy-Various types of gene transfer techniques, clinical applications and recent advances in gene therapy. **12 Hours**

Unit 4:

Gene mapping and cloning of disease gene. Genetic variation and its role in health/ pharmacology. Pharmacogenomics, polymorphisms affecting drug metabolism, Genetic variation in drug transporters, Genetic variation in G protein coupled receptors. **12 Hours**

Unit 5:

Cell culture techniques: Basic equipment 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. Biosimilars. **12 Hours**

REFERENCES

1. Molecular Biology of The Cell - Bruce Alberts and et al. 5th ed. Garland Science.
2. Cell and Molecular Biology - E.D.P. De Robertis & E.M.F. De Robertis Jr. 8th ed. Wolter Publications.
3. Molecular Cell Biology - Harvey Lodish et al. 6th ed. W.H. Freeman & Company.
4. Molecular Biology and Biotechnology - John M Walker & Ralph Raple. 5th ed. RSC Publications.
5. A Concise Reference Advanced Molecular Biology - R.M. Twyman, Viva Books Pvt. Ltd.
6. Principles of Gene Manipulation and Genomics - S.B. Primrose & R.M. Twyman. 7th edn.
7. The Cell, A Molecular Approach - Geoffrey M Cooper.
8. Pharmacogenomics - J. Licinio & M.L. Wong
9. Handbook of Cell Signaling – A. Ralph et al. 2nd ed.
10. Molecular Pharmacology: From DNA to Drug Discovery - John Dickenson et al.
11. Basic Cell Culture Protocols - Cheril D Helgason & Cindy L Miller

12. Basic Cell Culture (Practical Approach) - J. M. Davis.
13. Animal Cell Culture: A Practical Approach - John R Masters.
14. Current Protocols in Molecular Biology - Frederick M. Ausuvel et al. Vol 1 to 6.

PHARMACOLOGY PRACTICAL – I (MPL 105P)

1. Enzyme based in vitro assays (MPO, AChEs, α amylase, α glucosidase)
2. Handling of laboratory animals
3. Various routes of drug administration.
4. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using software
5. Enzyme inhibition and induction activity
6. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
7. Extraction of drug from various biological samples and estimation of drug in biological fluids using different analytical techniques (HPLC)
8. Predictions of drug - drug interactions using software

PHARMACOLOGY PRACTICAL – II (MPL 106P)

1. Functional observation battery tests (modified Irwin test).
2. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
3. Evaluation of analgesic & anti-inflammatory.
4. Evaluation of local anesthetic, mydriatic and miotic activity.
5. Evaluation of diuretic activity.
6. Evaluation of antiulcer activity models
7. Estimation of glucose and lipid parameters in blood samples.
8. Estimation of lipid levels in tissues.
9. Oral glucose tolerance test, oral fat tolerance test.

Second Semester

ADVANCED PHARMACOLOGY – II (MPL 201T)

Unit 1:

Chemotherapy: Basic concepts of chemotherapy, pharmacology of antibacterial resistance, pharmacology of antibacterial agents – β – lactams, aminoglycosides, tetracyclins, chloramphenicol, macrolide antibiotics, fluoroquinolines, antitubercular, antileprotic, antiprotozoal (antimalarial, asntiamoebics., etc.) and anthelmintics. **12 Hours**

Unit 2:

Antiviral, antifungal, anticancer drugs: Drugs acting on immune disorders (rhematoid arthritis, asthma, COPD), immunosupressants. **12 Hours**

Unit 3:

Endocrine pharmacology: Pharmacology of hormones (hormones of hypothalamic pituitary axis), pancreatic hormones, pharmacology of antithyroid drugs, oral contraceptives, oral hypoglycemic drugs, corticosteroids, drugs affecting calcium regulation. **12 Hours**

Unit 4:

GIT pharmacology: Antiulcer drugs, antiemetics, antidiarrhoeals, drugs used for intestinal bowel disorders (IBD) and constipation.

Respiratory Pharmacology: Antiasthmatics, cough suppressants, expectorants and drugs used in COPD. **12 Hours**

Unit 5:

Autacoid pharmacology: Physiological and pathological role of histamines, serotonin, prostaglandins, kinins, interleukins, substance P, neuropeptides, NFkβ. Pharmacology of antihistamines, 5 HT antagonists. Concept of chronopharmacology, circadian rhythm and its applications. **12 Hours**

REFERENCES

1. Goodman and Gillman's The Pharmacological Basis of Therapeutics. 10th ed.
2. Principles of Pharmacology: The Pathophysiologic Basis of Drug Therapy - David E Golan, Armen H Tashjian Jr, Ehrin J Armstrong & April W Armstrong. Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology - B.G. Katzung
4. Rang and Dale's Pharmacology - James Ritter, Rod Flower, Graeme Henderson, Yoon Kong Loke, David MacEwan & Humphrey Rang
5. Text book of Therapeutics, Drug and Disease Management - E T. Herfindal & Gourley.
6. Robbins & Cortan Pathologic Basis of Disease, 9th ed. (Robbins Pathology)
7. A Complete Text Book of Medical Pharmacology - S.K. Srivastava. APC Avichal Publishing.
8. Essentials of Medical Pharmacology - K.D. Tripathi.
9. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy - David E Golan, H. Armen, Tashjian Jr, J. Ehrin, Armstrong, W. April & Armstrong. Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
10. Relevant Research and Review articles

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS (MPL 202T)

Unit 1:

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, OECD, ICH, EPA guidelines to conduct experiments on animals. Good laboratory practice. Bioassay - Principles, scope and limitations and methods of Immunoassays. **12 Hours**

Unit 2:

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. General principles of preclinical screening. **12 Hours**

CNS Pharmacology: Behavioral and muscle co ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimer's and multiple sclerosis. Screening of drugs acting on Autonomic Nervous System

Unit 3:

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-diarrheals and laxative. **12 Hours**

Unit 4: 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, anti-dyslipidemic agents. Anti-cancer agents. Hepatoprotective screening methods. **12 Hours**

Unit 5:

Toxicity studies (acute, sub acute and chronic) oral, inhalation and dermal toxicity studies. Reproductive toxicity – Teratogenicity, genotoxicity (Ames test, in vitro, in vivo micronucleus, chromosomal aberrations) carcinogenicity. Introduction to IND Studies.

12 Hours

REFERENCES

1. Biological Standardization - J.H. Burn, D.J. Finney & I.G. Goodwin.
2. Screening Methods in Pharmacology - A. Robert Turner.
3. Evaluation of Drugs Activities - Laurence & Bachrach.
4. Fundamentals of Experimental Pharmacology - M.N. Ghosh.
5. Pharmacological Experiments on Intact Preparations - Churchill Livingstone
6. Drug Discovery and Evaluation – H.G. Vogel.
7. Experimental Pharmacology - R.K. Goyal.
8. Handbook of Experimental Pharmacology – S.K. Kulkarni
9. Practical Pharmacology and Clinical Pharmacy - S.K. Kulkarni, 3rd ed.
10. Screening Methods in Pharmacology - Robert A Turner.
11. Rodents for Pharmacological Experiments - Tapan Kumar Chatterjee.
12. Practical Manual of Experimental and Clinical Pharmacology - Bikash Medhi & Ajay Prakash.
13. Methods in Pharmacology - Arnold Schwartz.
14. Preclinical Evaluation of New Drugs - S.K. Guta.
15. Animal Models in Cardiovascular Research - David R Gross, 2nd ed. Kluwer Academic Publishing.
16. OECD Test Guidelines.
17. Relevant Research and Review articles and guidelines

PRINCIPLES OF DRUG DISCOVERY (MPL 203T)

Unit 1:

An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. Target Discovery and validation. **12 Hours**

Unit 2:

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. Lead identification - combinatorial chemistry & high throughput screening, in silico lead discovery techniques. Assay development for hit identification. **12 Hours**

Unit 3:

Rational drug design - Traditional vs. rational drug design. Methods followed in traditional drug design. High throughput screening, Concepts of rational drug design. **12 Hours**

Unit 4:

Rational drug design methods: Structure and pharmacophore based approaches. Molecular docking - rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of structure activity relationship. **12 Hours**

Unit 5:

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

REFERENCES

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

CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL 204T)

Unit 1:

Regulatory perspectives of clinical trials: Origin and principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines.

Ethical committee: Institutional Review Board, ethical guidelines for biomedical research and human participant - Schedule Y. ICMR informed consent process: structure and content of an informed consent process, ethical principles governing informed consent process.

12 Hours

Unit 2:

Clinical trials: Types and design of experimental study- RCT and non RCT.

Observation study: Cohort, case control, cross sectional clinical trial study - Team roles and responsibilities of clinical trial personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management. **12 Hours**

Unit 3:

Clinical trial documentation: Guidelines to the preparation of documents, preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report.

Clinical trial monitoring - Safety monitoring in clinical trial adverse drug reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions;

Terminologies of ADR. **12 Hours**

Unit 4:

Basic aspects, terminologies and establishment of pharmacovigilance: History and progress of pharmacovigilance. Significance of safety monitoring. Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, establishing pharmacovigilance centres in hospitals, industry and national programmes related to pharmacovigilance. Roles and responsibilities in pharmacovigilance, guidelines for ADR reporting, Argus, Aris G Pharmacovigilance, Vigi Flow. Statistical methods for evaluating medication safety data. Methods, ADR reporting and tools used in pharmacovigilance. **12 Hours**

Unit 5:

Pharmacoepidimology and pharmacoeconomics: Definition and scope, measurement of outcomes, Pharmacoepidimology methods, Definition evaluation and applications of pharmacoeconomic methods. **12 Hours**

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 - David Machin, Simon Day & Sylvan Green. John Wiley and Sons, March 2005.
5. Clinical Data Management – R.K. Rondels, S.A. Varley & C.F. Webbs. 2nd ed. Wiley Publications, Jan 2000.
6. Handbook of Clinical Research - Julia Lloyd & Ann Raven. Churchill Livingstone.
7. Principles of Clinical Research - Giovanna di Ignazio & Di Giovannaand Haynes.
8. Relevant Research and Review articles and guidelines

PHARMACOLOGY PRACTICAL – III (MPL 205P)

1. Recording of rat BP, heart rate and ECG
2. Recording of rat ECG
3. Drug absorption studies by averted rat ileum preparation
4. Acute oral toxicity studies as per OECD guidelines
5. Acute dermal toxicity studies as per OECD guidelines
6. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies
8. Protocol design for clinical trial.(3 Nos.)
9. To record the DRC of agonist using suitable isolated tissues preparation
10. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation
11. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation
12. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation

13. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation
14. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation
15. Estimation of PA2 values of various antagonists using suitable isolated tissue preparations
16. To study the effects of various drugs on isolated heart preparations

Note: Minimum 10 Experiments from the above is mandatory

Third Semester

RESEARCH METHODOLOGY & BIOSTATISTICS (MRM 301T)

(Note: Common Paper for all specializations)

Unit 1:

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. **12 Hours**

Unit 2:

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (Wilcoxan rank tests, analysis of variance, correlation, Chi-square test), null hypothesis, P values, degree of freedom, interpretation of P values. **12 Hours**

Unit 3:

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-malfeasance, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality. **12 Hours**

Unit 4:

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. **12 Hours**

Unit 5:

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care. **12 Hours**

REFERENCES

1. Pharmaceutical Statistics: Practical and Clinical Applications - Stanford Bolton & Charles Bon. 5th ed. CRC Press.
2. Biostatistics: A Foundation for Analysis in the Health Sciences - Wayne W Daniel. 10th ed. John Wiley & Sons.
3. Introduction to Research in the Health Sciences - Stephen Polgar & Shane Thomas. 7th ed. Elsevier.
4. www.cpcsea.nic.in
5. www.wma.net