2016

THE MASTER OF PHARMACY (M. PHARM.)

COURSE REGULATION 2014

(BASED ON NOTIFICATION IN THE GAZETTE OF INDIA No. 362, DATED DECEMBER 11, 2014)

SCHEME AND SYLLABUS

PHARMACY COUNCIL OF INDIA
Combined Council's Building, Kotla Road,
Alwan-E-Ghalib Marg, New Delhi-110 002.
Website : www.pci.nic.

COURSE STRUCTURE AND SYLLABUS
For
M. PHARM

MPH R 20 Regulations

(Applicable for batches admitted from 2020-2021)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY: KAKINADA
KAKINADA - 533 003, Andhra Pradesh, India

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ADITYA COLLEGE OF PHARMACY SURAMPALEM

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Aditya College of Pharmacy
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PHARMACY COUNCIL OF INDIA

NOTIFICATION

New Delhi, the 10th December, 2014

The Master of Pharmacy (M.Pharm) Course Regulations, 2014

No. 14-136/ 2014-PCI.—In exercise of the powers conferred by Sections 10 and 18 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government hereby makes the following regulations namely–

CHAPTER –I: REGULATIONS

1. Short Title and Commencement

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

2. Minimum qualification for admission

A Pass in the following examinations

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

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

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

3. Duration of the program

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

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

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

6. Attendance and progress

- A student shall be eligible to write University examinations if he acquires a minimum of 75% of attendance in aggregate of all the subjects/courses, and with minimum 50% in each and every course including practicals.
- Condonation of shortage of attendance in aggregate up to 10% (65% and above and below 75%) in each semester shall be granted by the College Academic Committee.
- Shortage of Attendance below 65% in aggregate shall not be condoned and not eligible to write their end semester examination of that class.
- Students whose shortage of attendance is not condoned in any semester are not eligible to write their end semester examination of that class.
- A prescribed fee shall be payable towards Condonation of shortage of attendance.
- A student shall not be promoted to the next semester unless, he satisfies the attendance requirement of the present semester, as applicable. They may seek re-admission into that semester when offered next. If any candidate fulfills the

attendance requirement in the present semester, he shall not be eligible for re-admission into the same class.

7. Program/Course credit structure

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

7.1. Credit assignment

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

8. Academic work

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department/ teaching staff of respective courses.

M.Pharm I & II Semester Practicals:

- The individual student of the respective specialization need to carry out at least 75% of the practical prescribed in the syllabus.
- Based and depending upon the software available with the institute the practical can be designed.
- Some experiments have to be carried out only by Demonstration. Students are advised to know the Principle and Protocol of the experiment.

9. Course of study

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

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

S. No.	Specialization	Code
1.	Pharmaceutics	MPH
2.	Industrial Pharmacy	MIP
3.	Pharmaceutical Chemistry	MPC
4.	Pharmaceutical Analysis	MPA
5.	Pharmaceutical Quality Assurance	MQA
6.	Pharmaceutical Regulatory Affairs	MRA
7.	Pharmaceutical Biotechnology	MPB
8.	Pharmacy Practice	MPP
9.	Pharmacology	MPL
10.	Pharmacognosy	MPG

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

Table – 10: Course of study for (Pharmacology)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
Semester I					
MPL101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPL102T	AdvancedPharmacology-I	4	4	4	100
MPL103T	Pharmacological and Toxicological Screening Methods-I	4	4	4	100
MPL104T	Cellular and Molecular Pharmacology	4	4	4	100
MPL105PA	Pharmacology Practical I	6	3	6	75
MPL105PB	Pharmacology Practical II	6	3	6	75
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MPL201T	Advanced Pharmacology II	4	4	4	100
MPL202T	Pharmacological and Toxicological Screening Methods-II	4	4	4	100
MPL203T	Principles of Drug Discovery	4	4	4	100
MPL204T	Clinical Research and Pharmacovigilance	4	4	4	100
MPL205PA	Pharmacology Practical III	6	3	6	75
MPL205PB	Pharmacology Practical IV	6	3	6	75
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

PHARMACOLOGY (MPL)

SEMESTER - I

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPL 101T)

Scope

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

Objectives

After completion of course student is able to know about,

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

	THEORY	60Hrs
1.	a) UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. 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 (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. d) Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.	10 Hrs
2	NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.	10 Hrs
3	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Metastable ions, Isotopic peaks and Applications of Mass spectroscopy.	10 Hrs
4	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:	10 Hrs

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

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

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

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

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

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

REFERENCES

1. Spectrometric Identification of Organic compounds- Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A.Nieman, 5th edition, Easternpress, Bangalore, 1998.
3. Instrumental methods of analysis– Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry– Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy- William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation-PDSethi, 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, 2nd edn., P.S /Kalsi, Wileyestern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

ADVANCED PHARMACOLOGY - I
(MPL 102T)

Scope

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

Objectives

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

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

THEORY 60 Hrs

1. General Pharmacology 12 Hrs

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.

2 Neurotransmission 12 Hrs

a. General aspects and steps involved in neurotransmission.
b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetylcholine).
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

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

Para sympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction.

3	Central nervous system Pharmacology General and local anesthetics Sedatives and hypnotics, drugs used to treat anxiety. Depression, psychosis, mania, epilepsy, neurodegenerative diseases. Narcotic and non-narcotic analgesics.	12 Hrs
4	Cardiovascular Pharmacology Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants, anticoagulants, fibrinolytics and anti- platelet drugs	12 Hrs
5	Autocoid Pharmacology The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5 HT antagonists.	12 Hrs

REFEERENCES

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. Handbook of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists.
10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company
12. KD.Tripathi. Essentials of Medical Pharmacology.
13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14. Clinical Pharmacokinetics & Pharmacodynamics: Concepts and Applications – Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
15. Applied Biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I

(MPL 103T)

Scope

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

Objectives

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

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

THEORY — 60 Hrs

1. **Laboratory Animals** — 12 Hrs

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

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

   Maintenance and breeding of laboratory animals. CPCSEA guidelines to conduct experiments on animals

   Good laboratory practice.

   Bioassay- Principle, scope and limitations and methods

2. Preclinical screening of new substances for the pharmacological activity using in vivo, invitro and other possible animal alternative models. — 12 Hrs

   General principles of preclinical screening. CNS Pharmacology: behavioral and muscle co ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, antiepileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.

3. Preclinical screening of new substances for the pharmacological activity using in vivo, invitro and other possible animal alternative models. — 12 Hrs

   Respiratory Pharmacology: anti-asthmatics, drugs for COPD and antiallergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, anti-inflammatory and antipyreticagents. Gastrointestinal drugs: antiulcer, anti- emetic, anti- diarrheal and laxatives.

4. Preclinical screening of new substances for the pharmacological activity using in vivo, invitro, and other possible animal alternative models. 12 Hrs
Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods.

5. Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. 12 Hrs
Iimmunomodulators, Immunosuppressants and immunostimulants
General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immuno assay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin.
Limitations of animal experimentation and alternate animal experiments. Extrapolation of invitro data to preclinical and preclinical to humans.

REFERENCES

1. Biological standardization by J.H.BurnD.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 Edi, 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), AjayPrakash (Author)

CELLULAR AND MOLECULAR PHARMACOLOGY
(MPL 104T)

Scope:

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

Objectives:

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

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

THEORY — 60 Hrs

1. **Cellbiology** — 12 Hrs

   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.

2. **Cell signaling** — 12 Hrs

   Intercellular and intracellular signaling pathways.
   Classification of receptor family and molecular structure ligandgated 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, Januskinase (JAK)/ signal transducer and activator of transcription (STAT) signaling pathway.

3. Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, — 12 Hrs

   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.

4. Pharmacogenomics — 12 Hrs

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
Applicationsofproteomicsscience:Genomics,proteomics,metabolomics, functionomics, nutrigenomicsImmunotherapeutics
Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinicalpractice

5. a. Cell culturetechniques — 12 Hrs

Basicequipmentsusedincellculturelab.Cellculturemedia,varioustypes of cell culture, general procedure for cell cultures; isolation of cells, subculture,cryopreservation,characterizationofcellsandtheirapplication.
Principles and applications of cell viability assays, glucose uptake assay, Calcium influxassays
Principles and applications of flow cytometry
b. Biosimilars

REFERENCES:

1. The Cell, A Molecular Approach.Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J.Licinio and M-L.Wong
3. Handbook of Cell Signaling (Second Edition) Edited by RalphA.et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and CindyL.Miller
6. Basic Cell Culture (Practical Approach) by J.M.Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R.Masters (Editor)
8. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel etla.

PHARMACOLOGY PRACTICAL - I
(MPL 105PA)

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.
7. Various routes of drug administration.
8. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
9. Functional observation battery tests (modified Irwintest)
10. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
11. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and mioticactivity.
12. Evaluation of diureticactivity.
13. Evaluation of antiulcer activity by pylorus ligation method.
14. Oral glucose tolerance test.

PHARMACOLOGY PRACTICAL - II
(MPL 105PB)

Handling of laboratory animals.

1. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goatliver).
2. Isolation of RNA from yeast
3. Estimation of proteins by Braford/Lowry's in biological samples.
4. Estimation of RNA/DNA by UV Spectroscopy
5. Gene amplification by PCR.
6. Protein quantification Western Blotting.
7. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
8. Cell viability assays (MTT/Trypan blue/SRB).
9. DNA fragmentation assay by agarose gel electrophoresis.
10. DNA damage study by Comet assay.
11. Apoptosis determination by fluorescent imaging studies.
12. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
13. Enzyme inhibition and induction activity
14. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques(UV)
15. 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 VogelH.G.
5. Spectrometric Identification of Organic compounds- Robert M Silverstein,
6. Principles of Instrumental Analysis- Doglas ASkoog, F.James Holler, Timothy A. Nieman,
7. Vogel's Textbook of quantitative chemical analysis- Jeffery, Basset, Mendham, Denney,
8. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Mille
9. Basic Cell Culture (Practical Approach) by J.M.Davis (Editor)
10. Animal Cell Culture: A Practical Approach by John R.Masters (Editor)
11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi(Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt.Ltd

SEMESTER – II

ADVANCED PHARMACOLOGY - II (MPL 201T)

Scope

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

Objectives

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

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

THEORY — 60 Hrs

1. EndocrinePharmacology — 12 Hrs

   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.

2. Chemotherapy — 12 Hrs

   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.

3. Chemotherapy — 12 Hrs

   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.

4. GIT Pharmacology — 12 Hrs

   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.

5 Free radicals Pharmacology

Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidant
Recent Advances in Treatment:
Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus

12 Hrs

REFERENCES

1. The Pharmacological basis of therapeutics – Goodman and Gillman'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. Handbook of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists
9. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
10. A Complete Textbook of Medical Pharmacology by Dr. S.KSrivastava published by APC Avichal Publishing Company.
11. KD.Tripathi. Essentials of Medical Pharmacology
12. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by DavidE Golan, Armen H, Tashjian Jr, Ehrin J, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II

(MPL 202T)

Scope:

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

Objectives:

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

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

	THEORY	60 Hrs
1.	Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice (GLP) History, concept and its importance in drug development	12 Hrs
2	Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization- importance and methods in regulatory toxicology studies.	12 Hrs
3	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) Invivo carcinogenicity studies.	12 Hrs
4	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.	12 Hrs
5	Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.	12 Hrs

REFERENCES

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glp-handbook.pdf).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministryofhealth andfamilywelfare (department ofhealth) New Delhi
3. Drugs from discovery to approval by RickNG.
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/guidance compliance regulatory information/ guidances/ ucm073246.pdf)

PRINCIPLES OF DRUG DISCOVERY
(MPL 203T)

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

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

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

THEORY — 60 Hrs

1. An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. — 12 Hrs
   Target Discovery and validation- Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisenseoligo nucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

2. Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification. — 12 Hrs
   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.

3. Rational DrugDesign — 12 Hrs
   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,

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

5	QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA Prodrug design- Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design	12 Hrs

REFERENCES

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

CLINICAL RESEARCH AND PHARMACOVIGILANCE
(MPL 204T)

Scope:

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

Objectives:

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

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

THEORY 60 Hrs

1. Regulatory Perspectives of Clinical Trials: 10 Hrs

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.

2 Clinical Trials: Types and Design Experimental Study-RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional 10 Hrs

Clinical Trial Study Team

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

3 Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring- Safety Monitoring in CT 10 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.

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.	10 Hrs
5	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. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, ARISg Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.	10 Hrs
6	Pharmacoepidemiology, pharmacoeconomics safety pharmacology	10 Hrs

REFERENCES

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

PHARMACOLOGY PRACTICAL - III
(MPL 205PA)

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of PA2 values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG

PHARMACOLOGY PRACTICAL - IV
(MPL 205PB)

1. Drug absorption studies by averted rat ileum preparation.
2. Acute oral toxicity studies as per OECD guidelines.
3. Acute dermal toxicity studies as per OECD guidelines.
4. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
5. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
6. Protocol design for clinical trial.(3Nos.)
7. Design of ADR monitoring protocol.
8. In-silico docking studies. (2Nos.)
9. In-silico pharmacophore based screening.
10. In-silico QSAR studies.
11. ADR reporting.

REFERENCES

1. Fundamentals of experimental Pharmacology -by M.N. Ghosh
2. Handbook of Experimental Pharmacology- S.K. Kulakarni
3. Textbook of in-vitro practical Pharmacology by IanKitchen
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.