SVU COLLEGE OF PHARMACEUTICAL SCIENCES
SRI VENKATESWARA UNIVERSITY,
Tirupati - 517502

RESTRUCTURED CURRICULUM FOR M. PHARMACY PROGRAMME (Self Supporting Course) TO BE IMPLEMENTED WITH EFFECT FROM THE ACADEMIC YEAR 2021-2022

SYLLABUS
Choice based credit system (CBCS) Pattern

M. PHARMACY PROGRAMME
Choice based credit system (CBCS) Pattern

(Pharmacology)

Vision

1. To impart quality and value embedded education and research in Pharmaceutical Sciences.
2. To create technologically superior and ethically strong global manpower, in the arena of drug innovation.
3. Carving the youth as dynamic, competent, valued and knowledgeable Professionals in the field of Pharmacology.

Mission

1. Transforming Students into Full-fledged Pharmacists and participate actively in the field of Pharmacy.
2. Promoting Quality Research in Emerging Areas of Pharmaceutical Sciences.
3. To instill scientific zeal and develop skilled human resource to meet contemporary challenges in Pharmacy Profession.
4. To facilitate young adult learners with opportunities to hone their ethics and leadership potential.
5. Imparting technical education that encourages Independent thinking, develops strong domain of knowledge, hones contemporary skills and Positive attitudes towards holistic growth of young minds.
6. Evolving the Institution into a Center of Academic and Research Excellence in Pharmaceutical Education and lead the field of pharmaceutical sciences and pharmacy practice with the mission of strengthening the healthcare of the country.

Programme Objectives

1. To uphold all laws, regulations, safety and ethical standards that apply to the experimental procedures in animals and the environment

2. To impart adequate hands-on training in various animal models and determine the effects of drugs using animal models

3. To provide practical inputs in pharmacokinetic studies of various drugs and formulations in animals to establish in-vitro and in-vivo correlations
4. Acquire practical knowledge in various analytical techniques used in molecular biology
5. To train students in using suitable statistical methods for interpretation of results
6. To prepare the students in teamwork, lifelong learning and continuous improvement

Programme Outcomes

After the completion of the M.Pharm Pharmacology Programme the students will be able to,

1. Produce Pharmacy graduates with strong basics and high technical knowledge to cater the various areas of Drug Development
2. Develop an understanding for the need of pharmaceutical sciences and technology towards giving quality life to people in society through the quality of drugs.
3. Apply the knowledge and skills gained through education to gain recognition in professional course and society.
4. Act efficiently as a leader in the diverse areas of the profession to demonstrate the ability to plan and implement professional activities.
5. Develop ability for in-depth information and critical thinking in order to identify, formulate and solve the issues related to Pharmaceutical Industry, Regulatory Agencies, Hospital Pharmacy & clinical Pharmacy for better services to the community.
6. Identify the goals and regulations involved in the drug discovery and development, manufacture, distribution and sale of medicines and develop problem-based learning approach and analytical thinking in his/her academic and professional life.
7. Update the knowledge through continuous learning to face the challenges for better services to the community.
8. Design and develop process to perform experiments in various pharmaceutical areas like Pharmacognosy, Pharmaceutical Chemistry including Analytical Chemistry, Pharmaceutical Biotechnology, Pharmacology, Formulation and Development.
9. Fill the gap with other health care communities to provide innovative solutions for the purpose of maintain public health.
10. Develop team spirit for the development of student profession to the social needs and professional ethics.
11. Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, educators, managers, employers, employees).
12. Create a talent pool by involving students in research projects and to make students to undertake research projects under faculty guidance for publication.

Programme Specific Outcomes

At the end of successful completion of programme, a Post graduate will

1. Have adequate knowledge and scientific information regarding basic principles of Pharmacology, and Pharmacognosy including herbal medicines.
2. Be able to develop new dosage regimens including those of herbal origin as per standards of official books.
3. Be able to perform experimental procedures as per laboratory standards in the area of Pharmacology.
4. Be able to counsel the patients leading to physical and social well being and work as a team member of clinical trial.
5. Be able to perform research on various medical aspects and implement the Pharmaceutical knowledge in formulating the best suitable dosage form to provide high quality medicines to the society.

STRUCTURE OF COURSES
MASTER OF PHARMACY

TABLE –1: COURSE OF STUDY FOR M. PHARM - PHARMACOLOGY

I SEMESTER						
Course code	**Course**	**Credit hours**	**Credit points**	**Hrs/wk**	**Marks**	**Core/Elective**
MPL101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100	Core
MPL102T	Advanced Pharmacology-I	4	4	4	100	Core
MPL103T	Pharmacological and Toxicological Screening Methods-I	4	4	4	100	Core
MPL104T	Cellular and Molecular Biology	4	4	4	100	Core
MPL105P	Pharmacology Practical I	12	6	12	150	
	Seminar/Assignment	7	4	7	100	
Total		**35**	**26**	**35**	**650**	
II SEMESTER						
Course code	**Course**	**Credit Hours**	**Credit points**	**Hrs/wk**	**Marks**	**Core/Elective**
MPL201T	Advanced Pharmacology II	4	4	4	100	Core
MPL202T	Pharmacological and Toxicological Screening Methods-II	4	4	4	100	Core
MPL204T	Clinical Research and Pharmacovigilance	4	4	4	100	Core
-	**Elective**	4	4	4	100	
MPL205P	Pharmacology Practical II	12	6	12	150	
	Seminar/Assignment	7	4	7	100	
Total		**35**	**26**	**35**	**650**	
ELECTIVES OFFERED						

Course code	Course	Credit Hours	Credit points	Hrs/wk	Marks	Core/Elective
MPH 203T	Computer Aided Drug Delivery System	4	4	4	**100**	Elective
MPC 203T	Computer Aided Drug Design	4	4	4	**100**	Elective
MPA 203T	Quality Control & Quality Assurance	4	4	4	**100**	Elective
MPH 204T	Cosmetic & Cosmeceuticals	4	4	4	**100**	Elective
MPL 203T	Principles of Drug Discovery	4	4	4	**100**	Elective

TABLE 2: COURSE OF STUDY FOR M. PHARM - PHARMACEUTICS

I SEMESTER						
Course code	**Course**	**Credit hours**	**Credit points**	**Hrs/wk**	**Marks**	**Core/Elective**
MPH101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100	Core
MPH102T	Drug Delivery System	4	4	4	100	Core
MPH103T	Modern Pharmaceutics	4	4	4	100	Core
MPH104T	Regulatory Affairs	4	4	4	100	Core
MPH105P	Pharmaceutics Practical I	12	6	12	150	
	Seminar/Assignment	7	4	7	100	
	Total	**35**	**26**	**35**	**650**	
II SEMESTER						
Course code	**Course**	**Credit Hours**	**Credit points**	**Hrs/wk**	**Marks**	**Core/Elective**
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100	Core
MPH202T	Advance Bio Pharmaceutics and Pharmacokinetics	4	4	4	100	Core
MPH 204T	Cosmetic & Cosmeceuticals	4	4	4	100	Core
-	**Elective**	4	4	4	100	

MPH205P	Pharmaceutics Practical II	12	6	12	150	
	Seminar/Assignment	7	4	7	100	
Total		**35**	**26**	**35**	**650**	

ELECTIVES OFFERED

Course code	**Course**	**Credit Hours**	**Credit points**	**Hrs/ wk**	**Marks**	**Core/Elective**
MPH 203T	Computer Aided Drug Delivery System	4	4	4	**100**	Elective
MPC 203T	Computer Aided Drug Design	4	4	4	**100**	Elective
MPA 203T	Quality Control & Quality Assurance	4	4	4	**100**	Elective
MPL 204T	Clinical Research & Pharmacovigilance	4	4	4	**100**	Elective
MPL 203T	Principles of Drug Discovery	4	4	4	**100**	Elective

TABLE –3: COURSE OF STUDY FOR M. PHARM III SEMESTER (COMMONFOR ALL SPECIALIZATIONS)

Course code	**Course**	**Credit Hours**	**Credit points**	**Marks**
MRM 301T	Research Methodology and Biostatistics*	4	4	100
-	Journal club*	2	2	50
-	Research Proposal Presentation*	8	4	100
-	Viva Voce*	1	1	25
Total		15	11	275

*Non University Examination

TABLE – 4: COURSE OF STUDY FOR M. PHARM. IV SEMESTER (COMMONFOR ALL SPECIALIZATIONS)

Course code	**Course**	**Credit Hours**	**Credit points**	**Marks**
-	Thesis Evaluation	40	20	500
-	Research work and Colloquium	10	10	250
Total		50	30	750

FIRST SEMESTER

Course Code	Course Title	No of Hours Per week	No of Credits
MPA 101T	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES	04	04
Sessional Marks: 15		Continuous mode:10	
End Semester Examination Marks: 75		Totalmarks:100	

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

COURSE CONTENT:

UNIT- I

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

a. 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.

b. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. c. Flame emission spectroscopy and atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

UNIT-II

1HNMR spectroscopy Principle, Instrumentation, Solvent requirement in 1HNMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Applications of 1HNMR spectroscopy. Brief outline of principles of 13C NMR.

Unit III

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

UNIT-IV

Chromatography: Principle, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a. High Performance Thin Layer Chromatography. b. Gas chromatography c. High Performance Liquid chromatography d. Ultra-High Performance Liquid chromatography e. LC-MS f. Affinity chromatography

UNIT-V

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.

UNIT-VI

a. Immunoassays: Principles, procedures and types of RIA, ELISA b. Thermal techniques: Principle, instrumentation and pharmaceutical applications of DTA, DSC, TGA.

REFERENCES:

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

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

COURSE OUTCOMES:

1. Explain the importance of modern instrumentation in pharmaceutical analysis.Describe the fundamental principles and applications of spectroscopic techniques Viz., UV- Visible, IR,Students also able to demonstrate and use flame photometry, nepheloturbidometry
2. To determine the structural and functional group identification by using NMR-C13 and H1
3. Qualitative and quantitative identification of compound by Mass spectroscopy using different ionization technique
4. The chromatographic techniques for qualitative and quantitative analysis of pharmaceutical compounds.
5. The electrophoresis techniques and their applications in pharmaceutical industry.
6. Principle procedures involved in immunoassay and pharmaceutical applications: RIA, ELISA. DTA, DSC, TGA.

CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	2	1	3	2	1	2	1	2	3	1
CO2	3	1	2	3	2	2	1	2	3	3
CO3	1	1	2	1	3	1	2	3	1	3
CO4	3	2	3	2	1	2	3	3	1	1
CO5	3	2	3	2	1	2	3	2	1	3
CO6	2	1	2	3	1	2	3	1	2	1

Course Code	**Course Title**	**No of Hours Per week**	**No of Credits**
MPL 102T	**ADVANCED PHARMACOLOGY-I**	**04**	**04**
Sessional Marks: 15			**Continuous mode:10**
End Semester Examination Marks: 75			**Totalmarks:100**

OBJECTIVES:

1. Upon completion of the course the students shall be able to:
2. Discuss the pathophysiology and pharmacotherapy of certain diseases
3. Explain the mechanism of drug actions at cellular and molecular level
4. Understand the adverse effects and contraindications
5. Understand clinical uses of drugs used in treatment of diseases

COURSE CONTENT:

UNIT- I

Neurotransmission

1. General aspects and steps involved in neurotransmission.
2. Neurohumoral transmissioninautonomicnervoussystem(Detailedstudy about neurotransmitters - Adrenaline and Acetyl choline).
3. Neurohumoral transmission in centralnervoussystem(Detailed study about neurotransmitter pathways - Serotonergic, dopaminergic, GABA, glutamate and glycine pathways).
4. Non adrenergic non cholinergic transmission (NANC). Cotransmission
5. Peptidenergic neurotransmission: Neuropeptides and Neuromodulators

UNIT-II

SystemicPharmacology

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

Autonomic Pharmacology

Parasympathomimetics and Parasympatholytics, Sympathomimetics and Sympatholytics

Unit III

CentralnervoussystemPharmacology

General and local anesthetics. Sedatives and hypnotics, drugs used to treat anxiety. Depression, psychosis, mania, epilepsy, neurodegenerative diseases. Narcotic and non-
narcotic analgesics.

UNIT-IV

CardiovascularPharmacology

Diuretics, anti-hypertensives, anti-ischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants , anticoagulants, fibrinolytics and antiplatelet drugs.

UNIT-V

Autocoid Pharmacology

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

REFERENCES:

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman ‘s
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and AndrewB.C.Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists. Robbins & Cortan Pathologic Basis of Disease,9th Ed. (Robbins Pathology
10. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published byAPC Avichal Publishing Compan
11. KD.Tripathi. Essentials of Medical Pharmacology.

12. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E.,Lippincott Publishers
13. Clinical Pharmacokinetics & Pharmacodynamics: Concepts and Applications – Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers
14. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics andDrugmetabolismforindustrialscientists
15. Modern Pharmacology,Craig CR. &Stitzel RE, Little Brown Company

COURSE OUTCOMES:

1. Explain general pharmacological concepts such as pharmacodynamics and pharmacokinetics
2. Explain the general concept of Neurotransmission, neurotransmitters and drugs affecting it &Explain the Pharmacology of sympathetic and parasympathetic neurotransmitters including their agonist and antagonist
3. Explain the different Classes of drugs used in various CNS disorders like anxiety, depression, mania,psychosis, epilepsy, neurodegenerative diseases &Describe the Pharmacology of general and local anesthetics &Classify & Explain the Pharmacology of narcotic and non-narcotic analgesics
4. Explain the Pharmacology of cardiovascular drugs such as diuretics, anti-hypertensives, anti-ischemic, anti-hyperlipidemic, drugs used in CCF,hematinics, coagulants, anti-coagulants, fibrinolytics and antiplatelet drugs
5. Describe the physiological and pathological role of histamine,5-HT, Kinins,prostaglandins, opioid autacoids and Pharmacology of antihistamines and 5-HT antagonist.

CO-PO-MAPING

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	3	1	1	2	1	1	1	2	2	1	3	2
CO2	3	2	2	3	1	2	3	2	2	1	2	1
CO3	2	1	3	2	2	3	1	2	3	2	2	3
CO4	1	1	2	1	3	1	2	1	1	3	1	1
CO5	2	1	2	2	2	1	2	1	2	2	1	2

3- High, 2- Medium, 1- Low

Course Code	Course Title	No of Hours Per week	No of Credits
MPL 103T	**Pharmacological And Toxicological Screening Methods-I**	**04**	**04**
Sessional Marks: 15			**Continuous mode:10**
End Semester Examination Marks: 75			**Totalmarks:100**

OBJECTIVES:

1. Upon completion of the course the student shall be able to,
2. Appraise the regulations and ethical requirement for the usage of experimental animals.
3. Describe the various animals used in the drug discovery process and good laboratorypractices in maintenance and handling of experimental animals
4. Describe the various newer screening methods involved in the drug discovery process
5. Appreciate and correlate the preclinical data to humans

COURSE CONTENT:

UNIT- I

Laboratory Animals

Common laboratory animals: Description, handling and applications of different species and strains of animals.
Transgenic animals: Production, maintenance and applications. Anaesthesia and euthanasia of experimental animals.
Maintenance and breeding of laboratoryanimals.
CPCSEA guidelines to conduct experiments on animals.

UNIT-II

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

General principles of preclinical screening.

CNS Pharmacology, CNS stimulants and depressants, anxiolytics, anti-psychotics and anti-epileptics

Drugs for neurodegenerative diseases like Parkinsonism and Alzheimers.

Drugs acting on Autonomic Nervous System.

Unit III

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

Respiratory Pharmacology: anti-asthmatics and anti-allergics.

Reproductive Pharmacology: Aphrodisiacs and anti-fertility agents. Analgesics, anti-inflammatory and anti-pyretic agents.

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

UNIT-IV

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

Cardiovascular Pharmacology: anti-hypertensives, anti-arrythmics, anti-ischemics,anti- atherosclerotic agents and diuretics.

Drugs for metabolic disorders like anti-diabetic, anti-dyslipidemic agents. Anti-cancer agents. Hepatoprotective screening methods

UNIT-V

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

Immunomodulators, Immunosuppressants and immunostimulants Limitations of animal experimentation

Alternate animal experiments- In silico and in vitro approaches

Extrapolation of in vitro data to preclinical and preclinical to humans

REFERENCES:

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M.N.Ghosh
6. Pharmacological experiment on intact preparations by Churchill Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K.Goyal.
9. Preclinical evaluation of new drugs by S.K. Guta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3rd Edition.
12. David R.Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.
13. Screening Methods in Pharmacology, Robert A.Turner.
14. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)

COURSE OUTCOMES:

1. Describe the regulations and ethical requirement for the usage of various species and strains of experimental animals and explain CPCSEA guidelines, GLP,
2. Classify Bioassay, Explain the principle, scope, limitations and methods of bioassay

3. Classify and explain various preclinical invitro ,invivo and other possible animal alternative models for the screening of following classes of drugs such as behavioral and muscle co ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics.
4. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.
5. Classify and explain various preclinical invitro ,invivo and other possible animal alternative models for the screening of following classes of drugs such as Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory agents

CO-PO-MAPING

course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	3	1	2	2	1	2	1	2	2	1	3	3
CO2	3	2	3	3	1	2	3	2	2	1	2	2
CO3	3	3	2	2	2	3	3	2	3	2	2	2
CO4	2	2	1	1	1	2	2	2	2	2	1	2
CO5	2	1	2	1	1	1	2	1	1	1	2	2

Course Code	**Course Title**	**No of Hours Per week**	**No of Credits**
MPL 104T	**Cellular and Molecular Pharmacology**	**04**	**04**
Sessional Marks: 15		**Continuous mode:10**	
End Semester Examination Marks: 75		**Totalmarks:100**	

OBJECTIVES:

1. Upon completion of the course, the student shall be able to,
2. Explain the receptor signal transduction processes.
3. Explain the molecular pathways affected by drugs.
4. Appreciate the applicability of molecular pharmacology and biomarkers in drugdiscovery process.
5. Demonstrate molecular biology techniques as applicable for pharmacology

COURSE CONTENT:

UNIT- I

Cell biology

Structure and functions of cell and its organelles. Introduction to Cell Biology
Protein Structure and Function. Membranes and Cell Architecture. MembraneTransport. Genes, Genomics and Chromosomes.Applications of siRNA and micro RNA, gene mapping and gene sequencing.

UNIT-II

Cell signaling

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

Unit III

Molecular pharmacology

Pharmacology of sodium, calcium, potassium and chloride channels and their modulators. NMDA, GABA, Glycine, Serotonin, Dopamine, Histamine and Endothelin (ET) receptors,
their classification, signal transduction mechanism, agonists and antagonists.
Role of Cytokines, Prostaglandins, TNF-α, Bradykinins, Leucotrienes, PAF, Interferons and Adhesion molecules in Inflammation.

UNIT-IV

Cell Cycle

Introduction to the Cell Cycle, Phase and Regulation of Cell cycle and Cell Proliferation, Mitosis, Meiosis and Cytokinesis.
Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis.
Necrosis and autophagy

UNIT-V

CellculturetechniquesandBiosimilars

Basic equipment's 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: Definitions, Generics and Branded drugs, biosimilars, introduction to biologics, differences between biosimilars and generics, manufacturing process and technical challenges associated with production of biosimilar molecules, current status of biosimilars.

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.

COURSE OUTCOMES:

1. Explain cellular structure and functions and cell regulation
2. Describe molecular and cellular cell signaling pathways & Describe in detail Principles and applications of genomic and proteomic tools
3. Principles ,applications and recent advances in gene therapy & Describe in detail Principles and applications of Pharmacogenomics
4. Explain the Principles and applications of proteomics science
5. Describe in detail Principles and applications of Immunotherapeutics& Describe Cell culture techniques and biosimilars

CO-PO MAPING

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	3	2	3	1	1	1	2	1	1	2	1	1

CO2	3	3	3	2	1	1	2	1	1	1	2	1
CO3	3	3	3	3	1	1	1	1	1	1	2	1
CO4	2	2	3	2	2	1	1	1	2	1	1	1
CO5	2	1	3	1	1	1	1	1	2	1	1	1

Course Code	**Course Title**	**No of Hours Per week**	**No of Credits**
MPL 104T	**PharmacologicalPractical-I**	**04**	**04**
Totalmarks:150			

COURSE CONTENT:

1. AnalysisofpharmacopoeialcompoundsandtheirformulationsbyUV Vis spectrophotometer
2. SimultaneousestimationofmulticomponentcontainingformulationsbyUV spectrophotometry
3. Experiments based on, PC, TLC & HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry.
7. Handling of laboratory animals.
8. Various routes of drug administration.
9. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
10. Functional observation battery tests (modified Irwin test)
11. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
12. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
13. Evaluation of diuretic activity.
14. Evaluation of antiulcer activity by pylorus ligation method.
15. Oral glucose tolerance test.
16. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
17. Isolation of RNA from yeast
18. Estimation of proteins by Braford/Lowry's in biological samples.
19. Estimation of RNA/DNA by UV Spectroscopy
20. Gene amplification by PCR.
21. Protein quantification Western Blotting.
22. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
23. Cell viability assays (MTT/Trypan blue/SRB).
24. DNA fragmentation assay by agarose gel electrophoresis.
25. DNA damage study by Comet assay.
26. Apoptosis determination by fluorescent imaging studies.
27. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
28. Enzyme inhibition and induction activity
29. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
30. Extraction of drug from various biological samples and estimation of drugsin biological fluids using different analytical techniques (HPLC).

REFERENCES:

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds - Robert M Silverstein,
6. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler,Timothy A. Nieman,
7. Vogel's Text book of quantitative chemical analysis - Jeffery, Bass 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 Bikas Medhi(Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd

COURSE OUTCOMES:

1. The subject is designed to strengthen the basic knowledge in the field of pharmacology and to
2. impart recent advances in the drugs used for the treatment of variousdiseases.
3. In addition, this subject helps the students to understand the concepts of drug action an mechanisms involved Understand the adverse effects.
4. Contraindications and clinical uses of Explain the mechanism of drug actions at cellular and molecular level.
5. Discuss the pathophysiology and pharmacotherapy of certain diseases Objectives Upon completion of the course the student shall be able to : drugs used in treatment of diseases

CO-PO MAPING

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	3	2	3	1	1	1	2	1	1	2	1	1
CO2	3	3	3	2	1	1	2	1	1	1	2	1
CO3	3	3	3	3	1	1	1	1	1	1	2	1
CO4	2	2	3	2	2	1	1	1	2	1	1	1
CO5	2	1	3	1	1	1	1	1	2	1	1	1

SECOND SEMESTER

Course Code	Course Title	No of Hours Per week	No of Credits
MPL201T	AdvancedPharmacology–II	04	04
Sessional Marks: 15 End Semester Examination Marks: 75		Continuous mode:10 Totalmarks:100	

OBJECTIVES:

1. Upon completion of the course the student shall be able to:
2. Explain the mechanism of drug actions at cellular and molecular level
3. Discuss the Pathophysiology and pharmacotherapy of certain diseases
4. Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

COURSE CONTENT:

UNIT- I

Endocrine Pharmacology

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

UNIT-II

Chemotherapy

1) 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.
2) Drugs used in Protozoal InfectionsDrugs used in the treatment of HelminthiasisChemotherapyofcancer.

Unit III

Immunopharmacology :

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

Pharmacotherapy of asthma and COPD.

Immunosuppressants and Immunostimulants

UNIT-IV

GIT Pharmacology

Antiulcer drugs, Prokinetics, anti-emetics, anti-diarrheals and drugs for constipation and irritable bowelsyndrome

UNIT-V

Pharmacology of Free radicals

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 antioxidants.

Recent Advances in antioxidant treatment of Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus

REFERENCES:

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

COURSE OUTCOMES:

1. The subject is designed to strengthen the basic knowledge in the field of pharmacology
2. Toimpart recent advances in the drugs used for the treatment of various diseases.
3. In addition, this subject helps the students to understand the concepts of drug action an mechanisms involved Understand the adverse effects.
4. Contraindications and clinical uses of Explain the mechanism of drug actions at cellular and molecular level.
5. Discuss the pathophysiology and pharmacotherapy of certain diseases Objectives Upon completion of the course the student shall be able to: drugs used in treatment of diseases

CO-PO MAPING

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	2	3	2	3	3	1	1	3	1	1	1	3
CO2	3	3	2	2	2	3	2	1	1	1	2	2
CO3	2	3	1	1	2	2	2	2	1	1	1	3
CO4	2	2	1	1	2	2	2	1	1	1	3	1
CO5	2	2	2	1	1	1	1	2	2	1	1	1

Course Code	Course Title	No of Hours Per week	No of Credits
MPL202T	PharmacologicalAndToxicological ScreeningMethods-II	04	04
Sessional Marks: 15			Continuous mode:10
End Semester Examination Marks: 75			Totalmarks:100

OBJECTIVES:

1) Upon completion of the course, the student shall be able to,
2) Explain the various types of toxicity studies.
3) Appreciate the importance of ethical and regulatory requirements for toxicity studies.
4) Demonstrate the practical skills required to conduct the preclinical toxicity studies.

COURSE CONTENT:

UNIT- I

Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive)

Regulatory guidelines for conducting toxicity studies OECD, ICH and EPA. OECD principles of Good laboratory practice (GLP).

History, concept and its importance in drug development

UNIT-II

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

Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization-importance and methods in regulatory toxicology studies.

Unit III

Reproductive toxicology studies.

Male reproductive toxicity studies, female reproductive studies (segment I and segment III),Teratogenecity studies (segment II)

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

UNIT-IV

IND enabling studies (IND studies)

Definition of IND, importance of IND, industry perspective, list of studies needed for INDsubmission.Safety pharmacology studies-origin,concepts and importance of safety pharmacology. HERG assay.

UNIT-V

Toxicokinetics

Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies.

Alternative methods to animal toxicity testing- US FDA, ECVAM, CAAT and OECD approved methods.

REFERENCES:

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

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

COURSE OUTCOMES:

1) Explain the basics and the types of toxicology&Describe the regulatory guidelines for conducting toxicological studies
2) Explain various toxicity studies as per OECD guidelines
3) Describe special toxicity studies & Describe in detail about various methods employed in drugdiscovery and development
4) Explain the concept of Safety pharmacology studies
5) Explain the Importance and applications of toxicokinetics& Explain Alternative methods to animal toxicity testing.

CO-PO MAPING

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	3	3	2	2	3	1	2	1	3	2	1	1
CO2	3	2	2	2	2	1	2	1	2	1	1	2
CO3	3	1	3	1	2	1	2	1	2	1	1	1
CO4	2	1	2	2	2	2	1	2	1	2	1	2
CO5	2	1	1	3	2	3	1	1	1	1	1	1

Course Code	Course Title	No of Hours Per week	No of Credits
MPL204T	**ClinicalResearchAndPharmacovigilance**	04	04
Sessional Marks: 15		**Continuous mode:10**	
End Semester Examination Marks: 75		**Totalmarks:100**	

COURSE OBJECTIVES

1. Upon completion of the course, the student shall be able to,
2. Explain the regulatory requirements for conducting clinical trial
3. Demonstrate the types of clinical trial designs
4. Explain the responsibilities of key players involved in clinical trials
5. Execute safety monitoring, reporting and close-out activities
6. Explain the principles of Pharmacovigilance
7. Detect new adverse drug reactions and their assessment
8. Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance

COURSE CONTENT

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.

2. Clinical Trials: Types and Design
Experimental Study- RCT and Non RCT
Observation Study: Cohort, Case Control, Cross sectional
Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management

3. Clinical Trial Documentation
Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.

4. Basic aspects, terminologies and establishment of pharmacovigilance
History and progress of pharmacovigilance. Significance of safety monitoring. Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, establishing pharmacovigilance centres in hospitals, industry and national programmes related to pharmacovigilance. Roles and responsibilities in pharmacovigilance.

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

6.Pharmaco epidemiology.

Study methodology, measurement of treatments and outcomes, sources of bias and control ofconfounding, techniques to reduce bias and confounding.

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 Giovanna and Haynes.
8. Relevant Research and Review articles and guidelines

COURSE OUTCOMES

1. Explain the regulatory requirements for conducting clinical trial
2. Describe in detail about various types of clinical trial designs & Explain the responsibilities of key players involved in clinical trials
3. Describe the documentational requirements for Clinical trials
4. Explain Adverse drug reaction and its management &Describe basic concepts, and establishment of Pharmacovigilence
5. Explain ADR reporting, methods and tools used in Pharmacovigilence
6. Describe Pharmacoepidemiology, pharmacoeconomics and safety pharmacology

CO-PO MAPING

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	3	3	3	1	3	2	2	3	2	3	2	1
CO2	3	2	3	2	3	2	1	1	2	2	2	1
CO3	3	2	3	2	3	2	1	2	2	2	1	1
CO4	2	2	2	1	3	3	1	2	2	1	1	1
CO5	2	1	1	1	2	1	1	2	2	1	1	1

CO6	1	1	1	1	1	1	1	1	1	1	1	1

Course Code	Course Title	No of Hours Per week	No of Credits
MPL205P	**PharmacologyPractical–II**	04	04
Totalmarks:150			

COURSE CONTENT

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC ofagonist 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 suitabletissue preparation.
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of PA2 values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial.(3 Nos.)
17. Design of ADR monitoring protocol.
18. In-silico docking studies. (2 Nos.)
19. In-silico pharmacophore based screening.
20. In-silico QSAR studies.
21. ADR reporting

REFERENCES

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

COURSE OUTCOMES:

1. This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development.
2. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines.
3. Basic knowledge of various in-vitro and in-vivo preclinical evaluation processes Appraise the regulations and ethical requirement for the usage of Objectives Upon completion of the course the student shall be able to, Describe the various animals used in the drug discovery process and experimental animals.
4. Good laboratory practices in maintenance and handling of experimental Describe the various newer screening methods involved in the drug animals
5. Appreciate and correlate the preclinical data to humans discovery process

CO-PO MAPING

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	3	2	3	1	1	1	2	1	1	2	1	1
CO2	3	3	3	2	1	1	2	1	1	1	2	1
CO3	3	3	3	3	1	1	1	1	1	1	2	1
CO4	2	2	3	2	2	1	1	1	2	1	1	1
CO5	2	1	3	1	1	1	1	1	2	1	1	1

Course Code	Course Title	No of Hours Per week	No of Credits
MPA203T	QualityControlAndQualityAssurance	04	04
Sessional Marks: 15			**Continuous mode:10**
End Semester Examination Marks: 75			**Totalmarks:100**

COURSE OBJECTIVES

1. At the completion of this subject it is expected that the student shall be able to know
2. The cGMP aspects in a pharmaceutical industry
3. To appreciate the importance of documentation
4. To understand the scope of quality certifications applicable to Pharmaceutical industries
5. To understand the responsibilities of QA & QC departments

COURSE CONTENT

1. Concept and Evolution of Quality Control and Quality Assurance

Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines.

Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non-clinical testing, control on animal house, report preparation and documentation.

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

3. Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3)

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

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

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

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.

2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol.69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, SusmitPublishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.

COURSE OUTCOMES

1. Understand and differentiate quality control and quality assurance &Learn good laboratory practices for non clinical laboratory
2. Discuss GMP guidelines by various regulated countries &Learn pharmacopoeal guidelines about in process quality control testing
3. Appreciate the need of documentation in pharmaceutical industry &Overview of CTDs and their requirements in regulated markets
4. Learn the quality assurance aspects of manufacturing and process control
5. Discuss about intellectual property rights and their scope in pharmaceutical industry

CO-PO MAPPING

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	3	2	3	1	3	2	2	3	2	3	2	2
CO2	3	2	2	2	3	2	1	1	1	2	2	1
CO3	3	3	3	2	2	1	1	2	1	1	1	1
CO4	2	2	2	1	3	3	1	2	2	1	1	1
CO5	2	1	1	1	2	1	1	2	2	1	1	1

THIRD SEMESTER

Course Code	Course Title	No of Hours Per week	No of Credits
MPL 301 T	**Research Methodology & Biostatistics**	04	04
Sessional Marks: 15		**Continuous mode:10**	
End Semester Examination Marks: 75		**Totalmarks:100**	

COURSE CONTENT

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

2.Biostatistics: Definition, applications, sample size, importance of sample size, factors influencing sample size, drop outs, statistical tests of significance, Spearman correlation, regression analysis, null hypothesis, P values, degrees of freedom, interpretation of P values.

3.Parametric tests -students "t" test, ANOVA non-parametric tests - chi square test, Sign test, Signed rank test, wilcoxon rank-sum test.

4.Medical and Human Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non- maleficence, 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.

5. 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, record keeping, SOPs, personnel and training, transport of lab

COURSE OUTCOMES

1. Learn general research methodology & Understand the basic concepts of biostatistics
2. Learn different parametric and non-parametric tests
3. Understand the functions of ethics committees in medical research
4. Learn the guidelines for developing animal facilities & Explain the guidelines and importance of medical research
5. Learn the guidelines for the experimentation on animalUnderstand the genesis of bioethics with special reference toHelsinkldeclaration

CO-PO MAPPING

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	3	3	3	1	3	2	3	3	2	3	2	3
CO2	2	3	2	2	3	3	1	1	3	2	2	2
CO3	3	1	1	2	2	1	2	3	1	2	3	1
CO4	1	2	2	1	1	3	1	1	2	3	2	3
CO5	2	1	1	1	2	1	1	2	2	1	1	1