ANDHRA KESARI UNIVERSITY:: ONGOLE
(A State University, Recognised by UGC)
M.PHARMACY (PHARMACOLOGY)
R23 COURSE STRUCTURE AND SYLLABUS
(For the students admitted from the academic year 2025-2026 onwards)
COURSE STRUCTURE & SCHEME OF MARKS

I YEAR I Semester

Component of Study	Course Code	Course Title	L	T	P	Credits	Internal	External	Total
Professional Core-I	R23PC11	Advanced Pharmacology – I	3	1	0	4	25	75	100
Professional Core-II	R23PC12	Clinical Pharmacology and Pharmacotherapeutics	3	1	0	4	25	75	100
Professional Elective-I	R23PC13A R23PC13B R23PC13C	1. Pharmacokinetics and Drug Metabolism 2. Clinical Research and Pharmacovigilance 3. Principles of Drug Discovery	3	1	0	4	25	75	100
Professional Elective-II	R23PC14A R23PC14B R23PC14C	1. Molecular Biology 2. Principles of Toxicology 3. Modernanalytical techniques	3	1	0	4	25	75	100
	R23PC15	Research Methodology and IPR	2	0	0	2	50	-	50
Laboratory-I	R23PC16	Advanced Pharmacology – I Lab	0	0	6	4	25	75	100
Laboratory-II	R23PC17	Clinical Pharmacology and Pharmacotherapeutics Lab	0	0	6	4	25	75	100
Audit-I	R23PC18	Audit Course-I (Non Credit)	2	0	0	0	--	--	--
		Seminar & Assignment	0	0	4	2	50 (25+25)	--	50
		TOTAL	**16**	**4**	**16**	**28**	**250**	**450**	**700**

I YEAR II Semester

Component of Study	CourseCode	Course Title	L	T	P	Credits	Internal	External	Total
Professional Core-III	R23PC21	Advanced Pharmacology–II	3	1	0	4	25	75	100
Professional Core-IV	R23PC22	Pharmacological Screening Methods and Toxicology	3	1	0	4	25	75	100
Professional Elective-III	R23PC23A R23PC23B R23PC23C	1. Animal Cell Cultures and Applications 2. Pharmacoepidemiology and Pharmacoeconomics 3. Advanced Drug Delivery Systems	3	1	0	4	25	75	100
Professional Elective-IV	R23PC24A R23PC24B R23PC24C	1. Pharmaceutical Management 2. Nutraceuticals 3. Pharmacokinetic and Therapeutic Drug Monitoring	3	1	0	4	25	75	100
Laboratory-III	R23PC25	Advanced Pharmacology–IILab	0	0	6	4	25	75	100

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Laboratory-IV	R23PC26	Pharmacological Screening Methods and Toxicology Lab	0	0	6	4	25	75	100
	R23PC27	Mini project t(withpresentation)& Assignment	2	0	4	4	100 (50+50)		100
Audit-II	R23PC28	Audit Course–II (non-credit)	2	0	0	0			
		TOTAL	**16**	**4**	**16**	**28**	**250**	**450**	**700**

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II YEAR I Semester

Component of Study	Course Code	Course Title	L	T	P	Credits	Internal	External	Total
Professional Elective-V	R23PC31A R23PC31B R23PC31C	1. Biostatistics 2. Hospital and Community Pharmacy 3. Medicinal Plant Biotechnology	3	1	0	4	25	75	100
OpenElective	R23PC32	1. Cosmeticology 2. Pharmaceutical Administration 3. Drug Regulatory affairs 4. Project Management 5. Audits and Regulatory compliance	3	1	0	4	25	75	100
	R23PC33	Comprehensive Viva-Voce	0	0	8	4		100	100
	R23PC34	Dissertation Work Review-II	0	0	24	10	50	50	100
		TOTAL	**6**	**2**	**32**	**22**	**100**	**300**	**400**

Important Note: The students are required to start their project work/Dissertation work from IInd year Ist semester only(i.e from III rd semester onwards) as per resolution of BOS meeting held on 08.01.2026.

II YEAR II Semester

Component of Study	Course Code	Course Title	L	T	P	Credits	Internal	External	Total
Dissertation	R23PC41	Dissertation Work Review- III	0	0	24	10	50	50	100
Dissertation	R23PC42	Dissertation Viva - Voce	0	0	20	10		100	100
		TOTAL	**0**	**0**	**44**	**20**	**50**	**150**	**200**
						98	**Total Marks**		**2000**

ANDHRA KESARI UNIVERSITY : ONGOLE

M.Pharm I Year I Sem (Pharmacology) ADVANCED

PHARMACOLOGY- I (Professional Core-I) (R23PC11)

Course Objective: The subject is designed to strengthen the basic knowledge in the field of pharmacology and toimpart 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.

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

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

UNIT I

General Pharmacology:

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

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

UNIT II

Neurotransmission

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). Cotransmission

Systemic Pharmacology A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems Autonomic Pharmacology Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

UNIT III

Central nervous system Pharmacology

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

UNIT IV

Cardiovascular Pharmacology

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

UNIT V

Autacoid Pharmacology

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

REFERENCE BOOKS:

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman‘s
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapyby David E Golan, Armen H, Tashjian Jr, EhrinJ, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B. G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B. C. Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Dipiro Pharmacology, Pathophysiological approach.
8. Advnced Pharmacology by Bikash Medhi.

ANDHRA KESARI UNIVERSITY : ONGOLE
M.Pharm I Year I Sem (Pharmacology)

CLINICAL PHARMACOLOGY AND PHARMACOTHERAPEUTICS (Professional Core - II) (R23PC12)

Course Objective

This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

Course Outcome: At completion of this subject it is expected that students will be able to understand –

- the pathophysiology of selected disease states and the rationale for drug therapy;
- the controversies in drug therapy;
- the importance of preparation of individualised therapeutic plans based on diagnosis;
- needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
- summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
- Therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).
- Pathophysiology and applied Pharmacotherapeutics of diseases associated with following system/diseases with of special reference to the drug of choice.

UNIT I

Principles of Pharacokinetics

1. Revision of basic concepts.
2. Clinical Pharmacokinetics.
    a. Dose – response inman
    b. Influence of renal and hepatic disease on Pharmacokinetics
    c. Therapeutics drug monitoring & individualization of drug therapy
    d. Population Pharmacokinetics.

UNIT II

Adverse Drug Reactions, Drug Interactions, ADR monitoring & Pharmacovigilance.

UNIT III

Pathophysiology and drug therapy of the following disorders.

Schizophrenia, anxiety, depression, epilepsy, Parkinson's, alzheimer's diseases, migraine, hypertension, angina pectoris, arrhythmias, atherosclerosis, myocardial infaraction.

UNIT IV

Pathophysiology and drug therapy of the following disorders.

TB, leprosy, leukemia, solid tumors, lymphomas, psoriasis, respiratory, urinary, g.i. tract infections, endocarditis, fungal and HIV infection, rheumatoid arthritis, glaucoma, menstrual disorders, menopause.

UNIT V

Drug therapy in

a) Geriatrics

b) Pediatrics
c) Pregnancy & Lactation.
d) Renal & hepatic insufficiency

REFERENCE BOOKS:

1. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.
2. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange.
3. Pathologic basis of disease - Robins SL, W.B. Saunders publication.
4. Clinical Pharmacy and Pharmacotherapeutics, K. Ravi Shankar, G. V. N. Kiranmayi, Pharmamed Press
5. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication.
6. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication.
7. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
8. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
9. Relevant review articles from recent medical and pharmaceutical literature.
10. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange
11. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
12. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA

ANDHRA KESARI UNIVERSITY: ONGOLE

M.Pharm I Year I Sem (Pharmacology)

PHARMACOKIENTICS AND DRUG METABOLISM (Professional Elective - I) (R23PC13A)

Course Objective: In current methods of treatment which involves individualization of drug therapy, the student should have sound knowledge in pharmacokinetics and the effects of changes in pharmacokinetic parameters on therapeutic efficacy of the drugs.

Course Outcomes: Upon completion of the subject student shall be able to (Know, do, appreciate);

- Understand various pharmacokinetic parameters
- Influence of these parameters on efficacy of drugs
- Identify and resolve drug related problems;
- Pharmacogenetics

UNIT I

Drug Absorption: Gastrointestinal, percutaneous, and rectal kinetics and factors affecting drug absorption. Absorption kinetics

UNIT II

Drug Distribution: Plasma protein binding – factors affecting plasma protein binding – Tissue binding – transfer of drugs through biological barriers their therapeutic implication in drug action. Volume of distribution. Reaction of the body to foreign substances:
Biotransformation of drugs, phase I and phase II metabolic reactions. Hepatic Clearance

UNIT III

Elimination of drugs: Concept of renal clearance and excretion of drugs –biological half – life, area under curve.

UNIT IV

Bioavailability of drug products: Bioavailability tests. Bioequivalence. Compartment models and relevant pharmacokinetic parameters.

UNIT V

Pharmacogenetics: Inter racial and individual variability in drug metabolism.

REFERENCE BOOKS:

1. Shargel and Leon. Applied Biopharmaceutics and pharmacokinetics. Latest edition. Publisher: Prentice Hall, London.
2. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi b. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia.
3. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
4. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
5. Biopharmaceutics and Pharmacokinetics; By Robert F Notari f. Biopharmaceutics; By Swarbrick
6. Biopharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi
7. Cilincal Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozer, Lea and Febrger, Philadelphia, 1995.

8. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
9. Biopharmaceutics and Clinical Pharmacokinetics - An introduction 4th edition Revised and expanded by Robert F Notari Marcel Dekker Inn, New York and Basel, 1987.
10. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, Roylan, Marcel Dekker Inc, New York 1996.

ANDHRA KESARI UNIVERSITY: ONGOLE

M.Pharm I Year I Sem (Pharmacology)

CLINICAL RESEARCH AND PHARMACOVIGILANCE (Professional Elective - I) (R23PC13B)

Course Objective: 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.

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

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

UNIT I

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

UNIT II

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.

UNIT III

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.

UNIT IV

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.

UNIT V

Methods, ADR reporting and tools used in pharmacovigilance: International classification of

diseases, International Nonproprietary 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, Vigi Flow, Statistical methods for evaluating medication safety data.

REFERENCE BOOKS:

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 1996.230
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. A Textbook of Clinical Research and Pharmacovigilance by KPR Chowdary, Pharmamed Press
7. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
8. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
9. Textbook of Pharmacovigilance: Concept and Practice. G. P. Mohanta and P. K. Manna. 2016, Pharma Med Press.
10. A textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. Second Edition, 2012, University Press

ANDHRA KESARI UNIVERSITY: ONGOLE

M.Pharm I Year I Sem (Pharmacology)

PRINCIPLES OF DRUG DISCOVERY (Professional Elective-I) (R23PC13C)

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

Course Outcome: 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

UNIT I

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

UNIT II

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

UNIT III

Rational Drug Design: Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches. Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore-based Screening,

UNIT IV

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

UNIT V

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.

REFERENCE BOOKS:

1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targets and Treatment Options. 2007 Humana Press Inc.

2. Darryl León. Scott 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.
6. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
7. Abby L. Parrill. M. Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
8. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.
9. Current Concepts in Drug Design,T Durai Ananda Kumar,Pharma Med Press

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M.Pharm I Year I Sem (Pharmacology)

MOLECULAR BIOLOGY (Professional Elective - II) (R23PC14A)

Course Objective: The subject imparts basic knowledge of molecular biology. This information will make the student Competent in molecular biology DNA topology, mutations and Transcriptions and Translations and Gene expressions.

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

- Explain the various structure and chemistry of DNA, RNA etc.
- Explain topology of DNA, organization of DNA in chromosomes
- Appreciate the importance and mechanism of mutations and their repar.
- Explain various mechanism of DNA replications and Transcription
- Appreciate the importance of gene expression.

UNIT I

Introduction to Molecular biology

Nucleic acids - DNA and RNA structure and functions, DNA as genetic material. Griffth, Avery-McCarty-MCLeod, Hershy- Chase, Franklin Conrat Experiments

DNA Structure: Chemistry of DNA, Forces stabilizing DNA structure, Helix parameters, Forms of DNA (A,B,C,D,T and Z), Watson – Crick and Hoogsteen base pairing , Physical Properties of ds DNA (UV absorption spectra Denaturation and renaturation), Chemical that react with DNA.

UNIT II

DNA topology: DNA supercoiling, Supercoiled form of DNA, Superhelical density, Energetic of supercoiled DNA, Biology of supercoiled DNA (Topological domain of DNA, DNA topoisomerases, Mechanisms of supercoiling in cells, mechanisms of action of topoisomerase I and II, effect of supercoiling on structure of DNA and role of supercoiling in gene expression and DNA replication).

Organization of DNA into chromosomes: Packaging of DNA and organization of chromosome in bacteria and eukaryotic cells; packaging of DNA in eukaryotic nucleosome and chromatin condensation assembly of nucleosomes upon replication. Chromatin modification and genome expression.

UNIT III

Mutations- molecular mechanism - types of DNA mutations and its significance. DNA repair - repair mechanisms - need of DNA repairs, DNA recombination – molecular mechanism of recombination-relationship between repair and recombination, SOS mechanism. Proteins and enzymes involved DNA repair and recombination.

DNA – Protein Interactions: General features interaction of Helix- turn Helix motif, B sheet, Zn- DNA binding domain etc with DNA.

UNIT IV

DNA Replication: Mechanism of DNA polymerase catalyzed synthesis of DNA, types of DNA polymerases in bacteria and their role. Initiation of chromosomal DNA replication and its regulation in prokaryotes assembly of replisome and progress of replication fork, termination of replication. Types and function of eukaryotic DNA polymerases initiation of replication in eukaryotes, role of telomerases in replication of eukaryotic chromosomes. Inhibitor of DNA replication (Blocking precursor synthesis nucleotide polymerization, altering DNA structure).

Transcription: RNA polymerases, features of prokaryotic and eukaryotic promoters. Strong and weak promoters. Assembly of transcription initiation complex in prokaryotes and eukaryotes and its

regulation; synthesis and processing of prokaryotic and eukaryotic transcripts. Transport of RNA within eukaryotic cell. Regulatory elements of genes-promoters. Fate of mRNA.

UNIT V

Translation- Synthesis and Processing of Proteome: Structure and role of tRNA in protein synthesis, ribosome structure, basic feature of genetic code and its deciphering, translation (initiation, elongation and termination in detail in prokaryotes as well as eukaryotes), Post translational processing of protein (protein folding, processing by proteolytic cleavage, processing by chemical modification, inteins). Protein degradation.

Regulation of Gene expression in prokaryotes and eukaryotes: Positive and negative regulation. lac-, ara-, his- and trp- operon regulation; antitermination, global regulatory responses; Regulation of gene expression in eukaryotes: Transcriptional, translational and processing level control mechanisms.

DNA- transposable elements- types of transposable elements, its importance in variation and evolution. Possible origin of virus, Oncogenes.

REFERENCE BOOKS:

1. Cell & Molecular Biology: Cell and Molecular Biology: Concepts and Experiments, Gerald Karp, John Wiley, NY
2. Molecular Cell Biology, H.S. Bramrah, Anmol Publications Pvt. Ltd., New Delhi
3. Advanced Molecular Biology, H.S. Bhamrah Viva Books, Pvt. Ltd., New Delhi
4. Plant Biochemistry and Molecular Biology, Hans Walter Held, Oxford, NY
5. Molecular Biology of the Gene, Watson, Baker, Bell, Gann Levine, Losick, Pearson Education Pvt. Ltd., New Delhi
6. Essential Molecular Biology: A Practical Approach, TA Brown, Oxford

ANDHRA KESARI UNIVERSITY : ONGOLE

M.Pharm I Year I Sem (Pharmacology)

PRINCIPLES OF TOXICOLOGY (Professional Elective - II) (R23PC14B)

Course Objective: The subject imparts basic knowledge of toxicology. This information will make the student Competent in various toxicologies of liver, neuro, kidney etc

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

- Explain the various toxicologies
- Explain various toxicologies of lungs, liver, gentic etc
- Appreciate the importance and mechanism of skin and reproductive toxicology
- Explain various mechanisms and affects of pesticides

UNIT I

Introduction to General Toxicology: History of toxicology, classification of toxicology, toxicants exposure, routes exposure and exposure characterization. animal and plant toxins, mechanisms of toxicity, toxicokinetic, biotransformation of xenobiotics.

UNIT - II

Toxicology of the liver, Toxicology of the Lung, Chemical Carcinogenesis & Genetic Toxicology

UNIT - III

Neurotoxicology, Cardiovascular Toxicology, Molecular Toxicology & Toxicogenomic, Immuno-toxicology, Toxicology of the Kidney

UNIT - IV

Toxicology of the Intestine, Toxicology of the Skin, Reproductive Toxicology & Teratology, Risk Assessment

UNIT - V

Nanotoxicology, Ecotoxicology, Toxicology of Metals, Analytical/Forensic Toxicology, Toxic Effects of Pesticides, Pesticide Regulation at EPA

REFERENCE BOOKS:

1. Essential Concepts in Toxicology: Compendium for Pharmacy, Medical, Forensic and Veterinary Toxicology, P K Gupta, Pharmamed Press
2. Casarett & Doull's Essentials of Toxicology by Curtis D. Klaassen, John B. Watkins
3. Principles of Toxicology by Karen Stine, Thomas M. Brown
4. Text Book of Pathology by Harsh Mohan

ANDHRA KESARI UNIVERSITY: ONGOLE

M.Pharm I Year I Sem

MODERN ANALYTICAL TECHNIQUES

(Professional Elective - II) (R23PC14C)

Course Objective: The course is designed to impart the knowledge in the field of Pharmaceutical Analysis. The various modern analytical techniques like UV-Visible, IR, NMR, Mass, GC, HPLC, different chromatographic methods and other important topics are taught to enable the students to understand and apply the principles involved in the determination of different bulk drugs and their formulation. In addition to the theoretical aspects, the basic practical knowledge relevant to the analysis is also imparted.

Course Outcome: The appreciable knowledge will be gained by the students in the Modern Analytical Techniques and can apply the theories in the Analysis of various bulk drugs and their formulations. The students will also be in a position to apply their knowledge in developing the new methods for the determination and validate the procedures.

UNIT I

Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation

a. **Column Chromatography:** Adsorption and partition, theory, preparation, procedure and methods of detection
b. **Thin Layer Chromatography:** Theory, preparation, procedures, detection of compounds
c. **Paper Chromatography:** Theory, different techniques employed, filter papers used, qualitative and quantitative detection

UNIT II

a. **Gas chromatography:** Introduction, fundamentals, instrumentation, columns: preparation and operation, detection, derivatization.
b. **HPLC:** Basic parameters, Principles and instrumentation, solvents and columns used, Operational modes, detection and applications of HPLC
c. **HPTLC:** Theory and principle, instrumentation, elution techniques and pharmaceutical applications

UNIT III

a. **UV-Visible spectroscopy:** Introduction, electromagnetic spectrum, absorbance laws and limitations, instrumentation-design and working principle, chromophore concept, auxochromes, Wood-Fisher rules for calculating absorption maximum, applications of UV-Visible spectroscopy
b. **IR spectroscopy:** Basic principles -Molecular vibrations, vibrational frequency, factors influencing vibrational frequencies, sampling techniques, instrumentation, interpretation of spectra, FT-IR, theory and applications

UNIT IV

Mass spectrometry: Theory, ionization techniques: electron impact ionization, chemical ionization, field ionization, fast atom bombardment, plasma desorption, fragmentation process: types of fission, resolution, GC/MS, ***interpretation of spectra*** and applications for identification and structure determination.

UNIT V

NMR: Theory, instrumentation, chemical shift, shielding and deshielding effects, splitting of signals, spin-spin coupling, proton exchange reactions, coupling constant(J), nuclear overhauser effect (NOE), ^{13}CNMR spectra and its applications, 2D-NMR, COSY and applications in pharmacy.

REFERENCE BOOKS:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma 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. A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
5. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
6. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
7. Organic Chemistry by I. L. Finar
8. Organic spectroscopy by William Kemp
9. Quantitative Analysis of Drugs by D. C. Garrett
10. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
11. Spectrophotometric identification of Organic Compounds by Silverstein
12. HPTLC by P.D. Seth
13. Indian Pharmacopoeia 2007
14. High Performance thin layer chromatography for the analysis of medicinal plants by Eike Reich, Anne Schibli
15. Introduction to instrumental analysis by Robert. D. Braun
16. Theory and Practice of Chromatographic Techniques, Sanjay B. Bari By Pharmamed Press.

ANDHRA KESARI UNIVERSITY : ONGOLE

M.Pharm I Year I Sem (Pharmacology)

RESEARCH METHODOLOGY AND IPR (R23PC15)

Course Objectives:

- To understand the research problem
- To know the literature studies, plagiarism and ethics
- To get the knowledge about technical writing
- To analyze the nature of intellectual property rights and new developments
- To know the patent rights

Course Outcomes: At the end of this course, students will be able to

- Understand research problem formulation.
- Analyze research related information
- Follow research ethics
- Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
- Understanding that when IPR would take such important place in growth of individuals & nation, it is needless to emphasis the need of information about Intellectual Property Right to be promoted among students in general & engineering in particular.
- Understand that IPR protection provides an incentive to inventors for further research work and investment in R & D, which leads to creation of new and better products, and in turn brings about, economic growth and social benefits.

UNIT - I

Meaning of research problem, Sources of research problem, Criteria Characteristics of a good research problem, Errors in selecting a research problem, Scope and objectives of research problem. Approaches of investigation of solutions for research problem, data collection, analysis, interpretation, Necessary instrumentations

UNIT - II

Effective literature studies approaches, analysis, Plagiarism, Research ethics

UNIT - III

Effective technical writing, how to write report, Paper Developing a Research Proposal, Format of research proposal, a presentation and assessment by a review committee

UNIT - IV

Nature of Intellectual Property: Patents, Designs, Trade and Copyright. Process of Patenting and Development: technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT.

UNIT-V:

Patent Rights: Scope of Patent Rights. Licensing and transfer of technology. Patent information and databases. Geographical Indications. New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies, IPR and IITs.

TEXT BOOKS:

1. Stuart Melville and Wayne Goddard, “Research methodology: an introduction for science &engineering students’”
2. Wayne Goddard and Stuart Melville, “Research Methodology: An Introduction”
3. Pharmaceutical Research Methodology and BioStatistics, B Subba Rao, Pharmamed Press
4. Intellectual Property Rights in Pharmaceutical Industry, B Subba Rao, Pharmamed Press

REFERENCE BOOKS:

1. Ranjit Kumar, 2nd Edition, “Research Methodology: A Step by Step Guide for beginners”
2. Halbert, “Resisting Intellectual Property”, Taylor & Francis Ltd ,2007.
3. Mayall, “Industrial Design”, McGraw Hill, 1992.
4. Niebel, “Product Design”, McGraw Hill, 1974.
5. Asimov, “Introduction to Design”, Prentice Hall, 1962.
6. Robert P. Merges, Peter S. Menell, Mark A. Lemley, “Intellectual Property in New Technological Age”, 2016.
7. T. Ramappa, “Intellectual Property Rights Under WTO”, S. Chand, 2008

ANDHRA KESARI UNIVERSITY : ONGOLE

M.Pharm I Year I Sem (Pharmacology)

ADVANDED PHARMACOLOGY – I LAB (Lab – I) (R23PC16)

List of experiments

Handling of laboratory animals.

1. Various routes of drug administration.
2. Study of techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. To record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.
4. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.
5. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three point method.
6. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by four point method.
7. Estimation of pA2 value on isolated tissues
8. Bioassay of 5-HT using rat fundus strip
9. Bioassay of oxytocin using rat uterus
10. Bioassay of Acetylcholine using isolated tissue of coccyx muscles by three-point/ four-point method.
11. Bioassay of Adrenaline/ Acetylcholine using isolated blood vessels by three-point/ four-point method.

REFERENCE BOOKS:

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. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd
6. A practical book of Pharmacology by Ramesh Alluri
7. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd.

ANDHRA KESARI UNIVERSITY : ONGOLE

M.Pharm I Year I Sem (Pharmacology)

CLINICAL PHARMACOLOGY AND PHARMACOTHERAPEUTICS LAB (Lab – II) (R23PC17)

The students are required to be collect Prescriptions and of clinical details of different patients for their exposure with therapeutic management and other clinical aspects. They are expected to have experience and do a case presentation in the following clinical conditions. The students have to make at least 5 case presentations covering most common diseases. The student should also submit a record of the cases presented. The list of clinical cases presented should include follow-upof the clinical cases mentioned below from the day of admission till discharge and presented in the SOAP (Subjective, Objective, Assessment and Plan) format.

I. The cases may be selected from the following diseases:
   1. Neurology& Psychiatry
   2. Oncology
   3. Infectious Diseases & Immunology
   4. Gynecologic & Obstetric Disorders/ Ophthalmology
   5. Cardiology
   6. Dermatology
   7. Endocrinology

II. Rational use of medicines in special population (three)
III. Calculation of Bioavailability and Bioequivalence from the given data (two)
IV. Interpretation of Therapeutic Drug Monitoring reports of a given patient (three)
V. Calculation of various Pharmacoeconomic outcome analysis for the given data (two)

Assignments

The students are required to submit a minimum of three written assignments (1500 to 2000 words) selected from the topics on different disease conditions given to them. The students are required to discuss both the clinical and therapeutic aspects in the same.

ANDHRA KESARI UNIVERSITY: ONGOLE

M.Pharm I Year II Sem (Pharmacology)

ADVANCED PHARMACOLOGY – II (Professional Core - III) (R23PC21)

Course Objective: 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

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

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

UNIT I

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 I Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.

UNIT III

Chemotherapy II: Drugs used in Protozoal Infections Drugs used in the treatment of Helminthiasis Chemotherapy of cancer Immunopharmacology Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD. Immunosuppressants and Immunostimulants.

UNIT IV

GIT Pharmacology: Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome. Chrono pharmacology Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma, and peptic ulcer

UNIT V

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

REFERENCE BOOKS:

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 A P C Avichal Publishing Company.
11. K D. Tripathi. Essentials of Medical Pharmacology Principles of Pharmacology.
12. The Pathophysiologic basis of drug Therapyby David E Golan, Armen H, Tashjian Jr., EhrinJ, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers
13. Advanced Pharmacology by Bikash Medhi

ANDHRA KESARI UNIVERSITY : ONGOLE

M.Pharm I Year II Sem (Pharmacology)

PHARMACOLOGICAL SCREENING METHODS AND TOXICOLOGY
(Professional Core - IV) (R23PC22)

Course Objective: 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

Course Outcome: 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

UNIT I

Laboratory Animals: Common laboratory animals: Description, handling and applications of different species and strains of animals. Transgenic animals: Production, maintenance and applications Anesthesia and euthanasia of experimental animals. Maintenance and breeding of laboratory animals. CPCSEA guidelines to conduct experiments on animals Good laboratory practice. Bioassay- Principle, scope and limitations and methods

UNIT II

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

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

UNIT III

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

Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, anti-inflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti -emetic, antidiarrheal and laxatives.

UNIT IV

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

Cardiovascular Pharmacology: antihypertensives, antiarrhythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods.

UNIT V

Toxicology:

Principles of Toxicology, Mutagenesis and Carcinogenesis.

Teratogenecity & its mechanisms, Councelling of women about teratogenic risks.

Acute and Subacute, Chronic toxicity studies

Classification of Poisons, Principles of Management of Acute Poisoning, General treatment of poisoning

REFERENCE BOOKS:

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. Gupta
10. Pharmacological Screening Methods & Toxicology by A. Srinivasa Rao
11. Handbook of Experimental Pharmacology, S K. Kulkarni
12. Practical Pharmacology and Clinical Pharmacy, S K. Kulkarni, 3rd Edition.
13. David R. Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.
14. Screening Methods in Pharmacology, Robert A. Turner.
15. Rodents for Pharmacological Experiments, Dr. Tapan Kumar chatterjee.
16. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)

ANDHRAKESARI UNIVERSITY, ONGOLE

M.Pharm I Year II Sem (Pharmacology)

ANIMAL CELL CULTURE (Professional Elective-III) **(R23PC23A)**

Course Objective: The subject imparts basic knowledge of animal cell culture. This information will make the student Competent in various cell culture techniques and their applications.

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

- Explain the various types of cell cultures, their requirements and advantages
- Appreciate the importance of the bioreactor, cell lines and their applications
- Explain various culture, preservation and maintenance techniques
- Explain various IVF techniques, embryo cultures and gene transfer
- Appreciate the importance of the role embryo culture in and its applications

UNITI

Introduction to Animal Biotechnology and its applications: History and scope of animal cell and tissue culture, Advantages and disadvantages of tissue culture, Laboratory facilities for tissue culture. Primary and secondary cell lines cell culture environment, Safety measures laminar hood,

UNIT II

Basic tissue culture techniques, various types of cultures, Bioreactors, Common cell lines and aseptic methods, Culture media, maintenance and preservation of cell cultures, freezing media, treatment of substrate surfaces.

UNIT III

Feeder layers on substrate, gas phase for tissue culture, Culture media for cells and tissues, Culture procedures, Disaggregation (enzymatic and mechanical) of tissue and primary culture

UNIT IV

Cultured cells and evolution of cell lines, Maintenance of culture-cell lines, Tissue culture (slide, flask and test tube cultures), Organ culture, Whole embryo culture, Tissue engineering (artificial skin and artificial cartilage). Cell cultures as a source of valuable products

UNIT V

In VitroFertilization &Transgenic Animals Invitro fertilization (IVF)in humans; embryo transfer(ET)in humans; super ovulation, IVF and embryo culture in farm animals (e.g. cow); embryo transfer in cattle, Gene transfer or transfection (using eggs and cultured stem cells); targeted gene transfer; transgenic animals. (mice, sheep, pigs, rabbits, goats, cows, fish).

REFERENCEBOOKS:

1. IntroductiontoBiotechnology, P.K.Gupta,KalyaniPublishers,secondedition.
2. Introduction to plant Biotechnology, H.S.Chawala, second ed., PHI
3. Plant Biotechnology–P.C.Trivedi
4. Applied Plant Biotechnology–Ignacimuthu
5. Animal Biotechnology–Babinnk and Philips.
6. Biotechnology–B.D.Singh.
7. Plant Tissue Culture–S.S.Bhojwani, M.K.Razdan.
8. Biotechnology Fundamentals and Applications–PurohitSS
9. Biotechnology in the Welfare of Mankind–AliKhan

ANDHRA KESARI UNIVERSITY: ONGOLE

M.Pharm I Year II Sem (Pharmacology)

PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (Professional Elective - III) (R23PC23B)

Course Objective: This course enables students to understand various pharmacoepidemiologic methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health care regimen.

Course Outcome: Upon completion of this course it is expected that students shall be able to:

- Understand the various epidemiological methods and their applications
- Understand the fundamental principles of Pharmacoeconomics.
- Identify and determine relevant cost and consequences associated with pharmacy products and services.
- Perform the key Pharmacoeconomics analysis methods
- Understand the Pharmacoeconomic decision analysis methods and itsapplications.
- Describe current Pharmacoeconomic methods and issues.
- Understand the applications of Pharmacoeconomics to various pharmacy settings.

UNIT I

Introduction to Pharmacoepidemiology: Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements. Concept of risk: Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio

UNIT II

Pharmacoepidemiologic Methods: Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds' ratio, Meta analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology

UNIT III

Introduction to Pharmacoeconomics: Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs. Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost-effective Ratio, Average Cost-Effective Ratio. Person Time, Willingness To Pay, Time Trade Off and Discounting.

UNIT IV

Pharmacoeconomic evaluations: Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).

UNIT V

Definition, Steps involved, Applications, Advantages and disadvantages of the following:

Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, Common HRQOL measures. Definition, Steps involved, Applications of the following: Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in Pharmacoeconomic analysis, Applications of Pharmacoeconomics.

REFERENCE BOOKS:

1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwer Lippincott Williams & Wilkins, Philadelphia.
2. Pharmacoepidemiology and Pharmacoeconomics Concepts and Practice, KG. Revikumar, Pharmamed Press
3. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds, John Wiley & Sons, USA.
4. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modeling for Health Economic Evaluation, Oxford University Press, London.
5. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programs Oxford University Press, London.
6. George E Mackinnon III. Understanding health outcomes and Pharmacoeconomics.
7. Graker, Dennis. Pharmacoeconomics and outcomes.
8. Walley, Pharmacoeconomics.
9. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
10. Relevant review articles from recent medical and pharmaceutical literature
11. Guru Prasad Mohanta and P K Manna, Textbook of Pharmacovigilance Concepts and Practice

ANDHRA KESARI UNIVERSITY : ONGOLE

M.Pharm I Year II Sem (Pharmacology)

ADVANCED DRUG DELIVERY SYSTEMS (Professional Elective - III) (R23PC23C)

Course Objective: The students shall know the pharmacokinetic and pharmacodynamic on the basis of CDDS. They also know the design evaluation and application related to oral, parenteral, transdermal, implants, bioadhesives and targeted drug delivery systems.

Course Outcomes: Students will know the fabrication, design, evaluation and application of above drug delivery systems.

UNIT - I

Fundamentals of controlled drug delivery systems, pharmacokinetic and pharmacodynamic basis of controlled drug delivery. Design, fabrication, evaluation and applications of the following controlled releasing systems

a. Controlled release oral drug delivery systems
b. Parenteral controlled release drug delivery systems

UNIT - II

Design, fabrication, evaluation, and applications of the following:

1. Implantable Therapeutic systems
2. Transdermal delivery systems
3. Ocular and Intrauterine delivery systems
4. Vaccine delivery: Delivery systems used to promote uptake, absorption enhancers, oral immunization, controlled release microparticles form vaccine development

UNIT - III

Biochemical and molecular biology approaches to controlled drug delivery of

a. Bioadhesive drug delivery systems
b. Nasal drug delivery systems
c. Drug delivery to Colon

UNIT - IV

Biochemical and molecular biology approaches to control drug delivery of

a. Liposomes
b. Niosomes
c. Microspheres
d. Nanoparticles
e. Resealed erythrocytes

UNIT - V

Drug targeting to particular organs

a. Delivery to lungs
b. Delivery to the brain and problems involved
c. Drug targeting in neoplasams

TEXT BOOKS:

a. Novel Drug Delivery System by Yie W. Chien.
b. Controlled Drug Delivery by Joseph R. Robinson and Vincent H. L. Lee.
c. Controlled and Novel Drug Delivery Systems by N. K. Jain.
d. Targeted and Controlled Drug Delivery (Novel carrier systems) by S. P. Vyas and Khar.

e. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
f. Advances in Drug Delivery, Vol 1, 2, 3,4 by Y. Madhusudan Rao, A. V. Jithan
g. Oral Drug Delivery Technology, 2nd ed, by Aukunuru Jithan

ANDHRA KESARI UNIVERSITY : ONGOLE

M.Pharm I Year II Sem (Pharmacology)

PHARMACEUTICAL MANAGEMENT (Professional Elective - IV) (R23PC24A)

Course Objective: The topics which are present in the pharmaceutical management are very much useful to the students in personality development become a perfect Pharma professional.

Course Outcomes:

- These topics are useful for the students to know how to manage a Pharma industry and its various departments viz QA, QC, RA, Production etc.
- Along with this it aids the students to develop leadership qualities, communication &interpersonal skills, decisions making, motivation, organization &various managerial functions & professional skills required for a dynamic professional.
- Management helps to understand the concept of managerial control, its levels &role, importance in pharma industry

UNIT I

Pharmaceutical Management: Meaning, Evolution-scientific, administrative and human relation approach. Process of management: Planning, organizing, staffing, directing, coordinating and controlling– a preliminary idea of concepts, processes and techniques.

UNIT II

Fundamental concepts of production, financial, personal, legal and marketing functions with special reference to Pharmaceutical Management. Introduction to budgeting, costing, accounting, auditing, and budgetary control. Entrepreneurship development.

UNIT III

Understanding organizations: Meaning, process, types of organization structures and departmentation, line/staff authority, promoting organizational culture. Organizations, pharmaceutical services and functioning of hospital pharmacy, bulk drug unit, formulation unit, Ayurvedic and Unani manufacturing units and testing labs etc.

UNIT IV

Professional Mangers; Tasks, responsibilities and skills needed. Leadership; Styles and managing change. Decision Making; Types, procedures, evaluation and selection of alternatives, decision making under various situations. Management information and decision support systems and time management.
Personnel Management: Job Analysis, recruitment, selection, orientation and training, performance appraisal and compensation. Retrenchment, lay off and discharge.

UNIT V

Management of Industrial Relations: Industrial disputes, settlement of disputes through various routes such as bargaining, etc.
Motivational aspects, theories of motivation, group dynamics, rewards and incentives, interpersonal skills, significance of communication, its processes, measures for effective communication, conflict management. Stress management.

TEXT AND REFERENCE BOOKS:

1. Marketing Management by Philip Kotlar; Prentice-Hall of India Ltd., New Delhi.
2. Management and Organization by Louis A. Allen; McGraw Hill, Tokyo.
3. Pharmaceutical Industrial Management, G. Vidya Sagar, Pharmamed Press

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
M.Pharm I Year II Sem (Pharmacology)

NUTRACEUTICALS (Professional Elective - IV) (R23PC24B)

Course Objectives: The students will expose to characteristic features of various phytochemicals as nutraceuticals in various diseased conditions and also know the role of antioxidant in free radical induced disease conditions and will expose to various food laws and regulations

Course Outcome: Helps the student to understand the importance of Nutraceuticals in various common problems with the concept of free radicals.

UNIT I

a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer etc.

b. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods: Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT II

Phytochemicals as neutraceuticals: Occurrence and characteristic features (chemical nature medicinal benefits) of following

a) Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, lutein
b) Sulfides: Diallylsulfides, Allyltrisulfide.
c) Polyphenolics: Reservetrol
d) Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones
e) Prebiotates / Probiotics.: Fructo oligosaccharides, Lacto bacillum
f) Phytoestrogens: Isoflavones, daidzein, Geebustin, lignans
g) Tocopherols

UNIT III

a) Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.
b) Measurement of free radicals: Lipid peroxidation products, lipid hydroperoxide, malondialdehyde.

UNIT IV

a. Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.
b. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α- Lipoic acid, melatonin
Synthetic antioxidants: Butylatedhydroxy Toluene, Butylatedhydroxy Anisole.

UNIT V

Food Laws and Regulations; FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.
Regulations and Claims – Current Products: Label Claims, Nutrient Content Claims, Health Claims, Dietary Supplements Claims.

REFERENCE BOOKS:

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and nutraceuticals in preventing diseases by K. T Agusti and P. Faizal: BS Publication.
3. Advanced Nutritional Therapies by Cooper. K. A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F. Balch and Phyllis A. Balch 2nd Edn. Avery Publishing Group, NY (1997).
6. G. Gibson and C. Williams Editors *2000 Functional foods* Woodhead Publ. Co. London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
8. Labuza, T. P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M. K. Sachmidl and T. P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

ANDHRA KESARI UNIVERSITY: ONGOLE

M.Pharm I Year II Sem (Pharmacology)

PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING
(Professional Elective - IV) (R23PC24C)

Course Objective: This course is designed to enable students to understand the basics principles and applications of pharmacokinetics in designing the individualized dosage regimen, to interpret the plasma drug concentration profile in pharmacokinetics, drug interactions and in therapeutic drug monitoring processes to optimize the drug dosage regimen. Also, it enables students to understand the basic concepts of HPLC, Immunoassays and TDM of selected drugs.

Course Outcome: Upon completion of this course it is expected that students shall be able to:

- Design the drug dosage regimen for individual patients
- Interpret and correlate the plasma drug concentrations with patients' therapeutic outcomes □ Recommend dosage adjustment for patients IV Infusion to Oral dosing □ Recommend dosage adjustment for depening on patients response
- Manage TDM of selected drugs
- Apply pharmacokinetic parameters in analytical determination

UNIT I

Introduction to pharmacokinetics: Compartmental and Non-compartmental models, Renal and non- renal clearance, Organ extraction and models of hepatic clearance, Estimation and determinants of bioavailability, Multiple dosing, Calculation of loading and maintenance doses.

UNIT II

Therapeutic Drug Monitoring

Introduction, Necessity of TDM, Criteria for valid TDM, Essentials for effective TDM, Organization of a TDM service, information requirements for TDM, effectiveness of TDM.

UNIT III

Drug selection, Dosage regimen design, Pharmacokinetics of the Drug, Patient compliance, Evaluation of pateint's response, Measurement of serum drug concentrations, Monitoring serum drug concentrations, Design of dose regimens. Conversion from i.v. infusion to oral dosing. Determination of dose frequently, dosing of drugs in elderly.

UNIT IV

Analytical aspects of TDM, Uses of HPLC and Immunoassays in TDM

UNIT V

TDM of selected individual drugs - Aminoglycosides, Carbamazepine, Theophulline Digoxin, Methotrexate, Phenytoin, Aspirin, Lithium, Valproic acid.

TEXT BOOKS:

1. Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel and B.C. Andrew
2. Therapeutic Drug Monitoring and Clinical Biochemistry by Mike Halworth and Nigel Capps.
3. Biopharmaceutics and Pharmacokinetics by Robert E. Notari.
4. Therapeutic Drug Monitoring by Gerald E Schumacher, Pharmamed Press
5. Principles and Prescriptives in Drug Bioavailability by S.Karger.
6. Pharmaceutics and Pharmacy Practice by Gilbert S.Banker
7. Remington's Pharmaceutical Sciences
8. Dissolution, bio-availability and bio-equivalence by Abdou
9. Pharma Review by Leon Shargel

10. Current concepts in Pharmaceutical Sciences by James Swarbrick
11. Drug Disposition and Pharmacokientics by Stephen H. Curry
12. Pharmacokinetics by MiloGilbaldi and Donald Perrier 2nded Marcel Dekker Inc. New York 1982.
13. Drug Level monitoring, Analghical Techniques, metabolism and pharmacokinetics.
14. Simkin: Handbook of TDM.
15. Goodman & Gilman's The pharmacological Basis of Therapeutics Ed. J.G. Hardman, L.E. Limbird,
16. P.B. Molinoff and R.W. Ruddon. International Edition. McGraw Hill.
17. Principles of drug action the basis of pharmacology by goldstein A., Arrow L. and Kalman S.M. 2nd ed. John Wiley & sons. Inc.New York 1974.
18. Clinical pharmacokinetics. Concepts and Applications by rowland M and Tozert.N. 3rd ed. Lea and Febiger Philadelphia, 1995.
19. Pharmacokinetics for pharmaceutical scientists Wagner J.G. Technomic. Inc. Lancaster PA 1993.
20. Integration of pharmacokinetics, pharmacodynamics and Toxico kinetics in Rational Drug Development Plenum, New York, 1993.
21. Applied Pharmacokinetics, Principles of Therapeutic Drug monitoring, by Evans W.E., Schentag J.J. and Jusko W.J. (Eds). 3rd ed. Applied Therapeutics Inc. Vancouvers HA. 1992.

ANDHRA KESARI UNIVERSITY: ONGOLE

M.Pharm I Year II Sem (Pharmacology)

ADVANCED PHARMACOLOGY - II LAB (Lab – III) (R23PC25)

List of Experiments

1. To record the dose response curve of Histamine using isolated guinea-pig ileum preparation.
2. Study of agonistic and antagonistic effects of drugs using isolated guinea-pig ileum / rat fundus strip preparation.
3. To carry out bioassay of Histamine using isolated guinea-pig ileum preparation by interpolation method.
4. To carry out bioassay of Histamine using guinea-pig ileum preparation by three point method.
5. To carry out bioassay of Histamine using guinea-pig ileum preparation by four point method.
6. Effect of drugs on chick/rat mean arterial blood pressure (MABP) by using Condon's mercury manometer.
7. Effect of drugs on perfused frog heart

REFERENCE BOOKS:

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. A practical book of Pharmacology by Ramesh Alluri
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 A P C Avichal Publishing Company.

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M.Pharm I Year II Sem (Pharmacology) PHARMACOLOGICAL

SCREENING METHODS AND TOXICOLOGY LAB (Lab – IV) (R23PC26)

List of Experiments

Study of theory, principle, procedure involved, and interpretation of given results for the following experiments:

1. Analgesic property of drug using analgesiometer.
2. Anti-inflammatory effect of drugs using rat-paw edema method.
3. Anticonvulsant activity of drugs using maximal electroshock and pentylenetetrazole methods.
4. Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods.
5. Locomotor activity evaluation of drugs using actophotometer and rotorod.
6. Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.
7. Antidiabetic activity using rats / mice.n
8. Hepatoprotective activity
9. Anti ulcer activity
10. Antioxidant activity
11. Toxicity studies as per OECD guidelines.
12. Functional observation battery tests (modified Irwin test)

REFERENCE BOOKS

1. Screening Methods in Pharmacology, Robert A. Turner.
2. Biological standardization by J. H. Burn D.J. Finney and I.G. Goodwin
3. Screening methods in Pharmacology by Robert Turner. A
4. Evaluation of drugs activities by Laurence and Bachrach
5. Methods in Pharmacology by Arnold Schwartz.
6. Fundamentals of experimental Pharmacology by M. N. Ghosh
7. Pharmacological experiment on intact preparations by Churchill Livingstone
8. Pharmacological screening methods and toxicology by A. Srinivasa Rao
9. Experimental Pharmacology by R. K. Goyal.
10. Preclinical evaluation of new drugs by S. K. Guta
11. Handbook of Experimental Pharmacology, S K. Kulkarni
12. Practical Pharmacology and Clinical Pharmacy, S K. Kulkarni, 3rd Edition.

ANDHRA KESARI UNIVERSITY :: ONGOLE
M.Pharm II Year I Sem (Pharmacology)

BIOSTATISTICS (Professional Elective - V) (R23PC231A)

Course Objective: The student shall know the introduction, scope of biostatistics and Research work, calculation and present of the data

Course Outcome: The student will be known the Biostatistics arrangement, presentation and formation of tables and charts. They also know the correlation and regression & application of different methods, analysis of data

UNIT I
Introduction and scope of biostatistics: Use of statistics in Pharmacy. Population and Sample collection. Stages of research, types of data and methods of data collections. Data arrangement and presentation, formation of table and charts.

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

UNIT III
Measures of Correlation and Regression
Probability rules: Binomial, Poison and Normal distribution.

UNIT IV
Experimental designing, planning of an experiment, replication and randomization.
Analysis of Variance (ANOVA): 1-way, 2- Way

UNIT V
Hypothesis testing: Student 't' test, Chi square test,
Non- Parametric Tests: Sign Test, Sign Rank Test, Wilcoxon Sign Rank Test

TEXT BOOKS:
1. Statistics for business and economics 3rd edition by Vikas books publications
2. Biostatistics & Computer applications by GN Rao and NK Tiwari
3. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
4. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
5. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.

REFERENCE BOOKS:
1. Remington"s Pharmaceutical Sciences
2. Theory & Practice of Industrial Pharmacy by Lachman
3. Statistics for business and economics 3rd edition by Vikas books publications
4. Biostatistics & Computer applications by GN Rao and NK Tiwari
5. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
6. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
7. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.

8. A Textbook of Research Methodologies and Biostatistics for Pharmacy Students, KPR Chowdary, Pharmamed Press
9. Biostatistics and Computer Applications by G.N. Rao and N.K. Tiwari
10. Fundamentals of Biostatistics by Khan and Khanum
11. Research Methodology by RK Khanna bis and Suvasis Saha
12. Research methods and Quantity methods by G.N.Rao
13. A practical approach to PG dissertation

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M.Pharm II Year I Sem (Pharmacology)

HOSPITAL AND COMMUNITY PHARMACY (Professional Elective - V) (R23PC31B)

Course Objective: This course is designed to impart basic knowledge and skills that are required to practice pharmacy in both hospital and community settings.

Course Outcome:

- Upon completion of this course it is expected that students shall be able to:
- Understand the organizational structure of hospital pharmacy
- Understand drug policy and drug committees
- Know about procurement & drug distribution practices
- Know the admixtures of radiopharmaceuticals
- Understand the community pharmacy management
- Know about value added services in community pharmacies

UNIT I

Introduction to Hospitals – Definition, classification, organizational structure Hospital Pharmacy: Definition, Relationship of hospital pharmacy department with other departments, Organizational structure, legal requirements, work load statistics, Infrastructural requirements, Hospital Pharmacy Budget and Hospital Pharmacy management

Hospital Drug Policy: Pharmacy & Therapeutics Committee, Infection Control committee, Research & Ethics Committee, Management of Medicines as per NABH

UNIT II

Hospital Formulary Guidelines and its development, Developing Therapeutic guidelines, Drug procurement process, and methods of Inventory control, Methods of Drug distribution, Intravenous admixtures, Hospital Waste Management

UNIT III

Education and training: Training of technical staff, training and continuing education for pharmacists, Pharmacy students, Medical staff and students, Nursing staff and students, Formal and informal meetings and lectures, Drug and therapeutics newsletter.

Community Pharmacy Practice: Definition, roles & responsibilities of community pharmacists, and their relationship with other health care providers.

Community Pharmacy management: Legal requirements to start community pharmacy, site selection, lay out & design, drug display, super drug store model, accounts and audits, Good dispensing practices, Different softwares & databases used in community pharmacies. Entrepreneurship in community pharmacy.

UNIT IV

Prescription – Legal requirements & interpretation, prescription related problems responding to symptoms of minor ailments: Head ache, pyrexia, menstrual pains, food and drug allergy, OTC medication: Rational use of over the counter medications Medication counseling and use of patient information leaflets Medication adherence – Definition, factors influencing adherence behavior, strategies to improve medication adherence Patient referrals to the doctors. ADR monitoring in community pharmacies

UNIT V

Health Promotion – Definition and health promotion activities, family planning, Health screening services, first aid, prevention of communicable and non-communicable diseases, smoking cessation, Child & mother care

National Health Programs- Role of Community Pharmacist in Malaria and TB control programs Home Medicines review program **–** Definition, objectives, Guidelines, method and outcomes Research in community pharmacy Practice

REFERENCE BOOKS:

1. Community Pharmacy Practice **–** Ramesh Adepu, BSP Publishers, Hyderabad
2. Hospital Pharmacy - Hassan WE. Lea and Febiger publication.
3. Textbook of hospital pharmacy - Allwood MC and Blackwell.
4. Avery's Drug Treatment, Adis International Limited.
5. Remington Pharmaceutical Sciences.
6. Relevant review articles from recent medical and pharmaceutical literature
7. Pharmacy Practice: Essentials of Hospital, Clinical and Community Pharmacy y Sanjaykumar B. Bari, Vishal C. Gurumukhi, Pravinkumar V. Ingle,Pharmamed Press

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M.Pharm II Year I Sem (Pharmacology)

MEDICINAL PLANT BIOTECHNOLOGY (Professional Elective - V) (R23PC31C)

Course Objective: The topics are designed to help the students to get exposed to various techniques of plant tissue culture. Use the biotechnological techniques for obtaining and improving the quality of natural products/medicinal plants.

Course Outcome: Students will gain the knowledge about various strategies of plant tissue culture and students will gain knowledge about various secondary metabolites produced by plant tissue culture.

UNIT I

Introduction to Plant biotechnology: Historical perspectives, prospects for development of plant biotechnology as a source of medicinal agents. Laboratory Organization, Sterilization techniques (Aseptic transfer) Concepts of Totipotency, Nutritional requirements, Media preparation, Explant preparation, Establishment of Aseptic cultures. Biotechnological applications of Plant Tissue culture in pharmacy and allied fields.

UNIT II

Different tissue culture techniques: Types and techniques of plant tissue culture, Organogenesis and embryogenesis, Protoplast fusion, synthetic seed and Micro propagation of medicinal and aromatic plants.

UNIT III

Immobilization techniques & Secondary Metabolite Production: Immobilization techniques of plant cell and its application, Precursors and elicitors on production of secondary metabolites, Cryopreservation of germ plasm.

UNIT IV

Biotransformation and Trangenesis: Biotransformation of Plant Cell Culture and its importance in secondary metabolite production. Bioreactors for pilot and large scale cultures of plant cells and retention of biosynthetic potential in cell culture**.** Transgenic technology-Hairy root multiple shoot cultures and their applications.

UNIT V

Secondary metabolism in tissue cultures with emphasis on production of medicinal agents-
Production of Secondary metabolites from callus culture and suspension culture with emphasis on production of biomedicinals like- Ajmalicine, Artemisin, Shikonin, Carotenoids and Rosemarinic acid.

REFERENCE BOOKS:

1. Pharmacognosy and Pharmacobiotechnology by Ashutoshkar
2. Introduction to plant tissue culture by M.K. Razadam
3. Plant Tissue Culture by Bhojwani
4. Medicinal Plant Biotechnology by ciddi veeresham
5. Molecular Biology and Biotechnology by J.M. Walker and E.D. Gingo
6. Advanced methods in Plant breeding and Biotechnology by David R Mirray
7. Biotechnology by Purohit and Mathur, Agro-Bio, 3rd revised edition.
8. Biotechnological applications to tissue culture by Shargool, Peter D, Shargoal, CKC Press.
9. Pharmacognosy by Varo E. Tyler, Lynn R. Brady and James E. Robberrt, That Tjen, NG
10. Plant tissue culture by Street
11. Medicinal plant biotechnology by Ciddi Veeresham
12. Pharmaceuticals biotechnology by S.P. Vyas & V.K. Dixit

Andhra Kesari University, Ongole

M.Pharm II Year I Sem (Pharmacology)

COSMETICOLOGY (Open Elective) R23PC32A

Course Objective: This subject will impart knowledge about physiological structure of skin, hair, nail and eye. This gives the information about rheological properties of different cosmetic properties. It will teach the students on preparation and evaluation of different cosmetic products and their excipients. It will teach the students in developing cosmetic safety and new technology in developing cosmetics.

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

- Explain the physiological structures of skin, hair, nail and eye.
- It gives the knowledge about rheological property determination
- Explain the evaluation process, safety use of cosmetics and new technology development.
- Explain the principles involved in liposomes, multiple emulsions and creams.

UNIT I

1) Physiological consideration: skin, hair, nail and eye - in relation to cosmetic application.
2) Rheology of cosmetics: Rheological additives in cosmetics, rheology of nail products, antiperspirants, deodorants, dentifrices, hair products, creams and lotions.

UNIT II

3) Evaluation of cosmetics: Performance, physicochemical, microbiological and psychometric evaluation of cosmetics.
4) Design and Assessment of preservative systems for cosmetics, valuation of preservatives in cosmetic products and factors affecting activity of preservatives. Testing of moisturizers, deodorants, antiperspirants, sunscreen and antiaging products.

UNIT III

5) Clinical safety testing: Irritation, sensitization, photoirritation, photoallergy ocular irritation and protocols for the same.
6) Herbal cosmetics: Formulation development

UNIT IV

7) Packaging: Package development and design for cosmetics including aerosol packs
8) Regulatory requirements: Manufacturing and sale of cosmetics

UNIT V

9) Advances in cosmetics: Liposomes, multiple and microemulsions, tooth pastes, hair waving, hair planting, permanent hair coloration, cosmetic surgery, contact lenses.
10) Manufacturing techniques: cosmetics creams, powders, compacts, sticks, liquids, foam and aerosol cosmetics.

RECOMMENDED BOOKS:

1. J. Knowlton and S. Rearce; Handbook of cosmetic sciences and technology; Elsevier science publisher.
2. J.B. Wilkinson and R.J. Moore; Harry's cosmetology; Longman Science and Technical.
3. S.N. Katju's; Law of Drugs; Law Publishers (India) Pvt. Ltd.
4. E.G. Thomssen; Modern cosmetics; Universal Publishing Corporation.
5. M.S. Balsam and E. Sagarin ; Cosmetics, science and technology; John Wiley and Sons.
6. R. L. Elder; Cosmetic Ingredients, their safety assessment; Pathotox
7. H.R. Moskowitz; Cosmetic Product Testing; Marcel Dekker.
8. W. C. Waggoner; Clinical safety and efficacy testing of cosmetics; Marcel Dekker.

9. C.G. Gebelein, T.C.Cheng and V.C. Yang ; Cosmetic and pharmaceutical applications of polymers; Plenum.
10. L. Appell; The formulation and preparation of cosmetics, fragrances and flavours; Micelle Press.
11. W.A. Poucher; Poucher's Perfumes, cosmetics and soaps; vol. 3, Chapman and Hall
12. Dr.Laba; 'Rheological properties of cosmetics and toiletries; Marcel Dekker.

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M.Pharm II Year I Sem (Pharmacology)

PHARMACEUTICAL ADMINISTRATION (Open Elective) R23PC32B

Course Objective: This subject will provide principles of pharmaceutical industrial management, forms of business organization, plant location and layout. It will teach the students on workman safety, export and import of drugs and pharmaceuticals and briefly on industrial accounting.

Course Outcome: Upon completion of the course, the student shall be able to, · Explain the Indian pharmaceutical industry development, knowledge about Pharmaxil and its involvement · Explain the books of accounting, journals, ledger, cashbook and balance sheet.

UNIT I

Pharmaceutical Industrial administration: Principles of Pharmaceutical Industrial Management in relation to the Introduction to forms of Business Organization. Manufacturing Management: Plant location, factory building lay-out, production management goals and organization, operating problems, production policy, initiation of production, purchasing and inventory control, works lay-out and plant management.

UNIT II

Workman Safety: measures to health hazards and prevention of environmental pollution. Organization of Distribution and Marketing: Factors in distributions, Sales organization and sales promotions. General principles of medical detailing. Export and Import trade. GATT,WTO- New product development. .

UNIT III

Indian pharmaceutical industry: Pharmaceutical industry in India, milestones in the development of pharmaceutical industry, current status and its role in national economy and national health. Structure of the industry, organized sector, small sector, manufacture of pharmaceuticals in public sector. Progress in the manufacture of basic drugs – synthetic and drugs of vegetable origin.

UNIT IV

Export and import of drugs and pharmaceuticals -knowledge of PHRMEXIL. Various types of insurances including marine insurance. Pharmaceutical associations and societies, statutory councils governing the profession. Principle of Drug store and community pharmacy administration: Drug store management: Drug store planning and lay – out, sales promotion and salesmanship in drug store. Accounting records in drug stores.

UNIT V

Elements of industrial accounting accountancy: Elements of double entry, books of accounts, journal, ledger and cashbook. The balance sheet, profit and loss account. Principles of costing and estimating.

RECOMMENDED BOOKS:

1. Essentials of management by Dr.Herold Koontz and Heinz Weitnrich, published by McGraw Hill publishing company.
2. Managing productivity in organizations by Kopelman, published by McGraw Hill publishing company.
3. Effective supervision: A practical approach by Hodgetts, published by McGraw Hill publishing company.

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M.Pharm II Year I Sem (Pharmacology)

DRUG REGULATORY AFFAIRS (Open Elective) R23PC32C

Course Objective: The topics which are present in the Drug regulatory affairs are very much useful which increases the knowledge regarding the regulatory aspects in the pharmaceutical industries.

Course Outcome:

- Students will come to know the different competent regulatory authorities globally.
- Students be aware of technical aspects pertaining to the marketing authoritization application (MAA)
- The regulatory guidelines and directions framed by the regulatory authorities will be helpful to place the drug products in market for marketing approvals.

UNIT I

Drug Regulatory Aspects (India)

1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA)
2. Drugs and Cosmmetics Act and Rules with latest Amendments (Selective)
3. Special emphasis - Schedule M and Y
4. New drugs - Importation, Registration, development, Clinical Trials, BE NOC& BE studies
5. Various Licences – Test Lic., Import lic., for testing of drugs and API's, Manufacturing Contract and Loan licence manufacturing.

UNIT II

Good Manufacturing Practices (GMP)

1. Indian GMP certification, WHO GMP certification.
2. ICH guidelines for stability testing and other relevant ones (Q1-Q10)
3. Export permissions and manufacturing for semi-regulated countries
4. Understanding of the plant layouts with special emphasis on the environment & safety. (HVAC, Water Systems, Stores Management, Effluent etc.)
5. Quality Assurance and Qulaity Control - Basic understanding for in-built quality.

UNIT III

A detailed study of regulatory aspects that affect drug product design, manufacture and distribution in a developed country such as USA and in a developing country such as Brazil, Hatch Waxmann Act; Bolar Provisions and other FDA Regulations. Regulatory aspects of pharmaceutical and bulk drug manufacture, regulatory drug analysis.

UNIT IV

Documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls.
Quality, safety and legislation for cosmetic products and herbal products.

UNIT V

Governing Regulatory Bodies across the globe.

Country Authority Submission

a. U.S Food & Drug Administration USDMF
b. Canada Therapeutic Product DirectorateDMF
c. Europe
    1) European Medicines Agency (EMEA/ National Authorities) EDMF
    2) European Directorate for Quality of Medicines CEP/COS & Health Care Products.
    3) MHRA - Medicines and Health Care Products Regulatory Agency
d. Product Filing

e. Responding Regulatory Deficiencies
f. Final Approval Procedure

Preparation, review and submission of Drug Master Files to Regulatory Authorities as per their specific requirements.

RECOMMENDED BOOKS:

1. Original laws published by Govt. of India.
2. Text Book of Forensic Pharmacy by Mithal B. M.; Vallabh Prakashan, New Delhi.
3. Laws of Drugs in India by Hussain.
4. Text Book of Forensic Pharmacy by Jain N. K.; Vallabh Prakashan, New Delhi.
5. Pharmaceutical Regulatory Affairs - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi - 2013

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M.Pharm II Year I Sem (Pharmacology)

Project Management R23PC32D

Course Objective: This subject will provide introduction of project life cycle, its duties, planning for project life cycle leaders and their involvement project management. It will teach the students on role of project managers, clients, customers etc. This subject also focuses on project planning process, executing and heading the project team and responsibilities.

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

- Explain the project management and its life cycle
- Involves in different duties as project manager, clients and customers
- Explain the responsibilities of key players involved in project management
- Execute project as project leaders and team responsibilities.

UNIT I

Introduction & Project Life Cycle

The difference between a project manager and a project engineer / project leader, duties of a project engineer /project leader, relationship between scope/schedule/budget/resources and how it relates to all project activities

Project Life Cycle and how it relates to project definition and control, feasibilities and feasibility study, key elements of working in a group and group dynamics.

UNIT II

Pre-Planning for Project Management:

Importance of project management, organizing for project management, Role of project manager, Role of clients, customers and others, setting up planning and control system.

UNIT III

Project Planning Process:

Defining project, creating work breakdown structure, estimating activities, sequencing activities, calculating the critical path, scheduling project, resources planning, preparing planning budgets, approval of projects, setting up a monitoring and control process.

UNIT IV

Executing the Project

Initiating the project, controlling project objectives, reporting on project objectives, controlling changes in the project, conducting project evaluations, managing risks in project management,
Closing the project.

UNIT V

Heading the Project Team

Developing project teams, managing conflicts, communicating effectively, holding effective meetings, making team decisions, using sources of power wisely, making changes, managing performance

RECOMMENDED BOOKS:

1. Project management; step by step By Larry Richman Publisher: Prentice-Hall of India Pvt. Ltd Year of publication 2008
2. Project management: The managerial process By Clifford F. Gray and Eric W. Larson Publisher: Tata Mc Graw Hill Third edition
3. Rethinking project management By Erling S. Andersen Publisher: Prentice- Hall Year of publication 2008
4. Project management By Jeffery K. Pinto Publisher: Prentice-Hall Year of publication 2007.

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AUDITS AND REGULATORY COMPLIANCE (Open Elective) R23PC32E

Course Objectives: This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Course Outcomes: Upon completion of this course the student should be able to

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

UNIT I

Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies

UNIT II

Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.

UNIT III

Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.

UNIT IV

Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.

UNIT V

Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.

RECOMMENDED BOOKS:

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C.Singer, Raluca-Ioana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).