**KL UNIVERSITY**
Green Fields, Vaddeswaram.

*List of Pre-Ph.D Courses approved by*

**DEPARTMENT OF PHARMACY**

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*Signature*

**Dr. K.L. NARAYANA**
DEAN (R & D)
K.L. UNIVERSITY
VADDESWARAM (POST)-522 502
Tadepalli Mandal, Guntur Dt.
SYLLABUS OF PRE-PH.D. COURSE WORK

Code: 15 RM SCI 102

RESEARCH METHODOLOGY
SYLLABUS
[COMMON TO MATHS, PHYSICS, CHEMISTRY & PHARMACY]

Unit - I INTRODUCTION TO METHODOLOGY:
Format of thesis and dissertation, Research article, Reviews, Monographs, Bibliography, Literature search, Significance of research, Research methods versus methodology, Research and Scientific methods, Defining the research Problem and Research design.

Unit-II Quantitative Methods for Problem Solving:

UNIT III : Physical Statistical Methods
Definition and Scope; Types of data; Collection and presentation of Data (Tables, Graphs, Diagrams); Measure of Central Tendency; Dispersion; Goodness of fit (X2 Test).

UNIT IV: Sampling Fundamentals:
Census and sample Survey, Steps in sample design, Different types sample design, Selection of a random sample, Estimation, Estimating the population mean and population proportion.

Unit-V : Interpretation and Report Writing:
Meaning of interpretation; Techniques of interpretation; Precautions in Interpretation; Significance of Report writing; Different steps in Report writing; Layout of Research Project; Types of Reports; Patent writing and filing and Oral presentation.

Text Books:

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MODERN ANALYTICAL TECHNIQUES
SYLLABUS
[COMMON TO ALL BRANCH OF PHARMACY]

Unit-I:
1. UV-VISIBLE SPECTROSCOPY:

2. INFRARED SPECTROPHOTOMETRY:
Introduction, basic principles, and sampling techniques, interpretation of spectra, applications in Pharmacy. FT-IR, Attenuated Total Reflectance (ATR), near infra red Spectroscopy (NIR) -theory and applications.

Unit-II:
1. NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY:
   Fundamental Principle and Theory, Instrumentation, solvents, chemical shift, and factors affecting chemical shift, spin-spin coupling, coupling constant, and factors influencing the value of coupling constant, spin-spin decoupling, proton exchange reactions, simplification of complex spectra, FT-NMR, 2D -NMR and applications in Pharmacy, interpretation of spectra. C13 NMR-Introduction, Natural abundance, C13 NMR Spectra and its structural applications. 2. MASS SPECTROMETRY:
   Basic principles and instrumentation, ion formation and types, fragmentation processes and fragmentation pattern, Chemical ionization mass spectroscopy (CIMS), Field Ionization Mass Spectrometry (FIMS), Fast Atom Bombardment MS (FAB MS), Matrix Assisted laser desorption / ionization MS (MALDI-MS), interpretation of spectra and applications in Pharmacy.

Unit-III:
1. ATOMIC ABSORPTION AND PLASMA EMISSION SPECTROSCOPY:
   Principle, instrumentation, interferences and applications in Pharmacy.
2. THERMAL METHODS OF ANALYSIS:
   Theory, instrumentation and applications of Thermo Gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC). And Thermo Mechanical Analysis (TMA).

Unit-IV:
1. OPTICAL ROTARY DISPERSION:
   Principle, Plain curves, curves with cotton effect, octant rule and its applications with example, circular dichroism and its relation to ORD.
2. X-RAY DIFFRACTION METHODS:
   Introduction, generation of X-rays, X-ray diffraction, Bragg’s law, X-ray powder diffraction, interpretation of diffraction patterns and applications.

Unit-V:
1. CHROMATOGRAPHIC TECHNIQUES:
   a) Classification of chromatographic methods based on mechanism of separation. Theories of chromatographic separation.
   b) Principles, elution techniques, instrumentation, derivatization and applications of gas chromatography, HPLC and HPTLC.
   c) Principles, elution techniques, applications of ion exchange and ion pair chromatography,
affinity chromatography, size exclusion chromatography, and chiral chromatography, super fluid chromatography (SFC), GC-MS and LC-MS.

2. ELECTROPHORESIS:
Theory and principles, classifications, instrumentation, moving boundary electrophoresis, Zone Electrophoresis (ZE), Isoelectric focusing (IEF) and applications.

Reference Books:
8. Instrumental Methods of Analysis – Willard, Merritt, Dean, CBS, Delhi.
ADVANCES IN PHARMACEUTICAL TECHNOLOGY

Unit-I:
Fundamentals of controlled drug delivery systems, use of polymers in controlled drug delivery, 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 (c) Implantable therapeutic systems

Unit-II:
(a) Transdermal delivery systems including iontophoresis (b) Ocular and intrauterine delivery systems (c) Bioadhesive drug delivery systems (d) Proteins and peptide drug delivery

Unit-III:
Biochemical and molecular biology approaches to controlled drug delivery of 1. Micro particulate drug carriers: Liposomes, Niosomes, Microspheres, Nanoparticle and Resealed erythrocytes. 2. Monoclonal antibodies

Unit-IV:
Drug targeting to particular organs: (a) Drug delivery to respiratory systems (b) Problems of drug delivery to the brain and targeting to brain (c) Drug delivery to eye (d) Drug targeting in neoplastic diseases

Unit-V:
Drug carrier systems targeted to widely dispersed cells a) Delivery to Macrophages b) Delivery to lymphoid cells of immune network c) Delivery to lysosomal storage diseases

Reference Books:

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ADVANCED PHARMACOLOGY

Unit-I:

01. Detailed study of guidelines for maintenance, breeding techniques and experimentation using laboratory animals: a) CPCSEA  b) OECD  c) ICH d) GLP  e) ICMR  f) Guidelines according to official compendia

02. Alternatives to animal experimentation: a) Animal cell lines and their uses b) Radioligand binding assay c) Patch clamp and ELISA d) Stem cell research etc.

Unit-II:

01. Organization of screening: Pharmacological activity of new substances and safety assessment tests.

02. Toxicity studies: acute, subacute (Repeated dose), subchronic and chronic toxicity.

Unit-III:

Introduction to Pharmacogenomics, Proteomics and Array technology
Fundamentals of Molecular mechanism of drug action:

a) Receptor occupancy and cellular signaling systems such as G-proteins, cyclic nucleotides, calcium and calcium binding proteins, phosphatidyl inositol. Ion channels and their modulators.

b) Endogenous bioactive molecules: Cytokines, neuropeptides and their modulators, neurosteroids, nitric oxide, phosphodiesterase enzyme and protein kinase C, arachidonic acid metabolites, COX-2 regulators and their role in inflammation, endothelium derived vascular substances (NO, endothelins) and their modulators. Pharmacology of atrial peptides, reactive oxygen intermediates, antioxidants and their therapeutic implications.

Unit-IV:

Recent trends on different classes of receptors and drugs acting on them:

(i) Angiotensin receptors
(ii) Excitatory amino acid receptors
(iii) Kinin receptors
(iv) Adrenoceptors
(v) Low molecular weight heparins, hirudins and GP IIb/IIIa receptor antagonists
(vi) Imidazole receptors
(vii) Cholinergic receptors
(viii) Dopamine receptors
(ix) Serotonin receptors
(x) Hormone receptors
(xi) GABA and Benzodiazepine receptors
(xii) Opioid receptors
(xiii) Purinergic receptors
(xiv) Glutamate receptors
Unit-V:

01. a) Ion channel and their modulators: calcium, potassium, sodium and chloride channels.

b) Apoptosis: basic functions, mechanisms and role of caspases. Pharmacological and clinical implications.

02. a) Gene therapy: Concept of gene therapy and recent development in the treatment of various hereditary diseases. Human genome mapping and its potential in drug research.


Reference Books:
1. Pharmacological basis of Therapeutics—Goodman and Gilman
2. Pharmacology—Rang and Dale
3. Principles of Pharmacology—Paul L. Munson
4. Lewis's Pharmacology—James Crossland—Churchil Livingstone
5. Modern Pharmacology with clinical applications—Craig, Charles R.
6. Lippincott's illustrated reviews of Pharmacology—Mycek Mary J.
7. Goth's Medical Pharmacology—Wesley G. Clark
8. Principles of pharmacology—H. L. Sharma
9. Essentials of medical pharmacology—K. D. Tripathi
ADVANCED PHARMACOGNOSY & PHYTOCHEMISTRY

Unit-I:

01. Introduction, use of natural products in traditional medicines, potential of natural products, Natural products in drug discovery and development.

02. Recent development in the research on Natural medicinal products: Introduction, Biological and Pharmacological activities, Isolation and characterization studies of different class of Phytoconstituents (Alkaloids, Glycosides, Steroids, Saponins etc).

Unit-II:

01. Natural product drug discovery from different sources (Marine, Microbial, Mineral etc): Introduction, recent development, methods of extraction and isolation, applications etc

02. Extraction and Isolation techniques: Introduction, Principle and Applications of different extraction & isolation methods viz Soxhlet extraction, microwave extraction, supercritical fluid extraction, solid phase extraction, Column chromatography, Flash chromatography etc.

Unit-III:

01. Overview of Novel herbal formulations: Phytosomes, Liposomes, Microspheres, novel vesicular herbal formulations etc

02. Standardization of herbal drugs/formulations: Conventional methods, Modern techniques (Role of genetic markers, RAPD, DNA fingerprinting technique etc)

Unit-IV:

WHO Guidelines for assessment of crude drugs Evaluation of identity, purity, and quality of crude drugs. Determination of pesticide residue Determination of Micro-organisms Determination of Arsenic and heavy metals

Unit-V:

Herbal Drug Regulatory affairs Role and importance of national and international regulatory bodies in assessment of quality of herbal drugs and formulations.

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Reference Books:

1. Recent progress in medicinal plants: Volumes 1 to 22.
2. Ramstad-Modern pharmaconosy
3. Herskowitz- Principles of Genetics
4. Stricknerger- Genetics
5. Hess-Plant Physiology
6. Kruse Patterson- Tissue culture methods and Applications
7. Handa SS and Kaul KS – Supplement to cultivation and utilization of medicinal plants
8. Wealth of India, raw materials
10. Purthi JS- Major spices of India.

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ADVANCED PHARMACEUTICAL ANALYSIS

Unit-I:

01. Application of analytical methods to product obtained through genetic engineering , Amino acid sequence analysis, Tryptic mapping, ion exchange amino acid analysis, isoelectric focusing etc.

02. Regulatory requirement in pharmaceutical analysis – US-FDA, ICH

Unit-II:

01. Solid state analysis of drug substance including related substances, and impurities present in drugs and their effect on drug stability and therapeutic action.

02. Applications of various analytical techniques in preformulation analysis and its importance.

Unit-III:


02. a) Quality control of radio pharmaceuticals and radio chemical method in analysis.

b) Analysis of cosmetics.

Unit-IV:

A detailed study of principle and procedures involved in various physicochemical methods of analysis including instrumental methods of analysis of Pharmaceutical dosage forms containing the following classes of drugs:

Unit-V:

Principles and procedures involved in the use of the following reagents in Pharmaceutical analysis :
a. N1-naphthyl ethylene diamine. b. p-dimethylaminobenzaldehyde (PDAB). c. 2,6-Dichloro quinone chloride. d. 1,2-Naphtho quinone 4 - sulphonate. e. 2,3,5-Triphenyl Tetrazolium Salt. f. Ninhydrin. g. Folin - Ciocalteau reagent. h. P-dimethyl amino cinnamaldehyde. i. 3-methyl-2-benzothiazoline hydrazone (MBTH). j. 2,4-dinitrophenylhydrazine.
References Books:
2. S. Ahuja, Modern Pharmaceutical Analysis
4. Peptide and Protein Drug Analysis, by Reid, (Marcel Dekker).
5. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
7. Methods of sampling and test for various cosmetics as laid down by Indian Standard Institution (BIS).
8. Indian Pharmacopoeia, Vol. I and Vol. II - 1996. The Controller of Publications; New Delhi, Govt. of India,
ADVANCED MEDICINAL CHEMISTRY

Unit-I:
Methods of determining reaction mechanisms (kinetic and non-kinetic methods); Energy profile diagrams, reaction intermediates, crossover experiments and isotopic labelling; Order of reactions, reversible, consecutive and parallel reactions, solvent, ionic strength and salt effects; Multicomponent reactions of pharmaceutical importance such as Biginelli reaction, Hantzsch reaction, Ugi reaction, Passerini reaction and Strecker synthesis.

Unit-II:
General principles, Identification and study of targets for development of various therapeutic agents, Rational approach for drug design, Computer aided drug design, Study of recently developed drugs and molecules in development pipeline.

Unit-III:
01. Various targets for drug action and theory of drug action – agonist, antagonism/ blockers and enzyme inhibition (IC50, EC50 concept)- an overview

02. A general study of stereochemistry and physicochemical properties of the drug/druglike molecules and their importance in drug action. Correlation between physicochemical properties and drug action, establishing structure activity relationship (SAR) and its analysis. Isosterism and bioisosterism as guides to structural variations and Prodrug design its application in lead optimization.

Unit-IV:

02. Pharmacokinetics (Absorption, Distribution, Metabolism Elimination i.e. ADME) in drug discovery.

Unit-V:
01. Computer Aided Drug Design (CADD) – Molecular modeling a. Basic concepts of computational chemistry like Quantum Mechanics, Molecular Mechanics, Force Field, Energy minimization, Conformational generation and analysis, geometry optimization, Molecular Dynamics b. Ligand based drug design, Analogue approach, Pharmacophore Mapping, importance of ligand shape and Excluded volume techniques, Artificial intelligence methods. c. Structure based drug design, requirement of SBDD, utilization of target structure derived from NMR and X-ray Crystallography techniques, understanding of drug–receptor/enzyme/target interactions, preparation of protein/target along with active site analysis, docking process, various docking methods. De novo drug design. d. Drug design based on antagonism and enzyme inhibition. Various software used in CADD.

02. Virtual screening of huge compound databases by using Pharmacophore mapping as well as docking methods
References Books:
2. H Smith & H J William – Introduction to the Principal of Drug Design, John Wright & Sons Ltd.
   , John Wiley & Sons
4. Copmuter assisted Drug Design by Edward C. Olson (America Chemical Society, ACD
   symposium series 112).
7. Molecular Modeling in Drug Design by Cohen N. C.
8. C. G. Wermuth - The Practice of Medicinal Chemistry, Elsevier publication.
9. E. H. Kerns and L. Di - Drug like properties, concepts, structure design and methods, Academic
   Press.