Ph.D. Course Work

Pre-Ph.D. Examination Syllabus

w.e.f: AY: 2024-25

DEPARTMENT OF PHARMACY,

K L Deemed to be University,

Koneru Lakshmaiah Education Foundation

VADDESWARAM - 522502, ANDHRA PRADESH, INDIA

KL University
KL College of Pharmacy
List of Pre-Ph.D. Courses

I. COMMON TO ALL SPECIALIZATIONS OF PHARMACY

S. No	Paper-1	Code
1.	RESEARCH METHODOLOGY	24RES102

II. COMMON TO ALL SPECIALIZATIONS OF PHARMACY

S. No	Paper-2	Code
1.	MODERN ANALYTICAL TECHNIQUES	24PY201

III. SPECIALIZATION COURSES IN PHARMACY

S. No	Paper-3	Code
1.	ADVANCES IN PHARMACEUTICAL TECHNOLOGY	24PY301
2.	ADVANCED PHARMACOLOGY	24PY302
3.	ADVANCED PHARMACOGNOSY & PHYTOCHEMISTRY	24PY303
4.	ADVANCED PHARMACEUTICAL ANALYSIS	24PY304
5.	ADVANCED MEDICINAL CHEMISTRY	24PY305
6.	CLINICAL PHARMACY PRACTICE	24PY306

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Code: 24RES102

RESEARCH METHODOLOGY
SYLLABUS
[COMMON TO ALL BRANCHES OF 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. Ethics in medical research, history, values, guidelines and ethics committees.

Unit-II: Quantitative Methods for Problem Solving: Introduction to Statistical Modeling and Analysis, Concepts of Correlation and Regression, Fundamentals of Time Series Analysis and Spectral Analysis, Error Analysis. Applications of Spectral Analysis.

UNIT III: 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). Statistical Software's to Industrial and Clinical Trial Approach like Minitab, GraphPad Prism etc

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:

1. Kothari, C.R; II ed. (2006). Research Methodology, Methods and techniques: New Age International (p) Ltd., Publishers, New Delhi.: 2. Kumar K. L.' (1997), Educational Technology. New Age International (P) Ltd., New Delhi.

References:

1. Donald R. Cooper, Pamela S. etc., Business Research Methods,8th Edition. Tata McGraw Hill Co.Ltd.2006.
2. Tony Bates A.W. Technology, (2005), e-Learning and Distance Education. New York.

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Code: 24PY201

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

Unit-1:

1. UV-Visible Spectroscopy: Introduction, theory, laws and instrumentation, chromophore concept, choice of solvent and solvent effects and applications of UV-Visible spectroscopy. Woodward Fischer rules, interpretation of spectra. Multi-component analysis, difference spectra and derivative spectra.

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

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, spin-spin decoupling, proton exchange, nuclear Overhauser effect and applications of 1H NMR. Fundamental principles and theory, and applications of FT-NMR, 2D-NMR and C13 NMR.

2. Mass Spectrometry: Basic principles and theory, instrumentation, ionisation and types, analysers, fragmentation processes and, applications in Pharmacy.

Unit-III:

Thermal Methods of Analysis: Theory, instrumentation and applications in Pharmacy of Thermo Gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) and Thermo Mechanical Analysis (TMA).

Unit-IV:

1. Atomic Absorption and Atomic Emission Spectroscopy: Principle, instrumentation, interferences and applications in Pharmacy.

2. X-Ray Diffraction Methods: Introduction, generation of X-rays, X-ray diffraction, Bragg's law, rotating crystal technique, X-ray powder diffraction, and applications in pharmacy.

Unit-V:

Chromatographic Techniques:

a) Classification of chromatographic methods. Theories of chromatographic separation.

b) Principles, elution techniques, instrumentation, Derivatization and applications of gas chromatography, HPLC, HPTLC, GC-MS and LC-MS.

c) Principles, elution techniques, applications of ion exchange and ion pair chromatography, affinity chromatography, size exclusion chromatography, and chiral chromatography, supercritical fluid chromatography (SFC).

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Reference Books:

1. Spectrometric identification of Organic Compounds, Robert. M. Silverstein, Basseler. Morril (John Wiley and Sons. N.Y).
2. Spectroscopy of Organic Compounds by P. S. Kalsi.
3. Principles of Instrumental Analysis by Donglas A. Skoog, James, J. Leary. 4th Edition.
4. Pharmaceutical Analysis - Modern Methods - Part A, Part B, James W. Munson 2001.
5. Organic Spectroscopy - William Kemp, 3rd Edition.
6. Chromatographic Analysis of Pharmaceuticals, John A. Adamovics, 2nd Edition.
7. Practical Pharmaceutical Chemistry, Part two, A. H. Beckett & J. B. Stenlake-4th edition
8. Instrumental Methods of Analysis - Willard, Merritt, Dean, CBS, Delhi.
9. Techniques and Practice of Chromatography - Raymond P. W. Scott, Vol. 70.
10. Identification of Drugs and Pharmaceutical Formulations by Thin Layer Chromatography - P. D. Sethi, Dilip Charegaonkar, 2nd Edition.
11. HPTLC-Quantitative Analysis of Pharmaceutical Formulations - P. D. Sethi.
12. Liquid Chromatography - Mass Spectrometry, W. M. A. Niessen, J. Van Der Greet, Vol. 58.
13. Modern Methods of Pharmaceutical Analysis, Vol. 1, 2, RE Schirmer, Franklin Book.

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Code: 24PY301

ADVANCES IN PHARMACEUTICAL TECHNOLOGY

Unit-1:

01. Pre-formulation Studies: Introduction, pre-formulation testing criteria, regulatory requirements, testing systems, solid-state characterization, transport across biological membranes.

02 Polymers: Polymer classification, physiochemical properties and polymers, application of polymers in drug delivery.

03. Optimization of formulations: Introduction to statistical methods and factorial design, quality by design (QbD).

Unit-II: Controlled drugs delivery system: Design, fabrication, evaluation and applications of the following controlled releasing systems (a) Oral drug delivery systems (b) Parenteral drug delivery systems (c) Implantable therapeutic systems. (d) Transdermal delivery systems including iontophoresis.

Unit-III:

01. **Particulate drug delivery systems**: Formulation, evaluation and applications of following drug delivery systems 1. Micro particulate drug carriers: Liposomes, Niosomes, Microspheres, Nanoparticle and Resealed erythrocytes. 2. Monoclonal antibodies.

Unit-IV:

01. **Targeted drug delivery systems**: (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. (e). Proteins and peptide drug delivery.

02. **Bioequivalence studies:** Basic pharmacokinetic concepts, *in vitro* and *in vivo* methods in establishment of bioequivalence.

Unit-V:

Gene Therapy: Nucleic acid based therapeutic delivery system: Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and non-viral gene transfer). Liposomal gene delivery systems.

Reference Books:

1. Novel Drug Delivery System by Yie W. Chien.
2. Controlled Drug Deliver by Joseph R. Robinson and Vincent H. L. Lee.
3. Controlled and Novel drug delivery systems by N. K. Jain.
4. Targeted and Controlled Drug Delivery (Novel carrier systems) by S. P. Vyas and Khar.
5. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
6. Controlled Drug Deliver by N.K Jain.

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Code: 24PY302

ADVANCED PHARMACOLOGY

Unit-1:

01. Guidelines for experimentation using laboratory animals:

a) CCSEA. b) OECD. c) ICH. d) ICMR. and e) 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. **Toxicity Studies**: Acute, Sub-acute (Repeated dose), sub-chronic and chronic toxicity.

02. Carcinogenicity and mutagenicity.

Unit -III:

01. Molecular mechanism of drug action: Receptor occupancy and cellular signalling systems, types of drug targets, important families of receptors, ion channels, and signal transduction mechanisms, coupling receptors to cellular function.

02. Cellular Mechanisms of Drug Action: Regulation of cellular function (excitation, contraction and secretion), slower mechanisms of cell response (cell proliferation, apoptosis) and their pathophysiological significance.

Unit-IV:

Receptors and drugs that target them,

i. Angiotensin Receptors
ii. Excitatory and inhibitory amino acid receptors
iii. Kinin receptors
iv. Low molecular weight heparins, hirudin, and GP II/IIIa receptor antagonists
v. imidazole receptors
vi. Cholinergic receptors
vii. Catecholamine receptors
viii. Hormone receptors
ix. Opioid receptors
x. Purinergic receptors

Unit-V:

a) Ion channel and their modulators.
b) Apoptosis.
c) Gene therapy.
d) Immunopharmacology and Monoclonal antibodies.

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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

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Code: 24PY303

ADVANCED PHARMACOGNOSY AND PHYTOCHEMISTRY

Unit-I:

Introduction, use of natural products in traditional medicines in drug discovery and development. Plant primary and secondary metabolism. Advancements in Natural drug discovery, 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). Extraction and Isolation techniques: Soxhlet extraction, microwave extraction, supercritical fluid extraction, solid phase extraction, Column chromatography, Flash chromatography etc.

02. Solvents used in extraction.

Unit-III:

01. Phytochemistry (NMR, Mass, LCMS). Overview of Novel herbal formulations: Phytosomes, Liposomes. Microspheres, novel vesicular herbal formulations etc. Standardization of herbal drugs/formulations.

02. Herbal-herbal and Herbal-drug, herbal-food interactions.

Unit-IV:

Guidelines for assessment of crude drugs, Evaluation of identity, purity, and quality of crude drugs. Determination of pesticide residues, adulteration of crude drugs.

Unit-V:

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

Reference Books

1. Recent progress in medicinal plants Volumes 1 to 22.
2. Ramstad-Modem 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
9. Atal & Kappor- Cultivation and utilization of medicinal plants
10. Purthi 1S. Major spices of India
11. Pharmacognosy and Pharmacobiotechnology Robbers JL Speedie MK. Tyler VI William and Wilkins USA. 1996
12. Medicinal Natural Products a biosynthetic Approach Dewick PM John Wiley and Sons Toronto, 1998.
13. Chemistry of Natural products. Bhat SV. Nagasampagi BA Meenakshi S. Narosa Publishing.

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Code: 24PY304

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 and Q2B and Q3USFDA guidelines.

Unit-II:

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

02. Applications of various analytical techniques in pre-formulation analysis and its importance.

Unit-III:

01. Analysis of solid oral and injectable dosage form, automated analysis. Compendial methods for evaluation of crude drug and herbal formulation.

02. a) Quality control of radio pharmaceuticals b) Analysis of cosmetics. c) Analysis of drugs in biological samples.

03. Immunoassays like ELISA, Bioluminescence assay and RIA.

Unit-IV:

Principle and procedures of physicochemical and instrumental methods of analysis of Pharmaceutical dosage forms of following drugs:

a) Sulphonamides.

b) Barbiturates - i.e., Barbituric acid derivatives.

c) Steroids such as adrenocortical steroids, Progesterone, Androgens and Cholesterol.

d) Vitamins like Vitamin A, B1, B2, B12, C & E.

e) Antibiotics like Chloramphenicol, Erythromycin, Penicillin & Streptomycin.

f) Alkaloids of Cinchona, Ergot, Opium & Rauwolfia.

g) Glycosides such as Digitoxin, Digoxin & Strophanthin.

Unit-V:

Principles and procedures involved in the use of the following reagents in Pharmaceutical analysis:

a) N-(l-naphthyl) ethylene diamine.

b) p-dimethyl aminobenzaldehyde (PDAB).

c. 2,6-Dichloro quinone chlorimide.

d) 1,2-Naphtho quinone 4 – sulphonate

e. 2,3,5-Iriphenyl Tetrazolium Salt.

f) Ninhydrin.

g. Folin- Ciocalteau reagent.

h. *p*-dimethyl amino cinnamaldehyde.

i. 3-methyl-2-benzothiazoline hydrazone (MBTH).

j. 2,4-dinitrophyenylhydrazine (2,4-DNP).

References Books

1. Harry G Brittain. Spectroscopy of Pharmaceutical Solids, Drugs andPharmSci Series, Vol. 160, Tasks and Francis, 2006 NY
2. S Ahuna Modern Pharmaceutical Analysis
3. Lena Ohannesian and Anthony J Streeter, Hand Book of Pharmaceutical Analysis, Pharm Sci senes Vol 117, Maarcel Dekker Inc. NY
4. Peptide and Protein Drug Analysis, by Reid, (Marcel Dekker).
5. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIN)
6. Cosmetic and toilet goods-methods of sampling IS 3958 of Indian Standards Institution (BIS)
7. Methods of sampling and test for various cosmetics as laid down by Indian Standard Institution
   (BIS), New Delhi, Govt.
8. Indian Pharmacopocia, Vol. Land Vol. II- 1996. The Controller of Publicationsof India and
9. The International Pharmacopoeia Vol 1,2,3,4, 3rd Edition General methods of analysis 10. Quality quality specifications for pharmaceutical substances, excipients, dosage forms. materials Vol.1 and
10. Assurance of Pharmaceuticals A compendium of guidelines and related VOL.2, WHO, (1999)
11. Basic tests for pharmaceutical substances WHO (1988)
12. Basic tests for pharmaceutical dosage forms - WHO (1991)
13. Phytochemical Methods by J.B.Haroborne.

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Code: 24PY305

ADVANCED MEDICINAL CHEMISTRY

Unit-I:

Drug Design: Introduction, Development of new drugs, Concept of lead compounds and lead modifications, structure-activity relationship (SAR), factors affecting bioactivity and bio-isosterism. Theories of drug activity: occupancy theory, rate theory, induced fit theory.

Unit-II: Molecular Properties and QSAR: Physicochemical and biological factors that influence drug permeability by passive diffusion, lipophilicity of metabolites. Prediction and analysis of ADMET properties of new molecules and its importance in drug design. Deriving 2D-QSAR equations. 3D-QSAR approaches and contour map analysis. Statistical methods used in QSAR analysis and importance of statistical parameters.

Unit III: **Molecular Modeling and Docking:** Molecular and Quantum Mechanics in drug design. Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation. Molecular docking and drug receptor interactions. Structure and ligand-based drug design approaches.

Unit IV: Pharmacophore Mapping and Virtual Screening

Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modelling; Conformational search used in pharmacophore mapping. *In Silico* Drug Design and Virtual Screening Techniques. Similarity based methods and Pharmacophore based screening, structure based *In-silico* virtual screening protocols

Unit V: Green Chemistry:

Introduction, principles of green chemistry, Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis.

References Books:

1. Ariens, - Drug Design, vol. VII. Academic Press.
2. H Smith & HJ William Introduction to the Principal of Drug Design, John Wright & Sons Ltd.
3. Burgers Medicinal Chemistry - The Basis of Medicinal Chemistry by Manfred S. Wolff, Part - 1 John Wiley & Sons
4. Computer assisted Drug Design by Edward C. Olson (America Chemical Society, ACD symposium series 112).
5. W. O. Foye - Principles of Medicinal Chemistry. Lipincott Williams and Wilkins.
6. C. Hansch and Leo - Comprehensive Medicinal Chemistry Vol. 4. Pergamon Press.
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.

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Code: 24PY306

CLINICAL PHARMACY PRACTICE

Unit-I:

Concept and definition of Clinical Pharmacy, functions of Clinical Pharmacist, Medication history review, medication errors, essential drug concept, Rational drug use, irrational use of Antibiotics, injectables and NSAID'S. Patient Counselling, Medication Adherence, Drug Compliance and Drug Interactions.

Unit-II:

Concept of Pharmacoeconomics, Pharmacoepidemiology, Pharmacovigilance, Therapeutic Drug Monitoring, Medication use in Neonates, Pediatrics, Geriatrics, Pregnancy & lactation, and Total Parental Nutrition.

Unit-III:

01. Drug therapy in treatment of diseases like Tuberculosis, HIV, Malaria, Typhoid and Filaria.

02. Drug therapy in the treatment of Skin disorders like Eczema, Impetigo, Psoriasis, Seborrheic dermatitis, Acne vulgaris and Glaucoma (open angle and closed angle).

03. Drug therapy in the treatment of Thyroid and parathyroid disorders, Menstrual cycle disorders, Menopause, Erectile dysfunction, Osteoporosis and Diabetes mellitus.

Unit-IV:

01. Introduction to Pharmacovigilance. History of Pharmacovigilance in India, its importance, scope, outcomes and various methods in Pharmacovigilance.

02. Introduction to Adverse Drug Reactions, their classification, mechanism and susceptibility. Study of various adverse events reporting forms, quality assurance in Pharmacovigilance, Pharmacogenetics in Pharmacovigilance, Ethical consideration in Pharmacovigilance and various banned drugs.

Unit-V:

01. International Conference on Harmonization - Good Clinical Practice ICH-GCP Guidelines: Origin and Principles of 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.

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

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References books.

1. Clinical Pharmacy and Therapeutics: Roger Walker and Clive Edwords.
2. Clinical Pharmacy & Therapeutics, 4th edition by Eric T. Herfindal, Dick R. Gourley and Linda Lloyd hart.
3. A text book of Clinical Pharmacy Practice – Essential Concepts and skills by G. Parthasarathi, Karin Nyfort-Hansen, Malip C. Nahata.
4. Clinical Pharmacy by Dr. H. P. Tipnis, Dr. Amrita Bajaj; Career Publications. 5. Fundamentals of Clinical Pharmacy Practice by D. Sudheer Kumar, J. Krishnaveni, P. Manjula.
5. Goodman & Gilman's The Pharmacological basis of Therapeutics Ed. J.G.
6. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
7. International Conference on Harmonization of Technical requirements for registration of
8. Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good
9. Clinical Practice. E6; May 1996.230
10. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
11. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

BOS Chairman

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Ph.D. Course Work

Pre-Ph.D. Examination Syllabus

w.e.f: AY: 2016-17

DEPARTMENT OF PHARMACY,

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List of Pre-Ph.D Courses approved by

DEPARTMENT OF PHARMACY

S.NO	PAPER - 1	Code
01.	RESEARCH METHODOLOGY	**15 RM SCI 102**

S.NO	PAPER - 2	Code	PAPER - 3	Code
01.	MODERN ANALYTICAL TECHNIQUES (Common to all)	**16 PH 201**	ADVANCES IN PHARMACEUTICAL TECHNOLOGY	**16 PH 301**
02.			ADVANCED PHARMACOLOGY	**16 PH 302**
03.			ADVANCED PHARMACOGNOSY & PHYTOCHEMISTRY	**16 PH 303**
04.			ADVANCED PHARMACEUTICAL ANALYSIS	**16 PH 304**
05.			ADVANCED MEDICINAL CHEMISTRY	**16 PH 305**

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K L University
Pre-Ph.D. Examination

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:
Introduction to Statistical Modeling and Analysis, Concepts of Correlation and Regression, Fundamentals of Time Series Analysis and Spectral Analysis, Error Analysis, Applications of Spectral Analysis.

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:

1. Kothari, C.R; II ed. (2006), Research Methodology, Methods and techniques; New Age Internartional (p) Ltd., Publishers, New Delhi. : 2. Kumar K. L.' (1997), Educational Technology, New Age International (P) Ltd., New Delhi. References:
1. Donald R. Cooper,Pamela S. etc., Business Research Methods,8th Edition, Tata McGraw Hill Co.Ltd.2006 2. Tony Bates A.W. Technology, (2005), e-Learning and Distance Education, New York.

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Code:16 PH201

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

Unit-I:

1. UV-VISIBLE SPECTROSCOPY:

Brief review of electromagnetic spectrum and absorption of radiations. The chromophore concept, absorption law and limitations. Theory of electronic spectroscopy, absorption by organic molecules, choice of solvent and solvent effects. Applications of UV-Visible spectroscopy, Woodward – Fischer rules for calculating absorption maximum, interpretation of spectra, multi-component assay, difference spectra and derivative spectra.

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,

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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:

1. Spectrometric identification of Organic Compounds, Robert. M. Silverstein, Basseler, Morril (John Wiley and Sons. N.Y).
2. Spectroscopy of Organic Compounds by P. S. Kalsi.
3. Principles of Instrumental Analysis by Donglas A. Skoog, James, J. Leary, 4th Edition.
4. Pharmaceutical Analysis – Modern Methods – Part A, Part B, James W. Munson 2001.
5. Organic Spectroscopy – William Kemp, 3rd Edition.
6. Chromatographic Analysis of Pharmaceuticals, John A. Adamovics, 2nd Edition.
7. Practical Pharmaceutical Chemistry, Part two, A. H. Beckett & J. B. Stenlake – 4th dition. 8. Instrumental Methods of Analysis – Willard, Merritt, Dean, CBS, Delhi.
9. Techniques and Practice of Chromatography – Raymond P. W. Scott, Vol. 70.
10. Identification of Drugs and Pharmaceutical Formulations by Thin Layer Chromatography – P. D. Sethi, Dilip Charegaonkar, 2nd Edition.
11. HPTLC – Quantitative Analysis of Pharmaceutical Formulations – P. D. Sethi.
12. Liquid Chromatography – Mass Spectrometry, W. M. A. Niessen, J. Van Der Greef, Vol. 58.
13. Modern Methods of Pharmaceutical Analysis, Vol.1, 2, RE Schirmer,Franklin Book

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Code:16 PH 301

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:
1. Novel Drug Delivery System by Yie W. Chien.
2. Controlled Drug Deliver by Joseph R. Robinson and Vincent H. L. Lee.
3. Controlled and Novel drug delivery systems by N. K. Jain.
4. Targeted and Controlled Drug Delivery (Novel carrier systems) by S. P. Vyas and Khar.
5. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
6. Controlled Drug Deliver by N.K Jain.

Code:16 PH 302

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, phosphodiestrase 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 II/IIIa receptor antagonists
(vi) Imidazole receptors
(vii)Cholinergic receptors
(viii)Dopamine receptors
(ix)Serotonin receptors
(x) Hormone receptors
(xi) GABA and Benzodiazepine receptors
(xii)Opiod receptors
(xiii)Purinergic receptors
(xiv)Glutamate receptors

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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.

b)Immunopharmacology: antibody dependent and cellular cytotoxicity. Monoclonal antibodies and its importance.

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

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Code:16 PH 303

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
9. Atal & Kappor- Cultivation and utilization of medicinal plants.
10. Purthi JS- Major spices of India.
11. Pharmacognosy and Pharmacobiotechnology. Robbers JE, Speedie MK, Tyler VE. William and Wilkins, USA; 1996.
12. Medicinal Natural Products a biosynthetic Approach. Dewick PM. John Wiley and Sons, Torronto, 1998.
13. Chemistry of Natural products. Bhat SV, Nagasampagi BA, Meenakshi S. Narosa Publishing house, New Delhi, 2005.

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Code:16 PH 304

ADVANCED PHARMACEUTICAL ANALYSIS

Unit-I:

01. Application of analytical methods to product obtained through genetic engineering , Amino acid sequence analysis, Tryptic maping, 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:

01. Analysis of solid oral dosage form, Analysis of injectable dosage form , Compendial testing, Automated analysis. Compendial methods for evaluation of crude drug and herbal formulation.
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:
a. Sulphonamides. b. Barbiturates - i.e., Barbituric acid derivatives and Xanthine derivatives. c. Steroids such as Adrenocortical steroids, Progesterone, Androgens and Cholesterol. d. Vitamins like Vitamin A, Bl, B2, B12, C & E. e. Antibiotics like Chloramphenicol, Erythromycin, Penicillin & Streptomycin. f. Alkaloids of Cinchona, Ergot, Opium & Rauwolfia. g. Glycosides such as Digitoxin, Digoxin & Strophanthin.

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 chlorimide. 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-dinitrophyenylhydrazine.

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References Books:

1. Harry G Brittain, Spectroscopy of Pharmaceutical Solids, Drugs andPharmSci.Series,Vol. 160, Taylor and Francis, 2006 N.Y.
2. S. Ahuja, Modern Pharmaceutical Analysis
3. Lena Ohannesian and Anthony J. Streeter, Hand Book of Pharmaceutical Analysis, Pharm Sci. series, Vol. 117, Maarcel Dekker Inc., N.Y
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).
6. Cosmetic and toilet goods – methods of sampling 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,
9. The International Pharmacopoeia Vol 1,2,3,4, 3rd Edition General methods of analysis and quality specifications for pharmaceutical substances, excipients, dosage forms. 10. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials Vol.1 and Vol.2, WHO, (1999)
11. Basic tests for pharmaceutical substances – WHO (1988)
12. Basic tests for pharmaceutical dosage forms – WHO (1991)
13. Phytochemical Methods by J.B.Haroborne.

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Code:16 PH 305

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; Multi-component 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 bio-isosterism as guides to structural variations and Prodrug design its application in lead optimization.

Unit-IV:

01.Quantitative Structure Activity Relationship QSAR- brief introduction to various methods of QSAR – Physicochemical parameters – lipophilic, electronic and steric. Detail study on Hansch LFER model, Free Wilson analysis and mixed approach. Various basic statistical methods useful in QSAR development. a. 3D QSAR – importance and various models (COMFA, MSA, HASL, Apex 3D, DISCO, GFA) used for it.

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:

1. Ariens – Drug Design, vol. VII, Academic Press.
2. H Smith & H J William – Introduction to the Principal of Drug Design, John Wright & Sons Ltd.
3. Burgers Medicinal Chemistry – The Basis of Medicinal Chemistry by Manfred S. Wolff, Part – I , John Wiley & Sons
4. Copmuter assisted Drug Design by Edward C. Olson (America Chemical Society, ACD symposium series 112).
5. W. O. Foye - Principles of Medicinal Chemistry, Lipincott Williams and Wilkins.
6. C. Hansch and Leo - Comprehensive Medicinal Chemistry Vol. 4, Pergamon Press.
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.

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