Syllabus for Pre-Ph. D Course Work (2025-26 Admitted Batch)

Course code	Branch	Name of the Course	Credits
RS8003	Common for all Students	Research Methodology	4
RS8005		Research and Publication Ethics	2

Course code	Name of the Course	Credits
PH60001	Advanced Techniques for Drug Analysis	4
PH60101	Pharmaceutical Technology & Novel Formulations	4
PH60201	Advanced Prospective of Medicinal Chemistry	4
PH60301	Current Trends in Pharmacology	4
PH60401	Current Trends in Pharmacognosy	4

Assessment:
Seminar - 30 Marks
Mid Semester Examination- 20 Marks
End Semester Examination- 50 Marks

N.B: The course code PH60001 is mandatory for all M. Pharm specialization.
A scholar of any specialization can select any one of the subjects having course code namely PH60101, PH60201, PH60301 & PH60401.

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Advanced Techniques for Drug Analysis

Course Code- PH60001
Credits: 4
Objectives:

This subject is designed to impart knowledge about recent development on the various instrument and analytical techniques that can be applied for the analysis of drug molecules in the marketed formulations as well as to understand the degradation pathways or study of impurities.

Course Outcomes: After completion of course, the students are able to:

1. Understand the instruments and their purpose during analysis of drug molecules.
2. Apply analytical techniques for the quantification of drug molecules in the marketed formulations.
3. Explain structural elucidation of the isolated compounds, using different instrumental methods.
4. Apply and interpret theoretical principle, instrumentation and applications of liquid chromatographic techniques.
5. Understand instrumentation and applications of NMR-Spectroscopy.
6. Understand instrumentation and applications of Mass Spectrometry.

Unit-I

Absorption and emission spectroscopic techniques

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

Atomic absorption spectroscopy: Principle, instrumentation, interferences and applications. Inductively coupled plasma atomic emissions spectroscopy (ICPAES): Principle, instrumentation, interferences and applications.

Unit-II

Principles and Applications of NMR-Spectroscopy

Fundamentals of NMR spectroscopy; Working principle; Instrumentation; Solvent requirement in NMR; Relaxation process; NMR signals in various compounds; Chemical shift, Factors influencing chemical shift; Spin-spin coupling; Coupling -NMR. 13C NMR: Chemical environment, shielding and 13C chemical shift, calculation; Nuclear Overhauser Enhancement (NOE).

Distortionless Enhancement by Polarisation Transfer (DEPT): Introduction of DEPT Spectroscopy, Types of DEPT NMR, Examples and applications.

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Unit-III

Liquid Chromatography in Pharmaceutical Analysis

HPLC method development for biomolecules; Assay and stability testing by HPLC, application of HPLC for cleaning validation, HPLC in dissolution testing, HPLC in chiral analysis of Pharmaceuticals; New developments in HPLC role of Ultra, Nano liquid chromatography in Pharmaceutical Analysis. Development and troubleshooting of HPLC methods: HPLC column selection and mobile phases, mobile phase additives; HPLC method development by using different stationary phases, mechanism of interactions, Analytical method validation in accordance with ICH guidelines.

Unit-IV

Mass Spectrometry in Pharmaceutical Analysis

Importance of chromatographic separation, mass analysers, atmospheric pressure ionization techniques: ESI, APPI, APCI; Interpretation of API mass spectra: Molecular weight determination, typical fragmentation behaviour for individual functional groups: (i) phosphorous (ii) sulphur (iii) nitrogen (iv) oxygen (v) halogen substitute's (vi) alkyl and aryl substitution on the aromatic ring, polycyclic aromatic hydrocarbons, alkenes and alkynes. Liquid chromatography-electro spray ionization-mass spectrometry (LC-ESI-MS) to the detection and characterisation of small molecules; Development, Validation as per USFDA and transfer for high throughput bioanalytical LC-MS/MS Methods.

Unit-V

Analytical Chemometrics

General introduction and its application in optimization, Modelling and parameter estimation, sampling; Calibration, Resolution, Factor analysis, signal processing, structure-property relationship, pattern recognition; Propagation of measurement uncertainties (Inaccuracy and imprecision); Multivariate Calibration, Multivariate Curve Resolution, Chemo informatics, Library Searching, Data Preprocessing and Feature Selection, Image Analysis, Microarrays.

References:

1. Grinberg N, Carr PW, editors. Advances in Chromatography. Vol. 57. Boca Raton (FL): CRC Press; 2020.
2. Snyder LR, Kirkland JJ, Dolan JW. Introduction to Modern Liquid Chromatography. 3rd ed. Hoboken (NJ): John Wiley & Sons; 2011.
3. Snyder LR, Kirkland JJ, Glajch JL. Practical HPLC Method Development. 2nd ed. Hoboken

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4. Aboul-Enein HY. Chiral Separations by Liquid Chromatography and Related Technologies. Boca Raton (FL): CRC Press.
5. Gross JH. Mass Spectrometry: A Textbook. 3rd ed. Berlin/Heidelberg: Springer; 2017. DOI: 10.1007/978-3-319-54399-4.
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7. Miller JN, Miller JC, Miller RD. Statistics and Chemometrics for Analytical Chemistry. 7th ed. Harlow (UK): Pearson; 2018.
8. Komsta L, Vander Heyden Y, Sherma J. Chemometrics in Chromatography. 1st ed. Boca Raton (FL): CRC Press; 2009.
9. Pavia DL, Lampman GM, Kriz GS, Vyvyan JA. Introduction to Spectroscopy. 4th ed. Boston (MA): Cengage Learning; 2014.
10. Silverstein RM, Webster FX, Kiemle DJ. Spectrometric Identification of Organic Compounds. 6th ed. Hoboken (NJ): John Wiley & Sons; 2004.

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Pharmaceutical Technology & Novel Formulations

Course Code- PH60101
Credits: 4
Objectives:

Course is designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries, skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving.

Course Outcomes:

Upon completion of this course, it is expected that students will be able to

1. Understand Pharmaceutical excipients used in various dosage forms, elements of pre formulation studies.
2. Apply various Optimization techniques and Drug Stability testing, drug solubility, dissolution, and Bioavailability enhancement for poorly water soluble drugs.
3. Explain applicative approach of biopharmaceutics and pharmacokinetics in dosage form design.
4. Understand the basic concepts of sustained and controlled release drug delivery systems.
5. Apply various approaches for development of novel drug delivery systems through different routes oral, parenteral, transdermal, ocular, implantable drug delivery system.
6. Understand gene delivery and vaccine delivery, CADD, advanced cosmeticology, Tissue culture.

Unit – I

Advanced Pharmaceutical Formulations Excipients and Drug stability studies:

Advanced Excipient for Pharmaceutical Formulations:

Pharmaceutical excipients and important polymers in various dosage forms –Solid, liquid, semi-solid and gaseous dosage forms. Co-processed and advanced excipients for parenteral, lipid excipients.

Pre-formulation studies:

Protocols – Physical, chemical, Micromeritic studies and stability considerations in pre – formulation, Drug-Excipient compatibility studies (FTIR, DSC, DTA, XRD, SEM, TEM, TLC, HPTLC, HPLC).

Drug stability studies:

Stability calculations, rate equation, complex order kinetics, kinetics of some decompositions, strategy of stability testing, Freeze Thaw, centrifugal methods, temperature and humidity control. ICH guidelines.

Solubility, Dissolution & Pre-formulation studies:

Solubility, dissolution, and Bioavailability enhancement approach for poorly soluble drugs. Dissolution mechanisms, kinetic models for drug release - zero order, first order, Hixson Crowell's,

Higuchi, Peppas, dissolution profiles comparison- difference factor (f1), similarity factor (f2).

Unit – II

Advanced Drug delivery system

Mucoadhesive (buccal, nasal, pulmonary) drug delivery system, Gastro-retentive, Parenteral Pulsatile, colon specific, Transdermal Drug Delivery System, Ocular, Pulmonary drug delivery system. pH, Enzyme, and Osmotic activated Drug Delivery Systems, and Chronopharmacotherapeutics.

Unit – III

Targeted, Nanocarriesr, Dispersed Drug delivery system

Microcapsules, Microsphere, Microemulsion, drug targeted to brain, lungs, liver, Tumor, and Stem cells. Nanoparticles, Liposomes, Niosomes, Proniosomes, Aquasomes, Phytosomes, Dendrimers, Ethosomes, Transethosomes, Transferosomes, Electrosomes, Pharmacosomes, Resealed erythrocytes, Nanoemulsion, Nanosuspension, Exosome, SMEDDS, and SNEDDS. Macromolecular Drug Delivery – Proteins and peptides drug delivery system, and Customized drug delivery systems.

Unit – IV

Pharmacokinetics and Computer Aided Drug Development

Pharmacokinetics:

Application compartment models to determine the various pharmacokinetic parameters pertaining to Absorption, Distribution, and Elimination, under the conditions of Intravenous bolus injection, Intravenous infusion, Single dose oral administration, Multiple dose injections, and Multiple dosage oral administration Noninvasive methods of estimating pharmacokinetics parameters with emphasis on Blood, salivary, and urinary compartments. Non-Linear Pharmacokinetics.

Computer Aided Drug Development:

Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design, Statistical design, response surface method, contour designs, factorial designs and application in formulation. Computer-aided biopharmaceutical characterization, Computer Simulations in Pharmacokinetics and Pharmacodynamics, Computers in Clinical Development, Artificial Intelligence (AI), Robotics and Computational fluid dynamics.

Unit -V

Macromolecular Drug Delivery with Pharmaceutical Biotechnology approach & Cosmeticology:

Macromolecular Drug Delivery with Pharmaceutical Biotechnology approach:

Recombinant DNA technology, Monoclonal Antibodies, Proteins and peptides drug delivery system Vaccines (immunotherapy) Therapy, Gene therapy, Gene expression system, Knowledge of therapeutic antisense molecules and aptamers as drugs of future. Animal Tissue culture.

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Cosmeticology:

Design of advanced cosmetic formulations, Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor, dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations. Herbal Cosmetic formulations.

References:

1. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy. 3rd ed. Philadelphia: Lippincott Williams & Wilkins; 1986. 902 p.
2. Lieberman HA, Lachman L, Schwartz JB, editors. Pharmaceutical Dosage Forms- Tablets. 2nd rev. & expanded ed. Vols 1-3. New York: Marcel Dekker; 1980–1990. Vol.1: 1436 p.
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8. Aulton ME. Pharmaceutics: The Science of Dosage Form Design. 2nd ed. Edinburgh: Churchill Livingstone; 2002.
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14. Carstensen JT, Rhodes CT, editors. Drug Stability: Principles and Practices. 3rd ed. New York: Marcel Dekker; 2000.

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18. Shargel L, Yu AC. Applied Biopharmaceutics & Pharmacokinetics. 7th/8th eds. New York: McGraw-Hill; latest ed. 2016–2022.

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Current Trends in Pharmacology

Course Code- PH60301
Credits: 4
Objectives: The subject is designed to impart knowledge about recent advances in the field of pharmacology including preclinical studies, molecular biology techniques, genomics, proteomics, and regulatory toxicological studies

Course Outcomes: After completion of course, the students are able to

1. Understand structural influences of compounds on the mechanism of pharmacologic action.
2. Explain guidelines and procedures for laboratory animal maintenance, handling & alternate models
3. Apply Molecular biology techniques in drug development.
4. Understand importance of genomics and proteomics in drug discovery.
5. Apply the principles of regulatory toxicology in toxicity study of drug molecules.
6. Understand three-dimensional cell-culture models.

Unit –I

General principles of in-vitro preclinical screening; Extrapolation of preclinical data to predict clinical implications and its limitations. Cell culture techniques: Basic equipment used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures, isolation of cells, subculture, cryopreservation, characterization of cells, and their applications, implications of cell-based assay in preclinical screening.

Unit- II

General principles of in-vivo preclinical screening, Common laboratory animals, CCSEA guidelines to conduct experiments on animals, good laboratory practice: issues and implementation, transgenic animals, xenograft study, Zebrafish model. Animal model used to study different models of disease, maping the pathways from genes to disease pathology, Limitations of animal experimentation and alternates to animal experiments, Three-dimensional cell-culture models including organoids and spheroids etc.

Unit-III

Principles and applications of molecular biology techniques: DNA electrophoresis, PCR (reverse transcription and real time), Recombinant DNA technology, Gene cloning, Gene sequencing, micro array technique, SDS page, ELISA and western blotting

Unit- IV

Genomics in drug discovery: Gene expression and its regulation, gene silencing methods (gene knockdown, and gene knockout), gene over expression, and gene mapping, gene therapy. Role of epigenetic modifications in cancer, neurodegenerative diseases, and Diabetes etc. Proteomics in Drug Discovery: Two-dimension gel electrophoresis; In-gel digestion etc. Microarray technology (principle and application), Protein arrays.

Unit- V

General principles of regulatory toxicology. Use of animals in preclinical toxicology studies and the role of preclinical toxicology in drug discovery and development. Experimental considerations for assessing possible human risk. Flow chart for development of preclinical testing. Dose conversion factors, clinical signs toxicity. Acute and chronic toxicity, genetic toxicity: Single dose and repeat dose toxicity studies; Factors influencing toxicity studies. Determination of Maximum Tolerated Dose (MTD) and LD50 as per revised OECD guidelines. Genotoxicity testing, Allergenicity testing, dermal toxicity and *in vitro* methods of toxicology.

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3. Masters JRW, editor. Animal Cell Culture: A Practical Approach. 3rd ed. Oxford: Oxford University Press; 2000. doi:10.1093/oso/9780199637973.001.0001.
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