COURSES OF STUDY

M.S.(Pharm.); M.Pharm.; M.Tech.; Ph.D.

2026 - 27

राष्ट्रीय औषधीय शिक्षा एवं अनुसंधान संस्थान (नाईपर)

हाजीपुर

NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION & RESEARCH (NIPER)

HAJIPUR

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POSTGRADUATE - COURSE STRUCTURE

(M.S.(Pharm.); M.Pharm.; M.Tech.)

POSTGRADUATE - COURSE STRUCTURE

(M.S. Pharm./M.Pharm./M.Tech.)

Abbreviations:

IO: Industry-oriented

LPS: Laboratory Practical Session

OE: Open Elective

PC: Programme Core

PE: Programme Elective

PW: Project work

SD: Skill Development

SL: Self Learning

T: Theory

TS: Technical Seminar

Name of Departments:

BT: Biotechnology

PA: Pharmaceutical Analysis

RS: Pharmaceutical Regulatory Sciences

PE: Pharmaceutics

PP: Pharmacy Practice

PT: Pharmacology and Toxicology

POSTGRADUATE - COMMON COURSE STRUCTURE

SEMESTER – I

S. No	Course Code	Course Title	Type	Hrs per week	Credits	Category
1	**BT/ PA/ RS/ PE/ PP/ PT - 511**	Core course – 1	T	2	2	PC
2	**BT/ PA/ RS/ PE/ PP/ PT - 512**	Core course – 2	T	2	2	PC
3	**BT/ PA/ RS/ PE/ PP/ PT - 513**	Core course – 3	T	2	2	PC
4	**BT/ PA/ RS/ PE/ PP/ PT - 514**	Core course – 4	T	2	2	PC
5	**BT/ PA/ RS/ PE/ PP/ PT - 515**	Core course – 5	T	2	2	PC
6	**GE-516**	Biostatistics and Data Analytics	T	2	2	SD
7	**GE-517**	Artificial Intelligence and Machine Learning in Pharmaceuticals	T	1	1	IO
8	**SM-518**	Seminar	TS	1	1	SL

9	**GL-519**	General Lab Experience	LPS	18-24	6	PC
		Total	**--**	**32-38**	**20**	**--**

SEMESTER – II

S. No	Course Code	Course Title	Type	Hrs per week	Credits	Category
1	**BT/ PA/ RS/ PE/ PP/ PT-521**	Core course – 1	T	2	2	PC
2	**BT/ PA/ RS/ PE/ PP/ PT - 522**	Core course – 2	T	2	2	PC
3	**BT/ PA/ RS/ PE/ PP/ PT - 523**	Core course – 3	T	2	2	PC
4	**BT/ PA/ RS/ PE/ PP/ PT - 524**	Core course – 4	T	2	2	PC
5	**EL -525**	Programme Elective *	T	2	2	PE
6	**GE-526**	Intellectual Property Rights and Regulatory Affairs in Pharmaceuticals	T	2	2	SD
7	**GE-527**	Research Culture and Ethics in the Pharmaceutical Industry	T	2	2	IO
8	**SM-528**	Seminar	TS	1	1	SL
9	**GL-529**	General Lab Experience in the Area of Specialization	LPS	18-24	6	PC
		Total	**--**	**33-39**	**21**	**--**

*** EL-525 (Programme Elective):** The scholar should select any one course from the list of courses offered by other departments.

<u>List of Department-wise Programme Electives (EL- 525) – 2 Credits:</u>

(Scholars must select any one elective course from any department other than their own department)

Name of Department	Course title	Credits/ Course
BT	BT-525 (A): Nanobiotechnology BT-525 (B): Omics in Drug Discovery	2
PA	PA-525 (A): Analytical characterization of Biosimillars	2

	PA-525 (B): Mass spectrometry in Omics	
RS	RS-522: Skills in Documentation and Regulatory Writing RS-523: Regulation of Cosmetic and Herbal products	2
PE	PE-521: Pharmaceutical Product Development II PE-522: Biopharmaceutics and Pharmacokinetics	2
PP	PP-522: Patient Safety and Health Related Outcomes PP-523: Clinical Research PP-524: Evidence-Based Medicine	2
PT	PC-525 (A): Principles and Methods in Toxicology PC-525 (B): Introduction to Regulatory Toxicology	2

SEMESTER - III

S. No	Course Code	Course Title	Type	Hrs per week	Credits	Category
1	**TH-611**	Synopsis	PW	28	15	PC
2	**TH-612**	Presentation	PW	--	3	PC
3	**EL-613**	Self-learning Courses *	IO	4	2	OE
____	_____	**Total**	**--**	**32**	**20**	**--**

*** EL-613:** Industry/academic-oriented skill courses must be chosen by students. Individual departments must set the SOP for the same.

SEMESTER - IV

S. No	Course Code	Course Title	Type	Hrs per week	Credits	Category
1	**TH-621**	Thesis	PW	30	15	PC
2	**TH-622**	Defence of Thesis	PW	--	5	PC
Total			**--**	**30**	**20**	**--**
Grand Total (I to IV Semesters)					**81**	_____

Semester - I

GE-516: Biostatistics and Data Analytics (2 credits)

1: Introduction to Statistics and Data Handling

Introduction, role, and applications of statistics in pharmaceutical and biomedical research. Data collection, organization, graphical and pictorial representation. Measures of central tendency and dispersion, coefficient of variation, skewness, and kurtosis. Data normalization and introduction to data analytics in health research. Overview of statistical software tools (e.g., JMP/SAS) for data visualization.

2: Probability and Distributions

Basic concepts of probability, common probability distributions, and normal distribution. Introduction to Bayesian analysis and its applications in healthcare.

3: Sampling and Study Design

Sampling techniques including simple random and other sampling methods. Distribution of sample mean and proportion. Overview of study designs (observational and experimental), sampling bias, and principles of data entry, cleaning, and validation.

4: Estimation and Hypothesis Testing

Point and interval estimation, confidence intervals, and fiducial limits. Concepts of hypothesis testing, types of errors, and statistical significance. Parametric tests including Student's t-test and Chi-square test. Measures of association including risk ratio, odds ratio, and Mantel–Haenszel methods. Sample size determination and power analysis.

5: Experimental Design and ANOVA

Principles of experimental design including completely randomized, randomized block, Latin square, and factorial designs. Analysis of variance (ANOVA), post-hoc tests, and repeated measures design.

6: Correlation and Regression Analysis

Graphical representation of relationships between variables. Pearson correlation and its significance. Linear regression, coefficient of determination, and hypothesis testing for regression parameters. Introduction to multiple regression, logistic regression (logit), probit models, and dummy variables.

7: Non-Parametric Tests

Non-parametric statistical tests including Sign test, Mann–Whitney U test, Wilcoxon matched-pair test, Kruskal–Wallis test, Friedman test, Spearman rank correlation, Fisher's exact test, and Cochran's Q-test.

8: Advanced Data Analytics Techniques

Introduction to multivariate analysis techniques including clustering, principal component analysis (PCA), and decision trees. Model selection and validation methods such as cross-validation and ROC curves.

9: Survival Analysis

Concept of time-to-event data. Kaplan–Meier survival curves and Cox proportional hazards model. Interpretation and applications in clinical research.

10: Health Analytics and Real-World Data

Introduction to health analytics including disease trends and outbreak analysis. Time-series analysis, spatial statistics, and predictive modeling in healthcare. Application of analytics using real-world datasets and case studies.

Recommended Books

1. Fundamentals of Biostatistics – Bernard Rosner
2. Pharmaceutical Statistics: Practical and Clinical Applications – Bolton & Bon
3. Statistical Misconceptions – Huck
4. Biostatistics: A Foundation for Analysis in the Health Sciences – Daniel & Cross
5. Practical Statistics for Medical Research – Altman
6. An Introduction to Statistical Learning – James et al.
7. JMP Start Statistics – John Sall et al.
8. Relevant research & review articles from recent medical and pharmaceutical literature

GE-517: Artificial Intelligence and Machine Learning in Pharmaceuticals (1 credit)

1: Introduction to AI, Machine Learning, and Deep Learning

History and evolution of AI. Definitions and basic concepts of artificial intelligence, machine learning, and deep learning. General applications, challenges, and scope of AI/ML in pharmaceutical sciences and healthcare.

2: AI/ML Algorithms and Data Concepts

Overview of pattern recognition, data attributes, and feature selection. Types of machine learning (supervised, unsupervised, reinforcement learning). Basic learning algorithms, model concepts, limitations of ML, and introduction to open-source tools and platforms.

3: Data Handling and Datasets in Pharmaceuticals

Data curation, preprocessing, and normalization. Types of datasets used in pharmaceutical research including therapeutic, clinical, and omics datasets. Role of AI in digital transformation of healthcare data.

4: Supervised and Unsupervised Learning Techniques

Regression and classification methods in supervised learning. Clustering and dimensionality reduction in unsupervised learning. Data splitting (training/testing), overview of model development and basic evaluation metrics, and performance assessment.

5: Deep Learning and Neural Networks

Introduction to deep learning and its distinction from machine learning. Structure and working of neural networks including artificial neural networks (ANN), convolutional neural networks (CNN), and graph neural networks (GNN). Applications, advantages, and limitations.

6: AI in Drug Discovery and Molecular Modeling

AI/ML approaches in ligand-based and structure-based drug design including virtual screening, de novo drug design, molecular property prediction, and synthetic feasibility. Protein structure prediction (e.g., AlphaFold), binding site identification, and molecular docking.

7: Drug Repurposing and Network Pharmacology

Application of AI/ML in drug repurposing, drug–disease network analysis, LINCS database, target prediction models, and transfer learning approaches with relevant case studies.

8: Biomarker Discovery and Omics Data Analysis

Types of biomarkers and their identification. Role of AI/ML in biomarker discovery including genomic and proteomic data analysis.

9: ADME and Toxicity Prediction

Use of AI/ML models in prediction of ADME properties and drug toxicity. QSAR approaches and predictive modeling with case studies.

10: AI in Clinical Research and Formulation Development

Applications of AI in clinical trials including patient recruitment, virtual trials, and remote monitoring. Role of AI in formulation optimization, including solid dosage forms, modified-release systems, lipid nanoparticles, and prediction of drug–excipient interactions.

Recommended Books

1. Pattern Recognition and Machine Learning – Christopher M. Bishop
2. Machine Learning: A Probabilistic Perspective – Kevin P. Murphy
3. Feature Engineering for Machine Learning – Alice Zheng & Amanda Casari
4. Artificial Intelligence in Drug Discovery – Nathan Brown
5. Relevant research & review articles from recent pharmaceutical and biomedical literature

Semester - II

GE-526: Intellectual Property Rights and Regulatory Affairs in Pharmaceuticals (2 credits)

1. **Introduction to Regulatory Affairs:** Overview of drug development process; Regulatory requirements for biopharmaceutical products; Role of regulatory agencies in the approval process; Clinical trials: phases and regulations in US, India, and Europe; Investigational New Drug (IND) application: filing procedures and requirements; New Drug Application (NDA) and Abbreviated New Drug Application (ANDA): filing procedures and requirements.
2. **Global Regulatory Harmonization:** The impact of global regulatory harmonization on the biopharmaceutical industry; Differences in regulatory requirements across regions; Interaction between Indian and foreign laws during implementation. Global initiatives intended to drive harmonization and development, such as Asian-Pacific Economic Cooperation (APEC), International Council for Harmonization (ICH), The International Pharmaceutical Regulators Programme (IPRP), Pan American Network for Drug Regulatory Harmonization (PANDRH)
3. **Intellectual Property Rights (IPRs):** Concepts and fundamentals; Economic importance, mechanisms for protection of intellectual property patents, copyrights, trademark; Factors affecting choice of IP protection; Role of IP in pharmaceutical industry; Global ramifications and financial implications.
4. **Trade-Related Aspects of Intellectual Property Rights:** Intellectual property and international trade; Concept behind WTO (World Trade Organisation), WIPO (World Intellectual Property Organisation), TRIPs (Trade Related Intellectual Property Rights); Protection of plant and animal genetic resources; Biological materials; Gene patenting; Biotechnology; IPR issues; Status in India and other developing countries.
5. **Patenting, Copyright, and Trademark Protection:** Criteria for patentability, types of patents; Indian Patent Act, 1970; WTO and modifications under TRIPS; Filing of a patent application; Precautions before patenting disclosures/non-disclosures, publication-article/thesis.
6. **Ethical and Legal Issues:** Ethical considerations in drug regulatory affairs and intellectual property rights; Legal issues related to regulatory affairs and intellectual property rights.
7. **Future Trends:** Emerging trends in drug regulatory affairs and intellectual property rights.

Suggested reading:

1. New Drug Approval Process, edited by Richard A. Guarino.
2. The Pharmaceutical Regulatory Process, edited by Ira R. Berry.
3. Law Relating to Intellectual Property by B.L. Wadhera.
4. The Patents Act, 1970 (Bare Act with Short Notes) (New Delhi: Universal Law Publishing Company Pvt. Ltd. 2012).
5. Patent Agent Examination by Sheetal Chopra and Akash Taneja.
6. Biomedical Research- From Ideation to Publication by G. Jagadeesh and others.

GE-527: Research Culture and Ethics in the Pharmaceutical Industry (2 credits)

Unit 1: Pharmaceutical Research: Ethics and Economics (3 Hours)

Drug research at the interface of ethical obligations and economic constraints; sustainability in the 21st-century pharmaceutical industry; research pipelines and market dynamics.

Unit 2: Ethical Frameworks in Clinical Research (4 Hours)

Principles and applications of Good Clinical Practice (GCP); International Council for Harmonisation (ICH) guidelines; World Medical Association Declaration of Helsinki; Nuremberg Code; Belmont Report; and the Bolar provision.

Unit 3: Ethics in Special Populations and Drug Promotion (3 Hours)

Regulatory and ethical challenges in paediatric prescriptions; ethical issues in drug promotion and prescription practices.

Unit 4: Off-Label Drug Use: Ethical and Regulatory Perspectives (3 Hours)

Off-label indications; regulatory considerations; patient and physician perspectives on off-label drug use.

Unit 5: Pharmacoeconomics and Ethics (3 Hours)

Economic evaluation of drugs and therapies; ethical considerations in cost-effectiveness, accessibility, and healthcare decision-making.

Unit 6: Intellectual Property Rights and Drug Pricing (4 Hours)

Role of IPR in fostering innovation and research culture; return on investment; role of National Pharmaceutical Pricing Authority; Drug Price Control Order (DPCO).

Unit 7: Regulatory Frameworks and Policies in Drug Development (4 Hours)

Hatch-Waxman Act; Drug Price Competition and Patent Term Restoration Act (DPC & PTRA); research in neglected and orphan diseases; Uniform Code for Pharmaceutical Marketing Practices (UCPMP).

Unit 8: Research Misconduct and Compliance (3 Hours)

Fraudulent research practices; Current Good Manufacturing Practices (cGMP) violations; market compliance; refusal of voluntary drug recall; drug recall systems and rapid alert mechanisms.

Unit 9: R&D Management and Governance (4 Hours)

Research and development policies; leadership roles; organisational structures in pharmaceutical research and industry.

Recommended Books:

1. Santoro, M. A., & Gorrie, T. M. (2005). Ethics and the pharmaceutical industry. Cambridge University Press.
2. Henderson, R., & Cockburn, I. (1994). Scale, scope and spillovers: the determinants of research productivity in ethical drug discovery.
3. Uniform Code for Pharmaceutical Marketing Practices (UCPMP)

DEPARTMENT OF BIOTECHNOLOGY

SEMESTER - I

S. No	Course Code	Course Title	Type	Hrs per week	Credits	Category
1	**BT-511**	Biochemistry	T	2	2	PC
2	**BT-512**	Fundamentals of Cell Biology and Microbiology	T	2	2	PC
3	**BT-513**	Biochemical and Bioprocess Engineering	T	2	2	PC
4	**BT-514**	Bioinformatics	T	2	2	PC
5	**BT-515**	Analytical Techniques in Biotechnology and Biopharmaceuticals	T	2	2	PC
6	**GE-516**	Biostatistics and Data Analytics	T	2	2	SD
7	**GE-517**	Artificial Intelligence and Machine Learning in Pharmaceuticals	T	1	1	IO
8	**SM-518**	Seminar	TS	1	1	SL
9	**GL-519**	General Lab Experience	LPS	18-24	6	PC
		Total	**--**	**32-38**	**20**	**--**

SEMESTER – II

S. No	Course Code	Course Title	Type	Hrs per week	Credits	Category
1	**BT-521**	Molecular Biology and Genetic Engineering	T	2	2	PC
2	**BT-522**	Gene and Cell Therapy	T	2	2	PC
3	**BT-523**	Analysis, Diagnostics and Cell Based Screening	T	2	2	PC
4	**BT-524**	Immunology and Immunotechnology	T	2	2	PC
5	**EL -525**	Programme Elective *	T	2	2	PE
6	**GE-526**	Intellectual Property Rights and Regulatory Affairs in Pharmaceuticals	T	2	2	SD

7	**GE-527**	Research Culture and Ethics in the Pharmaceutical Industry	T	2	2	IO
8	**SM-528**	Seminar	TS	1	1	SL
9	**GL-529**	General Lab Experience in the Area of Specialization	LPS	18-24	6	PC
		Total	**--**	**33-39**	**21**	**--**

*** EL-525 (Programme Elective):** The scholar should select any one course from the list of courses offered by other departments.

List of Department-wise Programme Electives (EL- 525) – 2 Credits:

(Scholars must select any one elective course from any department other than their own department)

Name of Department	**Course title**	**Credits/ Course**
BT	BT-525 (A): Nanobiotechnology BT-525 (B): Omics in Drug Discovery	2
PA	PA-525 (A): Analytical characterization of Biosimillars PA-525 (B): Mass spectrometry in Omics	2
PE	PE-521: Pharmaceutical Product Development II PE-522: Biopharmaceutics and Pharmacokinetics	2
PP	PP-522: Patient Safety and Health Related Outcomes PP-523: Clinical Research PP-524: Evidence-Based Medicine	2
PT	PC-525 (A): Principles and Methods in Toxicology PC-525 (B): Introduction to Regulatory Toxicology	2

SEMESTER - III

S. No	**Course Code**	**Course Title**	**Type**	**Hrs per week**	**Credits**	**Category**
1	**TH-611**	Synopsis	PW	28	15	PC
2	**TH-612**	Presentation	PW	--	3	PC
3	**EL-613**	Self-learning Courses *	IO	4	2	OE
____	_____	**Total**	**--**	**32**	**20**	**--**

*** EL-613:** Industry/academic-oriented skill courses must be chosen by students. Individual departments must set the SOP for the same.

SEMESTER - IV

S. No	Course Code	Course Title	Type	Hrs per week	Credits	Category
1	**TH-621**	Thesis	PW	30	15	PC
2	**TH-622**	Defence of Thesis	PW	--	5	PC
Total			**--**	**30**	**20**	**--**
Grand Total (I to IV Semesters)					**81**	

Semester - I

BT-511: Biochemistry (2 credits)

1. **Biomolecules:** Introduction, different classes of biomolecules viz carbohydrates, lipids, Protein nucleic acids, structures and functions of biomolecules, pharmaceutical importance.
2. **Protein and Nucleic acids:** Synthesis, Structure (primary, secondary, tertiary and quaternary), properties, transport, signal transduction, pharmaceutical importance.
3. **Enzymes:** Classification, mode of action (activation, specificity), enzyme kinetics, enzyme inhibitors and regulators, allosteric enzymes, isoenzymes, multienzyme system, pharmaceutical importance.
4. **Coenzymes and cofactors:** Coenzymes, classification of vitamins, role and mechanism of action of some important coenzyme (NAD+/NADP+, FAD, lipoic acid, tetrahydrofolate, B12- coenzyme), role of cofactors with specific examples.
5. **Biochemical energetics:** Free energy, , concept of standard free energy, laws of thermodynamics, anabolism and catabolism, cellular respiration, photosynthesis etc exergonic and endergonic reactions, energy rich compounds, coupling of reaction, biological oxidation-reduction.
6. **Carbohydrate metabolism:** Glycolysis, gluconeogenesis, pentose phosphate pathways (PPP), TCA cycle, glyoxylic acid cycle, regulation of carbohydrate metabolism, electron transport chain and oxidative phosphorylation, disorders of carbohydrate metabolisms.
7. **Lipid metabolism:** Hydrolysis, absorption and transport of lipids, catabolism of lipids, beta and omega oxidation of fatty acids, ketone bodies formation, biosynthesis of fatty acids, disorders of lipid metabolisms.
8. **Amino acid metabolism:** Hydrolysis, of proteins, pathways of amino acid degradation, urea cycle and formation of uric acid, assimilation of ammonia, biosynthesis of amino acids, inborn error of protein metabolism.
9. **Nucleic Acid Metabolism:** Purine and pyrimidine biosynthesis, salvage pathway, degradation of nucleotides, role of ribonucleotide reductase, pharmaceutical importance, disorders of purine and pyrimidine metabolisms.

Suggested Reading:

1. Biochemistry by Lubert Stryer; Jeremy Berg; John Tymoczko and Gregory Gatto. Ninth Edition. 2019.
2. Lehninger Principles of Biochemistry by David L. Nelson and Michael M. Cox. Eighth Edition. 2021.

BT-512: Fundamentals of Cell Biology and Microbiology (2 credits)

1. **Cells as a unit of life:** Unity and diversity of cells, prokaryotic and eukaryotic cells, evolution of cells, applications of cell biology, model organisms.
2. **Tools and Techniques of Cell Biology:** Histology, staining, Light Microscopy fluorescence, confocal microscopy, TEM and SEM. Fluorescent dyes and GFP tagged proteins in visualization, FACS, cell fractionation, cell culture.
3. **Bacterial and Eukaryotic Cell Structure and Organization:** Bio-membranes, structure, Gram-positive and Gram-negative bacteria, cilia, flagella, pili, functions of eukaryotic cell organelles i.e. nucleus, ribosomes, ER, Golgi, lysosomes, peroxisomes, cytoskeleton.
4. **Organization of tissues:** Cell-Cell and cell-matrix interactions, cell adhesion molecules, components of the extracellular matrix, cellular junctions. Microbial communities and biofilms.
5. **Cellular Movement & Molecular Motors:** Types of movement, extravasation, role of cytoskeletal proteins in movement. Molecular motors, movement of vesicles, cilia and flagella.
6. **Gene regulation in prokaryotes:** Principles of gene regulation in E. coli, Regulation of transcription (operon concept), Translational control, Feedback inhibition, Modes of attenuation.
7. **Viruses:** Introduction, Structure, Classification, Life cycle (Lambda genome as an example), Purification, Quantification.
8. Microbiological tests and assays, Assays for antibiotics and bacterial endotoxins.
9. **Yeast:** Model organism, Genetic tool, Types of yeast vectors, Types of selection markers.

Suggested reading:

1. Karp's Cell and Molecular Biology (9th Edition).
2. Essential Cell Biology (5th Edition), Bruce Alberts.
3. Molecular Cell Biology (9th Edition) by Harvey Lodish, Arnold Berk, Chris A. Kaiser, Monty Krieger, Anthony Bretscher.
4. Lewin's Genes (12th edition).
5. Microbiology (11th edition) by Lansing Prescott, John Harley and Donald Klein.

BT-513: Biochemical and Bioprocess Engineering (2 credits)

1. **Homogeneous reactions:** Reaction thermodynamics; Reaction yield; Reaction rate; Reaction kinetics; Calculation of reaction rates from experimental data; General reaction kinetics for biological systems; Zero-order kinetics; First-order kinetics; Determining enzyme kinetic constants from batch data.

2. **Microbial growth:** Kinetics of microbial growth; substrate utilization and product formation; Structured and unstructured model of growth; Equations for substrate utilization and product formation and related numericals.
3. **Reactor design:** Bioreactor configurations; Stirred tank; Airlift reactor; Packed bed; Monitoring and control of bioreactors; Ideal reactor operation; Batch operation of a mixed reactor; Total time for batch reaction cycle; Fed-batch operation of a mixed reactor; Continuous operation of a mixed reactor; Chemostat cascade; Continuous operation of a plug flow reactor; Detailed studies on the batch, continuous and fed-batch bioreactors.
4. **Agitation:** Need of agitation in aerobic fermentation; Effect of agitation; How agitation helps aeration; Different types of agitational methods; impeller design and relationship with the characteristics of the fluid; flow behaviour etc.
5. **Aeration:** Need of aeration in aerobic fermentation; effect of aeration; how aeration helps agitation; different types of aeration methods; aeration in high density fermentation; aeration in qualescence and non-qualescence medium; flow behaviour etc.
6. **Sterilization of air and medium:** Different methods of sterilization; Kinetics of sterilization; batch and continuous sterilization; advantages and disadvantages thereof; Calculation of del factor and solving of numerical.
7. **Mass transfer:** Mass and energy balance in microbial processes; Resistance encountered in fermentation medium by the oxygen molecule; Role of Dissolved oxygen concentration in the mass transfer; Determination of mass transfer co-efficient (KLa), Factors affecting KLa and their relationship.
8. **Heat transfer in bioreactors:** Mechanisms of heat transfer; heat transfer between fluids, Calculation of heat transfer coefficients; Heat transfer equipment; Steady state conduction; LMTD calculation; Relationship between heat transfers; Cell concentration and stirring conditions.
9. **Dimensional analysis:** Various types of dimensionless analysis in terms of mass transfer; Heat transfer and momentum transfer; Importance of dimensionless number in designing the bioreactors, heat exchangers etc.
10. **Scale-up:** Principles and criteria; Different methods of scale up and the detailed analysis with case studies; Instrumentation and control of bioprocesses.

Suggested reading:

1. Bioprocess Engineering: Basic Concepts by Michael L. Shuler, Fikret Karg
2. Bioprocess Engineering Principles by Pauline M. Doran
3. Biochemical Engineering Fundamentals by James Edwin Bailey, David F. Ollis
   Principles of Fermentation Technology by Peter F. Stanbury, Allan Whitaker, Stephen J. Hall

BT- 514: Bioinformatics (2 credits)

1. **Basics of Computational Biology:** Database concept; Protein and nucleic acid databases, structural databases.
2. **The NCBI:** publicly available tools, Resources at NCBI and EBI, DNA and protein information resources on the web.
3. **DNA Sequence Analysis Part I:** Analysis of sequencing chromatogram editing and contig building. Sequence-function relationship; Detection of protein-coding regions,

promoters, transcription factor binding sites, restriction enzyme cleavage sites and intron-exon boundaries.

4. **DNA Sequence Analysis Part II:** Databases and search tools; Biological background for sequence analysis. Retrieval of DNA sequences and searching of databases for similar sequence. Submitting DNA sequence to databases, where and how to submit.
5. **Protein sequence analysis:** Comparison of protein sequences and database searching. Predictive methods for protein sequences.
6. Methods for discovering conserved patterns in protein sequences and structures and protein motifs.
7. **BLAST, various methods of DNA and protein BLAST and interpretation of output:** Sequence alignment, Pairwise alignment, Techniques, Multiple Sequence Alignment.
8. **Predicting secondary structure from protein sequences:** Protein structure prediction, homology modelling. Comparison of protein three-dimensional structures. Protein family- based methods for homology detection and analysis.
9. **Phylogentic analysis sequence-based taxonomy:** Overview and assumptions from Multiple Alignment to phylogeny. Neighbour joining, maximum likelihood vs. parsimony. Computational tools for phylogentic analysis.

Suggested reading:

1. Essential Bioinformatics, by Jin Xiong
2. Bioinformatics: Sequence and Genome Analysis, by David W. Mount
3. Systems Biology by Bernhard Palsson
4. Systems Biology in Practice, Concepts, Implementation and Application by E. Klipp, R. Herwig, A.Kowald, C. Wierling, H. Lehrach.

BT-515: Analytical Techniques in Biotechnology and Biopharmaceuticals (2 credits)

1. **Electrophoretic techniques:** Agarose and polyacrylamide gel electrophoresis, Native and denaturing gels, one- and two-dimensional, Blotting Techniques: Southern, Western & Northern, capillary electrophoresis.
2. **Chromatographic techniques:** General principles, classification of chromatographic techniques, normal and reverse phase, Separation based on size, charge, polarity, HPLC
3. **Spectrophotometric techniques:** Ultra-violet-visible, fluorescence (different formats), circular dichroism, infra-red.
4. **Spectroscopic techniques:** Nuclear magnetic resonance, X-ray diffraction.
5. **Binding and stoichiometry studies:** Surface plasmon resonance (SPR), isothermal titration calorimetry (ITC), Analytical ultracentrifugation (AUC)
6. **Mass spectrometry**: Introduction, instrumentation, high- and low-resolution molecular ions, their recognition, fragmentations and rearrangements. Protein identification by Mass spectrometry; Study of post-translational modifications and glycoprotein analysis by 2DGE and MS. ICP-MS.
7. **Peptide sequencing**: Using proteomics for drug discovery.

8. **Next-Generation Sequencing:** Introduction to next generation sequencing; basic NGS practices, NGS data acquisition, processing raw data, construction of de novo assembly transcript annotation and transcript quantification; applications of NGS.
9. Tools based on light scattering.

Suggested reading:

1. Protein Biotechnology: Isolation, Characterization, and Stabilization by Felix Franks.
2. Proteins by Thomas E. Creighton.
3. Current Protocols in Protein Science, Wiley (different collections).

GE-516: Biostatistics and Data Analytics (2 credits)

Refer to Postgraduate – Common Courses syllabus

GE-517: Artificial Intelligence, Machine Learning in Pharmaceuticals (1 credit)

Refer to Postgraduate –Common Courses syllabus

SM-518: Seminar (1 credit)

GL-519: General Lab Experience (6 credits)

1. UV-Visible spectroscopic analysis of a standard Protein
2. Protein estimation by Bradford Assay
3. Monitoring protein unfolding by Fluorescence spectroscopy
4. Enzyme kinetics and enzyme inhibition
5. Aseptic techniques and sterilization for microbial culture
6. Growth kinetics of E. coli
7. Antibacterial assay: Zone of inhibition, Minimal inhibitory concentration determination
8. Plasmid purification and analysis by agarose gel electrophoresis.
9. Polyacrylamide gel electrophoresis analysis of Protein
10. Visualization of protein structure in three dimensions using SWISS-PDB Viewer and PDB structural data.

Semester - II

BT-521: Molecular Biology and Genetic Engineering (2 credits)

1. **Genome Organization and DNA Structure:** Organization of bacterial genome, structure of eukaryotic chromosomes, nucleosome assembly, heterochromatin and euchromatin, Structure of DNA- A-, B-, Z-, P- and triplex DNA, measurement of properties-spectrophotometric, CD, AFM and electron microscope analysis of DNA structure.
2. **Replication:** DNA replication initiation, elongation and termination in prokaryotes and eukaryotes, enzymes and accessory proteins, fidelity, replication of single stranded circular DNA, gene stability, homologous and non- homologous, site-specific recombination.
3. **Transcription:** Transcription in prokaryotes, Transcription in eukaryotes, Post-Transcriptional modifications, RNA editing, Regulation of Transcription in Prokaryotes, Regulation of Transcription in eukaryotes, transcriptional and post transcriptional gene silencing, Splicing, RNA editing, mRNA stability, catalytic RNA.
4. **Translation:** Translation machinery; Ribosomes, composition and assembly, universal genetic code, degeneracy of codons, termination codons, Mechanism of initiation, elongation and termination, Co-and post translational modifications, genetic code in mitochondria, protein stability, protein turnover and degradation.
5. **DNA manipulative enzymes:** Type I, II and III restriction enzymes, reverse transcriptases, ligases, polymerases, kinases and phosphatases.
6. **PCR:** PCR enzymes, primer design, RT-PCR, Real time PCR, cDNA synthesis, applications of PCR, random and site directed mutagenesis.
7. **Cloning:** Principles of Gene Cloning, Desirable properties of vectors, Prokaryotic and Eukaryotic Expression Systems (Constitutive & Inducible): Plasmid Vectors, Phage Vectors, Cosmids, Phagemids, Artificial chromosomes, Construction of Genomic and cDNA Libraries, Lentiviral Vectors, Adenoviral Vectors, Plant Vectors, Insect Vectors.
8. **Gene targeting and Transgenic animals:** Random and specific, Cre/lox P system, Knock-ins & Knock-outs, nuclear transfer from somatic cells, stem cells, tests for pluripotency, mouse, frog, Drosophila.
9. **Nucleic acid therapeutics:** Antisense technology, siRNA, trans-splicing, ribozymes, aptamers, case studies, advantages and challenges.
10. **Targeted Genome Editing:** ZFNs, TALENs, CRISPRs, miRNA and siRNA induced silencing, Application of miRNA and siRNA.

Suggested reading:

1. Genes IX by Benjamin Lewin
2. Principles of Genetics by Gardner, Simmons and Snustard
3. Principles of Gene Manipulation and Genomics (7/e) by Sandy Primrose and Richard Twyman, Wiley-Blackwell
4. Analysis of Genes and Genomes by Richard J Reece, John Willey & Sons
5. Molecular Biotechnology: Principles and Applications of Recombinant DNA (4/e) by Bernard R. Glick, Jack J. Pasternak and Cheryl L. Patten. ASM Press

BT-522: Gene and Cell Therapy (2 credits)

1. **Overview of Gene Therapy:** Historical perspective, introduction, basic concepts, Somatic and germ line gene therapy.
2. **Gene Editing and Targeting:** Gene replacement and gene addition. Transductional and Transcriptional targeting. Transduction of antisense constructs, Intracellular antibodies, RNA interference; Gene editing by engineered nucleases: Zinc finger nucleases (ZFN), Transcription activator like effector nucleases (TALENs), Cas nucleases of CRISPR Cas 9 system.
3. **In vivo and ex vivo Gene Therapy:** Indications in in vivo and ex vivo gene therapy, viral vectors: adenovirus, retrovirus, adeno-associated virus, non-viral vectors, delivery systems, challenges.
4. **Gene Therapy in Cancer and Other Diseases:** Specific aspects of cancer gene therapy, Proliferation-dependent vectors; Combined therapy, RNA-DNA chimera, Criglar-Najjar syndrome I, severe combined immunodeficiency syndrome (SCID), Cystic fibrosis, Duchenne muscular dystrophy, Inherited coagulopathies, Tyrosinemia.
5. **Regulatory, Ethical Considerations and Recent Advancements in Gene Therapy:** Safety issues at preclinical and clinical stage, Regulatory laws, Ethical issues, FDA and other guidelines. Gene therapy products, commercially available products
6. **Introduction to Cell-Based Therapies:** Definitions and history of cell therapy; difference between cell therapies and traditional drugs; categories of cell therapies (autologous vs allogeneic, stem-cell vs non-stem-cell, single-cell vs multicellular)
7. **Stem Cell Biology and Fundamentals:** Stem cell definitions (self-renewal, potency); types of stem cells - embryonic, induced pluripotent (iPSC), and adult multipotent. Stem cell niches and differentiation, sources and expansion. Immunophenotypes and markers of stem cells.
8. **Stem Cell Therapeutic Applications:** Clinical uses of stem cells: hematopoietic stem cell transplant (leukemia, lymphoma), mesenchymal stem cells (tissue repair, immunomodulation), iPSC-derived therapies (vision, heart, diabetes models). Cell grafting (e.g. skin, cartilage) and tissue engineering basics. Case examples of approved/regenerative therapies and ongoing trials.
9. **Engineered Immune Cell Therapies:** Chimeric antigen receptor design, T cell engineering, autologous vs allogeneic CAR-T; Approved CAR-T products and key clinical outcomes. Challenges: cytokine release syndrome, antigen escape. Other genetically modified T cell therapies (TCR-T) and NK cell therapies.
10. **Translational Challenges and Future Directions:** Clinical translation hurdles: engraftment and survival of therapeutic cells, immune rejection, tumorigenicity (e.g. stem cell clones), and off-target effects. Economic and logistical issues: cost of goods, access in low-resource settings. Case study of a cell therapy trial or marketed product Emerging trends: gene-edited cell therapies (CRISPR-Cas9), in vivo cell programming, tissue-engineered organs, and combination with biomaterials.

Suggested reading:

1. Essentials of Stem Cell Biology-Edited by Robert Lanza, Anthony Atala (Academic Press, 4-Ed., 2021)
2. Principles of Regenerative Medicine - Edited by Anthony Atala, Robert Lanza, et al. (3nl ed., Academic Press, 2019)

3. Cell Therapy: Stern Cell Transplantation, Gene Therapy, and Cellular Immunotherapy Edited by Dwaine Emerich (Humana Press, 2010)
4. S. Friedman T. 1999. The Development of Human Gene Therapy. Cold Spring Harbor, NY: Cold Spring HarborLab. Press.
5. Knipe DM, Howley PM, eds. 2001. Fields Virology. Philadelphia, PA: Lippincott Williams & Wilkins.
6. Hackett NR, Crystal RG. 2000. Adenovirus vectors for gene therapy. In Gene Therapy, ed. NS Templeton, DD Lasic, pp.17-39. New York: Marcel Dekker.

BT- 523: Analysis, Diagnostics and Cell Based Screening (2 credits)

1. **Total protein assay:** Quantitative amino acids analysis, Folin-Lowry protein assay, BCA assay, UV spectrophotometry, etc.
2. **Purity:** Protein impurities, contaminants, electrophoretic analysis, HPLC based analysis, DNA content analysis, immunological assays for impurities, combined immunological and electrophoretic methods, host-cell impurities, etc. ICH guidelines.
3. **Potency assays:** In-vitro biochemical methods MTYT assay, assay for apoptosis, cell-line derived assays, whole animal assays, etc.
4. **Principles, methods and applications of immuno-diagnostics:** Principles and methods of some clinically used diagnostic immunoassays, e.g., homogeneous immunoassays, fluorescence, chemiluminescence and bioluminescence enzyme immunoassays, immunoblot, immunoaffinity, immunoprecipitation, biotinylation, immunosensors.
5. **Principles, methods and applications of DNA-based diagnostics:** DNA probe based diagnostics, sample preparation, hybridization, separation, detection, PCR-RFLP in paternity and forensic cases SNP detection MALDI and DHPLC.
6. **Diagnostics:** Cancer diagnostics, human retroviral diseases specially AIDS. Role of enzymes in diagnostics.
7. **High-throughput screening:** Requirements and parameters, Advantages and disadvantages of biochemical and cellular assays; miniaturization and automation.
8. **Cell-based screening assays:** Advantages over in vitro assays. Different formats: radioactive, luminescence, fluorescence, etc. Assays compatible with cell membranes: GTPγS, cAMP accumulation.
9. **Yeast two-hybrid system:** Different Y2H systems, their advantages and disadvantages, examples.
10. **GPCRs as targets:** Identification of drug molecules; Important parameters: intracellular calcium, cAMP, β-arrestin, receptor internalization, reporter gene assays; orphan GPCRs; desensitization and internalization.

Suggested reading:

1. The Immunoassay Handbook by David Wild
2. High Throughput Screening: The Discovery of Bioactive Substances by John P. Devlin

BT-524: Immunology and Immunotechnology (2 credits)

1. **Immunity:** Innate and adaptive, immune response memory, specificity and recognition of self and non-self, immunogenicity, antigenicity, physiology of immune response, epitope analysis, synthetic peptides and immune response, immunity to virus, bacteria, fungi.
2. **Cells and organs of the immune system:** Lymphoidcells, T cells, B cells, monocytes, phagocytes, mast cells and basophils, primary and secondary lymphoid organs, interplay between cells.
3. **Humoral immunity:** Antigen-antibody interactions, affinity, avidity, immunoglobulins, molecular mechanism of generation of antibody diversity, molecular biology of IgG.
4. **Cell mediated immunity:** T cell subsets and surface markers, T cell-dependent and-independent markers, structure and function of MHC, association of MHC with disease susceptibility, structure of T cell antigen receptor.
5. **Natural immunity:** Inflammation, stimuli, chemotaxis, arachidonic acid metabolite and cytokines, vascular modifications, healing and fibrosis.
6. **Natural killer cells:** Functional definition, mechanism of lysis, recognition structures, phosphorylation.
7. **Immune memory:** B-cell memory, significance, mutations and switches in memory cells, T- cell memory, lack of mutations and switches in T-cell memory, activation, super activation, loss of memory.
8. **Immune tolerance:** B-cell tolerance, reversible and irreversible tolerance, antigen induced tolerance, induction, T-cell tolerance, partial engagement of signal transducer, self- antigens, molecular consequence of tolerance.
9. **Disorders:** Hypersensitivity reaction, immunosuppression, autoimmune disorders, its molecular mechanism, immunodeficiency disorders (AIDS), tumor immunology.
10. **Immunobiotechnology:** Hybridoma, phage display technology, vaccines, Antibody engineering, second generation antibodies a brief outline.

Suggested reading:

1. Cellular and Molecular Immunology by Abdul K. Abbas, Andrew H. Lichtman and Shiv Pillai
2. Kuby Immunology by Thomas J. Kindt, Barbara A. Osborne, and Richard A. Goldsby

GE-526: Intellectual Property Rights and Regulatory Affairs in Pharmaceuticals (2 credits)

Refer to Postgraduate-Common Courses syllabus

GE-527: Research Culture and Ethics in the Pharmaceutical Industry (2 credits)

Refer to Postgraduate-Common Courses syllabus

SM-528: Seminar (1 credit)

GL-529: General Lab Experience in the Area of Specialization (6 credits)

1. Cloning: Restriction digestion, ligation.
2. Transformation of bacterial cells: Preparation of competent cells; Transformation by heat shock method; Estimation of transformation efficiency.
3. Protein purification by affinity chromatography / ion-exchange chromatography / gel-permeation chromatography.
4. Demonstration of Western Blotting
5. Drug protein interaction analysis by Isothermal Titration Calorimetry (ITC)
6. Culture of mammalian cells
7. Anticancer activity analysis by MTT Assay
8. Purification of Total RNA from mammalian cells
9. cDNA preparation from mRNA by Reverse Transcription
10. Gene expression analysis by Real time PCR (qPCR)
11. Estimation of a cytokine concentration by ELISA
12. Apoptosis analysis by Flow Cytometry

EL – 525: Programme Electives (2 Credits)

BT-525 (A): Nanobiotechnology (2 credits)

1. **Principles of nanoscale phenomena:** Quantum confinement, surface-to-volume ratio, and surface energy, Scope and convergence of nanotechnology with biotechnology
2. **Synthesis and Characterization:** Top-down (mechanical milling, lithography), Bottom-up (chemical vapor deposition, sol-gel, hydrothermal, microemulsion), Green synthesis using microbial and plant extracts, Characterization Techniques - UV-Vis, FTIR, XRD, DLS, SEM, TEM, AFM, Raman, Zeta potential, BET analysis.
3. **Optical properties**: Plasmon resonance, fluorescence, photonic crystals, quantum dots.
4. **Nanoscale structure and function of biological macromolecules**: Nanostructure based on DNA, proteins, enzymes, Cytoskeletal nanosystems and molecular motors,
5. **Nanobiosensing:** Introduction to nanobiosensing, Different types of biosensors, surface plasmon resonance based biosensor, electrochemical and potentiometric based biosensor, motion, temperature, chemical, light and pressure sensitive biosensors, Applications of biosensors in diagnostics, Nanopore sequencing, single-molecule tracking techniques.
6. **Nanomedicine:** Nanoparticle within a biological environment, nanoparticles for drug delivery, gene delivery, protein delivery, liposomes, dendrimers, carbon nanotubes, stimuli-responsive nanocarriers photothermal and photodynamic therapy, Theranostic nanoparticles, Nanozymes, Nanorobots, Nanomaterials for tissue engineering and prosthetics.
7. **Nanotoxicology:** Toxicology of nanomaterials, Cell and tissue response, Mechanistic toxicology, dose–response models, ecotoxicity.

BT-525 (B): Omics in Drug Discovery (2 credits)

1. **Genomics:** Introduction to genomics and genome sequencing technologies; single nucleotide polymorphisms (SNPs); cancer genomics, identification of disease genes, discovery of putative drug targets.

1. **Transcriptomics:** Evolution of sequencing technologies; quantification of the gene, transcript and isoform expression; gene and transcript annotation; single-cell transcriptomics; comparative transcriptomics; disease mechanisms, early prediction of adverse drug target effects, microarrays.

2. **Metabolomics:** Introduction to metabolomics, challenges and potential applications, targeted metabolomics, untargeted metabolomics, analytical platforms for data acquisition and processing.

3. **Experimental Approaches in Proteomics:** Introduction, applications, methods of protein resolution from complex mixtures: Cell lysates, Serum proteins using 2DE, DIGE, stable isotope labelling by amino acids in cell culture (SILAC), isotope coded affinity tag (ICAT). Biomarker identification from cells, tissue as well as biological fluids; understanding post-translational modification, drug target efficacy and safety evaluation.

4. **Lipidomics:** Application of lipidomics in biomedical sciences, metabolic syndrome, cancer, cardiovascular diseases, analytical tools.

5. **Single-Cell Multi-omics and its Techniques:** Introduction, single cell data generation, Flow Cytometry, Mass Cytometry, IsoLight, mutiparametric tissue imaging, genomic cytometry, biomarker discovery and novel target identification.

6. **Multi-omics in drug discovery:** Tumor and Cancer, Malaria, Viral diseases, Fungal diseases, Bacterial infections, Biomarkers.

Suggested reading:

1. Bioinformatics and Functional Genomics, Pevsner (3rd edition).
2. Practical Computing for Biologists, Haddock and Dunn.
3. Primrose SB, Twyman RM (2006). Principles of gene manipulation and genomics. Blackwell Publishing.
4. Simpson R (2002). Proteins and proteomics: A laboratory manual. Cold Spring Harbor Laboratory Press.

DEPARTMENT OF PHARMACEUTICAL ANALYSIS

SEMESTER - I

S. No	Course Code	Course Title	Type	Hrs per week	Credits	Category
1	**PA-511**	Analytical Techniques in Pharmaceutical Industry	T	2	2	PC
2	**PA-512**	Spectroscopy for Structure Elucidation	T	2	2	PC
3	**PA-513**	Analytical techniques for Separation and Characterization	T	2	2	PC
4	**PA -514**	Pharmaceutical Regulations	T	2	2	PC
5	**PE-511**	Pharmaceutical Preformulation I	T	2	2	PC
6	**GE-516**	Biostatistics and Data Analytics	T	2	2	SD
7	**GE-517**	Artificial Intelligence and Machine Learning in Pharmaceuticals	T	1	1	IO
8	**SM-518**	Seminar	TS	1	1	SL
9	**GL-519**	General Lab Experience	LPS	18-24	6	PC
Total			**--**	**32-38**	**20**	**--**

SEMESTER – II

S. No	Course Code	Course Title	Type	Hrs per week	Credits	Category
1	**PA-521**	Analytical Method Development and Validation	T	2	2	PC
2	**PA-522**	Instrumentation Techniques for Analysis of Pharmaceuticals	T	2	2	PC
3	**PA -523**	Stability Testing of Pharmaceuticals and Biologicals	T	2	2	PC
4	**PA-524**	Quality Control and Quality Assurance	T	2	2	PC

5	**EL -525**	Programme Elective *	T	2	2	PE
6	**GE-526**	Intellectual Property Rights and Regulatory Affairs in Pharmaceuticals	T	2	2	SD
7	**GE-527**	Research Culture and Ethics in the Pharmaceutical Industry	T	2	2	IO
8	**SM-528**	Seminar	TS	1	1	SL
9	**GL-529**	General Lab Experience in the Area of Specialization	LPS	18-24	6	PC
Total			**--**	**33-39**	**21**	**--**

*** EL-525 (Programme Elective):** The scholar should select any one course from the list of courses offered by other departments.

List of Department-wise Programme Electives (EL- 525) – 2 Credits:

(Scholars must select any one elective course from any department other than their own department)

Name of Department	**Course title**	**Credits/ Course**
BT	BT-525 (A): Nanobiotechnology BT-525 (B): Omics in Drug Discovery	2
PA	PA-525 (A): Analytical Characterization of Biosimillars PA-525 (B): Mass Spectrometry in Omics	2
PE	PE-521: Pharmaceutical Product Development II PE-522: Biopharmaceutics and Pharmacokinetics	2
PP	PP-522: Patient Safety and Health Related Outcomes PP-523: Clinical Research PP-524: Evidence-Based Medicine	2
PT	PC-525 (A): Principles and Methods in Toxicology PC-525 (B): Introduction to Regulatory Toxicology	2

SEMESTER - III

S. No	**Course Code**	**Course Title**	**Type**	**Hrs per week**	**Credits**	**Category**
1	**TH-611**	Synopsis	PW	28	15	PC
2	**TH-612**	Presentation	PW	--	3	PC

3	**EL-613**	Self-learning Courses *	IO	4	2	OE
____	_____	**Total**	**--**	**32**	**20**	**--**

*** EL-613:** Industry/academic-oriented skill courses must be chosen by students. Individual departments must set the SOP for the same.

SEMESTER - IV

S. No	Course Code	Course Title	Type	Hrs per week	Credits	Category
1	**TH-621**	Thesis	PW	30	15	PC
2	**TH-622**	Defence of Thesis	PW	--	5	PC
Total			**--**	**30**	**20**	**--**
Grand Total (I to IV Semesters)					**81**	_____

Semester - I

PA-511: Analytical Techniques in Pharmaceutical Industry (2 credits)

1. Introduction to pharmaceutical analysis and techniques: Scope and range of modern pharmaceutical analysis as per monograph. Listing of various techniques, with broad discussion on their applications with respect to monograph analysis.

2. Reference standards: Types (primary, secondary, working and test standards), preparation, containers, labelling and storage. Special precaution on handling of biological standards including peptides, proteins and enzyme. Concept of re-test period, CRM, COA, expiry date, batch number, Five batch analysis.

3. Raw material and product specifications: Definition of specifications, study of ICH Q6 guidelines and understanding of specifications through study of pharmacopoeial monographs on drug substances and products

4.Analytical techniques used in biological product characterization: structure of peptides, protein, antibody, siRNA, ADC. Analytical methods used in structural characterization of peptide, proteins and antibodies.

5. Physical tests: Viscosity, melting point, boiling point/range, water content and water analysis including Karl Fischer titration, loss on drying, loss on ignition, iodine value, peroxide value, acid value, optical rotation, pH, specific gravity, osmolality/osmolarity, refractive index, MVTR, etc.

6. Microbiological tests and assays: Antimicrobial (preservative) effectiveness testing, microbial limit tests, sterility test, vitamins assay (zone of exhibition), antibiotics assays, bacterial endotoxin test.

7.Testing of packaging materials: Instruments used, extractable and leachable, polymer characterization, polymer leaching in products, adduct impurity.

8. Calibration and qualification of equipment: Difference of definitions, calibration standards, calibration frequency. Calibration of pH meter, weighing balance, FTIR, UV spectrophotometer, GC and HPLC, Fluorimeter, DSC, DLS.

10. Automation and computer-aided analysis: The concept of auto samplers and high-throughput analysis, computer-controlled instrumentation, and networked laboratory. Peculiarities of laboratory information management systems (LIMS), In silico impurity profiling, and genotoxicity prediction.

Reference books:

1. Watson DG. *Pharmaceutical analysis*. 3rd ed. Edinburgh: Elsevier; 2012.
2. World Health Organization. *Quality assurance of pharmaceuticals: A compendium of guidelines and related materials*. Vol. 1–2. Geneva: WHO Press; 2013.
3. Adejare A, editor. *Remington: The science and practice of pharmacy*. 23rd ed. London: Academic Press; 2020.
4. Ermer J, Miller JHM, editors. *Method validation in pharmaceutical analysis: A guide to best practice*. Weinheim: Wiley-VCH; 2005.
5. Skoog DA, West DM, Holler FJ, Crouch SR. *Fundamentals of analytical chemistry*. 9th ed. Belmont (CA): Brooks/Cole; 2014**.**
6. Ahuja S, Scypinski S, editors. *Handbook of modern pharmaceutical analysis*. San Diego: Academic Press; 2001.

PA-512: Spectroscopy for Structure Elucidation (2 credits)

1. UV and IR spectroscopy: UV: Types of electronic transitions in organic compounds, proteins, inorganic complexes, solvent effects, effect of extended conjugation, Woodward-Fiesler rules, isomers and drug degradation by UV IR: Fundamental vibrations, Hooke's law, factors affecting functional group bond vibration and interpretation of FT-IR spectra.

2. Nuclear Magnetic Resonance Spectroscopy: Principles and theory of 1H-NMR spectroscopy. Factors affecting chemical shift and various shielding and deshielding mechanism, spin-spin interaction, and multiplicity, J-value, Karplus relationship, first-order splitting patterns, and structure correlation. NMR solvents, residual protons, sample preparation. H1-NMR in protein structure.

13CNMR: Natural abundance and sensitivity, interpretation, 13C-DEPT, Proton off resonance, steady-state NOE, saturation transfer.

2D-NMR: Principles of NMDR, COSY, NOESY, and HSQC, and their use in structure elucidation with examples.

3. Applications of UV, IR and NMR spectral methods (*Workshop/Problem or task based assignment):* *I*n structure determination of natural, synthetic compounds. Advancement of NMR spectroscopy for the determination of the absolute configuration of chiral molecules and its application in the structural revision of natural products and peptides, proteins

4. Mass spectrometry: Basic principle, base peak, metastable peak, fragmentation processes of organic molecules, and deduction of structural information. Cleavage of bonds. Different techniques like CSI, EI, FAB, and MALDI, etc., Structure elucidation by using Mass spectroscopic techniques with examples. Mass spectrometry-based omics.

5. Raman spectroscopy and AFM: Raman spectroscopy principle, IR spectra Vs Raman spectra, and basic instrumentation. Specific applications of Raman spectra in drug discovery and development with special emphasis to proteins and peptides with reference to recent research papers.

Reference books:

1. Silverstein RM, Webster FX, Kiemle DJ, Bryce DL. Spectrometric identification of organic compounds. 6th ed. Hoboken (NJ): John Wiley & Sons; 2014**.**
2. Kemp W. Organic spectroscopy. 3rd ed. London: Macmillan Education; 1991.
3. Pavia DL, Lampman GM, Kriz GS, Vyvyan JR. Introduction to spectroscopy. 5th ed. Boston: Cengage Learning; 2015.
4. Fleming I. Spectroscopic methods in organic chemistry. 6th ed. London: Springer; 2011.
5. Breitmaier E. Structure elucidation by NMR in organic chemistry: a practical guide. 3rd ed. Chichester: John Wiley & Sons; 2002**.**
6. Modern Raman Spectroscopy: A Practical Approach by Ewen Smith, Geoffery Dent.
7. Finar IL. Organic chemistry. Vol. 1: The fundamental principles. 6th ed. Harlow: Longman Scientific & Technical; 1973

PA-513: Analytical techniques for Separation and Characterization (2 credits)

1. Chromatography: Core principles underlying chromatographic separations, classification of different chromatographic and separation techniques. Adsorption and partition theory in separations, gravity column for natural products separation, column packing, sample loading, elution techniques and analysis of the different fractions collected.

2. Planar Chromatography: TLC/HPTLC: Principles, sample application, development of plates, densitometry, visualization techniques and 2D TLC.

3. High Performance Liquid Chromatography: Principles, instrumentation, isocratic & gradient, normal & reverse phase HPLC, peak shapes, resolution, different types of pumps, injectors, column chemistries, detectors; UV, PDA, Fluorescence, RI, ELSD, and CAD. Trouble shooting of HPLC peak elution, and its applications. Special focus on FPLC, IEC and preparative HPLC in peptide/protein separation and purifications.

4. Gas Chromatography: Principles, instrumentation, interface, types of injectors, split-splitless, head space, factors affecting resolution, different GC columns, detectors FID, ECD, TCD, MS, QQQ, and applications of HS-GC-MS/MS for analysing volatile compounds in pharmaceuticals.

5 Liquid Chromatography-Mass Spectrometry: Principles, instrumentation, tuning parameters, different ionization techniques (ESI, APCI, APPI etc.). Principle of different mass analyzers; Single quadrupole, triple quadrupole QQQ, Q-TOF, Orbitrap and their applications in pharmaceutical and biological products.

6. Liquid Chromatography-Inductively Coupled Plasma-Mass Spectrometry (LC-ICP-MS): Principles, instrumentation, sample preparation, microwave digestion, interferences and applications in quantitative analysis of heavy metals and their species with reference to scientific papers.

7. Other Hyphenated techniques: Principles and instrumentation, and literature based current application of LC-NMR, LC-IR, LC-NMR-MS, CE-MS/MS with reference to scientific papers.

8. Electrophoresis: Principles, Types, Chromatography Vs Electrophoresis in protein separation, SDS-PAGE, 2D-Gel in omics, staining techniques and interpretation. Immunoblotting and its application.

Reference books

1. Beckett, A. H.; Stenlake, J. B. Practical Pharmaceutical Chemistry, Part II, 4th ed.; CBS Publishers & Distributors: New Delhi, 2007.

2. Snyder LR, Kirkland JJ, Glajch JL. Practical HPLC method development. John Wiley & Sons; 2012.

3. Kazakevich YV, Lobrutto R. HPLC for pharmaceutical scientists. John Wiley & Sons; 2006 Dec 13.

4. Ardrey, R. E. Liquid Chromatography–Mass Spectrometry: An Introduction; Wiley: Chichester, U.K., 2003.

5. McNair HM, Miller JM. Basic Gas Chromatography. 2nd ed. Hoboken (NJ): Wiley; 2009.

6. Plant Drug Analysis A Thin Layer Chromatography Atlas by Wagner & Bladt.

7. Electrophoresis: The Basics by David M. Hawcroft.

Review Papers and Research Articles

1. Patel KN, Patel JK, Patel MP, Rajput GC, Patel HA. Introduction to hyphenated techniques and their applications in pharmacy. Pharmaceutical methods. 2010 Oct 1;1(1):2-13.

2. Wang T. Liquid chromatography–inductively coupled plasma mass spectrometry (LC–ICP–MS). Journal of liquid chromatography & related technologies. 2007 Feb 1;30(5-7):807-31.

PA-514: Pharmaceutical Regulations (2 Credits)

1. **OECD-GLP:** Scope and objectives of OECD, OECD countries, MAD agreement, Functioning of OECD-GLP in India.
2. **OECD documents:** OECD documents No 1. Good Laboratory Practices (GLP): Schedule L-1, Different OECD guidelines for testing of Physico-chemical testing. Organization structure of Test facility.
3. **Elements of OECD-GLP:** Roles and responsibility of Test facility management, QA, Study director, study personnel, Archivist, IT personnels.
4. **Good Manufacturing Practices (GMP) for Pharmaceuticals Products:** Schedule M and Schedule T for Indian System of Medicine.
5. **Quality assurance and data integrity:** OECD document 22 and 23.
6. **Test and reference item and analytical methods:** OECD document No. 8, method validation, CSV.
7. USFDA guidelines for Botanicals. WHO guidelines on Quality Assessment of Herbal Drugs. Quality Assurance and Control in Ayurveda/Herbal/Natural Products / Indian System of Medicine (ISM) industry: Guidelines & Challenges associated.

8. CDSCO Guidelines for development and manufacture of Phytopharmaceutical drug in country. Quality Control Quality Assurance and CDSCO guidelines for Phytopharmaceuticals / Ayurvedic Pharmacopoeia of India.
9. **Quality risk management:** Definition of quality risk management in ICH Q9 guideline. Its importance and application to analytical laboratory with examples. OECD document 24.

Reference books:

1. Handbook: Good laboratory practice (GLP) https://tdr.who.int/publications/i/item/handbook-good-laboratory-practice-(-glp)
2. OECD SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE MONITORING Number 1 OECD Principles on Good Laboratory Practice (as revised in 1997) https://www.oecd.org/content/dam/oecd/en/publications/reports/1998/01/oecd-principles-on-good-laboratory-practice_g1gh32e8/9789264078536-en.pdf
3. OECD https://www.oecd.org/en/topics/sub-issues/testing-of-chemicals/good-laboratory-practice-and-compliance-monitoring.html
4. Good Manufacturing Practice(GMP) standards- WHO GUIDELINES https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/norms-and-standards/gmp
5. Indian Pharmaceutical Associations- schedule-m-1.pdf https://ipapharma.org/wp-content/uploads/2019/02/schedule-m-1.pdf
6. CDSCO SCHEDULE M GUIDELINEShttps://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTA4MTU=
7. European Medicines Agency - ICH Topic Q 7 Good Manufacturing Practice for Active Pharmaceutical Ingredients https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q-7-good-manufacturing-practice-active-pharmaceutical-ingredients-step-5_en.pdf
8. Good Manufacturing Practice (GMP) guideline in pharmaceutical industries: implementation and its significance from the view of pharmacists https://www.researchgate.net/publication/358266087_GOOD_MANUFACTURING_PRACTICE_GMP_GUIDELINE_IN_PHARMACEUTICAL_INDUSTRIES_IMPLEMENTATION_AND_ITS_SIGNIFICANCE_FROM_THE_VIEW_OF_PHARMACISTS

PE-511: Pharmaceutical Preformulation I (2 credits)

Refer to the Department of Pharmaceutics syllabus

GE-516: Biostatistics and Data Analytics (2 credits)

Refer to Postgraduate-Common Courses syllabus

GE-517: Artificial Intelligence, Machine Learning in Pharmaceuticals (1 credit)

Refer to Postgraduate-Common Courses syllabus

SM-518: Seminar (1 credit)

There shall be two seminars one from the academic syllabi and from the technical papers (published research papers) in the area of the student research interest.

- Technical paper presentation shall be evaluated by atleast two examiners.
- Seminar shall be evaluated with appropriate rubrics system.

GL-519: General Lab Experience (6 credits)

Practical

1. Manual calculations including dilution factor, calibration standards,
2. Study and comparative review of different types of reagents, COA, CRM, SOPs, STPs etc.
3. Workshop on Endnote, AI/ML Tools, Power BI/Tableau, Chemdraw, Advance Excel, Prism Pad, and other relevant biostatic tools.
4. **Calibration of the common glassware:** (Volumetric flask, Burette, Pipette, Measuring Cylinder etc) and thermometer, hot air oven used in an analytical laboratory.
5. **Calibration of Instruments:** UV-Visible spectrophotometer, FT-IR, Muffle furnace pH Meter, Weighing Balance etc.
6. **Assay of single and multicomponent analysis using non-specific and** specific techniques (HPLC)
7. **Karl Fischer titration:** Standardization of Karl Fischer reagent and determination of water content in the given sample.
8. **FT-IR Analysis**: Sample preparation, pellet formation with FTIR analysis of a given drug sample.
9. **UV-Visible Spectrophotometer:** Calibration of UV-Visible Spectrophotometer and construction of calibration curve for a given drug. Determination of pka of given sample by spectrophotometric method.
10. **Dissolution test apparatus**: Qualification of Dissolution test apparatus or calculation for F1/F2 factors.
11. **HPLC:** Sample preparation, operation and handling of HPLC. Calibration of HPLC instrument. Demonstration on how to separate closely eluting peaks and improvise its resolution. Changing from reverse phase to normal phase chromatography for separation of compounds based on their polarity. System suitability and Column Performance Test (CPT) to find % purity of given compound by HPLC (Practical to be conducted in Central Instrumentation Laboratory (CIL)).
12. Determination of instrument calibration, melting behaviour and polymorphic behaviour of various compounds by DSC.
13. Spectrofluorimetric analysis of a given sample
14. Sample analysis using TGA and its interpretation. Study of hydrate forms of ampicillin trihydrate using TGA.
15. Quality control of API using Powder XRD
16. Sample preparation and demonstration of sample analysis using LCMS.
17. Interpretation exercise in 1D (H. C), 2D NMR (HMBC, HSQC, COSY, NOSEY) experiments

Semester - II

PA-521: Analytical Method Development and Validation (2 credits)

1. **Introduction to method development for SIAM:** Method development concepts, steps involved, intricacies at each step, insights on ICHQ14. Trouble shooting of HPLC methods and method transfer, SST. Requirements as per ICHQ1.
2. **Method validation:** Definition and methodology, discussion on each parameter with examples, special considerations in bioanalytical method validation as per USP, ICH Q2(R1) and ICHQ2(R2). Integration ICHQ14 with ICHQ2 for method development.
3. **Bioanalytical method**: Method development and validation as per FDA / ICH M10 for BA/PE studies using HPLC and LC-MS/MS. Full and partial validation as required for clinical phases in bioequivalence studies. Special emphasis on LBA methods for antibody determination in serum
4. **Impurity profiling:** Types of impurities in drug substances and products. Stability indicating-method development for impurity analysis, techniques, identification and quantitation. Detailing of ICH Q3 and correlation with Pharmacopeia
5. **QbD in Analytical method development:** Basic and concept of QbD in regulatory perspectives. Product QbD Vs AQbD Vs Enhanced approach (as per ICHQ14), QTPP, ATP, DoE, MODR, Control strategies, system and sample suitability tests and assessment. Concept of ICH Q8, Quality by Design QbD, Process Analytical Technology (PAT), advancements in PAT and process development report.
6. **Genotoxic impurity profiling:** Concept of genotoxic and mutagenic impurity, classifications, analytical methods, alert structures, nitrosamines, NDSRIs, Azido impurities. Risk assessment and control as per FDA. Specifications and concept as per ICH S2 and ICHM7.
7. **Methods for peptide and protein purification:** Approach of selection of chromatographic columns, conditions, scale-up (Analytical to preparative), common troubles in peptide and protein separation in HPLC and electrophoresis.

References-

1. Swartz ME, Krull IS. Analytical Method Development and Validation. Boca Raton (FL): CRC Press; 1997.
2. Swartz ME, Krull IS. Handbook of Analytical Validation. Boca Raton (FL): CRC Press; 2012.
3. Ermer J, Miller JH McB. Method Validation in Pharmaceutical Analysis: A Guide to Best Practice. Weinheim: Wiley-VCH; 2005.
4. Yoon IS, Cho HJ, editors. Method Development and Validation in Food and Pharmaceutical Analysis. Basel: MDPI; 2023.
5. Riley CM, Rosanske TW, Reid G. Specification of Drug Substances and Products: Development and Validation of Analytical Methods. 2nd ed. Amsterdam: Elsevier; 2020.s

PA-522: Instrumentation Techniques for Analysis of Pharmaceuticals (2 credits)

1. **Non-destructive analysis and pharmaceutical visualization:** Principle, instrumentation, qualitative and quantitative applications (including PAT and/or visualization) for the following equipment: FT-NIR, ATR, FT-Raman, X-Ray Diffraction (XRD), CD and fluorescence spectroscopy in protein structure.

2. **Thermal techniques**: DSC: Principle, thermal transitions, instrumentation (heat flux and power-compensation designs), modulated DSC, hyper DSC, experimental

parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, pharmaceutical applications. TGA: Principle, instrumentation, factors affecting results, pharmaceutical applications.

3. **Particle sizing:** Static & dynamic laser light scattering, Working Principle, Selection between Powder and Suspension Methods, DLS Vs NTA.

4. **Analysis of trace components**: Techniques employed for the qualitative and quantitative evaluation of impurities, degradation products, drug-drug and drug-excipient interaction products, metabolites, elemental impurities, residual solvents, etc.

5. **Microscopic Allied techniques:** Applications of Advanced Microscopic Techniques Optical Microscopy, Scanning Electron Microscopy (SEM), Transmission Electron Microscopy (TEM)-Basic Principles and Applications to API and Drug product characterization

6. **Case Studies & Troubleshooting (Self-learning and Group discussion)**: Industry related problems in the area of product characterization, choice of analytical techniques for defect analysis, alternative analytical tools for PAT, risk assessment-based exercise in method failure and method transfer.

Reference books

1. Skoog DA, Holler FJ, Crouch SR. Principles of Instrumental Analysis. 7th ed. Boston: Cengage Learning; 2018.
2. Barth HG, editor. Modern Methods of Particle Size Analysis. New York: Wiley; 1984.
3. Willard HH, Merritt LL, Dean JA, Settle FA. Instrumental Methods of Analysis. 7th ed. Belmont: Wadsworth Publishing Company; 1988.
4. Kar A. Pharmaceutical Drug Analysis. 4th ed. New Delhi: New Age International Publishers; 2005.
5. Smith E, Dent G. Modern Raman Spectroscopy: A Practical Approach. Chichester: John Wiley & Sons; 2005.
6. Smith BC. Fundamentals of Fourier Transform Infrared Spectroscopy. 2nd ed. Boca Raton: CRC Press; 2011

PA-523: Stability testing of pharmaceuticals and biologicals (2 credits)

1. Drug development cycles and stability testing: Role and types of stability studies during different stages of drug and product development.

2. Drug stability testing guidelines: International, Regional, and National drug stability guidelines.

3. WHO vs. ICH drug stability testing guidelines, Stability zones, Comparison of different aspects in WHO guidelines. Guidelines of ICH-Q, S, E, M with special emphasis on Q-series guidelines: Q1A(R2), Q1B, Q1C, Q1D, Q1E and Q1F.

4. Stability testing of Biosimillars (Peptides & antibodies): Protocols, Selection of Batches, Test parameters, Sampling frequency, Regulatory requirements and Complexities.

5. Stress testing and Stability-Indicating Method development: Role, regulatory aspects, protocols/approaches, practical considerations for pharmaceuticals and biologicals.

6. Stability Chambers: Types of stability chambers, design considerations, qualification and other critical issues. Specific consideration for cold storage systems.

7. Stability testing for Shipping & Distribution: Stability testing during transport, Transportation validation studies and approaches to increase stability.

8. CMC Studies: Chemistry, Manufacturing & Control Studies for Natural products/Phytopharmaceuticals as per regulatory guidelines for Botanical Raw Material, Botanical Substance and Finished products/Formulations. Generation of Certificate of Analysis CoA. Case studies with respect to Drugs, Herbal / AYUSH products, Phytopharmaceuticals.

Reference books

1. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). ICH guidelines [Internet]. Geneva: ICH; [cited 2026 Mar 11]. Available from: https://www.ich.org
2. World Health Organization (WHO). WHO guidelines [Internet]. Geneva: World Health Organization; [cited 2026 Mar 11]. Available from: https://www.who.int
3. Yoshioka S, Stella VJ. Stability of drugs and dosage forms. New York: Kluwer Academic/Plenum Publishers; 2000.
4. Huynh-Ba K. Handbook of stability testing in pharmaceutical development: regulations, methodologies, and best practices. New York: Springer; 2008.
5. Baertschi SW, Alsante KM, Reed RA. Pharmaceutical stress testing: predicting drug degradation. 2nd ed. New York: Informa Healthcare; 2011.
6. Bajaj S, Singh S. Methods for stability testing of pharmaceuticals. New Delhi: Pharmaceutical Press; 2010.

PA-524: Quality Control and Quality Assurance (2 credits)

1. **Basic principles and Concepts:** Quality Control (QC), Quality Assurance (QA), Total Quality Management (TQM), International Organization for Standardization (ISO system), Electronic quality management system (eQMS).
2. **Format & documents:** SOP, format, controlled documents, DCO, study plan, study reports, amendments,
3. **Good documentation Practice:** Writing and documentation-of SOP (ALCOA +), STPs, certificate of analysis, laboratory books: Typical documents used in a GLP laboratory including standard test protocols, COA and laboratory notebooks. Electronic records & signatures (21CFR Part-11 requirement). Three tier documentation, policy, procedures, work instructions, formats and records.

4. Basic principles on how to prepare, maintain, review, approval, issuance, storage, retrieval, Master Formula Record (MFR), Drug Master File (DMF), distribution records, packaging records, site master file and electronic document management system (e-DMS).

5. **Qualification of instruments:** Concept of Group A, B and C equipments. Difference between calibration, qualification and validation. Definition of qualification process involving URS [user requirement specification), DQ, IQ, OQ, CQ and PQ. Concept of computer system validation. 21CFR part 11 in analytical equipments.

6. **Qualification of facility and utilities:** Concepts, process, documentation of facility validation, Revalidation Criteria, USFDA guidelines on Process Validation. Qualification of HVAC, Pharmaceutical Water system and pure steam. Validation of Utility systems and facilities in sterile and non-sterile plants.

7. **Cleaning Validation:** Cleaning Method Development, basic requirements of cleaning and its validation. Cleaning of equipments, cleaning of facilities and Cleaning in Place (CIP).

8. **Quality Systems:** Handling of deviations, retesting, OOS and OTT test results. Quality Audit Plans, Non-Conformity (NC) and their reports. Complaints: Evaluation and handling of market complaints, Corrective & Preventive Actions (CAPA), returns and recalls.

9. **Laboratory inspections and audit**: Internal inspection, external audit, concepts, preparing for inspections and audits, study based- facility based- and critical phase inspections.

Reference books

1. Sharp J**.** Good pharmaceutical manufacturing practice: rationale and compliance. Boca Raton: CRC Press; 2005.
2. Bunn G.Good manufacturing practices for pharmaceuticals**.** 7th ed. Boca Raton: CRC Press; 2017.
3. World Health Organization**.** Quality assurance of pharmaceuticals: a compendium of guidelines and related materials. Vol. 1. Geneva: World Health Organization; 2007.
4. World Health Organization.Quality assurance of pharmaceuticals: a compendium of guidelines and related materials**.** Vol. 2. Geneva: World Health Organization; 2007.
5. Shah DH**.** QA manual**.** Mumbai: Business Horizons; 2000.
6. World Health Organization.WHO expert committee on specifications for pharmaceutical preparations: technical report series**.** Geneva: World Health Organization.
7. Shenoy P. Handbook of pharmaceutical quality assurance**.** New Delhi: CBS Publishers & Distributors; 2010.

GE-526: Intellectual Property Rights and Regulatory Affairs in Pharmaceuticals (2 credits)

Refer to Postgraduate-Common Courses syllabus

GE-527: Research Culture and Ethics in the Pharmaceutical Industry (2 credits)

Refer to Postgraduate-Common Courses syllabus

SM-528: Seminar (1 credit)

- There shall be two seminars one from the academic syllabi and from the technical papers (published research papers) in the area of the student research interest.
- Technical paper presentation shall be evaluated by at least two examiners.
- Seminar shall be evaluated with appropriate rubrics system.

GL-529: General Lab Experience in the Area of Specialization (6 credits)

1. Analysis of a drug sample by a pharmacopeial method and preparation of its certificate of analysis (CoA).

2.HPLC:

(a) Preparation of Standard and Working solutions and how to construct a calibration curve.

(b) Qualitative analysis of given sample.

(c) Identification and Quantification of given metabolite/standard by HPLC.

3. GC-FID:

(a) Sample preparation, operation and handling of Gas Chromatography (GC-FID).

(b Demonstration on how to change column in a GC & understanding of column chemistry.

(c) Calibration of GC instrument, preparation of standards, working solutions and how to construct a calibration curve in GC.

(d) Use of Head Space for volatile samples / Direct injections for determination of residual solvents.

(e) Qualitative and Quantitative analysis of given sample by GC-FID.

4. Accelerated Stability testing: Stress studies of a drug sample in proposed conditions (viz.acid, base, pH, temperature, photolytic) and establishment of a stability indicating assay method (SIAM) using HPLC

5. Standardization of acid/base reagents al determination of assay using potentiometric auto titrator (Practical to be conducted in Central Instrumentation Laboratory (CIL))

6. Accurate mass measurements by HRMS.

7. Demonstration and analysis of sample using electron microscope such as SEM, TEM, AFM, FE-SEM, PXRD and CLSM.

EL – 525: Programme Electives (2 Credits)

PA-525 (A): Analytical Characterization of Biosimillars (2 credits)

1. Introduction: Concept of innovators biologics, biosimillars, RLDs, handling and storage of RLDs, Biopharma Vs Pharma industry, challenges in development of biologics

2. Biological characterization: Structural and functional characterization of biologics, structure of antibodies, peptides, proteins and relevant analytical techniques to characterize. Post translational modifications.

3. Key Analytical methods: Mass spectrometry (MS) for sequencing and post-translational modifications, size-exclusion chromatography (SEC) for aggregation, and charge-based separation (cIEF/CEX) for variants.

4. Structural characterization: Structural characterization of peptides / proteins from microbial and mammalian cells. Peptide sequence, intact mass, di-sulphide glycan mapping, charge variant analysis, higher order structure, folding & misfolding,

5. Quality control & Impurity: Purity, Impurities, HCP, Host cell DNA, stability study for peptides and proteins, and relevant ICH & FDA requirements

6. Stability studies: Forced Degradation, The Freeze-Thaw Cycle, Simulates Clinical Usage Scenarios, Real-Time Stability / Long-Term Stability

7. Microbial safety control: Endotoxin, microbial limit, sterility testing and container integrity testing.

8. Next generations biologics: Definition, concept and therapeutic utility, design approach and rationale for recent biologics.

Reference books

1. **Chow SC.** Biosimilars: design and analysis of follow-on biologics. Boca Raton (FL): Chapman and Hall/CRC Press; 2014.
2. **Niazi SK.** Biosimilars and interchangeable biologics: strategic elements. Boca Raton (FL): CRC Press; 2019.
3. **Lill JR, Sandoval W, editors.** Analytical characterization of biotherapeutics. Cham: Springer; 2020.
4. **Gutka HJ, Yang H, Kakar S, editors.** Biosimilars: regulatory, clinical, and biopharmaceutical development. Cham: Springer; 2018.

Articles-

1. Berkowitz SA, Engen JR, Mazzeo JR, Jones GB. Analytical tools for characterizing biopharmaceuticals and the implications for biosimilars. Nature reviews Drug discovery. 2012 Jul;11(7):527-40.
2. Nupur N, Joshi S, Gulliarme D, Rathore AS. Analytical similarity assessment of biosimilars: global regulatory landscape, recent studies and major advancements in orthogonal platforms. Frontiers in bioengineering and biotechnology. 2022 Feb 9;10:832059.
3. Millán-Martín S, Jakes C, Carillo S, Bones J. Multi-attribute method (MAM) to assess analytical comparability of adalimumab biosimilars. Journal of Pharmaceutical and Biomedical Analysis. 2023 Sep 20;234:115543.

PA-525 (B): Mass Spectrometry in Omics (2 credits)

1) **Introduction to Omics:**Different types of omics, comparison, different analytical tools used, rationale for selection in efficacy, mechanism and mechanism studies.

2) Application of omics in drug discovery: Omics technologies such as genomics, proteomics, and metabolomics are used to identify disease mechanisms, biomarkers, and novel drug targets. Approaches enable personalized medicine by improving drug efficacy, safety, and patient-specific therapeutic strategies.

3) Protein profiling by mass spectrometry: Mass spectrometry-based proteomics used to identify, characterize, and quantify proteins in complex biological samples through techniques like LC-MS/MS. A key role in biomarker discovery, understanding disease pathways, and identifying potential drug targets.

4) Bottom-up and Top-down approach: Bottom-up approach involves enzymatic digestion of proteins into peptides followed by mass spectrometric analysis for protein identification. The top-down approach analyzes intact proteins directly, enabling detailed characterization of protein isoforms and post-translational modifications.

5) Peptide sequence: Peptide sequencing involves determining the amino acid order in peptides using techniques such as tandem mass spectrometry (MS/MS) and Edman degradation, and importance for protein identification, characterization of modifications, and understanding biological functions.

6) **PTM analysis:** PTM analysis for the identification and characterization of chemical modifications such as phosphorylation, glycosylation, and acetylation in proteins. Modifications regulate protein function, stability, and interactions, and are critical in disease mechanisms and drug discovery.

7) AI based tools in data processing: Artificial intelligence and machine learning tools used to analyze large and complex omics datasets for pattern recognition, prediction, and data interpretation. Approaches enhance accuracy, speed, and decision-making in biomarker discovery and drug development.

8) Metabolomics & Lipidomics: Metabolomics and lipidomics involve the comprehensive analysis of small molecules and lipids in biological systems using techniques like LC-MS and NMR. Approaches help in understanding metabolic pathways, disease mechanisms, and identifying biomarkers for drug discovery and therapeutic monitoring.

Reference books

1. Mass Spectrometry: A Textbook. Gross JH. *Mass spectrometry: a textbook*. 2nd ed. Cham: Springer; 2017**. (in library)**
2. Mass Spectrometry: Principles and Applications. de Hoffmann E, Stroobant V. *Mass spectrometry: principles and applications*. 3rd ed. Chichester: John Wiley & Sons; 2007**. (recommended for purchase)**
3. Mass Spectrometry-Based Metabolomics: A Practical Guide. Dettmer K, Aronov PA, Hammock BD, editors. *Mass spectrometry-based metabolomics: a practical guide*. Hoboken (NJ): Wiley; 2019.
4. Statistical Analysis of Proteomics, Metabolomics and Lipidomics Data. Li S. *Statistical analysis of proteomics, metabolomics, and lipidomics data*. Boca Raton (FL): CRC Press; 2016.
5. Proteomic and Metabolomic Approaches to Biomarker Discovery. Issaq HJ, Veenstra TD, editors. *Proteomic and metabolomic approaches to biomarker discovery*. Burlington (MA): Academic Press; 2013.
6. Mass Spectrometry for Metabolomics. González-Domínguez R. *Mass spectrometry for metabolomics*. Cham: Springer; 2017.

DEPARTMENT OF PHARMACEUTICAL REGULATORY SCIENCES

SEMESTER – I

S. No	Course Code	Course Title	Type	Hrs per week	Credits	Category
1	RS-511	GxP & Pharmaceutical Regulations	T	2	2	PC
2	RS-512	Registration and Regulations for API and Drug Product	T	2	2	PC
3	RS-513	Registration and Regulation of Medical Devices	T	2	2	PC
4	PA-511	Analytical techniques in Pharmaceutical Industry	T	2	2	PC
5	PE-511	Pharmaceutical Pre-formulation I	T	2	2	PC
6	GE-516	Biostatistics and Data Analytics	T	2	2	SD
7	GE-517	Artificial Intelligence and Machine Learning in Pharmaceuticals	T	1	1	IO
8	SM-518	Seminar	TS	1	1	SL
9	GL-519	General Lab Experience	LPS	18-24	6	PC
		Total	--	32-38	20	--

SEMESTER – II

S. No	Course Code	Course Title	Type	Hrs per week	Credits	Category
1	RS-521	Biopharmaceutical Regulatory Affairs	T	2	2	PC
2	RS-522	Skills in Documentation and Regulatory Writing	T	2	2	PC
3	RS-523	Regulation of Cosmetic and Herbal products	T	2	2	PC
4	PA-524	Quality Control and Quality Assurance	T	2	2	PC
5	EL-525	Programme Elective *	T	2	2	PE

6	GE-526	Intellectual Property Rights and Regulatory Affairs in Pharmaceuticals	T	2	2	SD
7	GE-527	Research culture and ethics in Pharmaceutical Industry	T	2	2	IO
8	SM-528	Seminar	TS	1	1	SL
9	GL-529	General Lab Experience	LPS	18-24	6	PC
		Total	--	33-39	21	--

*** EL-525 (Programme Elective):** The scholar should select any one course from the list of courses offered by other departments.

List of Department-wise Programme Electives (EL- 525) – 2 Credits:

(Scholars must select any one elective course from any department other than their own department)

Name of Department	**Course title**	**Credits/ Course**
BT	BT-525 (A): Nanobiotechnology BT-525 (B): Omics in Drug Discovery	2
PA	PA-525 (A): Analytical characterization of Biosimilar PA-525 (B): Mass Spectrometry in Omics PA-523: Stability Testing of Pharmaceuticals & Biologicals	2
RS	RS-522: Skills in Documentation and Regulatory Writing RS-523: Regulation of Cosmetic and Herbal products	2
PE	PE-521: Pharmaceutical Product Development II PE-522: Biopharmaceutics and Pharmacokinetics	2
PP	PP-522: Patient Safety and Health Related Outcomes PP-523: Clinical Research PP-524: Evidence-Based Medicine	2
PT	PC-525 (A): Principles and Methods in Toxicology PC-525 (B): Introduction to Regulatory Toxicology	2

SEMESTER - III

S. No	**Course Code**	**Course Title**	**Type**	**Hrs per week**	**Credits**	**Category**

1	**TH-611**	Synopsis	PW	28	15	PC
2	**TH-612**	Presentation	PW	--	3	PC
3	**EL-613**	Self-learning Courses *	IO	4	2	OE
____	_____	**Total**	**--**	**32**	**20**	**--**

*** EL-613:** Industry/academic-oriented skill courses must be chosen by students. Individual departments must set the SOP for the same.

SEMESTER - IV

S. No	Course Code	Course Title	Type	Hrs per week	Credits	Category
1	**TH-621**	Thesis	PW	30	15	PC
2	**TH-622**	Defence of Thesis	PW	--	5	PC
Total			**--**	**30**	**20**	**--**
Grand Total (I to IV Semesters)					**81**	_____

Semester-I

RS-511: GxP & Pharmaceutical Regulations (2 credits)

1. **Current Good Manufacturing Practices:** Introduction, 5Ps, US cGMP Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical device and IVDs Global Harmonization Task Force (GHTF) Guidance docs, pharmaceutical validation, Schedule M

2 **Good Laboratory Practices:** Introduction, USFDA GLP Regulations (Subpart A to Subpart K), FDA Inspection on GLP compliance, Warning letters, ISO and Quality Council of India (QCI) Standards for clinical and non-clinical laboratory, Good Automated Laboratory Practices, 21CFR part 11 and checklist. Schedule L

3. **Good regulatory practices (GRP):** Stakeholder Engagement, Evidence and Impact Analysis, Transparency and Predictability, International Alignment, Continuous Review and recent update on regulatory filing from WHO and FDA.

4. **ICH Quality guidelines:** Interpretation and understanding of Q1, Q3, Q8, Q9, Q10, Q11, Q12 in regulatory filing.

5. ICH Efficacy & Safety (E & S Series) for Filings: E6 Good Clinical Practice (GCP): Standards for designing, conducting, and reporting clinical trials. E2 Pharmacovigilance: Guidelines for expedited safety reporting and periodic safety update reports.

6.The regulatory filing procedure for medical and pharmaceutical products in India, recent developments and amendments in Central Drugs Standard Control Organization (CDSCO),

Pharmaceutical monographs, Indian pharmacopeia commission and Drugs and Cosmetic Act.

7. **Good clinical Practice (GCP):** Foundation principles as per ICH E6 (R3), recent regulatory amendments, Clinical trail regulation in India. Clinical data for eCTD and data integrity including ALCOA+, CDISC submission standards, FDA 21CFR Part 11, comprehensive safety and reconciliations.

Suggested reading:

1. Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth Edition Drugs and the Pharmaceutical Sciences, Vol.168
2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press
3. Establishing a cGMP Laboratory Audit System, A practical Guide by David M.Bleisner, Wiley Publication.
4. How to practice GLP by PP Sharma, Vandana Publications.
5. Laboratory Auditing for Quality and Regulatory compliance bu Donald C.Singer, Drugs and the Pharmaceutical Sciences, Vol.150.
6. Drugs & Cosmetics Act, Rules & Amendments

RS-512: Registration and Regulations for API and Drug Product (2 credits)

1. Evolution and history of Regulatory Affairs, Organizational structure and functions of FDA and EMA. Regulatory framework of ROW countries Code of Federal Regulations; Federal, Food, Drug and Cosmetic Act (FFDCA), Manufacturing, packaging, and labelling requirements for drug products.

2. Regulatory requirements for the approval and registration of API (including orphan drugs) and their products (single as well as fixed dose combinations), and novel formulations/therapies; Registration of generic drugs (including their BA-BE assessments)

3. Drug master profile: Different type and format requirement for DMF for different countries. US DMF, EU ADMF, CMC, LOA, Types of DMF as per FDA. Detailed format understanding of Type I, II, III, IV, V format of DMF.

4. ICH Multidisciplinary guidelines: Common Technical Document (M4 / eCTD): Module 1**:** Administrative information specific to each country or area. Module 2**:** Common summaries of quality, non-clinical, and clinical data. Module 3**:** Quality data regarding chemical and biological drug substances. Module 4**:** Non-clinical study and toxicological reports. Module 5: Clinical study reports and trial data.

5. Drug substances and drug product specification: ICH Q6A and 6B guidelines. ICH Q11 for technical requirement for API manufacturing. Marketing authorization procedure and mutual recognition procedure.

6. ANDA and NDA filing, Type of changes during and after filing, Variation in EU, post approval changes at ICH countries. Regulatory considerations for manufacturing, packaging, distribution and labelling of pharmaceuticals. Liaison between the industry and regulatory agencies.

7. Case studies on Dossier preparation and compliance handlings

Suggested reading:

1. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry and Robert P. Martin
2. Guidebook for drug regulatory submissions by Sandy Weinberg, John Wiley & Sons
3. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance by Fay A. Rozovsky and Rodney K. Adams
4. Preparation and maintenance of the IND application in eCTD Format by William K. Sietsema
5. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Second edition by Douglas J. Pisano and David S. Mantus
6. Biological Drug Products: Development and Strategies; Wei Wang and Manmohan Singh; By Wiley, 2013
7. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization by the Department of Biotechnology, CDSCO, Ministry of Health and Family Welfare, Govt. of India
8. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices, Second Edition by John J. Tobin and Gary Walsh
9. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics by Carmen
10. Quality System Information - Guidance documents released by regulatory agencies
11. Leachables and Extractables Handbook: Safety Evaluation, Qualification, and Best Practices Applied to Inhalation Drug Products, Douglas J. Ball, Daniel L. Norwood, Cheryl L. M. Stults and Lee M. Nagao
12. Scientific journals
13. Drugs & Cosmetics Act, Rules & Amendments
14. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
15. New Drug Approval Process: Accelerating Global Registrations by Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.

RS-513: Registration and Regulation of Medical Devices (2 credits)

Unit 1 — Introduction, Classification & Quality Management Systems (2 h) Healthcare technology ecosystem and stakeholders; definition of a medical device and IVD; intended use vs. indications for use; distinction from drugs, biologics, combination and borderline products; device categories (non-active, active, implantable, IVD, SaMD, wearable). Risk-based classification under the Medical Device Rules, 2017 (Classes A–D), US FDA (Class I–III) and EU MDR/IVDR. QMS principles and ISO 13485 structure; documentation hierarchy (Quality Manual, SOPs, Medical Device File, DMR, DHR); CAPA, internal/supplier audit, management review; QA/QC/RS roles; standards ecosystem (ISO, IEC, BIS, IMDRF, MDSAP).
Unit 2 — Design Controls, Systems Engineering & Requirements Management (2.5 h) Design and development process (ISO 13485 Cl. 7.3); stage-gate model; systems engineering, architecture, functional decomposition and interface control documents; requirements engineering — user needs, functional/non-functional/regulatory requirements, prioritisation and traceability using ALM tools (IBM DOORS, Jama). Design inputs and outputs; formal design reviews; bidirectional design traceability matrix; DHF, DMR, DHR and Technical File; design transfer, engineering change and configuration management (DFM/DFA/DFR).
Unit 3 — Risk Management, Human Factors, Verification & Validation (3 h) ISO 14971 and ISO/TR 24971 risk process; hazard identification, FMEA/DFMEA/PFMEA, FTA, HAZOP; risk evaluation, the control hierarchy, residual and benefit-risk analysis; human factors and usability engineering (IEC 62366-1), formative/summative studies; reliability engineering (MTBF, life testing); cybersecurity risk (STRIDE/DREAD). Verification vs. validation, the V-model and

statistical rationale; IQ/OQ/PQ and process validation; electrical safety and EMC (IEC 60601 series); biocompatibility (ISO 10993); sterilization and packaging validation (ISO 11135/11137/17665/11607); software V&V (IEC 62304).

Unit 4 — Device Technologies, Software, Digital Health & Cybersecurity (2.5 h) Non-active, active and implantable devices and biomaterials; IVD technologies (clinical chemistry, immunoassay, molecular, point-of-care); electronics, sensors and biomedical signal processing (ECG/EEG/PPG); imaging modalities (X-ray, CT, MRI, ultrasound); robotics, 3D-printed and combination products. Software lifecycle in a regulated environment and IEC 62304 safety classification; SaMD/SiMD and the IMDRF framework; AI/ML lifecycle, dataset governance, PCCP and GMLP; connectivity and interoperability (HL7, FHIR, DICOM); cloud, mobile and digital health; cybersecurity (threat modelling, SBOM); data privacy (HIPAA, GDPR, DPDP Act).

Unit 5 — Manufacturing Engineering & Product Realization (2.0 h) Product realisation and design transfer; manufacturing processes (machining, moulding, cleanroom assembly, PCB, additive manufacturing); supplier selection, qualification and criticality-based incoming inspection; production and process controls (SPC, Cp/Cpk, MSA, DOE); equipment qualification and process validation; sterilization and contamination control; packaging, labelling, UDI and traceability (DMR/DHR); lean, Six Sigma and continuous improvement.

Unit 6 — Regulatory Affairs, Market Authorization & Technical Documentation (2.5 h) Regulatory strategy and intelligence. India — MDR 2017, CDSCO, manufacturing/import licences (MD-3/5/9, MD-14/15), Device and Plant Master Files, Essential Principles. US FDA — 510(k), De Novo, PMA, IDE, QMSR/21 CFR 820, UDI. EU MDR/IVDR — GSPR, conformity assessment, notified bodies, CE marking, EUDAMED, PRRC; other markets (Health Canada, TGA, MHRA, PMDA, NMPA) and IMDRF/MDSAP harmonisation. Technical documentation — STED and IMDRF ToC, Essential Principles/GSPR checklists, Declaration of Conformity, IFU and labelling (ISO 15223-1), dossier assembly and deficiency responses.

Unit 7 — Clinical Affairs, Post-Market Surveillance & Lifecycle Management (1.5 h) Clinical evaluation (CEP/CER, MEDDEV 2.7/1 Rev. 4), equivalence and literature appraisal; clinical investigation (ISO 14155, GCP, Declaration of Helsinki); IVD analytical and clinical performance (CLSI EP series, sensitivity/specificity, ROC); biostatistics (Bland-Altman, Passing-Bablok). Post-market surveillance (PMS plan/report, PSUR); vigilance and materiovigilance (MvPI, US FDA MDR, EU vigilance); complaint handling and root-cause analysis (5-Why, fishbone, 8D); CAPA; field safety corrective actions and recalls; obsolescence and lifecycle management.

Suggested reading:

1. Medical Device Regulations: Global overview and guiding principles, World Health Organization.
2. Indian regulations on registration of medical devices.
3. ISO 13485, ISO 14971, IEC 62366-1, IEC 62304, ISO 10993, ISO 11607, ISO 14155
4. Medical Device Rules, 2017 (India) & CDSCO guidance
5. US FDA 21 CFR 800–898 / QMSR; EU MDR 2017/745 & IVDR 2017/746; IMDRF, MDCG & MDSAP guidance.
6. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics by Carmen
7. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP)

PA-511: Analytical Techniques in Pharmaceutical Industry (2 credits)

1. Introduction to pharmaceutical analysis and techniques: Scope and range of modern pharmaceutical analysis as per monograph. Listing of various techniques, with broad

discussion on their applications with respect to monograph analysis.

2. Reference standards: Types (primary, secondary, working and test standards), preparation, containers, labelling and storage. Special precaution on handling of biological standards including peptides, proteins and enzyme. Concept of re-test period, CRM, COA, expiry date, batch number, Five batch analysis.

3. Raw material and product specifications: Definition of specifications, study of ICH Q6 guidelines and understanding of specifications through study of pharmacopoeial monographs on drug substances and products

4. Analytical techniques used in biological product characterization: structure of peptides, protein, antibody, siRNA, ADC. Analytical methods used in structural characterization of peptide, proteins and antibodies.

5. Physical tests: Viscosity, melting point, boiling point/range, water content and water analysis including Karl Fischer titration, loss on drying, loss on ignition, iodine value, peroxide value, acid value, optical rotation, pH, specific gravity, osmolality/osmolarity, refractive index, MVTR, etc.

6. Microbiological tests and assays: Antimicrobial (preservative) effectiveness testing, microbial limit tests, sterility test, vitamins assay (zone of exhibition), antibiotics assays, bacterial endotoxin test.

7.Testing of packaging materials: Instruments used, extractable and leachable, polymer characterization, polymer leaching in products, adduct impurity.

8. Calibration and qualification of equipment: Difference of definitions, calibration standards, calibration frequency. Calibration of pH meter, weighing balance, FTIR, UV spectrophotometer, GC and HPLC, Fluorimeter, DSC, DLS.

9. Automation and computer-aided analysis: The concept of auto samplers and high-throughput analysis, computer-controlled instrumentation, and networked laboratory. Peculiarities of laboratory information management systems (LIMS), In silico impurity profiling, and genotoxicity prediction.

Reference books:

1. Watson DG. *Pharmaceutical analysis*. 3rd ed. Edinburgh: Elsevier; 2012.
2. World Health Organization. *Quality assurance of pharmaceuticals: A compendium of guidelines and related materials*. Vol. 1–2. Geneva: WHO Press; 2013.
3. Adejare A, editor. *Remington: The science and practice of pharmacy*. 23rd ed. London: Academic Press; 2020.
4. Ermer J, Miller JHM, editors. *Method validation in pharmaceutical analysis: A guide to best practice*. Weinheim: Wiley-VCH; 2005.
5. Skoog DA, West DM, Holler FJ, Crouch SR. *Fundamentals of analytical chemistry*. 9th ed. Belmont (CA): Brooks/Cole; 2014**.**
6. Ahuja S, Scypinski S, editors. *Handbook of modern pharmaceutical analysis*. San Diego: Academic Press; 2001.

PE-511: Pharmaceutical Preformulation – I (2 credits)

Unit 1: Introduction to Preformulation (4 Hours)

- Definition, objectives, and scope of preformulation
- Role in drug discovery and development
- Preformulation workflow and documentation
- Fundamental vs derived properties
- Material-sparing approaches in early development: Miniaturised experimental techniques, High-throughput screening (HTS), In silico prediction tools, use of sensitive analytical techniques, microfluidics (emerging approach)

Unit 2: Physicochemical Properties of Drug Substances (6 Hours)

- Solubility and dissolution behavior
- pKa, partition coefficient (log P/log D)
- Melting point and thermal behavior
- Hygroscopicity
- Stability (physical and chemical)
- Biopharmaceutics Classification System (BCS)
- Drugability assessment of new chemical entities (NCEs)

Unit 3: Solid-State Characterization (5 Hours)

- Polymorphism and crystal engineering
- Amorphous and metastable forms
- Co-crystals and solvates
- Solid-state stability
- Advanced tools overview and applications: DSC, XRD, FTIR, etc.

Unit 4: Preformulation of Biologics (Proteins & Peptides) (4 Hours)

- Unique challenges in biologics
- Stability issues (aggregation, denaturation)
- Formulation considerations
- Basic analytical characterization

Unit 5: Solubility and Solubilization Techniques (5 Hours)

- Solubility of non-electrolytes
- Surfactant-based solubilization
- Co-solvency techniques
- Complexation and inclusion complexes
- Solid-state modifications (amorphous systems)
- Lipid-based solubilization systems (SMEDS and SNEDS including classification, selection of surfactants, cosurfactants and solubilizers including manufacturing and regulatory considerations)
- Supersaturation and precipitation/crystallization inhibitors

Unit 6: Salt Selection and Optimization (4 Hours)

- Importance of salt formation
- pKa concept and salt selection rules
- Counter-ion selection
- Decision tree approach
- Comparison with co-crystals and non-salt forms

Unit 7: Preformulation in Drug Development & Modern Approaches (4 Hours)

- Preformulation support in formulation development
- Identification of developmental challenges
- Dosage form-specific preformulation
- In silico preformulation (property prediction tools)
- High-throughput screening methods (PAMPA, cell lines, 2-D and 3-D cell cultures)
- Early developability assessments such as cytotoxicity, genotoxicity, teratogenicity, immunogenicity, QT wave prolongation, hepatotoxicity, renal toxicity, in vitro efficacy with in silico techniques

References

1. Gibson, Mark. *Pharmaceutical Preformulation and Formulation: A Practical Guide from Candidate Drug Selection to Commercial Dosage Form*. 2nd ed. Boca Raton: CRC Press, 2009.
2. Aulton, Michael E., and Kevin M. G. Taylor. *Aulton's Pharmaceutics: The Design and Manufacture of Medicines*. 5th ed. London: Elsevier, 2018.

3. Leon Lachman, Herbert A. Lieberman, and Joseph L. Kanig. *The Theory and Practice of Industrial Pharmacy*. 3rd ed. Mumbai: Varghese Publishing House, 1987.
4. Florence, A. T., and David Attwood. *Physicochemical Principles of Pharmacy*. 6th ed. London: Pharmaceutical Press, 2016.
5. Martin, Alfred, Pilar Bustamante, and A. H. C. Chun. *Physical Pharmacy: Physical Chemical Principles in the Pharmaceutical Sciences*. 4th ed. Philadelphia: Lippincott Williams & Wilkins, 1993.
6. Brittain, Harry G., ed. *Preformulation in Solid Dosage Form Development*. New York: Informa Healthcare, 2007.
7. Waterbeemd, Han van de, and Erik Gifford. *ADMET in Silico Modelling: Towards Prediction Paradise?* London: Imperial College Press, 2003.
8. Di, Li, and Edward H. Kerns. *Drug-Like Properties: Concepts, Structure Design and Methods*. 2nd ed. Amsterdam: Elsevier, 2015.
9. Brittain, Harry G., ed. *Polymorphism in Pharmaceutical Solids*. 2nd ed. New York: Informa Healthcare, 2009.
10. Byrn, Stephen, Ralph Pfeiffer, and Michael Stowell. *Solid-State Chemistry of Drugs*. 2nd ed. West Lafayette: SSCI Inc., 1999.
11. Hancock, Bruno C., and George Zografi. "Characteristics and Significance of the Amorphous State in Pharmaceutical Systems." *Journal of Pharmaceutical Sciences* 86, no. 1 (1997): 1–12.
12. John Carpenter and Mark C. Manning, eds. *Rational Design of Stable Protein Formulations: Theory and Practice*. New York: Springer, 2002.
13. Jiskoot, Wim, Daniel J. A. Crommelin, eds. *Methods for Structural Analysis of Protein Pharmaceuticals*. Arlington: AAPS Press, 2005.
14. Yalkowsky, Samuel H. *Solubility and Solubilization in Aqueous Media*. 2nd ed. Oxford: Oxford University Press, 2010.
15. Stella, Valentino J., and Ronald T. Borchardt. *Pharmaceutical Profiling in Drug Discovery for Lead Selection*. New York: AAPS Press, 2006.
16. Stahl, Peter H., and Camille G. Wermuth, eds. *Handbook of Pharmaceutical Salts: Properties, Selection, and Use*. Weinheim: Wiley-VCH, 2002.
17. Aakeröy, Christer B., and David J. Salmon. "Building Co-crystals with Molecular Sense and Supramolecular Sensibility." *Crystal Engineering Communications* 7 (2005): 439–448.
18. Swarbrick, James, ed. *Encyclopedia of Pharmaceutical Technology*. 4th ed. New York: Informa Healthcare, 2013.
19. Troy, David B., ed. *Remington: The Science and Practice of Pharmacy*. 22nd ed. London: Pharmaceutical Press, 2012.
20. International Council for Harmonisation. *ICH Harmonised Guideline Q1A(R2): Stability Testing of New Drug Substances and Products*. Geneva: ICH, 2003.
21. International Council for Harmonisation. *ICH Harmonised Guideline Q6A: Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and Products*. Geneva: ICH, 1999.
22. US Food and Drug Administration. *Guidance for Industry: INDs for Phase 2 and 3 Studies—Chemistry, Manufacturing, and Controls Information*. Silver Spring, MD: FDA, 2003.

23. Lipinski, Christopher A. "Lead- and Drug-Like Compounds: The Rule-of-Five Revolution." *Drug Discovery Today: Technologies* 1, no. 4 (2004): 337–341.
24. Kerns, Edward H., and Li Di. *Drug-Like Properties: Concepts, Structure Design and Methods*. Amsterdam: Elsevier, 2008.

GE-516: Biostatistics and Data Analytics (2 credits)

Refer to Postgraduate-Common Courses syllabus

GE-517: Artificial Intelligence, Machine Learning in Pharmaceuticals (1 credit)

Refer to Postgraduate-Common Courses syllabus

SM-518: Seminar (1 credit)

Course objectives: This course aims to equip the students on self-learning and presentation skills in their area of interest relevant to pharmaceutical industry.
Course outcome: After completion the course, students shall able to

- Demonstrate the skills in literature search and technical paper reading and understanding.
- Present the scientific content in as power point presentation
- Develop their skills in teaching and scientific delivery in a research forum.

Contents/Description

- There shall be two seminars one from the academic syllabi and from the technical papers (published research papers) in the area of the student research interest.
- Technical paper presentation shall be evaluated by at least two examiners.
- Seminar shall be evaluated with appropriate rubrics system.

GL-519: General Lab Experience (6 credits)

1. Preparation of SOPs.
2. Case studies of Good Pharmaceutical Practices
3. Protocol preparation for documentation of various types of records (BMR, MFR, DR)
4. Labeling comparison between brand & generics.
5. Preparation of clinical trial protocol for registering trial in India
6. Registration for conducting BA/ BE studies in India
7. Import of drugs for research and developmental activities
8. Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM
9. GMP Audit Requirements as per CDSCO
10. Preparation of checklist for registration of NDA as per ICH CTD format.
11. Preparation of checklist for registration of ANDA as per ICH CTD format.
12. Case studies on response with scientific rationale to USFDA Warning Letter
13. Comparison study of marketing authorization procedures in EU.
14. Preparation of DMF and Review for different countries for API, intermediate and products
15. Preparation of Clinical Trial Application (CTA) for US submission

16. Preparation of Clinical Trial Application (CTA) for EU submission
17. Risk analysis per ISO 14971. Risk Management Plan, hazard analysis (normal & fault), Design FMEA and Fault Tree Analysis.
18. Medical Device and IVD classification and regulatory-pathway determination. For a selected device under CDSCO (Medical Device Rules, 2017, Classes A–D), US FDA (I–III) and EU MDR/IVDR.
19. Audit Checklist for Medical Device Facility
20. Clinical Investigation Plan for Medical Devices

Semester - II

RS-521: Biopharmaceutical Regulatory Affairs (2 credits)

1. Introduction to Biosimilars, FDA and CDSCO regulations, CDER process, key differences between regulatory filing of Biosimilars and pharmaceuticals.
2. ICH Guidelines on Biotechnological products (Q5A to Q5D and Q6B, Validation aspects of enzyme and ligand binding assays for antibodies. Stability requirements (Q5C, and Q5E)
3. Introduction to biologics and biosimilars, different biologic products, difference between biologic and small molecular drugs/products. Bio-similarity assessment Laws, regulations, and guidelines for the development of biosimilar/biologic and approval of biologics and biosimilars (IND, PMA, BLA, NDA).
4. Pre-clinical and clinical development Principles for the development, ICHQ6 guidelines, manufacturing, distribution, commercialization of biologics in USA, EU and India; Post-marketing surveillance and pharmacovigilance on biologics, Case studies.
5. Biosimilar Development Strategy: Dedicated module on the Totality-of-Evidence approach, analytical/PK-PD/clinical similarity exercise, extrapolation of indications, and US-specific interchangeability designation. This complements the existing Analytical characterization of Biosimilars elective with the regulatory strategy side
6. Regulatory Intelligence & eCTD Publishing Tools: Over view of industry-standard submission/publishing platforms (e.g., Lorenz docuBridge, ISI toolbox, Veeva Vault RIM) rather than only conceptual eCTD/NeeS coverage. Case studies on peptide and antibody filing to USFDA and CDSCO.
7. Expedited & Special Regulatory Pathways: Breakthrough Therapy, Accelerated Approval, Conditional Marketing Authorisation (EMA), PRIME and India's accelerated approval provisions – increasingly relevant given the rise of biologics. Eg. Cancer therapy and vaccine approval during COVID-19 pandemics.

Suggested reading:

1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
2. International Pharmaceutical Product Registration: Aspects of Quality, Safety and efficacy; Anthony C. Cartwright; Taylor & Francis Inc., USA.
3. New Drug Approval Process: The Global Challenge; Guarino, Richard A; Marcel Dekker Inc., NY.
4. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics;

Douglas J. Pisano, David Mantus; CRC Press, USA
5. EU Clinical Research Directive 2001: http://www.eortc.be/services/doc/clinical-udirective-04-april-01.pdf
6. Code of Federal Regulations, FDA: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
7. Guidelines of International Conference on Harmonization: http://www.ich.org/products/guidelines.html
8. Eudralex Guidelines: http://www.gmpcompliance.info/euguide.htm
9. Medicines and Healthcare products Regulatory Agency: http://www.mhra.gov.uk
10. Central Drugs Standard Control Organization Guidance for Industry: http://cdsco.nic.in/CDSCO-GuidanceForIndustry.pdf
11. ICMR Ethical Guidelines for Biomedical Research: http://icmr.nic.in/ethical_guidelines.pdf

RS-522: Skills in Documentation and Regulatory Writing (2 credits)

1. **Documentation in pharmaceutical industry:** Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF).

2. **Dossier preparation and submission:** Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions; Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non eCTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission. Submission in Sugam system of CDSCO.

3. **Audits:** Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document. ISO 13485.

4. **Inspections:** Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA).

5. **Product life cycle management:** Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Effected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard

Suggested reading:

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-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
5. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
6. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
7. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
8. Corporate Culture and the Quality Organization By James W. Fairfield- Sonn, Quorum Books, 2001
9. The Quality Management Sourcebook: An International Guide to Materials and Resources by Christine Avery; Diane Zabel, Routledge, 1997
10. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
11. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph
A. De Feo, ASQ Publications
12. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications

RS-523: Regulation of Cosmetic and Herbal Products (2 credits)

1. **Cosmetics:** Definitions, Classification & Global Regulatory Frameworks, Definition of a cosmetic; distinction from drugs and “cosmeceuticals”; borderline products. India — Drugs and Cosmetics Act and the Cosmetics Rules, 2020; CDSCO registration of imported cosmetics (Form COS-1/COS-2 and registration certificate), manufacturing and import provisions, labelling requirements and applicable BIS standards.
2. **Global frameworks:** EU Cosmetics Regulation (EC) No 1223/2009 (Responsible Person, CPNP notification, Annexes II–VI covering prohibited/restricted substances, colorants, preservatives and UV filters); US FDA under the FD&C Act and MoCRA 2022 (facility registration, product listing, adverse-event reporting); the ASEAN Cosmetic Directive and other markets. Ingredient regulation, INCI nomenclature, nanomaterials, and prohibited/restricted substance lists.
3. **Cosmetics:** Quality, Safety Assessment, Manufacturing & Post-Market (2.0 h) Cosmetic Good Manufacturing Practice (ISO 22716) — premises, equipment, personnel, production, quality control and subcontracting.
4. **Safety Assessment:** The Product Information File (PIF), the Cosmetic Product Safety Report (CPSR Parts A and B), the qualified safety assessor, toxicological profile, exposure assessment and Margin of Safety; alternatives to animal testing and the EU testing/marketing ban.
5. **Stability and compatibility testing:** preservative-efficacy (challenge) testing and microbiological quality; packaging compatibility. Claims substantiation and efficacy testing; labelling and shelf life (period-after-opening symbol). Cosmetovigilance — reporting of serious undesirable effects, post-market surveillance, complaint handling and recalls.
6. **Herbal products approvals:** Schedule T of Drug and Cosmettics Act, Product classification, Manufacturing, Quality control, standardizations, efficacy data, labelling, claims, stability and filing procedure. EMEA guidelines for herbal products.

7. **Nutraceutical approvals:** FSS Act 2006, Approval procedure for nutraceuticals, key requirements for nutraceutical filings; DSHEA approval at US, EFSA approval at Europe.

8. **Regulatory filing:** Product list, ingredients compliance, RDA limits, positive list, qualitative and quantitative compositions, manufacturing, QC, CoA, safety, efficacy, stability data, labelling and claims (mandatory disclosure, permission claims, statutory warning), administrative and legal documentation.

Suggested reading:

1. Harry's Cosmeticology. 8th edition.
2. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
3. Cosmetics- Formulation, Manufacture and quality control, P P. Sharma,4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3rdedition
5. Cosmetics: Cosmetics Rules, 2020 (India)
6. EU Cosmetics Regulation (EC) No 1223/2009
7. US FD&C Act & MoCRA 2022
8. ISO 22716 (Cosmetic GMP)
9. ASEAN Cosmetic Directive.
10. Drugs & Cosmetics Act, Rules & Amendments
11. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar
12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition

PA-524: Quality Control and Quality Assurance (2 credits)

1. Basic principles and Concepts: Quality Control (QC), Quality Assurance (QA), Total Quality Management (TQM), International Organization for Standardization (ISO system), Electronic quality management system (eQMS).
2. Format & documents: SOP, format, controlled documents, DCO, study plan, study reports, amendments,
3. Good documentation Practice: Writing and documentation-of SOP (ALCOA +), STPs, certificate of analysis, laboratory books: Typical documents used in a GLP laboratory including standard test protocols, COA and laboratory notebooks. Electronic records & signatures (21CFR Part-11 requirement). Three tier documentation, policy, procedures, work instructions, formats and records.
4. Basic principles on how to prepare, maintain, review, approval, issuance, storage, retrieval, Master Formula Record (MFR), Drug Master File (DMF), distribution records, packaging records, site master file and electronic document management system (e-DMS).
5. **Qualification of instruments:** Concept of Group A, B and C equipments. Difference between calibration, qualification and validation. Definition of qualification process involving URS [user requirement specification), DQ, IQ, OQ, CQ and PQ. Concept of computer system validation. 21CFR part 11 in analytical equipments.
6. **Qualification of facility and utilities:** Concepts, process, documentation of facility validation, Revalidation Criteria, USFDA guidelines on Process Validation. Qualification of HVAC, Pharmaceutical Water system and pure steam. Validation of Utility systems and facilities in sterile and non-sterile plants.

7. **Cleaning Validation:** Cleaning Method Development, basic requirements of cleaning and its validation. Cleaning of equipments, cleaning of facilities and Cleaning in Place (CIP).
8. **Quality Systems:** Handling of deviations, retesting, OOS and OTT test results. Quality Audit Plans, Non-Conformity (NC) and their reports. Complaints: Evaluation and handling of market complaints, Corrective & Preventive Actions (CAPA), returns and recalls.
9. **Laboratory inspections and audit**: Internal inspection, external audit, concepts, preparing for inspections and audits, study based- facility based- and critical phase inspections.

Suggested reading:

1. Sharp J. Good pharmaceutical manufacturing practice: rationale and compliance. Boca Raton: CRC Press; 2005.
2. Bunn G. Good manufacturing practices for pharmaceuticals. 7th ed. Boca Raton: CRC Press; 2017
3. World Health Organization. Quality assurance of pharmaceuticals: a compendium of guidelines and related materials. Vol. 1. Geneva: World Health Organization; 2007.
4. World Health Organization. Quality assurance of pharmaceuticals: a compendium of guidelines and related materials. Vol. 2. Geneva: World Health Organization; 2007.
5. Shah DH. QA manual. Mumbai: Business Horizons; 2000.
6. World Health Organization. WHO expert committee on specifications for pharmaceutical preparations: technical report series. Geneva: World Health Organization.
7. Shenoy P. Handbook of pharmaceutical quality assurance. New Delhi: CBS Publishers & Distributors; 2010.

GE-526: Intellectual Property Rights and Regulatory Affairs in Pharmaceuticals (2 credits)

Refer to Postgraduate-Common Courses syllabus

GE-527: Research Culture and Ethics in the Pharmaceutical Industry (2 credits)

Refer to Postgraduate-Common Courses syllabus

SM-528: Seminar (1 credits)

Course objectives: This course aims to equip the students on self-learning and presentation skills in their area of interest relevant to pharmaceutical industry.
Course outcome: After completion the course, students shall able to

- Demonstrate the skills in literature search and technical paper reading and understanding.
- Present the scientific content in as power point presentation
- Develop their skills in teaching and scientific delivery in a research forum.

Contents/Description

- There shall be two seminars one from the academic syllabi and from the technical papers (published research papers) in the area of the student research interest.
- Technical paper presentation shall be evaluated by atleast two examiners.
- Seminar shall be evaluated with appropriate rubrics system.

GL-529: General Lab Experience (6 credits)

1. Case studies on Change Management/ Change control Deviations

2. Corrective & Preventive Actions (CAPA)
3. Documentation of raw materials analysis as per official monographs
4. Preparation of audit checklist for various agencies
5. Preparation of submission to FDA using eCTD software
6. Preparation of submission to EMA using eCTD software
7. Report writing on recent FDA warning / compliance handling
8. Preparation of Biologics License Applications (BLA)
9. Comparison of clinical trial application requirements of US, EU and India of Biologics
10. Registration requirement comparison study in emerging markets (WHO) and preparing check list for market authorization
11. Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization
12. Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization
13. Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization
14. Checklist for CE marking for various classes of devices for EU
15. Cosmetic classification and pathway comparison. India (Cosmetics Rules, 2020; CDSCO import registration Form COS-1/COS-2), EU 1223/2009 (CPNP, Responsible Person) and US MoCRA 2022.
16.Cosmetic label and claims review. INCI ingredient listing; prohibited/restricted substances (EU Annexes II–VI)
17. Claims substantiation; PAO / shelf-life.
18. Cosmetic safety assessment (CPSR), Product Information File (PIF)
19. Cosmetic Product Safety Report (Parts A & B); stability studies and preservative-efficacy interpretation; Margin-of-Safety calculation.
20. Cosmetic GMP and cosmetovigilance. ISO 22716 GMP audit checklist; preservative-efficacy (challenge) test protocol; serious-undesirable-effects / adverse-event reporting procedure.

EL-525: Programme Electives (2 Credits)

RS-522: Skills in Documentation and Regulatory Writing

Refer to the Department of Pharmaceutical Regulatory Sciences syllabus

RS-523: Regulation of Cosmetic and Herbal products

Refer to the Department of Pharmaceutical Regulatory Sciences syllabus

DEPARTMENT OF PHARMACEUTICS

SEMESTER - I

S. No	Course Code	Course Title	Type	Hrs per week	Credits	Category
1	**PE-511**	Pharmaceutical Preformulation-I	T	2	2	PC
2	**PE-512**	Pharmaceutical Product Development-I	T	2	2	PC
3	**PE-513**	Pharmaceutical Preformulation II	T	2	2	PC
4	**PE -514**	Solid State Pharmaceutics	T	2	2	PC
5	**PA -512**	Spectroscopy for Structure Elucidation	T	2	2	PC
6	**GE-516**	Biostatistics and Data Analytics	T	2	2	SD
7	**GE-517**	Artificial Intelligence and Machine Learning in Pharmaceuticals	T	1	1	IO
8	**SM-518**	Seminar	TS	1	1	SL
9	**GL-519**	General Lab Experience	LPS	18-24	6	PC
Total			**--**	**32-38**	**20**	**--**

SEMESTER – II

S. No	Course Code	Course Title	Type	Hrs per week	Credits	Category
1	**PE -521**	Pharmaceutical Product Development II	T	2	2	PC
2	**PE -522**	Biopharmaceutics and Pharmacokinetics	T	2	2	PC
3	**PE -523**	Drug Delivery I (Controlled Drug Delivery)	T	2	2	PC
4	**PE -524**	Drug Delivery II (Targeted Drug Delivery and Novel Carrier Systems)	T	2	2	PC
5	**EL -525**	Programme Elective *	T	2	2	PE

6	**GE-526**	Intellectual Property Rights and Regulatory Affairs in Pharmaceuticals	T	2	2	SD
7	**GE-527**	Research Culture and Ethics in the Pharmaceutical Industry	T	2	2	IO
8	**SM-528**	Seminar	TS	1	1	SL
9	**GL-529**	General Lab Experience in the Area of Specialization	LPS	18-24	6	PC
Total			**--**	**33-39**	**21**	**--**

*** EL-525 (Programme Elective):** The scholar should select any one course from the list of courses offered by other departments.

List of Department-wise Programme Electives (EL- 525) – 2 Credits:

(Scholars must select any one elective course from any department other than their own department)

Name of Department	**Course title**	**Credits/ Course**
BT	BT-525 (A): Nanobiotechnology BT-525 (B): Omics in Drug Discovery	2
PA	PA-525 (A): Analytical characterization of Biosimillars PA-525 (B): Mass spectrometry in Omics	2
PE	PE-521: Pharmaceutical Product Development II PE-522: Biopharmaceutics and Pharmacokinetics	2
PP	PP-522: Patient Safety and Health Related Outcomes PP-523: Clinical Research PP-524: Evidence-Based Medicine	2
PT	PC-525 (A): Principles and Methods in Toxicology PC-525 (B): Introduction to Regulatory Toxicology	2

SEMESTER - III

S. No	**Course Code**	**Course Title**	**Type**	**Hrs per week**	**Credits**	**Category**
1	**TH-611**	Synopsis	PW	28	15	PC

2	**TH-612**	Presentation	PW	--	3	PC
3	**EL-613**	Self-learning Courses *	IO	4	2	OE
		Total	**--**	**32**	**20**	**--**

*** EL-613:** Industry/academic-oriented skill courses must be chosen by students. Individual departments must set the SOP for the same.

SEMESTER - IV

S. No	Course Code	Course Title	Type	Hrs per week	Credits	Category
1	**TH-621**	Thesis	PW	30	15	PC
2	**TH-622**	Defence of Thesis	PW	--	5	PC
Total			**--**	**30**	**20**	**--**
Grand Total (I to IV Semesters)					**81**	

Semester - I

PE-511: Pharmaceutical Preformulation – I (2 credits)

Unit 1: Introduction to Preformulation (4 Hours)

- Definition, objectives, and scope of preformulation
- Role in drug discovery and development
- Preformulation workflow and documentation
- Fundamental vs derived properties
- Material-sparing approaches in early development: Miniaturised experimental techniques, High-throughput screening (HTS), In silico prediction tools, use of sensitive analytical techniques, microfluidics (emerging approach)

Unit 2: Physicochemical Properties of Drug Substances (6 Hours)

- Solubility and dissolution behavior
- pKa, partition coefficient (log P/log D)
- Melting point and thermal behavior
- Hygroscopicity
- Stability (physical and chemical)
- Biopharmaceutics Classification System (BCS)
- Drugability assessment of new chemical entities (NCEs)

Unit 3: Solid-State Characterization (5 Hours)

- Polymorphism and crystal engineering
- Amorphous and metastable forms

- Co-crystals and solvates
- Solid-state stability
- Advanced tools overview and applications: DSC, XRD, FTIR, etc.

Unit 4: Preformulation of Biologics (Proteins & Peptides) (4 Hours)

- Unique challenges in biologics
- Stability issues (aggregation, denaturation)
- Formulation considerations
- Basic analytical characterization

Unit 5: Solubility and Solubilization Techniques (5 Hours)

- Solubility of non-electrolytes
- Surfactant-based solubilization
- Co-solvency techniques
- Complexation and inclusion complexes
- Solid-state modifications (amorphous systems)
- Lipid-based solubilization systems (SMEDS and SNEDS including classification, selection of surfactants, cosurfactants and solubilizers including manufacturing and regulatory considerations)
- Supersaturation and precipitation/crystallization inhibitors

Unit 6: Salt Selection and Optimization (4 Hours)

- Importance of salt formation
- pKa concept and salt selection rules
- Counter-ion selection
- Decision tree approach
- Comparison with co-crystals and non-salt forms

Unit 7: Preformulation in Drug Development & Modern Approaches (4 Hours)

- Preformulation support in formulation development
- Identification of developmental challenges
- Dosage form-specific preformulation
- In silico preformulation (property prediction tools)
- High-throughput screening methods (PAMPA, cell lines, 2-D and 3-D cell cultures)
- Early developability assessments such as cytotoxicity, genotoxicity, teratogenicity, immunogenicity, QT wave prolongation, hepatotoxicity, renal toxicity, in vitro efficacy with in silico techniques

References

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26. Aulton, Michael E., and Kevin M. G. Taylor. *Aulton's Pharmaceutics: The Design and Manufacture of Medicines*. 5th ed. London: Elsevier, 2018.
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30. Brittain, Harry G., ed. *Preformulation in Solid Dosage Form Development*. New York: Informa Healthcare, 2007.
31. Waterbeemd, Han van de, and Erik Gifford. *ADMET in Silico Modelling: Towards Prediction Paradise?* London: Imperial College Press, 2003.
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33. Brittain, Harry G., ed. *Polymorphism in Pharmaceutical Solids*. 2nd ed. New York: Informa Healthcare, 2009.
34. Byrn, Stephen, Ralph Pfeiffer, and Michael Stowell. *Solid-State Chemistry of Drugs*. 2nd ed. West Lafayette: SSCI Inc., 1999.
35. Hancock, Bruno C., and George Zografi. "Characteristics and Significance of the Amorphous State in Pharmaceutical Systems." *Journal of Pharmaceutical Sciences* 86, no. 1 (1997): 1–12.
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37. Jiskoot, Wim, Daniel J. A. Crommelin, eds. *Methods for Structural Analysis of Protein Pharmaceuticals*. Arlington: AAPS Press, 2005.
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43. Troy, David B., ed. *Remington: The Science and Practice of Pharmacy*. 22nd ed. London: Pharmaceutical Press, 2012.
44. International Council for Harmonisation. *ICH Harmonised Guideline Q1A(R2): Stability Testing of New Drug Substances and Products*. Geneva: ICH, 2003.
45. International Council for Harmonisation. *ICH Harmonised Guideline Q6A: Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and Products*. Geneva: ICH, 1999.
46. US Food and Drug Administration. *Guidance for Industry: INDs for Phase 2 and 3 Studies—Chemistry, Manufacturing, and Controls Information*. Silver Spring, MD: FDA, 2003.
47. Lipinski, Christopher A. "Lead- and Drug-Like Compounds: The Rule-of-Five Revolution." *Drug Discovery Today: Technologies* 1, no. 4 (2004): 337–341.

48. Kerns, Edward H., and Li Di. *Drug-Like Properties: Concepts, Structure Design and Methods*. Amsterdam: Elsevier, 2008.

PE-512: Pharmaceutical Product Development – I (2 credits)

Unit 1: Pharmaceutical Product Development (4 Hours)

- Overview of drug product lifecycle
- Four-stage development:
  a) Preformulation
  b) Prototype development
  c) Scale-up studies
  d) Commercialization
- Role of multidisciplinary teams
- Regulatory framework (ICH, USFDA, EMA)
- Case study: Tablet development from API to market

Unit 2: Preformulation and Material Properties (4 Hours)

- Physicochemical properties of drug substances:
  a) Solubility, pKa, polymorphism
  b) Stability considerations
- Drug–excipient compatibility studies
- Basic preformulation studies for the development of different dosage forms
- Analytical techniques in representative investigations
- Regulatory relevance (ICH Q1 stability guidelines)
- Case study: Stability failure investigation

Unit 3: Design of Materials and Product Specifications (4 Hours)

- Concepts of specification setting:
  a) Raw material specifications
  b) In-process controls
  c) Finished product specifications
- Acceptance criteria and limits
- Real specification sheets analysis
- Regulatory considerations/Comparison of pharmacopoeial standard (IP, USP, BP)
- Case study/Hands-on: Drafting of a specification document

Unit 4: Quality by Design (QbD) (5 Hours)

- Fundamentals of QbD
- Target Product Profile (QTPP)
- Critical Quality Attributes (CQA)
- Critical Material Attributes (CMA)
- Critical Process Parameters (CPP)
- Risk management tools (FMEA, Ishikawa, RPN)
- Process Analytical Technology (PAT) and its link with continuous manufacturing
- Control strategies

- Flowchart-based QbD model building
- Regulatory expectations (ICH, FDA guidance)
- Case study: At least one example of screening/optimization.

Unit 5: Optimization Techniques (4 Hours)

- Concept of optimization in formulation
- OVAT (One Variable at a Time)
- Basics of Design of Experiments (DoE):
  a) Factorial design
  b) Response Surface Methodology (RSM)
- Data interpretation and modeling
- Applications in pharmaceutical development
- Software-based DoE exposure (Design-Expert/Minitab)
- Graphical interpretation (Perturbation, Contour plots, 3D plots)
- Case study: At least one example of screening/optimization.

Unit 6: Pharmaceutical Packaging (7 Hours)

- Types of packaging: primary, secondary, tertiary
- Packaging materials: glass, plastics (PE, PP, PVC, & PET), metals (aluminium, tin, stainless steel)
- Elastomers and closures
- Selection criteria for packaging materials – Drug compatibility, protection (moisture, light, & oxygen), cost & availability, & regulatory requirements
- Advanced systems:
  a) Child-resistant
  b) Tamper-evident
  c) Barrier packaging (moisture, oxygen, light protection)
  d) Blister and strip
- Drug-device combination product (DDCs):
  a) Introduction & classification
  b) Examples: Metered dose inhalers (MDI), dry powder inhalers (DPI), nasal sprays, and prefilled syringes (PFS)
  c) Critical Quality Attributes: Device accuracy and dose uniformity, spray pattern and plume geometry, and aerodynamic particle size (for inhalation systems)
  d) Container closure integrity (CCI): leak testing, microbial ingress protection.
  e) Compatibility studies: Drug-device interaction, material compatibility (plastics, elastomers, & coatings)
  f) Extractables & leachables in DDCs: Sources & risks, special importance in inhalation & injectables
  g) Evaluation & testing: Delivered dose uniformity (DDU), spray content uniformity, aerodynamic particle size distribution (ASPD), CCI testing, & stability studies
  h) Regulatory considerations: Combination product guidelines by US-FDA & EMA, human factor studies, device-drug co-development
- Basic evaluation tests for packaging materials:
  a) Physical/Mechanical tests
  b) Barrier and permeability testing
  c) Thermal and stability testing

d) CCI testing
- Extractables and leachables
- Analytical techniques/equipment for testing
- QC testing standards
- Pharmaceutical labeling requirements
- Regulatory aspects for labelling, including Risk evaluation & mitigation strategies (REMS)
- Case study: Extractable/leachable contamination incident

Unit 7: Documentation and Regulatory Basics (7 Hours)

- Equipment mapping for pilot plant and commercial batches
- Documentation in product development:
  a) Bill of Material (BOM)
  b) Manufacturing Formula Record (MFR)
  c) Batch Manufacturing Record (BMR)
  d) Batch Packaging Record (BPR)
- Scale-up and engineering batch documentation
- Exhibit/submission batch manufacturing (Investigational product manufacturing)
- Process validation batches (first three batches, commercial batches)
- Process validation report
- Product life cycle management (PAS, CBE-30, CBE-0 in the US-FDA or equivalent terminologies in other regulatory agencies)
- Termination of production of the drug products (Section 506C of the Federal Food, Drug, and Cosmetic (FD&C) Act and 21 CFR 314.81(b)(3)(iii)), such as permanent discontinuation not due to the safety and efficacy concerns, voluntary product recalls, market withdrawal, and FDA-initiated or mandatory recalls.
- Principles of data integrity [Attributable, Legible, Contemporaneous, Original, Accurate (ALCOA) principles], including archival (annual report with all batches, and compilation of annual reports, 24×7×365 readiness)
- Overview of regulatory submissions (IND, NDAs, and ANDAs)

References

1. N. K. Jain. *Pharmaceutical Product Development*. New Delhi: CBS Publishers & Distributors, 2016.
2. Aulton, Michael E., and Kevin M. G. Taylor. *Aulton's Pharmaceutics: The Design and Manufacture of Medicines*. 5th ed. London: Elsevier, 2018.
3. Allen, Loyd V., Nicholas G. Popovich, and Howard C. Ansel. *Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems*. 10th ed. Philadelphia: Wolters Kluwer, 2014.
4. Leon Lachman, Herbert A. Lieberman, and Joseph L. Kanig. *The Theory and Practice of Industrial Pharmacy*. 3rd ed. Mumbai: Varghese Publishing House, 1987.
5. Gibson, Mark. *Pharmaceutical Preformulation and Formulation: A Practical Guide from Candidate Drug Selection to Commercial Dosage Form*. 2nd ed. Boca Raton: CRC Press, 2009.
6. Florence, A. T., and David Attwood. *Physicochemical Principles of Pharmacy*. 6th ed. London: Pharmaceutical Press, 2016.

7. Bolton, Sanford, and Charles Bon. *Pharmaceutical Statistics: Practical and Clinical Applications*. 5th ed. Boca Raton: CRC Press, 2010.
8. Lewis, George A., Debra Mathieu, and Roger Phan-Tan-Luu. *Pharmaceutical Experimental Design*. New York: Marcel Dekker, 1999.
9. Yu, Lawrence X. *Pharmaceutical Quality by Design: Product and Process Development, Understanding, and Control*. New York: Informa Healthcare, 2008.
10. D. A. Dean, and E. R. Evans. *Pharmaceutical Packaging Technology*. London: Taylor & Francis, 2000.
11. Paine, Frank A., and Heather Y. Paine. *A Handbook of Food Packaging*. 2nd ed. London: Blackie Academic & Professional, 1992.
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16. International Council for Harmonisation. *ICH Harmonised Guideline Q9: Quality Risk Management*. Geneva: ICH, 2005.
17. International Council for Harmonisation. *ICH Harmonised Guideline Q10: Pharmaceutical Quality System*. Geneva: ICH, 2008.
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20. US Food and Drug Administration. *Guidance for Industry: Process Validation: General Principles and Practices*. Silver Spring, MD: FDA, 2011.
21. European Medicines Agency. *Guideline on Process Validation for Finished Products*. London: EMA, 2014.
22. Indian Pharmacopoeia Commission. *Indian Pharmacopoeia*. Ghaziabad: IPC, 2022.
23. United States Pharmacopeial Convention. *United States Pharmacopoeia–National Formulary (USP–NF)*. Rockville, MD: USP, 2023.
24. British Pharmacopoeia Commission. *British Pharmacopoeia*. London: The Stationery Office, 2023.

PE-513: Pharmaceutical Preformulation – II (2 credits)

Unit 1 Preformulation Parameters and Drug Profiling (4 Hours)

- Concept and objectives of preformulation studies
- Drug profiling: physicochemical characterization (pKa, partition coefficient, solubility, permeability)
- Biopharmaceutics Classification System (BCS) and its relevance in formulation development

- Role of preformulation in dosage form selection and design
- Correlation between physicochemical properties and pharmacokinetic behavior

Unit 2 Drug–Excipient Interactions and Compatibility (3 Hours)

- Types of incompatibilities: physical, chemical, pharmaceutical, therapeutic
- Types of drug–excipient interactions
- Analytical techniques for characterization of drug-excipient incompatibilities

Unit 3 Micromeritics (4 Hours)

- Pharmaceutical importance of micromeritics
- Particle size and size distribution
- Methods for determining particle size (size-, density-, and volume-based methods)
- Advanced techniques for particle characterization (e.g., atomic force microscopy)
- Significance of particle size in different dosage forms including aerosols, parenterals, and solid dosage forms)

Unit 4 Complexation (3 Hours)

- Fundamentals of complexation, including metal complexes, organic molecular complexes, inclusion complexes
- Inclusion compounds with reference to cyclodextrins
- Chemical characteristics of inclusion complexes
- Methods of preparation of cyclodextrin complexes
- Pharmaceutical applications of complexation: Taste masking, enhancement of solubility, permeability, and oral bioavailability

Unit 5 Rheology (4 Hours)

- Newtonian and non-Newtonian flow properties
- Concept of viscoelasticity
- Thixotropy and its applications in development of dosage forms
- Methods for evaluation of viscosity
- Implications of viscosity on performance of liquid dosage forms (suspensions and emulsions)
- Advanced techniques/equipment employed in the rheological characterization of pharmaceutical products

Unit 6 Solubility Enhancement Techniques (3 Hours)

- Importance of solubility in drug development and bioavailability
- pH adjustment and salt formation
- Use of co-solvents and surfactants
- Solid dispersion techniques and amorphization
- Role of particle size reduction (nanonization) in solubility enhancement
- Comparative evaluation of solubility enhancement approaches

Unit 7 Fundamentals of Dissolution and Drug Release (4 Hours)

- Theories of dissolution
- Intrinsic dissolution rate

- Release rates and kinetic constants
- Mechanisms of conventional and controlled release
- Selection of dissolution media
- Bio-relevant media, QC release media
- Dissolution equipment – official and non-official apparatus
- Calibration of dissolution apparatus

Unit 8 Advanced Dissolution Testing, Data Analysis, and Regulatory Applications (4 Hours)

- Dissolution data handling and correction factors
- Calculation of similarity factor (f2)
- IVIVC (In vitro–In vivo correlation)
- IVRT (In vitro release testing)
- IVPT (In vitro permeation testing)
- In vitro bioequivalence
- Multimedia dissolution profile and its applicability for biowaiver
- Hyphenated tests for dissolution and intestinal permeability

Unit 9 Stability and Degradation of Drug Substances (5 Hours)

- Principles of drug stability
- Types of degradation: hydrolysis, oxidation, photolysis
- Kinetics of drug degradation (zero-order, first-order reactions)
- Factors affecting stability: temperature, pH, light, humidity
- Stabilization techniques (use of antioxidants, buffers, packaging)
- Accelerated stability studies and shelf-life prediction
- Overage calculations
- Stability indicating assays
- ICH guidelines for stability testing (overview)

READING MATERIAL

1. Physicochemical Principles of Pharmacy, 2006, Alexander T. Florence and David Attwood Pharmaceutical Press
2. Pharmaceutics: The Science of Dosage Form Design, Second Edition, 2006, M. E. Aulton Chrchill livingstone
3. Pharmaceutical Preformulation: The Physicochemical Properties of Drug Substances James I. Wells, Ellis Horwood Limited
4. Physical Pharmacy by Alfred Martin, 06th Edition
5. Martin's Physical Pharmacy and Pharmaceutical Sciences, Fifth Edition, edited by Patrick J. Sinko, BI Publications Pvt. Ltd.
6. Remington's Pharmaceutical Sciences, Mack Publishing Company, Pennsylvnia.
7. EMEA reflection paper for setting the dissolution specification.

PE-514: Solid State Pharmaceutics (2 credits)

Unit 1: Levels of solid-state properties (3 Hours)

Molecular/particle/bulk level properties, interdependence and correlation among different structural levels; role of different levels during pharmaceutical development and process development

Unit 2: Molecular level (3 Hours)

Crystalline form, definition, supramolecular arrangements and intermolecular interactions; building blocks of crystals, unit cell, basic types of unit cells, visualisation and interpretation of unit cells using crystal visualisation software

Unit 3: Polymorphism (3 Hours)

Definition, significance of polymorphism in drug product performance, packing / conformational polymorphism, thermodynamics of polymorphs, enantiotropy / monotropy with Gibbs free energy relationships, concept of phase transition behaviour and transition temperature determination, Burger and Ramberger rule

Unit 4: Crystallisation process (3 Hours)

Molecular aggregation events in crystallisation, Classical and non-classical nucleation theories, energetics of crystallisation, enthalpy entropy balance, types of nucleation, Ostwald's step rule, experimental protocols for polymorph screening

Unit 5: Implications of polymorphism in pharmaceutical development (3 Hours)

Regulatory concerns related to polymorphism, introduction to the latest regulatory position on polymorphism. Risk assessment of polymorphic transitions during processing and storage. Overview of current FDA, EMA, and ICH perspectives on polymorphism.

Unit 6: Amorphous state and its role in drug delivery (3 Hours)

Definition, long-range order versus short-range order, disorder in the amorphous state, concept of glass transition temperature (Tg), thermodynamic necessity for Tg, entropy crisis. Solubility advantage, spring parachute effect during solubility studies, physical instability of the amorphous form, techniques for stabilisation of amorphous form, and amorphous solid dispersions

Unit 7: Co-crystals (3 Hours)

Introduction, synthons used for formation of co-crystals, comparison of co-crystals with salts, polymorphs, and amorphous systems, Co-crystal screening strategies and selection criteria and applications in drug delivery.

Unit 8: Particulate level properties (3 Hours)

Crystal habit, generation of different crystal habits, implications of crystal habit on product performance and processing

Unit 9: Bulk level properties (3 Hours)

Bulk density, tapped density, porosity; compressibility and compactability, flow properties, cohesivity, electrostatics, aggregation, agglomeration, role in formulation development and powder handling, processing, scale-up, and manufacturing operations

Unit 10: Solid-State Characterisation Techniques (4 Hours)

Structural characterization using Single Crystal X-Ray Diffraction (SCXRD) and Powder X-Ray Diffraction (PXRD); thermal analysis using Differential Scanning Calorimetry (DSC), Thermogravimetric Analysis (TGA), and Hot Stage Microscopy (HSM); spectroscopic techniques including Fourier Transform Infrared Spectroscopy (FTIR), Raman spectroscopy, and Solid-State Nuclear Magnetic Resonance (SSNMR); surface and morphology analysis using Scanning Electron Microscopy (SEM) and Atomic Force Microscopy (AFM); particle and bulk property analysis using Dynamic Light Scattering (DLS), Brunauer Emmett Teller (BET) surface area analysis, and true density measurements.

Recommended Books:

1 Polymorphism in Pharmaceutical Solids, edited by Harry Brittain
2 Solid State Characterisation of Pharmaceuticals, edited by Angeline and Mark Zarkrzewski
3 Crystal Engineering: A textbook, edited by G. R. Desiraju, J. J.Vittal and A. Ramanan
4 Pharmaceutics – The Science of Dosage Form Design, edited by Michael E. Aulton & Kevin Taylor

PA-512: Spectroscopy for Structure Elucidation (2 credits)

Refer to Department of Pharmaceutical Analysis syllabus

GE-516: Biostatistics and Data Analytics (2 credits)

Refer to Postgraduate-Common Courses syllabus

GE-517: Artificial Intelligence, Machine Learning in Pharmaceuticals (1 credit)

Refer to Postgraduate-Common Courses syllabus

SM-518: Seminar (1 credit)

1. **Introduction to Scientific Research:** Scope of Pharmaceutical research and types of scientific communications
2. **Literature Search & Information Retrieval Systems:**
    a) **Use of Database:** PubMed, MEDLINE, Embase, Cochrane Library, Scopus, Web of Science, Google Scholar, ClinicalTrials.gov, SciFinder, DrugBank, Chemical Abstracts Service, ,icromedex, International Pharmaceutical Abstracts, and Shodhganga.
    b) Keywords, Boolean Operators.
    c) **Use of reference management tools:** Mendeley, Zotero, EndNote, and RefWorks.
3. **Scientific Writing Skills:** Writing term papers and reports; Structure of research articles (IMRAD format), and Abstract writing.
4. **Organization of scientific Documents:** Thesis and dissertation preparation; Reference styles (Vancouver, APA, Harvard); and Citation Management.
5. **Critical Reading and Analysis of Research Papers:** How to evaluate (study design, methodology, and data interpretation), and identify bias and limitations.

6. **Research Ethics:** Plagiarism and its prevention; use of plagiarism tools (Turnitin/iThenticate); and publication ethics.
7. **Oral & Visual Presentation Skills:** Seminar presentation techniques; use of PowerPoint and visual aids; and Scientific communication skills.
8. **Seminar Presentation:** Each student will present one seminar and participate in a discussion.

GL-519: General Lab Experience (6 credits)

1. Advanced Laboratory Practices & GLP:

a) Principles of Good Laboratory Practice
b) Laboratory safety and risk assessment
c) Calibration and validation concepts
d) Documentation (SOPs, logbooks, data integrity)

2. Handling and Calibration of Advanced Instruments:

a) Analytical balance (calibration)
b) pH meter (calibration and maintenance)
c) UV-Visible spectrophotometer
d) Dissolution apparatus (intro)
e) Brookfield viscometer

3. Pre-formulation Studies:

a) Drug–excipient compatibility studies
b) Solubility analysis
c) Partition coefficient
d) pKa determination

5. Formulation Development (Basic level to Intermediate):

a) Solid Dosage Forms - Granulation techniques (wet/dry—demonstration)
b) Liquid Dosage Forms - Suspensions (stability aspects) and Emulsions
c) Semisolid Dosage Forms -Creams and gels

6. Evaluation of Dosage Forms:

a) Drug content estimation using UV spectroscopy
b) In vitro dissolution – drug estimation using UV spectroscopy
c) In vitro drug release kinetics
d) Rheological studies
e) Stability testing (short-term studies)

7. Introduction to Novel Drug Delivery Systems (NDDS):

a) Preparation (demonstration level): Nanoparticles and Liposomes

8. Analytical Method Basics:

a) UV calibration curve preparation
b) Beer-Lambert law application
c) Assay of formulations

9. Animal handling:

a) Small animal handling (rats, mice, etc.)

b) Route of administration (demonstration)

10. Research Methodology Exposure:

a) Literature search
b) Data recording and interpretation
c) Basic statistical analysis
d) Report writing and presentation

Semester – II

PE-521: Pharmaceutical Product Development – II (2 credits)

Unit 1 Formulation Additives and Excipient Science (4 Hours)

- Types of additives: antioxidants, preservatives, coloring and flavouring agents, emulsifying and suspending agents, basic materials for ointment bases, diluents, and pharmaceutical solvents.
- Regulatory perspectives: International Pharmaceutical Excipient Council, GRAS, Inactive Ingredient Guide (IIG)
- New developments in excipients science: functional and co-processed excipients,
- International patented excipients
- Implications of quantitative selection of each excipient in product development

Unit 2 Advances in Tablet Production and Processing (3 Hours)

- Advances in materials and material handling
- Granulation technologies and equipment
- Process automation in tablet manufacturing
- Processing problems in tablet and troubleshooting

Unit 3 Tablet Coating Technologies (4 Hours)

- Advances in coating equipment
- Sugar coating
- Film coating
- Advanced coating technologies, Wurster process
- Aqueous-based film coating
- Solvent-free coating
- Coating defects and troubleshooting

Unit 4 Specialized Tablets (3 Hours)

- Formulation and evaluation of: Effervescent, Orodispersible, Chewable tablets

Unit 5 Poly-disperse Systems (5 Hours)

- **Suspensions:** theoretical considerations, flocculated and deflocculated systems, formulation additives, evaluation of stability.
- **Emulsions:** theory of emulsification, formulation aspects, stability evaluation, advances in emulsion technology: multiple, micro, and nano-emulsions.

Unit 6 Sterile Products and Admixtures (4 Hours)

- Introduction, advantages, limitations
- Formulation development, manufacturing steps
- Vehicles and other additives
- Containers and closures
- Evaluation of stability and sterility
- Requirements of facilities for production
- Recent advances and developments

Unit 7 Drug nanocrystals (3 Hours)

- Generation: Top-down, bottom-up, and hybrid approaches
- Physicochemical properties of nanocrystals
- Stabilization of nanocrystals
- Applications of nanocrystals

Unit 8 Inhalation products (5 Hours)

- Nebulizers and Inhalers: Metered Dose Inhalers (MDI) and Dry Powder Inhalers (DPIs)
- Types of excipients/propellants
- Formulation aspects
- Devices used
- Stability aspects
- Evaluation of inhalable products.

Unit 9 3D Printing as Emerging Manufacturing Technology (3 Hours)

- Introduction and classification of Additive Manufacturing (AM) technologies
- Advantages and limitations
- AM versus conventional manufacturing process
- AM for oral solids
- Stability, safety, efficacy, and scalability of AM technology
- Regulatory challenges and cost-effectiveness

READING MATERIAL

1. Pharmaceutical Dosage Forms: Tablets, Vol. 1-3, 2008, Herbert A. Lieberman, Leon Lachman and Joseph B. Schwartz, Marcel Dekker.
2. Pharmaceutical Dosage Forms: Disperse System, Vol. 1-3, 1996, Herbert A. Lieberman, Gilbert S. Banker and Martin M. Rieger, Marcel Dekker.
3. Pharmaceutical dosage forms: Parenteral medication, Vol. 1-3, 2005, Herbert A. Lieberman, Leon Lachman and Kenneth E. Avis, Marcel Dekker.
4. The Theory and Practice of Industrial Pharmacy, 1991, Herbert A. Lieberman, Leon Lachman and Joseph L. Kanig, Varghese Publication House.
5. Pharmaceutics: The Science of Dosage Form Design, Second Edition, 2006, M.E. Aulton, Chrchill Livingstone.
6. Pharmaceutical Coating Technology, edited by Graham Cole.

7. M.E. Aulton, Pharmaceutics, The Science& Dosage Form Design, Churchill Livingstone, Edinburgh.
8. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania.
9. Shape /Size guidance by US-FDA.
10. Score line guidance by US FDA.
11. Chewable Tablet guidance by US FDA.
12. USFDA guidance for orodispersible /orally disintegrating Tablets.

PE-522: Biopharmaceutics and Pharmacokinetics (2 credits)

Unit 1: Introduction (3 Hours)

- Definitions, ADME, Pharmacometrics, Biopharmaceutical Classification System (BCS)
- General guidelines for bioavailability (BA) and bioequivalence (BE)
- Pharmacokinetic evaluation in Phase I and II studies,
- Biopharmaceutics and pharmacokinetics in drug discovery and drug development
- Applications of Chronopharmacokinetics, pharmacokinetics v/s pharmacological/ clinical response, metabolic kinetics

Unit 2: Structure Property Relationship (3 Hours)

- Physicochemical properties; lipophilicity and partitioning behaviour
- Structure–solubility relationship; structure–dissolution relationship; structure–permeability relationship; structure–stability relationship; structure–bioavailability relationship.
- Regulatory and industrial perspectives with emphasis on Quality by Design (QbD), formulation development, and scale-up

Unit 3: ADME Processes (2 Hours)

- Mechanism, factor influencing, special populations
- Factors influencing ADME
- in vitro evaluation including permeability studies, metabolic stability, plasma protein binding, and tissue binding studies

Unit 4: Drug Metabolism (2 Hours)

- In silico tools for drug metabolism
- invitro methods such as human liver homogenate, microsomal and non-microsomal enzymes, recombinant fully humanized enzymes, 2D and 3D cell cultures for drug metabolism,
- preclinical animal model for metabolism, allometric scaling, mapping of phenotypic and genotypic polymorphism of enzymes, mass balance studies,
- first in human studies, Phase 1 and 2 metabolism, enterohepatic cycling and its influence on drug clearance, metabolic non linearity in pharmacokinetics, enzyme

induction and inhibition, including autoinduction and inhibition and hepatic impairment, classification, dosage regimen optimization in hepatic impairment.

Unit 5: Biopharmaceutical Classification System (3 Hours)

- Introduction, Classification, Solubility, Permeability, Absolute bioavailability, Dose number, Applications
- Regulatory guidelines, including Scale-Up and Post-Approval Changes (SUPAC)

Unit 6: Bioavailability and Bioequivalence (3 Hours)

- Definitions, federal requirements
- methods of determination of bioavailability using blood and urinary excretion data.
- Protocol design for bioavailability assessment.
- Methods for bioequivalence determination.

Unit 7: Compartmental Pharmacokinetics (3 Hours)

- Pharmacokinetics of drugs following one/two compartment open models with first order elimination kinetics as applied to rapid intravenous injection,
- Intravenous transfusion and oral administration.
- Determination of absorption rate constant using Wagner-Nelson, Loo-Riegelman methods.
- Flip-flop models, the method of residual.
- Urinary excretion data and its application in pharmacokinetic characterisation of drugs.
- Pharmacokinetics of multiple dosing.

Unit 8: Pharmacokinetics in special populations (3 Hours)

- Drugs in the elderly, children, obese and pregnant patients.
- Drugs and Pharmacokinetics in disease conditions, including renal impairment, hepatic impairment, and congestive heart failure.

Unit 9: Pharmacokinetics drug-drug interactions (3 Hours)

- Role of human cytochrome P450 enzymes in metabolism-based drug–drug interactions
- transporter-mediated drug–drug interactions with emphasis on membrane transporters;
- role of P-glycoprotein in drug ADME;
- contribution of gut mucosa and intestinal metabolism in drug–drug interactions;
- clinical significance of pharmacokinetic drug–drug interactions;
- regulatory and marketing perspectives

Unit 10: Nonlinear Pharmacokinetics (2 Hours)

- Various causes of non-linearity,
- Michaelis-Menten kinetics,
- in vivo estimation of Km and Vm.
- Case studies.

Unit 11: Physiologic pharmacokinetics models (2 Hours)

- Mean Residence Time; Statistical Moment Theory;
- Application and limitations of physiologic pharmacokinetic models.

Unit 12: Regulatory guidelines (2 Hours)

- ICH, EMA, and USFDA guidelines related to biopharmaceutics and pharmacokinetics

Recommended Books:

1. Applied Biopharmaceutics& Pharmacokinetics, by Shargel, L., S. Wu-Pong
2. Biopharmaceutics and Pharmacokinetics: An Introduction by Notari, R. E.
3. Introduction to Biopharmaceutics, by Gibaldi, M.
4. Biopharmaceutics and Relevant Pharmacokinetics, by Wagner, J. G.
5. Textbook of Biopharmaceutics and Clinical Pharmacokinetics by Niazi, S.K.
6. Handbook of Bioequivalence Testing, by Niazi, S.K.
7. Modelling in Biopharmaceutics, Pharmacokinetics, and Pharmacodynamics: Homogeneous and Heterogeneous Approaches, by Macheras, P. and A. Iliadis
8. Comparative Pharmacokinetics: Principles, Techniques and Applications, by Riviere, J. E
9. Foundations of Pharmacokinetics, by Rescigno, A.
10. Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications, by Rowland, M. and T. N. Tozer
11. Drug-Drug Interactions, second edition, A. David Rodrigues

PE-523: Drug Delivery - I (Controlled Drug Delivery) (2 credits)

Unit 1 Fundamentals of Controlled Drug Delivery Systems (3 Hours)

- Rationale for controlled drug delivery
- Influence of physicochemical properties, biological factors, and routes of administration on design and performance of sustained/controlled release products.

Unit 2 Biopharmaceutics and Pharmacokinetic Aspects of Peroral CRDDS (4 Hours)

- Strategies and design of controlled release systems
- Factors affecting CRDDS performance
- Computation of desired release rate and dose for CRDDS
- Pharmacokinetic design of DDS
- In vitro–in vivo considerations
- Release kinetics: zero-order, first-order, intermittent release

Unit 3 Polymeric Materials in Controlled Drug Delivery (3 Hours)

- Classification of polymers
- Co-polymers and block co-polymers in drug delivery.
- Physical and chemical characterization techniques of biomaterials
- Biocompatibility testing of biomaterials
- Pharmaceutical/biomedical applications in tissue engineering

Unit 4 Peroral Controlled Drug Delivery Systems (4 Hours)

- Design and fabrication of oral CR systems
- Dissolution-controlled release systems
- Diffusion and dissolution-controlled systems
- Ion-exchange resin systems
- pH-independent formulations
- Osmotically controlled systems
- Altered density formulations
- Case studies

Unit 5 Parenteral Controlled Drug Delivery Systems (4 Hours)

- Major routes of parenteral administration
- Selection, design and development of CR parenteral systems
- Biopharmaceutics of sustained/controlled release parenteral products
- Polymeric microspheres and dispersed DDS
- Biocompatibility considerations

Unit 6 Transdermal/Skin Drug Delivery Systems (4 Hours)

- Principles of skin permeation
- Factors affecting percutaneous absorption of drug
- Sorption promoters
- Absorption enhancement by energy input: iontophoresis, sonophoresis, electroporation
- Pharmacokinetics of skin permeation/transdermal delivery
- Design, development, and evaluation of transdermal patches
- Overview of microneedles in transdermal drug delivery

Unit 7 Implantable Therapeutic Systems (3 Hours)

- Historical background;
- Advantages, limitations, and applications
- Types of implantable therapeutic systems, including self-regulated and pump-based systems
- Biodegradable and non-biodegradable polymers used for implantable systems
- Tissue and blood compatibility testing

Unit 8 Protein and Peptide Drug Delivery Systems (3 Hours)

- Barriers: enzyme, epithelial, endothelial
- Pharmacokinetics
- Different routes of delivery
- Practical considerations

Unit 9 Ocular drug delivery systems (2 Hours)

- Ocular route of drug delivery
- Ocusert systems
- Ophthalmic punctal plugs

Unit 10 Regulatory Aspects of Controlled Release Formulations (2 Hours)

- Regulatory approval pathways: NDA and ANDA

Unit 11 Role of controlled release in veterinary formulations (2 Hours)

- Background and present scenario
- Formulation considerations
- Major hurdles and challenges
- Future prospects

READING MATERIAL

1. Controlled Drug Delivery: Fundamentals and Application, Second Edition, Vol. 29, 1987, Joseph R. Robinson and Vincent H. L. Lee, Marcel Dekker.
2. Novel Drug Delivery Systems, Second Edition, 1992, Yie W Chien: Marcel Dekker.
3. Modern Pharmaceutics, Fourth Edition, 2008, Gilbert S. Banker and Christophex T. Rhodes Marcel Dekker.
4. Controlled Drug Delivery: Concepts and Advances, 2008, S. P. Vyas and Roop K. Khar, Vallabh Prakashan.
5. Controlled and Novel Drug Delivery, Jain, N.K. 1997.
6. Advances in Novel and Controlled Drug Delivery, Jain, N.K., CBS publisher.
7. Targeted & Controlled Drug Delivery, Vyas S.P. & Khar R.K, CBS Publisher.
8. Applied Biopharmaceutics& Pharmacokinetics, by Shargel, L., S. Wu-Pong.
9. Biopharmaceutics and Pharmacokinetics: An Introduction by Notari, R. E.
10. Introduction to Biopharmaceutics, by Gibaldi, M.

PE-524: Drug Delivery – II (Targeted Drug Delivery and Novel Carrier Systems) (2 credits)

Unit 1: Fundamentals of Targeted Drug Delivery (4 Hours)

- Need and advantages of targeted drug delivery
- Levels of targeting: organ, tissue, cellular, subcellular
- Passive targeting: EPR (Enhanced Permeability and Retention) effect
- Active targeting: ligand–receptor interactions
- Multifunctional and precision targeting approaches
- Target Product Profile (TPP) and carrier selection strategy
- Examples: antibody-drug conjugates (ADCs), ligand-functionalized nanoparticles

Unit 2: Chemical and Prodrug-Based Targeting (4 Hours)

- Prodrug concept and applications in targeting
- Antibody Directed Enzyme Prodrug Therapy (ADEPT)
- Soft drug design
- Drug conjugates:
  a) Lipid–drug conjugates
  b) Polymer–drug conjugates
  c) PEGylation for stealth delivery

- Clinical examples of ADCs and PEGylated drugs

Unit 3: Targeted Drug Delivery to the Brain and Tumor (7 Hours)

A. Brain Targeting (5 hours)

- Structure, role, and transport challenges of the BBB
- Transport mechanisms:
  a) Receptor-mediated transport (RMT) - Transferrin, Insulin, and Low-density lipoprotein (LDL) receptors
  b) Carrier-mediated transport (CMT) – Glucose transporter (GLUT-1), Large neutral amino acid transporter (LAT-1), and monocarboxylate transporter
  c) Efflux transporters (P-gp) – P-glycoprotein (P-gp) and breast cancer resistant protein (BCRP)
- Intranasal (Nose-to-brain) Pathway:
  a) Olfactory neurons
  b) Trigeminal nerve
  c) Nasal epithelial receptors
  d) Formulation considerations
  e) Advantages and limitations
- Cellular-level targeting in the brain:
  a) Neuronal targeting
  b) Glial cell targeting
- Disease-specific molecular targets:
  a) Neurodegenerative diseases (Alzheimer's, Parkinson's)
  b) Brain tumors
  c) Neuroinflammation
- Emerging Nanocarrier Strategies:
  a) Ligand-functionalized nanoparticles
  b) Smart brain-targeted delivery

B. Tumor Targeting (2 Hours)

- Tumor microenvironment and vascular targets:
  a) Tumor vasculature
  b) EPF effect
- Targeting approaches & molecular targets:
  a) Passive versus active targeting
  b) Tumor ligands and receptors
- Biopharmaceutical considerations:
  a) Drug penetration and retention
  b) Role of carrier systems

Unit 4: Colloidal and Nanoparticulate Drug Delivery Systems (6 Hours)

- Principles, preparation, and evaluation
- Liposomes and niosomes
- Solid lipid nanoparticles (SLN) and nanostructured lipid carriers (NLC)
- Polymeric nanoparticles (natural and synthetic biodegradable polymers)
- Targeting modifications: Surface functionalization, PEGylation

- In vivo behaviour: Biodistribution, clearance

Unit 5: Specialized and Novel Carrier Systems (5 Hours)

- Vesicular and lipid-based systems: transferosomes, ethosomes, pharmacosomes
- Polymeric nanocarriers: dendrimers and polymeric micelles
- Self-assembled systems: nanoemulsions, self-emulsifying drug delivery systems (SEDDS)
- Lipid nanoparticles (LNPs) for mRNA/drug delivery
- Advantages and limitations of modern nanocarriers

Unit 6: Stimuli-Responsive and Smart Drug Delivery Systems (4 Hours)

- Multi-stimuli responsive systems:
  a) pH-sensitive systems
  b) Temperature-sensitive systems
  c) Enzyme-sensitive systems
- External stimuli triggers:
  a) Ultrasound
  b) Light
  c) Magnetic fields
- Organ- and Cell-specific Targeting:

  a) Liver targeting:

  i. Use of ASGPR receptors, liposomal carriers, and nanoparticle accumulation in hepatocytes

  ii. Clinical examples: targeted antiviral and anticancer therapeutics

  b) Macrophage targeting:

  i. Targeting infections, inflammation, and tumor-associated macrophages

  ii. Ligand-functionalized nanoparticles, liposomes

- Other Advanced Targets (Brief Overview):

  a) Colon, mitochondrial, and M-cell targeting

  b) Gene delivery systems (siRNA, mRNA)

Unit 7: Translational and Regulatory Considerations (3 Hours)

- Translational challenges:
  a) Toxicity of nanocarriers
  b) Immunogenicity issues
  c) Off-target effects
- In vivo performance:
  a) Biodistribution of drug delivery systems
  b) Clearance mechanisms (RES, renal, hepatic)
- Manufacturing and scale-up challenges:
  a) Reproducibility
  b) Stability issues

    c) Large-scale production constraints
- Regulatory considerations:
    a) Approval pathways for novel drug delivery systems
    b) Safety and quality requirements
    c) Regulatory perspectives (FDA, EMA)
- Case examples of approved targeted therapies

References

1. Devarajan, Padma V., and Sanyog Jain, eds. *Targeted Drug Delivery: Concepts and Design*. New York: Springer, 2015.
2. Hillery, Anya M., Andrew W. Lloyd, and James Swarbrick. *Drug Targeting and Delivery: Concepts in Dosage Form Design*. Boca Raton: CRC Press, 2001.
3. Narang, Ajay S., and Ram I. Mahato, eds. *Targeted Delivery of Small and Macromolecular Drugs*. Boca Raton: CRC Press, 2010.
4. Keservani, Raj K., Anil K. Sharma, and Rakesh K. Kesharwani, eds. *Drug Delivery Approaches and Nanosystems*. Boca Raton: CRC Press, 2017.
5. Aulton, Michael E., and Kevin M. G. Taylor. *Aulton's Pharmaceutics: The Design and Manufacture of Medicines*. 5th ed. London: Elsevier, 2018.
6. Allen, Loyd V., Nicholas G. Popovich, and Howard C. Ansel. *Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems*. 10th ed. Philadelphia: Wolters Kluwer, 2014.
7. Torchilin, Vladimir P., ed. *Handbook of Materials for Nanomedicine: Lipid-Based and Inorganic Nanomaterials*. Singapore: Pan Stanford Publishing, 2020.
8. Jain, N. K. *Controlled and Novel Drug Delivery*. New Delhi: CBS Publishers & Distributors, 2002.
9. Vyas, S. P., and Roop K. Khar. *Targeted and Controlled Drug Delivery: Novel Carrier Systems*. New Delhi: CBS Publishers & Distributors, 2002.
10. Swarbrick, James, ed. *Encyclopedia of Pharmaceutical Technology*. 4th ed. New York: Informa Healthcare, 2013.
11. Troy, David B., ed. *Remington: The Science and Practice of Pharmacy*. 22nd ed. London: Pharmaceutical Press, 2012.
12. Gad, Shayne C., ed. *Pharmaceutical Manufacturing Handbook: Production and Processes*. Hoboken: Wiley, 2008.
13. International Council for Harmonisation. *ICH Harmonised Guideline Q8(R2): Pharmaceutical Development*. Geneva: ICH, 2009.
14. International Council for Harmonisation. *ICH Harmonised Guideline Q9: Quality Risk Management*. Geneva: ICH, 2005.
15. International Council for Harmonisation. *ICH Harmonised Guideline Q10: Pharmaceutical Quality System*. Geneva: ICH, 2008.
16. International Council for Harmonisation. *ICH Harmonised Guideline Q11: Development and Manufacture of Drug Substances*. Geneva: ICH, 2012.
17. US Food and Drug Administration. *Guidance for Industry: Liposome Drug Products*. Silver Spring, MD: FDA, 2018.
18. US Food and Drug Administration. *Guidance for Industry: Drug Products, Including Biological Products, that Contain Nanomaterials*. Silver Spring, MD: FDA, 2022.
19. European Medicines Agency. *Reflection Paper on Nanotechnology-Based Medicinal Products for Human Use*. London: EMA, 2011.

20. European Medicines Agency. *Reflection Paper on the Data Requirements for Intravenous Liposomal Products Developed with Reference to an Innovator Liposomal Product*. London: EMA, 2013.

GE-526: Intellectual Property Rights and Regulatory Affairs in Pharmaceuticals (2 credits)

Refer to Postgraduate-Common Courses syllabus

GE-527: Research Culture and Ethics in the Pharmaceutical Industry (2 credits)

Refer to Postgraduate-Common Courses syllabus

SM - 528: Seminar (1 credit)

1. **Introduction to Scientific Research:** Scope of Pharmaceutical research and types of scientific communications
2. **Literature Search & Information Retrieval Systems:**
    d) **Use of Database:** PubMed, MEDLINE, Embase, Cochrane Library, Scopus, Web of Science, Google Scholar, ClinicalTrials.gov, SciFinder, DrugBank, Chemical Abstracts Service, ,icromedex, International Pharmaceutical Abstracts, and Shodhganga.
    e) Keywords, Boolean Operators.
    f) **Use of reference management tools:** Mendeley, Zotero, EndNote, and RefWorks.
3. **Scientific Writing Skills:** Writing term papers and reports; Structure of research articles (IMRAD format), and Abstract writing.
4. **Organization of scientific Documents:** Thesis and dissertation preparation; Reference styles (Vancouver, APA, Harvard); and Citation Management.
5. **Critical Reading and Analysis of Research Papers:** How to evaluate (study design, methodology, and data interpretation), and identify bias and limitations.
6. **Research Ethics:** Plagiarism and its prevention; use of plagiarism tools (Turnitin/iThenticate); and publication ethics.
7. **Oral & Visual Presentation Skills:** Seminar presentation techniques; use of PowerPoint and visual aids; and Scientific communication skills.
8. **Seminar Presentation:** Each student will present one seminar and participate in a discussion.

GL-529: General Lab Experience in the Area of Specialization (6 credits)

1. Advanced Formulation Development

a) Design and development of:
    1) Nano drug delivery systems (polymeric nanoparticles, SLNs, nanoemulsions)
    2) Immediate and modified release formulations
b) Selection of excipients and process parameters

2. Preparation of Novel Drug Delivery Systems (NDDS)

a) Polymeric nanoparticles (solvent evaporation/nanoprecipitation)
b) Solid lipid nanoparticles

c) Nanoemulsions/microemulsions
d) Liposomes

3. Characterization of NDDS

a) Particle size and polydispersity (concept/demo)
b) Zeta potential (intro)
c) Drug loading and entrapment efficiency
d) In vitro drug release studies

4. Advanced Processing Techniques (Hands-on / Demonstration)

a) Spray drying
b) Freeze drying (lyophilization)
c) Hot melt extrusion

5. Thermal and Solid-State Characterization

a) Differential Scanning Calorimetry
b) Basic interpretation of thermograms

6. Permeability and Drug Transport Studies

a) In vitro permeability studies - Diffusion cell (Franz diffusion cell)
b) Factors affecting drug permeation

7. In Vitro Evaluation Techniques

a) Dissolution studies (Immediate/modified release systems)
b) Release kinetics (zero order, first order, Higuchi model)
c) Stability studies (short-term/accelerated as per International Council for Harmonisation)

8. Formulation Optimization (Basic Introduction)

a) Concept of Design of Experiments
b) Effect of formulation variables
c) Data interpretation

9. Data Analysis and Reporting

a) Graph plotting and interpretation
b) Preparation of lab reports

EL – 525: Programme Electives (2 Credits)

PE-521: Pharmaceutical Product Development - II

Refer to the Department of Pharmaceutics syllabus

PE-522: Biopharmaceutics and Pharmacokinetics

Refer to the Department of Pharmaceutics syllabus

DEPARTMENT OF PHARMACY PRACTICE

SEMESTER – I

S. No	Course Code	Course Title	Type	Hrs per week	Credits	Category
1	**PP-511**	Hospital and Community Pharmacy Practice	T	2	2	PC
2	**PP-512**	Clinical Pharmacy Practice	T	2	2	PC
3	**PP-513**	Clinical and Applied Therapeutics –I	T	2	2	PC
4	**PP-514**	Clinical and Applied Therapeutics –II	T	2	2	PC
5	**PP-515**	Medication Safety and Clinical Risk Management	T	2	2	PC
6	**GE-516**	Biostatistics and Data Analytics	T	2	2	SD
7	**GE-517**	Artificial Intelligence and Machine Learning in Pharmaceuticals	T	1	1	IO
8	**SM-518**	Seminar	TS	1	1	SL
9	**GL-519**	General Lab Experience/Introductory Clinical Pharmacy Practice Experience	LPS	18-24	6	PC
Total			**--**	**32-38**	**20**	**--**

SEMESTER – II

S. No	Course Code	Course Title	Type	Hrs per week	Credits	Category
1	**PP-521**	Clinical and Applied Therapeutics –III	T	2	2	PC
2	**PP-522**	Patient Safety and Health Related Outcomes	T	2	2	PC
3	**PP-523**	Clinical Research	T	2	2	PC
4	**PP-524**	Evidence-Based Medicine	T	2	2	PC
5	**EL -525**	Programme Elective *	T	2	2	PE

6	**GE-526**	Intellectual Property Rights and Regulatory Affairs in Pharmaceuticals	T	2	2	SD
7	**GE-527**	Research Culture and Ethics in the Pharmaceutical Industry	T	2	2	IO
8	**SM-528**	Seminar	TS	1	1	SL
9	**GL-529**	General Lab Experience in the Area of Specialization / Advanced Clinical Pharmacy Practice Experience	LPS	18-24	6	PC
Total			**--**	**33-39**	**21**	**--**

*** EL-525 (Programme Elective):** The scholar should select any one course from the list of courses offered by other departments.

List of Department-wise Programme Electives (EL- 525) – 2 Credits:

(Scholars must select any one elective course from any department other than their own department)

Name of Department	**Course title**	**Credits/ Course**
BT	BT-525 (A): Nanobiotechnology BT-525 (B): Omics in Drug Discovery	2
PA	PA-525 (A): Analytical characterization of Biosimillars PA-525 (B): Mass spectrometry in Omics	2
PE	PE-521: Pharmaceutical Product Development - II PE-522: Biopharmaceutics and Pharmacokinetics	2
PP	PP-522: Patient Safety and Health Related Outcomes PP-523: Clinical Research PP-524: Evidence-Based Medicine	2
PT	PC-525 (A): Principles and Methods in Toxicology PC-525 (B): Introduction to Regulatory Toxicology	2

SEMESTER - III

S. No	**Course Code**	**Course Title**	**Type**	**Hrs per week**	**Credits**	**Category**

1	**TH-611**	Synopsis	PW	28	15	PC
2	**TH-612**	Presentation	PW	--	3	PC
3	**EL-613**	Self-learning Courses *	IO	4	2	OE
Total			**--**	**32**	**20**	**--**

*** EL-613:** Industry/academic-oriented skill courses must be chosen by students. Individual departments must set the SOP for the same.

SEMESTER - IV

S. No	Course Code	Course Title	Type	Hrs per week	Credits	Category
1	**TH-621**	Thesis	PW	30	15	PC
2	**TH-622**	Defence of Thesis	PW	--	5	PC
Total			**--**	**30**	**20**	**--**
Grand Total (I to IV Semesters)					**81**	

Semester – I

PP-511: Hospital and Community Pharmacy Practice (2 credits)

1. **Introduction to Hospitals:** Definition, classification, and organizational structure of Hospitals. Quality management system in hospitals and NABH accreditation.
2. **Hospital Pharmacy:** Definition, organizational structure, infrastructural requirements, legal requirements, budget requirements, and management of hospital pharmacy. Roles and responsibilities of hospital pharmacist including the dispensing of controlled and investigational medications.
3. **Hospital Committees:** Pharmacy & Therapeutic Committee, Medication Safety Committee, Infection Control Committee, Antibiotic Stewardship Committee, Opioid Stewardship Committee, and Research & Ethics Committee. Roles and responsibilities of the hospital pharmacist in these committees.
4. **Hospital Guidelines and Process:** Developing hospital formulary, preparation of emergency medication list, developing therapeutic guidelines, drug procurement process, methods of inventory control, economic order quantity, drug distribution process, and waste management process.
5. **Hospital Pharmacist Involvement in Counselling, Education and Training:** Patient counselling, training of pharmacy technicians, training and continuing education for pharmacists, and training of pharmacy, medical, and nursing students & staff.
6. **Community Pharmacy:** Definition, organizational structure, infrastructural requirements, legal requirements, budget requirements, and management of

community pharmacy. Roles and responsibilities of the community pharmacist.

7. **Medication Management:** Rational use of OTC medications, medication counselling, home medicines review, and identifying & acting upon **drug-related problems (DRPs) as per the Pharmaceutical Care Network Europe (PCNE) classification.**
8. **Communication Skills:** Verbal and non-verbal communication skills, reading, writing, listening, and critical thinking skills towards patients and other healthcare professionals.

Recommended Books:

1. A Practical Guide to Contemporary Pharmacy Practice and Compounding, by Judith E. Thomson, Wolters Kluwer.
2. Introduction to Hospital and Health-System Pharmacy Practice, by David A. Holdford and Thomas R. Brown, American Society of Health-System Pharmacists.
3. Communication Skills in Pharmacy Practice: A Practical Guide for Students and Practitioners, by Robert S. Beardsley, Wolters Kluwer.
4. Hospital Pharmacy, by Martin Stephens, Pharmaceutical Press.
5. Community Pharmacy Practice, by Ramesh Adepu, BSP Publishers.
6. Relevant research & review articles from recent medical and pharmaceutical literature.

PP-512: Clinical Pharmacy Practice (2 Credits)

1. Clinical Pharmacy Concept and Scope: Definition, origin, evolution, and scope of clinical pharmacy in India and globally. Concept and principles of pharmaceutical care process.

2. Clinical Pharmacy Setup in Hospital: Requirements for establishing a clinical pharmacy department and Drug & Poison Information Centre. Databases and software used in clinical pharmacy services.

3. Clinical Pharmacy Services Ward round participation; drug and poison information services; pediatric dosage calculation; patient medication history interview; treatment chart review; identification of medication-related problems; pharmacist interventions. Detection, reporting, and monitoring of adverse drug reactions (Pharmacovigilance); adverse events following immunization (Vaccine Pharmacovigilance); hemovigilance; and materiovigilance.

4. Patient Care Services and Regulation: Patient counselling, patient referrals, and medication adherence monitoring. Documentation and quality assurance of clinical pharmacy services. Overview of Medical Device Rules (MDR, 2017) and the role of pharmacists in medical device regulation.

5. Lab Data Interpretation and Therapeutic Monitoring: Interpretation of hematological, renal, liver, pulmonary, thyroid, and cardiac tests. Assessment of fluid, electrolyte, and acid–base balance. Interpretation of microbiological culture reports. Therapeutic drug monitoring and dosage adjustment of narrow therapeutic index drugs (e.g., digoxin, phenytoin, carbamazepine, gentamicin) and management of insulin and anticoagulants.

6. Precision Medicine and Pharmacogenomics: Principles of precision medicine and individualized therapy. Basics of pharmacogenomics, genetic polymorphisms, nomenclature, and clinical applications. Role of pharmacists in pharmacogenomics-guided therapy.

Recommended Books

1. A Textbook of Clinical Pharmacy Practice – Parthasarathi G, Karin Nyfort-Hansen, Milap Nahata
2. Oxford American Handbook of Clinical Pharmacy – Michelle McCarthy, Denise R. Kockler
3. Standards of Practice for Clinical Pharmacy Services – Society of Hospital Pharmacists of Australia
4. Basic Skills in Interpreting Laboratory Data – Mary Lee
5. Laboratory Tests and Diagnostic Procedures – Chernecky & Berger
6. Concepts in Pharmacogenomics – Martin M. Zdanowicz
7. Relevant research & review articles from recent medical and pharmaceutical literature

PP-513: Clinical and Applied Therapeutics – I (2 Credits)

1: Cardiovascular System

Etiopathogenesis and pharmacotherapy of cardiovascular disorders including hypertension, heart failure, angina pectoris, acute coronary syndrome, cardiac arrhythmias, and dyslipidemia. Emphasis on risk stratification, guideline-based management approaches, and emerging therapies such as PCSK9 inhibitors and biologics.

2: Respiratory System

Etiopathogenesis and pharmacotherapy of respiratory disorders including asthma, chronic obstructive pulmonary disease (COPD), asthma-COPD overlap syndrome, and drug-induced pulmonary disorders. Emphasis on stepwise management approaches (e.g., GINA/GOLD) and the role of biologics and biosimilars such as anti-IgE, anti-IL-5, and anti-IL-4 therapies.

3: Endocrine System

Etiopathogenesis and pharmacotherapy of endocrine disorders including metabolic syndrome, diabetes mellitus (Type 1, Type 2, gestational diabetes, and MODY), and thyroid disorders. Focus on individualized therapy, monitoring of complications, and advanced treatments including GLP-1 receptor agonists and emerging biologic agents.

4: Nephrology

Etiopathogenesis and pharmacotherapy of renal disorders including acute kidney injury, chronic kidney disease, and drug-induced renal disorders. Emphasis on hemodialysis, peritoneal dialysis, pharmacokinetic considerations, dose adjustment in renal impairment, and the role of the pharmacist in renal therapy management.

5: Integrative Therapeutic Approach

Application of clinical guidelines, therapeutic monitoring, and patient-specific factors in optimizing pharmacotherapy for chronic diseases.

Recommended Books

1. Koda-Kimble and Young's Applied Therapeutics: The Clinical Use of Drugs – Alldredge BK et al.
2. Pharmacotherapy: A Pathophysiologic Approach – DiPiro JT et al.

3. Clinical Pharmacy and Therapeutics – Walker R, Whittlesea C
4. Clinical Pharmacy and Therapeutics – Herfindal ET, Hirschman JL
5. Goodman & Gilman's The Pharmacological Basis of Therapeutics – Brunton LL et al.
6. Harrison's Principles of Internal Medicine – Jameson JL et al.
7. Relevant research & review articles from recent medical and pharmaceutical literature

PP-514: Clinical and Applied Therapeutics – II (2 Credits)

1: Principles of Infectious Disease Management

Etiopathogenesis and principles of management of infectious diseases including rational use of antibiotics and surgical prophylaxis, antimicrobial stewardship programs, antibiotic resistance mechanisms and prevention strategies, implementation of antibiotic policy in healthcare settings, and principles of sepsis management. Emphasis on empirical versus targeted therapy and antimicrobial de-escalation strategies.

2: Antimicrobial Agents

Classification, mechanism of action, spectrum of activity, pharmacokinetics, adverse effects, and clinical use of antimicrobial agents including beta-lactams (penicillins, cephalosporins, carbapenems), aminoglycosides, macrolides, lincosamides, tetracyclines, fluoroquinolones, glycopeptides, and sulfonamides with trimethoprim. Antitubercular drugs, antimalarials, antifungal agents, and antiviral drugs. Principles of rational antimicrobial therapy, selection of appropriate agents based on infection type and patient-specific factors, interpretation of culture and sensitivity reports, combination therapy, and prevention of antimicrobial resistance.

3: Major Infectious Diseases

Etiopathogenesis and pharmacotherapy of major infectious diseases including tuberculosis, malaria, HIV infection and associated opportunistic infections, meningitis, endocarditis, and septicemia. Management of common infections such as respiratory tract infections, urinary tract infections, and gastroenteritis. Overview of vector-borne and viral infections including dengue fever and Japanese encephalitis, along with pharmacotherapeutic approaches to protozoal, fungal, and viral infections with emphasis on appropriate antimicrobial selection and clinical management.

4: Advanced Therapeutic Approaches

Role of biologics and monoclonal antibodies in infectious diseases, immunotherapy approaches, and preventive strategies including vaccines and biologics.

5: Integrative Therapeutic Approach

Application of antimicrobial stewardship principles, clinical guidelines, and microbiological data in optimizing patient-specific anti-infective therapy.

Recommended Books

1. Koda-Kimble and Young’s Applied Therapeutics: The Clinical Use of Drugs – Alldredge BK et al.

2. Pharmacotherapy: A Pathophysiologic Approach – DiPiro JT et al.
3. Clinical Pharmacy and Therapeutics – Herfindal ET, Hirschman JL
4. Clinical Pharmacy and Therapeutics – Walker R, Whittlesea C
5. Goodman & Gilman's The Pharmacological Basis of Therapeutics – Brunton LL et al.
6. Harrison's Principles of Internal Medicine – Jameson JL et al.
7. Relevant research & review articles from recent medical and pharmaceutical literature

PP-515: Medication Safety and Clinical Risk Management (2 Credits)

1. Principles of Medication Safety

Concepts and scope of medication safety. Burden of medication-related harm. Systems approach to safety versus person approach. Swiss cheese model and safety frameworks. Human factors and ergonomics in medication use.

2. Medication Use Process and Error-Prone Stages

Medication use process (prescribing, transcribing, dispensing, administration, monitoring). Identification of high-risk steps and vulnerabilities. High-alert medications, LASA drugs, and error-prone abbreviations. Medication safety in transitions of care (without repeating reconciliation steps already covered elsewhere).

3. Clinical Risk Management Tools

Risk identification, risk assessment, and prioritization. Root cause analysis (RCA), failure mode and effects analysis (FMEA), and hazard analysis. Development and use of risk registers. Incident analysis and learning systems.

4. Medication Safety Strategies and System Design

Designing safer systems: standardization, simplification, forcing functions, and redundancy. Safe medication practices including dose standardization, labeling, storage, and use of protocols. Role of clinical decision support systems (CDSS), computerized physician order entry (CPOE), and automation in reducing errors.

5. High-Risk Situations and Special Safety Considerations

Medication safety in special populations (pediatrics, geriatrics, critically ill patients). Safety in use of high-risk drugs (e.g., anticoagulants, insulin, chemotherapy). Prevention of dosing errors and monitoring-related harm.

6. Quality Improvement and Safety Culture

Principles of continuous quality improvement (CQI). Medication safety indicators and performance measurement. Safety culture, teamwork, and communication in healthcare. Role of pharmacists in leading medication safety programs and system-level interventions.

Recommended Books

1. Medication Errors – Michael R. Cohen, American Pharmacists Association
2. Patient Safety – Charles Vincent, Wiley Blackwell

3. WHO Patient Safety Curriculum Guide for Health Professionals
4. Handbook of Human Factors and Ergonomics in Health Care and Patient Safety
5. Institute for Safe Medication Practices (ISMP) Guidelines
6. Relevant NABH and international medication safety guidelines
7. Relevant research & review articles from recent medical and pharmaceutical literature

GE-516: Biostatistics and Data Analytics (2 credits)

Refer to Postgraduate-Common Courses syllabus

GE-517: Artificial Intelligence, Machine Learning in Pharmaceuticals (1 credit)

Refer to Postgraduate-Common Courses syllabus

SM-518: Seminar (1 credit)

- Each student shall deliver two seminars: one based on topics from the academic syllabus and one based on a published research paper relevant to pharmacy practice or the student's research area
- Emphasis shall be given to literature search, critical analysis, and evidence-based interpretation of scientific data.
- Technical paper presentations shall be evaluated by at least two examiners.
- Evaluation shall be based on a structured rubric including content quality, critical appraisal, presentation skills, and ability to respond to queries.

GL-519: General Lab Experience/Introductory Clinical Pharmacy Practice Experience (6 credits)

1. Clinical Clerkship Activities (Hospital Posting)

- Participation in ward activities under supervision (medicine, ICU, or specialty wards).
- Observation and involvement in prescription review, medication chart analysis, and monitoring of drug therapy.
- Exposure to multidisciplinary team interactions and clinical decision-making processes.

2. Patient Data Collection and Documentation

- Collection of patient demographics, medical history, medication history, allergies, and relevant laboratory data.
- Preparation of **patient profiles (minimum 6 per semester)** with structured documentation.

3. Pharmaceutical Care Plan Development

- Identification of medication-related problems (MRPs).
- Development of therapeutic goals and interventions.
- Preparation and presentation of **case reports (minimum 2 per semester)** using the Pharmaceutical Care Plan model.

4. Case-Based Learning and Clinical Discussions

- Participation in **group discussions (minimum 6 per semester)** based on real patient cases.
- Application of clinical reasoning and evidence-based decision-making in therapeutic problem-solving.

5. Communication and Patient Counselling

- Interaction with patients and caregivers for medication history and counselling.
- Development of communication skills with healthcare professionals.
- Patient education on medication use, adherence, and safety.

6. Pharmacy / Clinical Services Exposure

- Minimum 18–24 hours per week of clinical/pharmacy exposure (2–3 days/week), including participation in ward activities, medication review, and clinical pharmacy services.

Distribution of Time (Indicative)

- Ward/Clinical Clerkship Activities → **12–14 hrs/week**
- Case Documentation & Care Plan Preparation → **3–4 hrs/week**
- Case Discussions / Presentations → **2–4 hrs/week**
- Pharmacy/Support Services Exposure → **1–2 hrs/week**

These experiential courses are designed to ensure progressive clinical competency through structured clerkship, integrating theoretical knowledge with real-world patient care.

Recommended Books / Resources

1. **Pharmaceutical Care Practice: The Patient-Centered Approach to Medication Management**
   – Cipolle RJ, Strand LM, Morley PC
   (Core text for pharmaceutical care plan development and clinical thinking)
2. **A Textbook of Clinical Pharmacy Practice – Essential Concepts and Skills**
   – Parthasarathi G, Nyfort-Hansen K, Nahata MC
   (Practical skills including patient data collection, counselling, and documentation)
3. **Clinical Pharmacy and Therapeutics**
   – Roger Walker, Cate Whittlesea
   (Useful for linking clinical cases with therapeutic decision-making)
4. **Pharmacotherapy: A Pathophysiologic Approach**
   – Joseph T. DiPiro et al.
   (Reference for case-based therapeutic planning during clerkship)
5. **Basic Skills in Interpreting Laboratory Data**
   – Mary Lee
   (Essential for understanding lab reports during patient case work)
6. **Communication Skills in Pharmacy Practice: A Practical Guide**
   – Robert S. Beardsley et al.
   (Supports development of patient counselling and interprofessional communication

skills)

7. **Documentation for Patient Care in Pharmacy Practice***(Recommended reference/guide)*
   – (ASHP/Clinical practice guidelines and institutional formats)
   (For SOAP notes, case documentation, and clinical reporting)

Additional Learning Resources (Recommended)

- WHO Patient Safety Curriculum Guide
- Standard Treatment Guidelines (National/Institutional)
- Hospital Formulary and Clinical Protocols
- Relevant clinical practice guidelines (e.g., ICMR, WHO, NICE)
- Recent research and review articles in clinical pharmacy and patient care

Semester – II

PP-521: Clinical and Applied Therapeutics – III (2 credits)

Etiopathogenesis and pharmacotherapy of diseases/disorders associated with the following systems:

1. Gastrointestinal System

Peptic ulcer disease, gastro-oesophageal reflux disease, inflammatory bowel disease, and liver disorders including alcoholic liver disease, viral hepatitis, and drug-induced liver disorders. Use of biologics such as anti-TNF agents and integrin inhibitors where applicable.

2. Nervous System Disorders

Pharmacotherapy of epilepsy, Parkinson's disease, Alzheimer's disease, and stroke with emphasis on long-term management, prevention of complications, and therapeutic monitoring.

3. Psychiatric Disorders

Management of schizophrenia, depression, anxiety disorders, sleep disorders, and drug-induced psychiatric conditions. Overview of recent advances in psychopharmacology.

4. Musculoskeletal and Autoimmune Disorders

Pharmacotherapy of rheumatoid arthritis, osteoarthritis, osteoporosis, gout, spondylitis, and systemic lupus erythematosus. Role of biologics and targeted therapies including TNF inhibitors, IL-6 inhibitors, and JAK inhibitors.

5. Oncology

Basic principles of cancer chemotherapy including mechanisms, combination therapy, and toxicity management. Pharmacotherapy of common cancers such as breast, cervical, gastric, lung, and head & neck cancers. Management of chemotherapy-induced adverse effects including nausea and vomiting. Role of targeted therapy, monoclonal antibodies, biosimilars,

and precision oncology approaches.

6. Special Population Pharmacotherapy

General prescribing guidelines for pediatric and geriatric patients. Drug use in pregnancy and breastfeeding. Dose adjustment, safety considerations, and the role of the pharmacist in optimizing therapy in special populations.

7. Integrative Therapeutic Approach

Application of clinical guidelines, evidence-based medicine, and patient-specific factors in optimizing pharmacotherapy for complex and multi-system disorders.

Recommended Books

1. Koda-Kimble and Young's Applied Therapeutics: The Clinical Use of Drugs – Alldredge BK et al.
2. Pharmacotherapy: A Pathophysiologic Approach – DiPiro JT et al.
3. Clinical Pharmacy and Therapeutics – Walker R, Whittlesea C
4. Clinical Pharmacy and Therapeutics – Herfindal ET, Hirschman JL
5. Goodman & Gilman's The Pharmacological Basis of Therapeutics – Brunton LL et al.
6. Harrison's Principles of Internal Medicine – Jameson JL et al.
7. Relevant research & review articles from recent medical and pharmaceutical literature

PP-522: Patient Safety and Health-Related Outcomes (2 credits)

1. Pharmacovigilance Systems and Drug Safety Monitoring

Overview of pharmacovigilance with focus on post-marketing surveillance systems. National and international pharmacovigilance programs and databases. Key terminologies and signal detection concepts. *(Focus on system-level safety surveillance and data interpretation; detailed medication error analysis is covered in the Medication Safety course.)*

2. Pharmacovigilance Methods and Safety Data Evaluation

Passive and active surveillance methods including spontaneous reporting systems, cohort event monitoring, and database studies. Signal detection, causality assessment (overview), and risk evaluation. Medication error reporting frameworks (conceptual linkage to safety systems without duplication of error analysis tools).

3. Materiovigilance and Device Safety Surveillance

Scope and importance of materiovigilance. National and global systems for medical device safety monitoring. Concepts of adverse device events, recalls, and field safety corrective actions. Device lifecycle safety monitoring and reporting frameworks.

4. Pharmacoepidemiology: Concepts and Applications

Definition, scope, and applications of pharmacoepidemiology in real-world evidence generation. Role in drug utilization, safety monitoring, and healthcare decision-making.

5. Measures and Methods in Pharmacoepidemiology

Outcome measures (incidence, prevalence), medication use measures (ATC/DDD), and risk measures (relative risk, odds ratio, hazard ratio, NNT, NNH). Study designs including cohort, case-control, cross-sectional, and post-marketing surveillance studies.

6. Patient-Centred Outcomes and Quality of Life

Concept and importance of health-related quality of life (HRQoL). Measurement tools including generic and disease-specific instruments. Application of patient-reported outcomes in clinical and policy decision-making.

7. Introduction to Pharmacoeconomics and Decision-Making

Concepts, need, and applications of pharmacoeconomics in healthcare systems. Role in formulary decisions and policy-making.

8. Pharmacoeconomic Evaluation Methods

Cost concepts (direct, indirect, intangible) and outcome measures (clinical, economic, humanistic). Methods including cost-minimization, cost-effectiveness, cost-utility, cost-benefit, and cost-of-illness analysis. Introduction to decision analysis and modeling (conceptual level).

9. Real-World Evidence and Health Outcomes Research

Use of real-world data sources such as electronic health records, registries, and claims databases. Integration of safety, effectiveness, and economic data for healthcare decision-making. Role of pharmacists in outcomes research.

Recommended Books

1. Pharmacoepidemiology – Brian L. Strom, Stephen E. Kimmel, Sean Hennessy
2. Understanding Pharmacoepidemiology – Yang Yi, Strum DW
3. Pharmacoepidemiology and Pharmacoeconomics – K.G. Revikumar
4. Essentials of Pharmacoeconomics – Karen Rascati
5. Decision Modelling for Health Economic Evaluation – Briggs, Claxton, Sculpher
6. Understanding Health Outcomes and Pharmacoeconomics – George E. MacKinnon III
7. Relevant research & review articles from recent medical and pharmaceutical literature

PP-523: Clinical Research (2 credits)

1. Drug Development and Regulatory Framework

Overview of drug development process and clinical trial phases. Regulatory pathways including investigational new drug (IND) and new drug application (NDA). Role of regulatory authorities and ethics committees. Principles of Good Clinical Practice (ICH-GCP, CDSCO, ICMR guidelines) and ethical considerations in human research.

2. Clinical Trial Designs and Methodologies

Types of clinical trial designs including randomized controlled trials, adaptive designs, and pragmatic trials. Methods of randomization, blinding, and allocation concealment (conceptual understanding). Overview of observational and quasi-experimental studies. Bioavailability and bioequivalence studies. Emerging models including decentralized and hybrid clinical trials.

3. Clinical Trial Operations and Study Team

Structure and functioning of clinical trial teams including roles of investigator, sponsor, CRO, monitor, and clinical research coordinator. Responsibilities and coordination among stakeholders in trial conduct.

4. Clinical Trial Documentation and Regulatory Compliance

Preparation and review of essential documents including protocol, investigator's brochure, informed consent form, case record form, and trial agreements. Regulatory documentation and compliance requirements.

5. Clinical Trial Start-up and Conduct

Site feasibility assessment, investigator selection, ethics committee submissions, and site initiation. Clinical trial procedures including investigational product management, site monitoring, and maintenance of essential documents (TMF, ISF, pharmacy file).

6. Quality Assurance and Inspection Readiness

Principles of quality assurance and quality control in clinical trials. Types of audits, audit processes, documentation, and inspection readiness. Handling protocol deviations, non-compliance, and research misconduct.

7. Clinical Data Management and Digital Tools

Overview of clinical data management systems including data collection, entry, validation, and database management. Introduction to electronic data capture systems and data integrity principles. Overview of analytical tools (e.g., SAS, R, SPSS) with focus on application rather than statistical theory.

Recommended Books

1. Principles of Clinical Research – Giovanna di Ignazio, Gareth Hayes
2. Textbook of Clinical Trials – David Machin, Simon Day, Sylvan Green
3. Good Clinical Practice Guidelines – CDSCO (India)
4. ICH-GCP Guidelines – International Council for Harmonisation
5. Ethical Guidelines for Biomedical Research – ICMR
6. Relevant research & review articles from recent medical and pharmaceutical literature

PP-524: Evidence-Based Medicine (2 credits)

1. Introduction to Evidence-Based Medicine

Definition, need, and steps of EBM. Levels of evidence and hierarchy in healthcare decision-making. Integration of evidence, clinical expertise, and patient preferences.

2. Literature Search and Evidence Retrieval

Formulation of clinical questions using PICO framework. Advanced literature search strategies including use of databases (PubMed, Cochrane, etc.), MeSH terms, Boolean operators, and filters. Identification of secondary sources such as clinical guidelines and evidence summaries.

3. Understanding Scientific Literature

Structure of research articles and interpretation of different sections. Reading and understanding scientific papers. Interpretation of study results and conclusions.

4. Study Designs and Evidence Hierarchy

Overview of study designs including randomized controlled trials, cohort, case-control, and systematic reviews. Evidence hierarchy and strength of recommendations (conceptual focus).

5. Critical Appraisal of Literature

Assessment of internal and external validity, bias, confounding, and applicability. Use of appraisal tools such as CASP, JBI, ROB 2.0, and AMSTAR-2.

6. Types of Reviews and Evidence Synthesis

Overview of narrative reviews, systematic reviews, scoping reviews, umbrella reviews, and diagnostic/prognostic reviews. Principles and steps of systematic review and meta-analysis including data extraction, heterogeneity, forest plots, and publication bias (conceptual understanding). PRISMA and MOOSE guidelines.

7. Interpretation of Clinical Research Outcomes

Understanding key research terminologies including sensitivity, specificity, predictive values, likelihood ratios, confidence intervals, p-values, survival analysis (Kaplan-Meier), and clinical vs statistical significance. (Focus on interpretation; statistical calculations covered elsewhere.)

8. Application of Evidence in Clinical Practice

Translation of evidence into clinical decision-making. Shared decision-making, evidence-to-decision (ETD) frameworks, and development/use of clinical guidelines.

9. Scientific Writing and Research Communication

Structure and ethical considerations in scientific writing including clinical study protocols, manuscripts, and reports. Overview of regulatory formats (ICH guidelines, CTD) and publication ethics (ICMJE, COPE, EQUATOR).

10. Real-World Evidence and Emerging Concepts

Use of real-world evidence from registries and observational studies. Ethical and legal considerations, publication bias, and misuse of evidence in healthcare decision-making.

Recommended Books

1. Evidence-Based Medicine: How to Practice and Teach EBM – Straus S et al.
2. How to Read a Paper – Trisha Greenhalgh
3. Essential Evidence-Based Medicine – Dan Mayer
4. The Pharmacist's Guide to Evidence-Based Medicine – Bryant PJ, Pace HA
5. Introduction to Meta-Analysis – Borenstein M et al.
6. Research Synthesis and Meta-Analysis – Harris Cooper
7. Cochrane Handbook for Systematic Reviews of Interventions – Higgins JPT et al.
8. Relevant research & review articles from recent medical and pharmaceutical literature

GE-526: Intellectual Property Rights and Regulatory Affairs in Pharmaceuticals (2 credits)

Refer to Postgraduate-Common Courses syllabus

GE-527: Research Culture and Ethics in the Pharmaceutical Industry (2 credits)

Refer to Postgraduate-Common Courses syllabus

SM-528: Seminar (1 credit)

- Each student shall deliver **two seminars** during the semester:
  - One based on recent advances or emerging topics in pharmacy practice or healthcare.
  - One based on a **published research paper** relevant to the student's research area or specialization.
- Emphasis shall be given to:
  - Literature search and evidence-based analysis
  - Critical appraisal of research methodology and findings
  - Clinical and practical relevance of the topic
- Seminar presentations shall include structured components such as introduction, methodology, results, discussion, and implications for practice/research.
- **Evaluation** shall be conducted by at least two examiners and based on a structured rubric including:
  - Content quality and depth
  - Critical analysis and interpretation
  - Presentation and communication skills
  - Ability to answer questions and defend the topic

Suggested Areas / Topics

- Recent advances in pharmacy practice and clinical therapeutics
- Emerging therapies (biologics, precision medicine, AI in healthcare)
- Public health challenges and patient safety issues
- Critical appraisal of recent high-impact research articles
- Healthcare policies and guidelines

Recommended Resources

- Recent research articles from indexed journals (PubMed, Scopus)
- Clinical practice guidelines (WHO, ICMR, NICE, etc.)
- Standard textbooks and reference books in pharmacy practice
- Databases such as PubMed, Cochrane Library, and Google Scholar

GL-529: General Lab Experience in the Area of Specialization/Advanced Clinical Pharmacy Practice Experience (6 Credits)

1. Advanced Clinical Clerkship Activities

Participation in ward rounds and multidisciplinary discussions, medication chart review, therapy monitoring, and identification of medication-related problems (MRPs) with appropriate documentation.

2. Patient Data Collection and Documentation

Comprehensive patient assessment including clinical, laboratory, and medication data. Preparation of **patient profiles (minimum 6–8 per semester)** using structured documentation formats such as SOAP notes.

3. Pharmaceutical Care Plan and Interventions

Development, implementation, and follow-up of pharmaceutical care plans. Documentation of **clinical interventions (minimum 4–6 cases)** along with therapeutic outcomes.

4. Case Presentations and Clinical Discussions

Presentation of case reports (minimum 3 per semester) and participation in case-based discussions (minimum 6 sessions) focusing on complex and multidisciplinary cases.

5. Patient Counselling and Communication Skills

Advanced patient counselling, medication adherence support, and communication of therapeutic recommendations to healthcare professionals.

6. Medication Safety and Outcome Evaluation

Assessment of high-risk medications, identification of medication-related harm, and evaluation of therapeutic outcomes and patient safety indicators.

7. Clinical / Pharmacy Service Exposure

- **Minimum 18–24 hours per week of clinical/pharmacy exposure (2–3 days/week)**
- Exposure to ward activities, clinical pharmacy services, and hospital pharmacy operations

Indicative Weekly Distribution

- Clinical/Ward Posting → **8–12 hrs/week (2–3 days)**
- Case Documentation & Interventions → **3–4 hrs/week**

- Case Discussions / Presentations → **2–3 hrs/week**
- Self-learning / EBM Integration → **2–5 hrs/week**

These experiential courses are designed to ensure progressive clinical competency through structured clerkship, integrating theoretical knowledge with real-world patient care.

EL – 525: Programme Electives (2 Credits)

PP-522: Patient Safety & Health Related Outcomes (2 credits)

Refer to the Department of Pharmacy Practice syllabus

PP-523: Clinical Research (2 credits)

Refer to the Department of Pharmacy Practice syllabus

PP-524: Evidence-Based Medicine (2 credits)

Refer to the Department of Pharmacy Practice syllabus

DEPARTMENT OF PHARMACOLOGY AND TOXICOLOGY

SEMESTER - I

Sl. No.	Course Code	Course Name	Type	Hours per week	Credits	Category
1	**PC-511**	Pathophysiology of Diseases	T	2	2	PC
2	**PC-512**	General and Molecular Pharmacology	T	2	2	PC
3	**PC-513**	Experimental Pharmacology and Pharmacological Screening	T	2	2	PC
4	**BT-515**	Analytical Techniques in Biotechnology and Biopharmaceuticals	T	2	2	PC
5	**PA-513**	Analytical techniques for Separation and Characterization	T	2	2	PC
6	**GE-516**	Biostatistics and Data Analytics	T	2	2	SD
7	**GE-517**	Artificial Intelligence and Machine Learning in Pharmaceuticals	T	1	1	IO
8	**SM-518**	Seminar	TS	1	1	SL
9	**GL-519**	General Lab Experience	LPS	18-24	6	PC
Total			**--**	**32-38**	**20**	**--**

SEMESTER - II

Sl. No.	Course Code	Course Name	Type	Hours per week	Credits	Category
1	**PC-521**	Advances in Systemic Pharmacology	T	2	2	PC
2	**PC-522**	Advances in Chemo- and Immunopharmacology of Cancer and Infectious Diseases	T	2	2	PC
3	**PC-523**	Clinical Pharmacology and Regulatory Toxicology	T	2	2	PC

4	**PE -522**	Biopharmaceutics and Pharmacokinetics	T	2	2	PC
5	**EL -525**	Programme Elective *	T	2	2	PE
6	**GE-526**	Intellectual Property Rights and Regulatory Affairs in Pharmaceuticals	T	2	2	SD
7	**GE-527**	Research Culture and Ethics in the Pharmaceutical Industry	T	2	2	IO
8	**SM-528**	Seminar	TS	1	1	SL
9	**GL-529**	General Lab Experience in the Area of Specialization	LPS	18-24	6	PC
Total			**--**	**33-39**	**21**	**--**

*** EL-525 (Programme Elective):** The scholar should select any one course from the list of courses offered by other departments.

List of Department-wise Programme Electives (EL- 525) – 2 Credits:

(Scholars must select any one elective course from any department other than their own department)

Name of Department	**Course title**	**Credits/ Course**
BT	BT-525 (A): Nanobiotechnology BT-525 (B): Omics in Drug Discovery	2
PA	PA-525 (A): Analytical characterization of Biosimillars PA-525 (B): Mass spectrometry in Omics	2
PE	PE-521: Pharmaceutical Product Development - II PE-522: Biopharmaceutics and Pharmacokinetics	2
PP	PP-522: Patient Safety and Health Related Outcomes PP-523: Clinical Research PP-524: Evidence-Based Medicine	2
PT	PC-525 (A): Principles and Methods in Toxicology PC-525 (B): Introduction to Regulatory Toxicology	2

SEMESTER - III

S. No	**Course Code**	**Course Title**	**Type**	**Hrs per week**	**Credits**	**Category**

1	**TH-611**	Synopsis	PW	28	15	PC
2	**TH-612**	Presentation	PW	--	3	PC
3	**EL-613**	Self-learning Courses *	IO	4	2	OE
____	_____	**Total**	**--**	**32**	**20**	**--**

*** EL-613:** Industry/academic-oriented skill courses must be chosen by students. Individual departments must set the SOP for the same.

SEMESTER - IV

S. No	Course Code	Course Title	Type	Hrs per week	Credits	Category
1	**TH-621**	Thesis	PW	30	15	PC
2	**TH-622**	Defence of Thesis	PW	--	5	PC
Total			**--**	**30**	**20**	**--**
Grand Total (I to IV Semesters)					**81**	_____

Semester - I

PC-511: Pathophysiology of Diseases (2 credits)

Pathogenesis, symptoms and signs, laboratory findings and complications of following disorders:

1. CNS Disorders: Common pathophysiological mechanisms of neurodegenerative disorders
2. and neuropsychiatric disorders Epilepsy
3. CVS Disorders: Hypertension, Angina, MI
4. Respiratory disorders: Asthma, Bronchial Asthma
5. GI disorders: Ulcer, Ulcerative colitis, IBD, hepatitis and cholecystitis, Pancreatitis
6. Haemostasis and haemopoietic system: Anaemia
7. Hepatic and Renal diseases
8. Rheumatoid arthritis, Gout, Autoimmune disorders

PC-512: General and Molecular Pharmacology (2 credits)

1. Introduction to general and molecular pharmacology
2. Receptors as a drug target.
3. Types of receptors
4. GPCR- Classification, structure, drug receptor interaction, G-protein, receptor theories, agonist, antagonist.
5. Receptor regulation: GPCR desensitization, down regulation, upregulation
6. Regulators of G-protein signalling
7. Ion channels and Ion channel linked receptors and their regulation
8. Nuclear receptors

9. Transmembrane signalling mechanisms
10. Transcription factors
11. Dose response relationship and different types of antagonism
12. Efficacy and Toxicity evaluation using different experimental models, dose-response analysis,
    margin of safety in pre-clinical development
13. Chronopharmacology and Chronotherapeutics
14. Computational pharmacology
15. Network pharmacology

PC-513: Experimental Pharmacology and Pharmacological Screening (2 credits)

1. Introduction to pharmacological research, Role of pharmacology in drug discovery, General principles of pharmacological screening.
2. Pharmacological screening models
3. Correlation between in-vitro and in-vivo screens.
4. Correlations between various animal models and human situations.
5. Drug solution preparations: Storage, concentration expression, common solvents, stabilizing agents, storage conditions, reference standards, False positive and false negative response.
6. *In vitro* experimentation: Advantages and disadvantages, applications of cell culture for drug screening. Aseptic handling, cell counting and cell viability assays. Tissue isolation, tissue fixation, common fixatives, preparation of single cell suspension.
7. Animal ethics, regulations for conducting animal experimentation, 3 R's concept,
8. Common laboratory animals and their physiological parameters, factors affecting the nature and degree of pharmacological responses; Handling and care of different animals; Bleeding and different routes of administration, anaesthetics used in animal research and chemical euthanasia.
9. Zebrafish model to screen pharmaceutical molecules
10. Animal experimentation: Advantages and disadvantages; Anaesthesia used in laboratory animals, common agents, dose calculations, cannulation methodology, ventilation rate, recording of arterial blood pressure, intestinal motility etc. precautions to be taken in behavioural experiments.
11. New Approach Methodologies (NAMs): Organoid, Organ-on-chip, AI-driven models, combined systems (AI + Biological NAMs)
12. Biochemical assays.
13. Imaging techniques in pharmacological research
14. High throughput screening and high content screening, Humanized and transgenic animal model for drug screening.
15. Metabolic stability studies
16. Research Ethics and Publication Ethics

BT-515: Analytical Techniques in Biotechnology and Biopharmaceuticals (2 credits)

Refer to the Department of Biotechnology syllabus

PA-513: Analytical techniques for Separation and Characterization (2 credits)

Refer to the Department of Pharmaceutical Analysis syllabus

GE-516: Biostatistics and Data Analytics (2 credits)

Refer to Postgraduate-Common Courses syllabus

GE-517: Artificial Intelligence, Machine Learning in Pharmaceuticals (1 credit)

Refer to Postgraduate-Common Courses syllabus

SM-518: Seminar (1 credit)

GL-519: General Lab Experience (6 credits)

i) Endnote
ii) AI/ML Tools
iii) Power BI/Tableau
iv) Chemdraw
v) Advance Excel
vi) Biostatistics and Data Analytics

Semester - II

PC-521: Advances in Systemic Pharmacology (2 credits)

1. CNS Pharmacology: Neurotransmitters, Neuromodulators, Neuropeptides, Nerve growth factors, Blood Brain Barrier and strategies to enhance BBB permeability,
2. CNS disease models, CNS drug discovery and challenges,
3. Advances in pharmacology of drugs used in the treatment of neurological, neuropsychiatric and neurodegenerative disorders: Gene therapy and cell-based therapy for CNS disorders
4. CVS Pharmacology: CVS disease models, CVS drug discovery and challenges; Pharmacology of CVS drugs and newer targets for hypertension, angina, myocardial infarction etc.
5. Pharmacology of Lipid lowering drugs, Newer antiplatelet agents and thrombolytic agents
6. Advances in pharmacology of drugs used in the treatment of CVS diseases: Gene therapy and cell-based therapy
7. Respiratory system Pharmacology: Pharmacology of bronchodilators, pharmacology of antiinflammatory
   agents used in asthma & COPD and cough suppressants.
8. Experimental models for Asthma/COPD.
9. Advances in endocrine pharmacology: Adenohypophyseal hormones and related substances; Thyroid and antithyroid drugs; Insulin and oral hypoglycemic agents, newer anti-diabetic drugs, Endocrine pancreas, Antiobesity agents; Adrenocortical hormones: adrenocortical steroids and inhibitors of the synthesis. ADH, ANP and Erythropoietin.
10. Advances in autacoids pharmacology
11. Diuretics and renal pharmacology
12. GI: Hormones and Digestion, Autocrine, Paracrine, and Neurocrine Actions

PC-522: Advances in Chemo- and Immunopharmacology of Cancer and Infectious Diseases (2 credits)

1. Introduction to Cancer
2. Diagnostic aspects and Staging of Cancer, biomarkers (Diagnostic, Prognostic and Predictive)
3. Cancer Chemotherapy: Types, classification, Adjuvant therapy
4. Precision Chemotherapeutics: Targeted Vs Untargeted
5. Chemoresistance and Chemo-sensitization
6. Introduction to immunopharmacology, immunomodulators, immunostimulants and immunosuppressants, CAR-T Chemotherapy, Oncolytic Viruses, Allogenic and Autogenic HLA Matching and HSCT, Bone marrow transplant
7. Introduction to microbial and parasitic disease.
8. General consideration of antimicrobial agents
9. Infectious diseases in different context; community- acquired infections, emerging infectious diseases, infectious diseases associated with travel, zoonotic diseases
10. Pathogenesis, Treatments, Resistance and New drug targets for the following diseases:
    a. Bacterial: TB, Pneumonia, UTI
    b. Viral: HIV, SARS like infections
    c. Fungal: Candidiasis, Cryptococcosis, Aspergillosis
    d. Parasitic: Malaria, Amoebiasis, Leishmaniasis

PC-523: Clinical Pharmacology and Regulatory Toxicology (2 credits)

1. Introduction to Clinical Pharmacology and Regulatory Toxicology
2. Preclinical testing strategy Vis-a-vis envisaged clinical studies; Experimental clarification of possible human risk; Technical details of experiments; Flow chart for development of preclinical testing, GLP Guidelines
3. Clinical Trials: Phases, applications, designs, International and National Regulatory Agencies, requirements; GCP guidelines
4. Individualization of drug therapy: Personalized medicine
5. Single dose and repeat dose toxicity studies: Factors influencing such studies such as species, sex, route, dose level; Data evaluation and regulatory requirements.
6. Reproductive toxicology: Spermatogenesis, Risk assessment of male reproductive toxicity, Oogenesis, Risk assessment of female reproductive toxicity; Oocyte toxicity
7. Mutagenicity: Mechanisms of mutagenesis, germ cell mutations, somatic cell mutation; Risk assessment of mutagenicity (Tests systems in vitro, test for gene mutation in bacteria, chromosome damage, in vivo micronucleus tests in rodent, metaphase analysis)
8. Carcinogenicity: Principles of carcinogenicity, dose-setting for carcinogenesis bio assay, transplacental carcinogenesis; carcinogenesis/tumor promotion.
9. Safety Pharmacology of pharmaceuticals, herbals and biopharmaceuticals - ICH S7 and S7B guidelines
10. Evidence-based Medicine

PE-522: Biopharmaceutics and Pharmacokinetics (2 credits)

Refer to the Department of Pharmaceutics Syllabus

GE-526: Intellectual Property Rights and Regulatory Affairs in Pharmaceuticals (2 credits)

Refer to Postgraduate-Common Courses syllabus

GE-527: Research Culture and Ethics in the Pharmaceutical Industry (2 credits)

Refer to Postgraduate-Common courses syllabus

SM-528: Seminar (1 credit)

GE-529: General Lab Experience in the Area of Specialization (6 credits)

1. Route of administration (ip, iv, po).
2. Blood collection and plasma separation.
3. Blood cell counting (manual and 5-part automation).
4. Tissue isolation and fixation.
5. Tissue processing and histological slide preparation.
6. Blood smear and histological slide staining (manual and automation).
7. Aseptic techniques.
8. Cell culture techniques.
9. Cytotoxicity determination by MTT, LDH and neutral red uptake assay
10. Use of statistics.
11. Data collection, interpretation and calculations.
12. Health check-ups, acclimatization, grouping, animal marking; Cage cards, dose calculation for mice and rats;
13. Common solvents, uses, storage conditions, dosing procedures (oral, intraperitoneal);
14. Common toxic symptoms definitions and observation, feed intake measurements, water intake measurements, urine output, anaesthesia and gross necropsy;
15. Blood removal from mice and rats and anticoagulants. Separation and isolation of plasma, case of haemolysis sample.
16. Body weight, organ weight, body to organ ratio calculation, different target organs isolation, fixative, preservations, autolysis, raw data collection, computation, statistics and report preparation

EL – 525: Programme Electives (2 Credits)

PC-525 (A): Principles and Methods in Toxicology (2 credits)

1. Introduction to general toxicology.
2. History of toxicology.
3. Classification and ramification in toxicology.
4. Toxicants: Types, Sources, Exposure, exposure characterization.
5. Routes of exposure: Organism environment interaction.
6. Human health risk assessment: Hazard identification, Hazard Characterization, Exposure assessment, Risk characterization
7. Risk prediction and management
8. Toxicokinetic and Toxicodynamics
9. Mechanisms of Toxicity: Reaction of the ultimate toxicant with the target molecule, Endocrine disruption, Cellular dysfunction and resultant toxicities, Inappropriate repair and adaptation, Adverse Outcome Pathways, Key Events, Immunotoxicology
10. AI in Toxicology prediction, Toxicology-related degrees and certifications (eg. DABT, ERT) and opportunities

Recommended books:

i) Casarett & Doull's Essentials of Toxicology by Curtis D. Klaassen, John B. Watkins
ii) Principles of Toxicology by Karen Stine, Thomas M. Brown
iii) Text Book of Pathology by Harsh Mohan

PC-525 (B): Introduction to Regulatory Toxicology (2 credits)

1. Discovery and development Regulations linked to Drug, Biologics & biosimilars (FDA,OECD,ICH) and Medical devices (ISO, USFDA, IMDRF)
2. Design non-clinical toxicity studies and clinical development: Novel drugs and clinical trial Rules 2019, ICH M3, IVIVE
3. Clinical risk/benefit analysis.
4. Drug discovery and registration: Regulatory affairs, WTO, patent regime, accreditation and harmonisation process.
5. Models and bioassay: Methods in toxicity testing, dose-response characterisation
6. Safety Pharmacology (ICH S7A and S7B)
7. Threshold limitations: Hormesis, lower dose extrapolation.
8. Animal to human extrapolation: Flow chart, "CasebyCase" basis in non-clinical development and its influences in safety assessment, usefulness and limitations.
9. New Approach Methodologies (NAMs) and Integrated Approaches to Testing and Assessment (IATA): 2D & 3D cell culture, organoids, organ-on-chips, AI/ML-based models, In chemico methods, Omics approaches, Evidence-based Toxicology
10. Influence of new technologies and their implications

Recommended books:

i) Regulatory Toxicology by Shayne C. Gad Taylor & Francis
ii) Principles and Methods of Toxicology by A. Wallace Hay
iii) Drug Discovery and Evaluation: Safety and Pharmacokinetic Assays by H. Gerhard Vogel (Deceased), Jochen Maas, Franz J. Hock, Dieter Mayer

Ph.D. COURSEWORK STRUCTURE

Ph.D. COURSEWORK STRUCTURE

(DOCTORAL COURSES FOR BOTH NIPER and NON-NIPER STUDENTS)

Abbreviations:

PC: Programme Core

SD: Skill Development

T: Theory

Name of Department:

BT: Biotechnology

PA: Pharmaceutical Analysis

PE: Pharmaceutics

PP: Pharmacy Practice

PT: Pharmacology and Toxicology

Ph.D. COURSEWORK - COMMON STRUCTURE

SEMESTER - I

S. No	Course Code	Course Title	Type	Hrs per week	Credits	Category
1	Refer provided list	Core course – 1 *	T	2	2	PC
2	Refer provided list	Core course – 2 *	T	2	2	PC
3	**GE -714**	Research Methodology	T	2	2	SD
		Total	--	6	6	--

* Candidate must select a minimum of 2 courses from the provided list of core courses.

List of Department-wise Core Courses (Sem-I) – 2 credits:

(Candidate must select a minimum of 2 courses/semester from the provided list)

Name of Department	Course title	Credits/ Course
BT	BT-711: Advanced Techniques in Biotechnology and Biopharmaceuticals BT-712: Bioconjugate Technology BT-713: Therapeutic and Diagnostic Approaches in Neglected Tropical Diseases	2
PA	PA-711: Hyphenated techniques in pharmaceutical development PA-712: Troubleshooting techniques in analytical method development PA-713: Analytical Chemometrics	2
PE	PE-711: Pharmaceutical Product Development and Translational Sciences	2

	PE-712: Implications of Solid-State Properties in Drug Delivery PC-713: Pharmacological and Toxicological Screening and Assays	
PP	PP-711: Advanced Clinical Decision-Making and Precision Pharmacotherapy PP-712: Pharmacoepidemiology and Real-World Evidence Analytics PP-713: Advanced Biostatistics and Data Science for Clinical Research	2
PT	PC-711: Mitochondrial Pharmacology in Human Diseases PC-712: Epigenetics and Diseases PC-713: Pharmacological and Toxicological Screening and Assays	2

SEMESTER - II

S. No	Course Code	Courses Title	Type	Hrs per Week	Credits	Category
1	Refer provided list	Core course – 1 *	T	2	2	PC
2	Refer provided list	Core course – 2 *	T	2	2	PC
3	**GE – 814**	Research Ethics	T	2	2	SD
		Total	--	6	6	--

* Candidate must select a minimum of 2 courses from the provided list of core courses.

List of Department-wise Core Courses (Sem-II) – 2 credits:

(Candidate must select a minimum of 2 courses from the provided list)

Name of Department	Course title	Credits/ Course
BT	BT-811: Protein Structure and Stability BT-812: Biomaterials and Tissue Engineering BT-813: Advanced Mammalian Cell Culture Techniques	2
PA	PA-811: Impurity profiling and regulatory requirement PA-812: Mass spectrometry in drug discovery PA-813: Characterization of New Biologicals and Biosimilars	2
PE	PE-811: Computational Biopharmaceutics and Pharmacokinetics PE-812: Novel and Advanced Approaches in Targeted Drug Delivery Systems	2

	BT-811: Protein structure and stability	
PP	PP-811: Scientific Writing, Grant Development, and Research Leadership PP-812: Advanced Pharmacovigilance and Patient Safety Science PP-813: Health Economics, HTA, and Policy Decision-Making	2
PT	PC-811: Regulatory Toxicology and Drug Safety Evaluation PC-812: Precision Therapeutics PC-813: Pharmacological Interventions for Ischemic Brain Injury	2

Semester – I

GE-714: Research Methodology (2 credits)

Module 1: Research Conceptualization and Problem Framing (5 Hours)

- Philosophy of research and scientific thinking
- Identifying research gaps
- Problem prioritization
- Frameworks: PICO, FINER
- Translating real-world problems into research questions

Module 2: Study Design Selection and Methodological Fit (5 Hours)

- Matching research questions with study designs
- Overview of:
    - Experimental (lab/preclinical)
    - Observational (clinical/population)
    - Qualitative approaches
- Internal vs external validity
- Feasibility vs rigor

Module 3: Translational and Interdisciplinary Research (5 Hours)

- Translational research (T1–T4)
- Bench-to-bedside and reverse translation
- Interdisciplinary research models
- Systems thinking in healthcare and pharma research

Module 4: Advanced Research Design Strategies (5 Hours)

- Pragmatic vs explanatory research
- Adaptive and hybrid designs (conceptual)
- Comparative effectiveness framework
- Multi-center and collaborative research

Module 5: Research Quality, Bias, and Validity (5 Hours)

- Types of bias (design-level understanding)
- Validity threats across study designs
- Reproducibility and research integrity (conceptual)
- Avoiding research waste

Module 6: Protocol Structuring and Research Translation (5 Hours)

- Core components of research protocol
- Design justification and outcome selection
- Identifying limitations
- Translating research into practice, policy, and innovation

Recommended Books (Full References)

1. Hulley SB, Cummings SR, Browner WS, Grady DG, Newman TB. *Designing Clinical Research*. 4th ed. Philadelphia: Wolters Kluwer; 2013.
2. Creswell JW, Creswell JD. *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches*. 5th ed. Thousand Oaks: Sage Publications; 2018.
3. Greenhalgh T. *How to Read a Paper: The Basics of Evidence-Based Medicine*. 6th ed. Oxford: Wiley-Blackwell; 2019.
4. Booth WC, Colomb GG, Williams JM, Bizup J, Fitzgerald WT. *The Craft of Research*. 4th ed. Chicago: University of Chicago Press; 2016.
5. Kothari CR, Garg G. *Research Methodology: Methods and Techniques*. 3rd ed. New Delhi: New Age International; 2014.
6. National Academy of Sciences. *On Being a Scientist: A Guide to Responsible Conduct in Research*. 3rd ed. Washington, DC: National Academies Press; 2009.
7. Indian Council of Medical Research (ICMR). *National Ethical Guidelines for Biomedical and Health Research Involving Human Participants*. Latest edition.

Semester – II

GE-814: Research Ethics (2 credits)

Module 1: Foundations of Research Ethics and Integrity

- Historical evolution of research ethics (e.g., Nuremberg, Helsinki)
- Core ethical principles:
  - Autonomy
  - Beneficence
  - Non-maleficence
  - Justice
- Responsible conduct of research (RCR)
- Ethics vs compliance

Module 2: Ethics in Human Research and Clinical Studies

- Informed consent (basic to complex scenarios)
- Vulnerable populations (children, elderly, economically disadvantaged)
- Risk–benefit assessment
- Privacy, confidentiality, and data protection
- Ethics in clinical trials and public health research

Module 3: Animal Ethics and Laboratory Research Integrity (5 Hours)

- Ethical use of animals in research (3Rs: Replace, Reduce, Refine)
- CPCSEA guidelines and institutional animal ethics committees
- Laboratory research integrity:
  - Data recording
  - Image manipulation
  - Reproducibility issues

Module 4: Research Misconduct and Publication Ethics (5 Hours)

- Types of misconduct:
    - Fabrication
    - Falsification
    - Plagiarism
- Duplicate publication, salami slicing
- Authorship criteria (ICMJE guidelines)
- Predatory journals and unethical publishing practices

Module 5: Regulatory Frameworks and Research Governance (5 Hours)

- National and international guidelines:
    - ICMR
    - ICH-GCP
    - CDSCO
- Institutional Ethics Committees (IEC/IRB) functioning
- Approval processes and documentation
- Data governance and accountability

Module 6: Emerging Ethical Issues in Modern Research (5 Hours)

- Ethics in AI and digital health research
- Big data, biobanking, and genomics ethics
- Data ownership and sharing
- Industry-sponsored research and conflict of interest
- Community engagement and public trust

Recommended Books

1. National Academy of Sciences. *On Being a Scientist: A Guide to Responsible Conduct in Research*. 3rd ed. Washington, DC: National Academies Press; 2009.
2. Shamoo AE, Resnik DB. *Responsible Conduct of Research*. 3rd ed. New York: Oxford University Press; 2015.
3. Emanuel EJ, Grady C, Crouch RA, et al., eds. *The Oxford Textbook of Clinical Research Ethics*. Oxford: Oxford University Press; 2008.
4. Indian Council of Medical Research (ICMR). *National Ethical Guidelines for Biomedical and Health Research Involving Human Participants*. New Delhi: ICMR; Latest edition.
5. World Medical Association. *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*. Latest version.
6. Council for International Organizations of Medical Sciences (CIOMS). *International Ethical Guidelines for Health-related Research Involving Humans*. Latest edition.
7. Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*. 8th ed. New York: Oxford University Press; 2019.

DEPARTMENT OF BIOTECHNOLOGY

Semester I

BT- 711: Advanced Techniques in Biotechnology and Biopharmaceuticals (2 credits)

1. **Genetic Manipulation of Cells:** Mammalian gene manipulation techniques and its applications.
2. **Advanced Microscopic Techniques:** Fluorescence and Near IR Imaging, Confocal microscopy, Flow Cytometry, AFM, SEM and TEM.
3. **Genomics and Transcriptomics:** Next generation sequencing, data analysis and it's applications.
4. **Proteomics:** Advances in proteomics, data analysis and its application in biomarker discovery.
5. **Metabolomics and Lipidomics:** Approaches and its applications.
6. **In vivo Imaging:** Fluorescence and Micro – CT imaging.
7. **Dynamic light scattering and related analytical tools**.

Suggested reading:

2. Green and Sambrook. Molecular Cloning: A Laboratory Manual.
3. Melanie Kappelmann-Fenzl. Next Generation Sequencing and Data Analysis.
4. Ron Wehrens, Reza Salek. Metabolomics – Practical Guide to Design and Analysis.
5. Simon R. Cherry, Ramsey D. Badawi, Jinyi Qi. Essentials of In Vivo Biomedical Imaging.

BT- 712: Bioconjugate Technology (2 credits)

1) **Introduction to bioconjugation:** Scope, significance, and applications in diagnostics, imaging, and therapeutics. Crosslinking strategies: covalent vs. non-covalent interactions.
2) **Types of crosslinkers:** Zero-length, homobifunctional, heterobifunctional, and cleavable linkers. Reactive chemistries targeting amine, carboxyl, thiol, hydroxyl, and aldehyde groups. Applications of PEGylation and click chemistry in bioconjugation.
3) **Conjugation techniques:** Antibody–enzyme conjugates, fluorescent probes, and oligonucleotide labelling. Methods for glycoprotein, liposome, and nanoparticle conjugation. Site-specific labelling and enzymatic modification strategies.
4) **Advanced systems:** Nanocarriers, polymer-drug conjugates, quantum dot labelling. Streptavidin–biotin systems, enzyme-targeted nanoconjugates.
5) **Assay development and quality control for bioconjugates:** Evaluation of toxicity, stability, and biological activity. Standard testing parameters and validation procedures.

6) **Recent developments and challenges in bioconjugate engineering:** Innovations in site-specific labelling, multifunctional conjugates, and smart delivery systems. Future trends and translational considerations.

Suggested Reading:

1. Bioconjugate Techniques by G.T. Hermanson, Academic Press.
2. Chemistry of Bioconjugates: Synthesis, Characterization, and Biomedical Applications by R. Narain, John Wiley & Sons 2013.

BT-713: Therapeutic and Diagnostic Approaches in Neglected Tropical Diseases (2 credits)

1. **Application of biotechnology in drug discovery:** Introduction, identification of sources for isolating the gene that encodes the target proteins, engineer expression system for target protein.
2. **Protein expression systems:** Optimization of cell expression system to maximize production of target proteins; application of TAP tagging in protein-protein interaction and drug discovery.
3. **Identification of potential vaccine candidates:** Basic concepts of vaccines, types of vaccines, techniques for identification of potential vaccine candidates, conventional vaccinology vs. reverse vaccinology.
4. **Genomics:** Key role of genomics in modern vaccine and drug design for emerging infectious diseases. Genomics and diagnosis of infectious diseases.
5. **Biomarkers in infectious diseases:** Introduction to biomarkers, classification of biomarkers, types of biomarkers-genes, proteins, RNA, biomarkers of infectious diseases, technologies for identification of biomarkers-PCR, Combined PCR-Elisa and other non PCR methods.
6. **Monoclonal antibodies as therapeutic targets:** Antibody structure and function, antibody classes and biological actions, monoclonal antibody and infectious diseases.
7. **Epitope mapping:** Epitope mapping and its application in vaccines and protein therapeutics, advantages of monoclonal antibodies over existing chemotherapy.
8. **Immunogenecity and immunotoxicity of Biopharmaceuticals:** Biotech derived products- cytokines, plasminogen, growth factors, monoclonal antibodies and fusion proteins, preclinical and clinical levels of biopharmaceuticals, rules for regulation of synthesis and testing of biopharmaceuticals.
9. **RNA silencing technologies in drug discovery and target validation:** Silencing of genes inducible and reversible RNAi mediated knockdown, antisense oligonucelotides, mechanism of action of antisense oligonucelotides, antisense oligonucelotides for neglected tropical diseases, RNAi as an anti-infectious agent.
10. **Generation of mutant strains for functional analysis of essential genes:** Gene knock out and knock in by double displacement and overexpression strategies.

GE-714: Research Methodology (2 credits)

Refer to PhD-Common Courses syllabus

Semester II

BT-811: Protein Structure and Stability (2 credit)

1. **Protein structure:** Diversity, Taxonomy, Higher levels of organization, Post-translational modifications.
2. **Analytical chromatographic methods:** Chromatography of peptides and high molecular weight proteins.
3. Spectroscopic techniques for protein structure analysis.
4. Strategies for sequence determination: Enzymatic and chemical.
5. Forces responsible for protein structure and stability: Thermodynamics.
6. **Kinetics of protein folding:** Two-state and multistate kinetics, Transition states and intermediates.
7. **Protein folding in the cell:** Lessons learnt
8. **Stability of proteins:** Kosmotropes and chaotropes. Denaturation and renaturation of proteins.
9. **Protein stabilization:** Theories, Role of additives.

BT-812: Biomaterials and Tissue Engineering (2 credit)

1. **Fundamentals of biomaterials:** Definition, classification, and key properties of biomaterials, Concepts of biocompatibility and biodegradation.
2. **Types of biomaterials:** Metallic (e.g., stainless steel, titanium alloys), polymeric (biodegradable and non-biodegradable), ceramic (bioinert, bioactive, resorbable), and composites.
3. **Biomaterial Application:** Drug delivery systems, controlled release mechanisms, applications in medical devices and implants.
4. **Biological response to biomaterials**: Concept and assessment of biocompatibility, immune response to foreign materials, Blood-material interactions, Significance of Polymer morphology in generating an appropriate host response.
5. **Biomaterials testing:** In vitro and in vivo methods, Sterilization techniques and packaging standards, Overview of regulatory frameworks and standards—ISO, FDA, CE.
6. **Scaffolds**: Material selection, properties, and fabrication methods, Bioreactors and mechanical stimulation for tissue development, Host integration and vascularization.
7. **Engineering of tissues:** Skin, cartilage, bone, and blood vessels. Role of growth factors and gene therapy.
8. **Advances in 3D bioprinting and organoid technology:** 3D bioprinting, Lab on a chip, organ on a chip, Spheroid culture, Organoid development techniques, Types of organoids, Organoids for drug testing and alternative to animal testing.
9. **Clinical case studies and translational applications:** Xenografts in tissue repair, Bioresorbable stents, Bioactive glass for dental regeneration, Injectable fillers / hydrogels for soft tissue augmentation etc.

10. **Immunological challenges and ethical considerations:** Foreign Body Response and immune cell activation, Immunotoxicity & Hypersensitivity, Immune rejection, Ethics in biomaterials research.

Suggested reading:

1. Biomaterials science: An introduction to materials in medicine by Ratner, B. D., et al. (2020). (4th ed.). Academic Press.
2. Park, J. B., & Bronzino, J. D. (2021). Biomaterials: Principles and applications (4th ed.). CRC Press.
3. Principles of tissue engineering by Lanza, R., Langer, R., & Vacanti, J. (2020). (5th ed.). Academic Press.
4. Biomaterials and tissue engineering: Integration and regeneration by Ramalingam, M., et al. (2023). (2nd ed.). CRC Press.

BT-813: Advanced Mammalian Cell Culture Techniques (2 credits)

1. **Basic Concepts:** Concept of aseptic techniques in tissue culture; design, layout and equipment of tissue culture laboratory
2. **Laboratory safety and Biohazards:** Bio-safety in animal cell culture, preventing culture related bio-hazards.
3. **Role of media components:** Balanced salt solution and tissue culture media, role of CO_2 in culture medium, Growth of cells in the serum free hormone(s) supplemented medium.
4. **Handling and storage of cell lines:** Detection of contamination, preservation, storage and shipment of cells.
5. **Cell culture technique:** Dispersion and disruption of tissue, monolayer and suspension culture techniques, measurement of growth and viability of cells in culture.
6. **Types of cell culture system:** Maintenance of cultured cell line, primary and established cell line cultures, cell separation (preparative).
7. **Scale up strategies:** Cell culture characteristics, scale up methods for propagation of anchorage dependent and suspension cell culture, concept of bioreactors for mass culture of mammalian cells, microcarrier culture.
8. **Complex culture systems:** Three dimensional cell culture systems, Organoid, Lab on a chip model.

GE-814: Research Ethics (2 credits)

Refer to PhD-Common Courses syllabus

DEPARTMENT OF PHARMACEUTICAL ANALYSIS

Semester - I

PA-711: Hyphenated techniques in pharmaceutical development (2 credits)

1. Basic principles of Mass Spectrometry Instrumentation: Ionization techniques: Electron ionization, Chemical ionization, Atmospheric pressure ionization (Electrospray ionization, APCI, and APPI), other sources: MALDI, ICP, etc.
2. Mass Analyzers: Quadrupole, Time of flight, Ion traps, LIT, FTICR, Orbitrap, High Resolution Mass Spectrometry
3. Hyphenated Mass Spectrometry: GC/MS, HPLC/UPLC-MS and Tandem Mass Spectrometry (Product ion scan, Precursor ion scan, neutral loss scan, SIM and MRM) 4. Interpretation of mass spectra: Isotopes and ion abundances, the Fragmentation pattern of organic molecules with different functional groups, Qualitative analysis, Quantitative analysis
4. Liquid chromatography-electrospray ionization-mass spectrometry (LC-ESI-MS) to the detection and determination of various drugs
5. Applications: Application of mass spectrometry in Pharmacology/Toxicology, Environmental Monitoring/Analysis and Organic chemistry (Structure elucidation of organic molecules, A brief outline of omics study including the scope of biomarkers study. Impurity profiling and drug metabolite profiling, reference standards development
6. Development, Validation, and transfer for high throughput bioanalytical LC-MS/MS Methods.
7. Other Hyphenated Systems: Utility for the same purpose of GC-MS, CE-MS, SFC-MS, CE-NMR, LC-FT-IR, ICP-MS, GC-HS, etc.

Reference books:

1. Silverstein RM, Webster FX, Kiemle DJ, Bryce DL. Spectrometric identification of organic compounds. 6th ed. Hoboken (NJ): John Wiley & Sons; 2014**.** (available in library)
2. Kemp W. Organic spectroscopy. 3rd ed. London: Macmillan Education; 1991.
3. Pavia DL, Lampman GM, Kriz GS, Vyvyan JR. Introduction to spectroscopy. 5th ed. Boston: Cengage Learning; 2015.
4. Fleming I. Spectroscopic methods in organic chemistry. 6th ed. London: Springer; 2011.
5. Breitmaier E. Structure elucidation by NMR in organic chemistry: a practical guide. 3rd ed. Chichester: John Wiley & Sons; 2002**.** (recommended for purchase)
6. Modern Raman Spectroscopy: A Practical Approach by Ewen Smith, Geoffery Dent.
7. Finar IL. Organic chemistry. Vol. 1: The fundamental principles. 6th ed. Harlow: Longman Scientific & Technical; 1973

PA-712: Troubleshooting techniques in analytical method development (2 credits)

1. Preparation of drug sample for analysis-Introduction, compatibility with the instrumental
   method, fundamental theories controlling preparation techniques.
2. Specific sample preparation techniques: Soxhlet extraction, Liquid –liquid extraction, solid phase extraction. Solid phase micro extraction, protein precipitation methods, Ultra filtration, direct injection methods, derivatization methods and applications to different pharmaceutical dosage forms: tablets, capsules, ointments etc.
3. GC Detectors, GC column characteristics, GC inlets and injectors, GC preparative maintenance and troubleshooting, residual samples preparation, method development process, method validation and QA Processes.
4. HPLC Detectors: PDA, ELSD, Conductivity, UV, Refractive Index, Fluorescence, Mass spectrometry, HPLC column selection and mobile phases, mobile phase additives.
5. HPLC method development by using different stationary phases, mechanism of interactions, HPLC preventive maintenance and troubleshooting, case studies.
6. Calibration methods: external, internal and standard addition methods.
7. Advancements in Liquid chromatography: Ultra and nano-HPLC, HPLC method development for biomolecules, monolithic stationary phases-applications, stationary phases packed by core-shell technology, molecularly imprinted polymers as sorbents for separation and extraction.

Reference books

1. Beckett, A. H.; Stenlake, J. B. Practical Pharmaceutical Chemistry, Part II, 4th ed.; CBS Publishers & Distributors: New Delhi, 2007. (available in library)
2. Snyder LR, Kirkland JJ, Glajch JL. Practical HPLC method development. John Wiley & Sons; 2012. (Recommended for Purchase)
3. Kazakevich YV, Lobrutto R. HPLC for pharmaceutical scientists. John Wiley & Sons; 2006 Dec 13. (available)
4. Ardrey, R. E. Liquid Chromatography–Mass Spectrometry: An Introduction; Wiley: Chichester, U.K., 2003.
5. McNair HM, Miller JM. Basic Gas Chromatography. 2nd ed. Hoboken (NJ): Wiley; 2009.

PA-713: Analytical Chemometrics (2 credits)

1. Descriptive Statistics: Normal Distribution, Lorentzian Distribution, handling Multivariate Data.

2. Pattern Recognition: Unsupervised Analysis: Choice of Variables, Measures between Objects, Clustering Techniques, Hierarchical Techniques, K-Means Algorithm, Principal Component Analysis (PCA) case studies.

3. Pattern Recognition: Supervised Learning: Discriminant Functions, Bayes' Theorem, Linear Discriminant Function, Nearest Neighbours, Artificial Neural Networks.

4. Calibration and Regression Analysis: Linear Regression, Errors, and Goodness of Fit, Polynomial Regression, Multivariate Regression.

5. Uncertainty in pharmaceutical method development and validation, Process capability and approaches in uncertainty calculation.

6. **Software for chemometric based calculation:** Case studies-based interpretation.

GE-714: Research Methodology (2 credits)

Refer to PhD Common Courses syllabus

Semester-II

PA-811: Impurity profiling and regulatory requirement (2 credits)

1. Introduction: Basic of impurity and Metabolite profiling.

2. Impurity profiling: Practical Approach

3. Metabolite identification: In-vitro/ In-vivo approaches and sample preparation.

4. Regulatory perspectives.

5. Basics of instrumentation techniques: HPLC, LC-MS, LC-IR, LC-NMR and metabolite identification using radio ligand technique.

6. Case studies: Impurity profiling, isolation and characterization.

7. Case studies: Metabolite profiling, isolation and characterization.

References:

1. Ahuja S, Scypinski S, editors. *Handbook of modern pharmaceutical analysis*. San Diego: Academic Press; 2001.
2. Mass Spectrometry: Principles and Applications. de Hoffmann E, Stroobant V. *Mass spectrometry: principles and applications*. 3rd ed. Chichester: John Wiley & Sons; 2007. (recommended for purchase)
3. Mass Spectrometry-Based Metabolomics: A Practical Guide. Dettmer K, Aronov PA, Hammock BD, editors. *Mass spectrometry-based metabolomics: a practical guide*. Hoboken (NJ): Wiley; 2019.
4. Snyder LR, Kirkland JJ, Glajch JL. Practical HPLC method development. John Wiley & Sons; 2012. (Recommended for Purchase)
5. 3. Kazakevich YV, Lobrutto R. HPLC for pharmaceutical scientists. John Wiley & Sons; 2006 Dec 13. (available)
6. 4. Ardrey, R. E. Liquid Chromatography–Mass Spectrometry: An Introduction; Wiley: Chichester, U.K., 2003.

7. OECD SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE MONITORING Number 1 OECD Principles on Good Laboratory Practice (as revised in 1997) https://www.oecd.org/content/dam/oecd/en/publications/reports/1998/01/oecd-principles-on-good-laboratory-practice_g1gh32e8/9789264078536-en.pdf
8. Good Manufacturing Practice (GMP) standards- WHO GUIDELINES https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/norms-and-standards/gmp

PA-812: Mass spectrometry in drug discovery (2 credits)

1. Basic principles of Mass Spectrometry Instrumentation: Ionization techniques: Electron ionization, Chemical ionization, Atmospheric pressure ionization (Electrospray ionization, APCI, and APPI), other sources: MALDI, ICP, etc.

3. Mass Analyzers: Quadrupole, Time of flight, Ion traps, LIT, FTICR, Orbitrap, High Resolution Mass Spectrometry

4. Hyphenated Mass Spectrometry: GC/MS, HPLC/UPLC-MS and Tandem Mass Spectrometry (Product ion scan, Precursor ion scan, neutral loss scan, SIM and MRM) 4. Interpretation of mass spectra: Isotopes and ion abundances, the Fragmentation pattern of organic molecules with different functional groups, Qualitative analysis, Quantitative analysis

5. Liquid chromatography-electrospray ionization-mass spectrometry (LC-ESI-MS) to the detection and determination of various drugs 5. Applications: Application of mass spectrometry in Pharmacology/Toxicology, Environmental Monitoring/Analysis and Organic chemistry (Structure elucidation of organic molecules, outline of omics study including the scope of biomarkers study.

6. Development, Validation, and transfer for high throughput bioanalytical LC-MS/MS Methods.

7: Fundamentals and analytical methodologies in metabolomics (a) Metabolomics: Significance in clinical research (b) Collection and preparation of clinical samples for metabolomics (c) Preparation of external and internal standards for quality control (d) Targeted and untargeted Metabolomic profiling by gas chromatography/liquid chromatography-mass spectrometry (e) Data interpretation and statistical analysis (f) Application of metabolomics in clinical cases.

8: Lipidomics (a) Basic fundamentals and importance of lipidomics (b) Sample preparation and internal standards for lipidomics (c) Lipids classification and characterization using mass spectrometry. (d) Shotgun lipidomics and LC-MS/MS based lipidomics (e) Targeted and global lipidomics. (f) Application of Lipidomics in Biomedical Research (g) Data interpretation and statistical analysis.

9: Proteomics (a) Basics and importance of proteomics. (b) Strategies in proteomics: Gel based and gel-free proteomics (c) Database and search engines in proteomics. (d) Applications of proteomics: Understanding mechanism of pathogenesis, Drug discovery, Disease diagnosis, identification, and characterization of novel proteins (e) Quantitative proteomics: Labeled and

label-free proteomics (f) PTM (post translational modifications) sample prep, enrichment and separation (g) Interactomics and its applications in biological sciences. (h) Advanced topics – Proteogenomics, Top-down proteomics (i) Data interpretation and statistical analysis (j) Bioinformatics for protein analysis: RAW files conversion (msconvert), analysis of MS data (PMF), analysis of MS/MS data, Quantitation tools and methods, DIA analysis tools, Blind PTM search, PTM site localization and annotation, Targeted protein, and PTM analysis

10. Phyto Metabolomics (a) Collection of Plant Material: Planning, Pressing, Drying, Poisoning, Mounting, Labeling, Storing (b)Extraction Techniques: Maceration, Infusion, Digestion, Decoction, Percolation, Soxhlet extraction, Microwave-assisted extraction, Ultrasound-assisted extraction, Supercritical fluid extraction, Pressurized hot water extraction, Pressurized fluid extraction, Membrane assisted solvent extraction, Stir-Bar sorptive Extraction. (c) Derivatization Techniques: Silylation, Alkylation/Methylation, Acylation, Esterification for GC-MS analysis. Derivatization method of amine, carboxyl, phenols, hydroxyl, carbonyl, thiols functional group for LC-MS/MS analysis.

11. Analytical Techniques: Phyto metabolomics analysis by NMR, GC-MS, GC-QTOF, LCMS, LC-QTOF, CE-MS, FTICR-MS (e) Data interpretation and statistical analysis.

Reference books:

1. Skoog DA, West DM, Holler FJ, Crouch SR. *Fundamentals of analytical chemistry*. 9th ed. Belmont (CA): Brooks/Cole; 2014**.** (recommended for purchase)
2. Ahuja S, Scypinski S, editors. *Handbook of modern pharmaceutical analysis*. San Diego: Academic Press; 2001.
3. Silverstein RM, Webster FX, Kiemle DJ, Bryce DL. Spectrometric identification of organic compounds. 6th ed. Hoboken (NJ): John Wiley & Sons; 2014**.** (available in library)
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5. Pavia DL, Lampman GM, Kriz GS, Vyvyan JR. Introduction to spectroscopy. 5th ed. Boston: Cengage Learning; 2015.
6. Fleming I. Spectroscopic methods in organic chemistry. 6th ed. London: Springer; 2011.
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8. Beckett, A. H.; Stenlake, J. B. Practical Pharmaceutical Chemistry, Part II, 4th ed.; CBS Publishers & Distributors: New Delhi, 2007. (available in library)
9. Snyder LR, Kirkland JJ, Glajch JL. Practical HPLC method development. John Wiley & Sons; 2012. (Recommended for Purchase)
10. Ardrey, R. E. Liquid Chromatography–Mass Spectrometry: An Introduction; Wiley: Chichester, U.K., 2003.
11. Mass Spectrometry-Based Metabolomics: A Practical Guide. Dettmer K, Aronov PA, Hammock BD, editors. *Mass spectrometry-based metabolomics: a practical guide*. Hoboken (NJ): Wiley; 2019.
12. Statistical Analysis of Proteomics, Metabolomics and Lipidomics Data. Li S. *Statistical analysis of proteomics, metabolomics, and lipidomics data*. Boca Raton (FL): CRC Press; 2016.

13. Proteomic and Metabolomic Approaches to Biomarker Discovery. Issaq HJ, Veenstra TD, editors. *Proteomic and metabolomic approaches to biomarker discovery*. Burlington (MA): Academic Press; 2013.

PA-813: Characterization of New Biologicals and Biosimilars (2 credits)

1. Introduction to biologics, Definition of biosimilars vs biologics, classification of biologicals - mono clonal antibodies, recombinant proteins, vaccines, insulin, cell culture technology, recombinant DNA technology, protein and peptide drugs.

Basics of biotechnology-Introduction to pharmaceutical biotechnology, Cell structure & function, Recombinant DNA technology, Gene cloning methods, Expression systems (bacteria, yeast, mammalian cells), Enzymes & their applications

2. Differences between biologicals and biosimilars from generic drugs, Manufacturing of biologics, Upstream & downstream processing of biologicals and biosimilars.

3. Biological & Functional Characterization

Bioassays: Cell-based assays, Enzyme activity assays.

Binding studies: ELISA, Surface Plasmon Resonance (SPR), Potency determination.

4. Clinical evaluation of biosimilars, Immunogenicity of biologics, factors effecting immunogenicity, Pharmacokinetics of biological drugs.

5. Analytical Method Development & Validation,Method development strategies for biologics, Validation parameters (ICH Q2)

Specific challenges in biologics.

6. Ingel digestion technique: Enzymatic digestion of gel-separated proteins (e.g., trypsin) followed by peptide extraction and analysis using LC–MS/MS or MALDI-TOF.

7. Bio pharma finder software applications: Peptide mapping analysis, Oligonucleotide analysis, Intact mass analysis, Top-down analysis, Connecting to the Ardia platform.

8. Impurity & Variant Analysis

a. Product-related impurities: Aggregates, fragments.

b. Process-related impurities: Host cell proteins (HCP), DNA impurities, Analytical techniques for impurity profiling

c. stability and formulation studies-Forced degradation studies.

9. Regulatory guidelines and approval pathway for biosimilars.

10. Analytical challenges in biologics.

11. Characterization techniques for Biologicals:

a. Primary and higher-order structure analysis using LC–MS/MS, MALDI-TOF, NMR, FT-IR, Circular Dichroism (CD), DSC.
b. Physicochemical and impurity profiling using HPLC (RP/SEC/IEX), CE-SDS, cIEF, DLS, SEC-MALS, LC-MS, HPAEC-PAD.
c. Functional and advanced characterization using ELISA, Surface Plasmon Resonance (SPR), cell-based bioassays, HDX-MS, Cryo-EM, Multi-Attribute Methods (MAM).

12. Case studies of approved biosimilars.

Reference books

1. Walsh, G. *Pharmaceutical Biotechnology: Concepts and Applications*. Wiley.
2. Walsh, G. *Biopharmaceuticals: Biochemistry and Biotechnology*. Wiley.
3. Chow, S. C. *Biosimilars: Science and Regulation of Highly Similar Biologics*. CRC Press.
4. Van de Ven, N. H. T. *Characterization of Biopharmaceuticals*. Springer.
5. Kaltashov, I. A., & Eyles, S. J. *Analytical Techniques for Biopharmaceutical Development*. Springer.
6. Banga, A. K. *Protein Pharmaceuticals: Formulation, Analytics and Delivery*. Springer.
7. Venn, R. F. *Principles and Practice of Bioanalysis*. CRC Press.
8. Joubert, L. M. K. *Immunogenicity of Biopharmaceuticals*. Springer.
9. Geigert, J. *Biologics Development: A Regulatory Overview*. Springer.
10. Elgert, M. A. (Ed.). *Monoclonal Antibodies: Methods and Protocols*. Springer.

GE-814: Research Ethics (2 credits)

Refer to PhD Common Courses syllabus

DEPARTMENT OF PHARMACEUTICS

Semester – I

PE-711: Pharmaceutical Product Development and Translational Sciences (2 credits)

Unit 1: Advanced Pharmaceutical Product Development Framework (4 Hours)

- Drug product lifecycle: Discovery, development, commercialization, lifecycle management
- Translational product development (lab-to-market challenges)
- Multidisciplinary integration (R&D, regulatory, manufacturing)
- Regulatory framework and harmonization
- Pharma 4.0 and digital transformation
- AI/ML applications in formulation and process development

Unit 2: Advanced Preformulation and Material Properties (4 Hours)

- Physicochemical properties of drug substances:
  a) Solubility, pKa, polymorphism
  b) Stability considerations
- Biopharmaceutics (BCS, BDDCS)
- Drug–excipient compatibility studies
- Basic preformulation studies for the development of different dosage forms
- Materials-sparing approaches – Miniaturized experimental techniques, High-throughput screening (HTS), In silico preformulation modelling, Use of advanced analytical techniques, parallel and combinatorial studies, and microfluidics (emerging technology).

Unit 3: Product and Process Design with Specifications 4 Hours

- Design of material and product specifications
- Raw materials, in-process, and finished product specifications
- Acceptance criteria and regulatory expectations
- Pharmacopoeial standards comparison (IP, USP, BP)
- Design space concept
- Risk-based specification setting
- Variability control strategies

Unit 4: Quality by Design (QbD) and Process Understanding 5 Hours

- QbD Fundamentals: QTPP, CQA, CMA, CPP
- Risk management tools (FMEA, Ishikawa, RPN)
- Process Analytical Technology (PAT) and its link with continuous manufacturing
- Real-time release testing (RTRT)
- Design space establishment
- Digital twins in pharmaceutical processes

Unit 5: Advanced Optimization & Data-Driven Development 5 Hours

- Optimization principles

- OVAT (One Variable at a Time)
- Design of Experiments (DoE):
  a) Factorial design
  b) Response Surface Methodology (RSM)
- Data interpretation and modeling
- Multivariate data analysis
- AI/ML-assisted optimization
- Predictive and mechanistic modeling

Unit 6: Packaging, Stability and Product Performance 4 Hours

- Advanced packaging systems and materials – High-performance plastics, multi-layer materials, coated glass and hybrid systems, elastomeric closures (advanced rubbers)
- Container-closure systems and selection
- Extractables and leachables (E&L)
- Stability strategies and shelf-life prediction
- Smart packaging (indicators, sensors, and data carriers) and track-and-trace (serialization, barcoding/QC codes, Radio frequency identification (RFID)) systems
- Container-closure interaction modelling
- Advanced analytical techniques for E&L

Unit 7: Regulatory Science, Documentation and Lifecycle Management 7 Hours

- Advanced Documentation Systems:
  - Documentation in product development:
    a) Bill of Material (BOM)
    b) Manufacturing Formula Record (MFR)
    c) Batch Manufacturing Record (BMR)
    d) Batch Packaging Record (BPR)
  - Digital documentation and e-records
- Data Integrity & Compliance:
  - ALCOA + principles
  - Data governance and audit readiness
- Regulatory Submissions & Strategies:
  - IND, NDA, ANDA (overview with scientific rationale)
  - Global submission strategies
- Lifecycle Management (Advanced):
  - Post-approval changes: SUPAC, PAS, CBE-30, CBE-0
  - Product discontinuation, recalls
- Translational Challenges (Very Important):
  - Scale-up challenges
  - Technology transfer (lab-pilot-commercial)
  - Manufacturing variability
- Emerging Regulatory Trends:
  - Continuous manufacturing approvals
  - Regulatory expectations for nanomedicine and complex generics

References

1. Aulton, Michael E., and Kevin M. G. Taylor. *Aulton's Pharmaceutics: The Design and Manufacture of Medicines*. 5th ed. London: Elsevier, 2018.
2. Gibson, Mark. *Pharmaceutical Preformulation and Formulation: A Practical Guide from Candidate Drug Selection to Commercial Dosage Form*. 2nd ed. Boca Raton: CRC Press, 2009.
3. Leon Lachman, Herbert A. Lieberman, and Joseph L. Kanig. *The Theory and Practice of Industrial Pharmacy*. 3rd ed. Mumbai: Varghese Publishing House, 1987.
4. Florence, A. T., and David Attwood. *Physicochemical Principles of Pharmacy*. 6th ed. London: Pharmaceutical Press, 2016.
5. Yu, L., et al. *Pharmaceutical Quality by Design: Principles and Applications*. Cambridge: Academic Press, 2020.
6. Juran, Joseph M., and Frank M. Gryna. *Juran's Quality Handbook: The Complete Guide to Performance Excellence*. 6th ed. New York: McGraw-Hill, 2010.
7. Montgomery, Douglas C. *Design and Analysis of Experiments*. 9th ed. Hoboken, NJ: Wiley, 2017.
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9. Martin, Alfred, Pilar Bustamante, and A. H. C. Chun. *Physical Pharmacy: Physical Chemical Principles in the Pharmaceutical Sciences*. 4th ed. Philadelphia: Lippincott Williams & Wilkins, 1993.
10. Waterbeemd, Han van de, and Erik Gifford. *ADMET in Silico Modelling: Towards Prediction Paradise?* London: Imperial College Press, 2003.
11. Kerns, Edward H., and Li Di. *Drug-Like Properties: Concepts, Structure Design and Methods*. 2nd ed. Amsterdam: Elsevier, 2015.
12. Lipinski, Christopher A., et al. "Experimental and Computational Approaches to Estimate Solubility and Permeability in Drug Discovery and Development Settings." *Advanced Drug Delivery Reviews* 46, no. 1-3 (2001): 3–26.
13. H. Aggarwal. *Pharmaceutical Packaging Technology*. 2nd ed. Boca Raton: CRC Press, 2014.
14. Ramachandran, C., et al. *Packaging Materials and Technologies for Pharmaceutical Products*. Cambridge: Woodhead Publishing, 2015.
15. Bauer-Brandl, Annette. *Drug-Excipient Interactions and Extractables & Leachables in Pharmaceutical Packaging*. Berlin: Springer, 2017.
16. Patel, Mahesh. *Smart Packaging Technologies for Pharmaceutical Applications*. Amsterdam: Elsevier, 2020
17. Rathore, Anurag S., and Suzanne Smelko. *Pharmaceutical Product Development: Translational Challenges, Scale-Up, and Technology Transfer*. Hoboken, NJ: Wiley, 2018.
18. International Council for Harmonisation. *ICH Harmonised Guideline Q8(R2): Pharmaceutical Development*. Geneva: ICH, 2009.
19. International Council for Harmonisation. *ICH Harmonised Guideline Q9: Quality Risk Management*. Geneva: ICH, 2005.
20. International Council for Harmonisation. *ICH Harmonised Guideline Q10: Pharmaceutical Quality System*. Geneva: ICH, 2008.

21. International Council for Harmonisation. *ICH Harmonised Guideline Q1A(R2): Stability Testing of New Drug Substances and Products*. Geneva: ICH, 2003.
22. US Food and Drug Administration. *Guidance for Industry: PAT—A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance*. Silver Spring, MD: FDA, 2004.
23. US Food and Drug Administration. *Guidance for Industry: Process Validation: General Principles and Practices*. Silver Spring, MD: FDA, 2011.
24. European Medicines Agency. *Guideline on Process Validation for Finished Products*. London: EMA, 2014.

PE-712: Implications of Solid-State Properties in Drug Delivery (2 credits)

Unit 1: Introduction and Barriers to Drug Delivery (3 Hours)

- Overview of drug delivery barriers:
  a) Aqueous solubility
  b) Permeability (BCS framework)
  c) First-pass metabolism
  d) Pre-systemic metabolism
- Role of solid-state properties in overcoming barriers
- Case study: Poorly soluble drugs and formulation strategies

Unit 2: Molecular-Level Solid State Properties (8 Hours)

- Polymorphism:
- Thermodynamic versus kinetic polymorphs
- Solubility and dissolution differences
- Impact on stability, manufacturing, and bioavailability
- Co-crystals:
- Crystal engineering strategies
- Selection of co-formers and supramolecular synthons
- Phase behaviour, solubility modulation, and intellectual property aspects
- Case study: Marketed pharmaceuticals
- Amorphous Forms:
- Thermodynamic and kinetic aspects
- Physical stability challenges
- Solubility and dissolution advantages
- Stabilization strategies: Polymeric carriers, co-amorphous systems, surface coatings
- Surface behaviour and re-crystallization control
- Miscellaneous:
- Solid state molecular modelling and predictive tools
- In silico solubility and permeability prediction

Unit 3: Particle-Level Solid State Properties (8 Hours)

1. Particle Size and Morphology:

- Micronization and nanonization techniques
- Nanocrystals and nanosuspensions

- Polymeric and small-molecule assisted nanocrystalline dispersions

2. Crystal Habit:

- Surface anisotropy and facet-specific dissolution
- Impact on wetting, aggregation, and bioavailability

3. Surface Engineering:

- Surface modification with polymers, surfactants, and lipid coatings
- Particle porosity and its effect on dissolution

4. Miscellaneous:

- Microfluidics for particle engineering
- Spray drying hot-met extrusion of particle design
- Nano-enabled solid dispersions

Unit 4: Implications for Drug Delivery and Biopharmaceutics (6 Hours)

- Influence on oral, parenteral, and pulmonary delivery
- IVIVC (In vitro–in vivo correlation) and BCS/BCS Biopharmaceutics tools
- Impact of solid state on absorption kinetics and pharmacokinetics
- Case studies:
  1. Amorphous versus crystalline formulations
  2. Co-crystal for solubility-limited drugs

Unit 5: Advanced Analytical and Predictive Approaches (5 Hours)

- Solid state characterization tools: PXRD, DSC, TGA, FTIR, ssNMR, AFM, and SEM
- Predictive modeling of solubility, dissolution, and stability
- Regulatory considerations for solid-state-based formulations
- Quality by Design (QbD) approach to solid state optimization

Unit 6: Emerging Topics in Solid State Drug Delivery (4 Hours)

- Amorphous nanoparticles and nanoamorphous systems
- Hybrid co-crystal/amorphous dispersions
- 3D printed solid-state formulations
- Solid-state properties in targeted and controlled-release systems
- Role in translational research and early-stage clinical development

References

1. Brittain, Harry G. *Polymorphism in Pharmaceutical Solids*. 3rd ed. New York: Informa Healthcare, 2009.
2. Byrn, Stephen R., Roger E. Pfeiffer, and Jerome S. Stowell. *Solid-State Chemistry of Drugs*. 2nd ed. West Lafayette, IN: SSCI Inc., 1999.
3. Hilfiker, René, ed. *Polymorphism in the Pharmaceutical Industry*. Weinheim: Wiley-VCH, 2006.
4. Aulton, Michael E., and Kevin M. G. Taylor. *Aulton's Pharmaceutics: The Design and Manufacture of Medicines*. 5th ed. London: Elsevier, 2018.
5. Childs, Samuel L., et al. *Pharmaceutical Co-Crystals and Amorphous Solid Dispersions*. Cambridge: Royal Society of Chemistry, 2018.
6. Yu, Li, et al. *Amorphous Pharmaceutical Solids: Preparation, Characterization and Stabilization*. London: Elsevier, 2014.

7. Hancock, Bruno C., and Shailendra H. Zografi. “Characteristics and Significance of the Amorphous State in Pharmaceutical Systems.” *Journal of Pharmaceutical Sciences* 86, no. 1 (1997): 1–12.
8. Qiu, Yihua, and Brian C. Hancock. *Amorphous Drug Delivery Systems: Physical Stability, Processing and Applications*. Cambridge: Woodhead Publishing, 2013.
9. Müller, Rainer H., Klaus Mäder, and Stefan Gohla. *Nanoparticulate Drug Delivery Systems: Strategies, Preparation, and Applications*. Stuttgart: Wissenschaftliche Verlagsgesellschaft, 2011.
10. Jain, Narendra K. *Advances in Controlled and Novel Drug Delivery*. 1st ed. New Delhi: CBS Publishers, 2001.
11. Patravale, Vandana B., Rekha Dandekar, and R. D. Vishwas. *Nanotechnology in Drug Delivery*. Amsterdam: Elsevier, 2018.
12. Zhang, Li, and Yihua Qiu. *Nanocrystals for Drug Delivery: Principles, Methods, and Applications*. Boca Raton: CRC Press, 2020.
13. Brittain, Harry G. *Analytical Techniques in the Pharmaceutical Sciences*. 2nd ed. New York: Informa Healthcare, 2010.
14. Mah, Edward, et al. *Solid-State Characterization of Pharmaceuticals*. Cambridge: Royal Society of Chemistry, 2017.
15. Ford, James L., and Geoffrey P. Martin. *Powder Characterization Techniques for Pharmaceutical Applications*. London: Pharmaceutical Press, 2015.
16. Hancock, Bruno C., et al. *Advanced Solid-State Analytical Techniques in Drug Development*. Amsterdam: Elsevier, 2016.
17. Rathore, Anurag S., and Michael W. L. Cheung, eds. *Process Analytical Technology and Quality by Design for Solid Dosage Forms*. Hoboken, NJ: Wiley, 2015.
18. Lipinski, Christopher A., et al. “Experimental and Computational Approaches to Estimate Solubility and Permeability in Drug Discovery and Development Settings.” *Advanced Drug Delivery Reviews* 46, no. 1-3 (2001): 3–26.
19. Waterbeemd, Han van de, and Erik Gifford. *ADMET in Silico Modelling: Towards Prediction Paradise?* London: Imperial College Press, 2003.
20. International Council for Harmonisation. *ICH Harmonised Tripartite Guidelines (Q8–Q11)*. Geneva: ICH, various years.

PC-713: Pharmacological and Toxicological Screening and Assays (2 credits)

Refer to the Department of Pharmacology & Toxicology - PhD syllabus

GE-714: Research Methodology (2 credits)

Refer to PhD-Common Courses syllabus

Semester – II

PE-811: Computational Biopharmaceutics and Pharmacokinetics (2 credits)

Unit 1: Introduction (3 Hours)

AI in drug discovery and development; computational tools in drug discovery; historical approaches; SAR; and SPR. Influence of combinatorial chemistry on pharmacokinetic properties. Methods for the mitigation of pharmacokinetic/clinical failures, including in silico approaches

Unit 2: Simulation Techniques (4 Hours)

Linear and nonlinear regression analysis; model development and validation considerations; outlier qualification; Monte Carlo simulations; Bootstrap; mathematical models, including top-down models (compartmental and non-compartmental analyses), UIR; and bottom-up models (semi-mechanistic and mechanistic models, nonlinear mixed-effect models, and population PK models).

Unit 3: Regulatory requirements (3 Hours)

ICH, USFDA, and EMA guidelines for model development and validation. Application of PK/PD models in the various stage of product development and life cycle management

Unit 4: Basics of Pharmacokinetics (3 Hours)

ADME processes, special populations such as paediatrics, geriatrics, and pregnancy. Influence of diseases such as hepatic, renal impairment, and congestive cardiac failure. Role of sex, bodyweight, smokers, industrial occupational exposures, demography, and ethnicity on model development and validation.

Unit 5: PBPK models -Oral drug products (3 Hours)

GI physiology in fasting and fed state, effect of coadministration of drugs, antacids, and pH/absorption modifiers, chelating agents. Oral mechanistic models and their advantages and disadvantages, absorption models based on in silico and in vitro inputs, in vivo dissolution, precipitation, and recrystallization, active transport systems, efflux transporters, biliary excretion, enterohepatic cycling, GI degradation, including mass balance

Unit 6: PBPK modelling – Respiratory (4 Hours)

Physiology of the respiratory system; different formulations (e.g., DPI/MDI); particle velocity and lung deposition; nasopharyngeal clearance; GI absorption; charcoal studies; device performance; in vitro tools (e.g., spray pattern, dose delivered, plume geometry, mass median aerodynamic diameters, device performance, etc.). Lung efficiency and model development for COPD and asthma patients

Unit 7: PBPK models – Alternative route of administration (4 Hours)

Ocular, intramuscular, and nasal model development and challenges, host response, physicochemical properties, and pharmaceutical properties, including device performance in model development and validation

Unit 8: Virtual BE studies and population trials (3 Hours)

Sample size, study design, population, demographic data, statistical approaches

Unit 9: PK/PD correlation (4 Hours)

PK linearity, clinical/PD markers, and estimation of those markers in biological fluids, selection of markers for PK/PD correlation. Clinical predictions using PK/PD models

Recommended Books:

1. Shargel and Yu's Applied Biopharmaceutics & Pharmacokinetics, 8th Edition (2022)
2. Modeling in Biopharmaceutics, Pharmacokinetics and Pharmacodynamics: Homogeneous and Heterogeneous Approaches by Panos Macheras and Athanassios Iliadis (2018)
3. Advances in Pharmacokinetics and Pharmacodynamics edited by Panos Macheras (2023)
4. Biopharmaceutics: From Fundamentals to Industrial Practice, edited by Hannah Batchelor (2021)
5. Biopharmaceutics and Pharmacokinetics - A Treatise by D.M. Brahmankar and S.B. Jaiswal (2015).

PE-812: Novel and Advanced Approaches in Targeted Drug Delivery Systems (2 credits)

Unit 1: Fundamentals of Targeted and Precision Drug Delivery 4 Hours

- Need and advantages of targeted drug delivery
- Levels of targeting: organ, tissue, cellular, subcellular
- Passive targeting: EPR (Enhanced Permeability and Retention) effect
- Active targeting: ligand–receptor interactions
- Multifunctional and precision targeting approaches
- Target Product Profile (TPP) and carrier selection strategy
- Precision medicine and personalized drug delivery
- AI/ML-assisted target and carrier selection
- Examples: antibody-drug conjugates (ADCs), ligand-functionalized nanoparticles

Unit 2: Chemical, Biological and Prodrug-Based Targeting 4 Hours

- Prodrug design for targeted delivery
- Antibody Directed Enzyme Prodrug Therapy (ADEPT)
- Soft drug concept and metabolic targeting
- Drug conjugates:
  a) Lipid–drug conjugates
  b) Polymer–drug conjugates
  c) PEGylation for stealth delivery
- Multifunctional and stimuli-activated prodrugs
- Bioconjugation strategies for targeted delivery
- Clinical examples of targeted conjugates (ADCs and PEGylated drugs)

Unit 3: Targeted Drug Delivery to the Brain and Tumor Microenvironment 7 Hours

A. Brain Targeting (5 Hours)

- Structure, role, and transport challenges of the BBB
- Transport mechanisms:

a) Receptor-mediated transport (RMT) - Transferrin, Insulin, and Low-density lipoprotein (LDL) receptors
b) Carrier-mediated transport (CMT) – Glucose transporter (GLUT-1), Large neutral amino acid transporter (LAT-1), and monocarboxylate transporter
c) Efflux transporters (P-gp) – P-glycoprotein (P-gp) and breast cancer resistant protein (BCRP)

- Intranasal (Nose-to-brain) delivery Pathways:
  a) Olfactory neurons
  b) Trigeminal nerve
  c) Nasal epithelial receptors
  d) Formulation considerations
  e) Advantages and limitations
- Cellular-level targeting in the brain:
  a) Neuronal targeting
  b) Glial cell targeting
- Disease-specific molecular targets:
  a) Neurodegenerative diseases (Alzheimer's, Parkinson's)
  b) Brain tumors
  c) Neuroinflammation
- Emerging Nanocarrier Strategies:
  a) Ligand-functionalized nanoparticles
  b) In silico prediction and modelling of BBB transport

B. Tumor Targeting (2 Hours)

- Tumor microenvironment and vascular targets:
  a) Tumor vasculature
  b) EPF effect
- Targeting approaches & molecular targets:
  a) Passive versus active targeting
  b) Tumor ligands and receptor-based targeting
  c) Immuno-targeting and combination therapies
  d) Tumor heterogenecity and precision targeting
- Biopharmaceutical considerations:
  a) Drug penetration and retention challenges
  b) Role of carrier systems

Unit 4: Colloidal and Nanoparticulate Drug Delivery Systems 6 Hours

- Principles, preparation, and evaluation
- Liposomes and niosomes
- Solid lipid nanoparticles (SLN) and nanostructured lipid carriers (NLC)
- Polymeric nanoparticles (natural and synthetic biodegradable polymers)
- Biomimetic and exosome-mimetic nanocarriers
- Targeted nanomedicine design strategies
- Targeting modifications: Surface functionalization, PEGylation
- In vivo behaviour: Biodistribution, clearance

Unit 5: Specialized and Emerging Carrier Systems 5 Hours

- Vesicular and lipid-based systems: transferosomes, ethosomes, pharmacosomes
- Polymeric nanocarriers: dendrimers and polymeric micelles

- Self-assembled systems: nanoemulsions, self-emulsifying drug delivery systems (SEDDS)
- Lipid nanoparticles (LNPs) for mRNA and nucleic acid delivery
- Gene delivery systems (siRNA, mRNA, CRISPR-based delivery)
- Theranostic nanocarriers (diagnostic + therapeutic)
- Personalized nanomedicine

Unit 6: Stimuli-Responsive and Organ-Specific Targeting 4 Hours

- Stimuli-responsive systems:
  a) pH-sensitive systems
  b) Temperature-sensitive systems
  c) Enzyme-sensitive systems
- External stimuli triggers:
  a) Ultrasound
  b) Light
  c) Magnetic fields
- Organ- and Cell-specific Targeting:
  a) Liver targeting:
  i. Use of ASGPR receptors, liposomal carriers, and nanoparticle accumulation in hepatocytes
  ii. Clinical examples: targeted antiviral and anticancer therapeutics
  b) Macrophage targeting:
  i. Targeting infections, inflammation, and tumor-associated macrophages
  ii. Ligand-functionalized nanoparticles, liposomes
- Other Advanced Targets:
  a) Colon, mitochondrial, and M-cell targeting
  b) Gene delivery systems (siRNA, mRNA)
  c) Smart and feedback-controlled drug delivery systems
  d) Integration with biosensors and wearable systems

Unit 7: Translational Challenges and Regulatory Considerations 3 Hours

- Translational challenges:
  a) Toxicity of nanocarriers
  b) Immunogenicity issues
  c) Off-target effects
- In vivo performance:
  a) Biodistribution of drug delivery systems
  b) Clearance mechanisms (RES, renal, hepatic)
- Manufacturing and scale-up challenges:
  a) Reproducibility
  b) Stability issues
  c) Large-scale production constraints
- Regulatory considerations:
  a) Approval pathways for nanomedicine and gene delivery
  b) Safety and quality requirements
  c) Regulatory perspectives (FDA, EMA)

References

1. Devarajan, Padma V., and Sanyog Jain, eds. *Targeted Drug Delivery: Concepts and Design*. New York: Springer, 2015.
2. Hillery, Anya M., Andrew W. Lloyd, and James Swarbrick. *Drug Targeting and Delivery: Concepts in Dosage Form Design*. Boca Raton: CRC Press, 2001.

3. Narang, Ajay S., and Ram I. Mahato, eds. *Targeted Delivery of Small and Macromolecular Drugs*. Boca Raton: CRC Press, 2010.
4. Keservani, Raj K., Anil K. Sharma, and Rakesh K. Kesharwani, eds. *Drug Delivery Approaches and Nanosystems*. Boca Raton: CRC Press, 2017.
5. Aulton, Michael E., and Kevin M. G. Taylor. *Aulton's Pharmaceutics: The Design and Manufacture of Medicines*. 5th ed. London: Elsevier, 2018.
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7. Torchilin, Vladimir P., ed. *Handbook of Materials for Nanomedicine: Lipid-Based and Inorganic Nanomaterials*. Singapore: Pan Stanford Publishing, 2020.
8. Jain, N. K. *Controlled and Novel Drug Delivery*. New Delhi: CBS Publishers & Distributors, 2002.
9. Vyas, S. P., and Roop K. Khar. *Targeted and Controlled Drug Delivery: Novel Carrier Systems*. New Delhi: CBS Publishers & Distributors, 2002.
10. Swarbrick, James, ed. *Encyclopedia of Pharmaceutical Technology*. 4th ed. New York: Informa Healthcare, 2013.
11. Troy, David B., ed. *Remington: The Science and Practice of Pharmacy*. 22nd ed. London: Pharmaceutical Press, 2012.
12. Gad, Shayne C., ed. *Pharmaceutical Manufacturing Handbook: Production and Processes*. Hoboken: Wiley, 2008.
13. International Council for Harmonisation. *ICH Harmonised Guideline Q8(R2): Pharmaceutical Development*. Geneva: ICH, 2009.
14. International Council for Harmonisation. *ICH Harmonised Guideline Q9: Quality Risk Management*. Geneva: ICH, 2005.
15. International Council for Harmonisation. *ICH Harmonised Guideline Q10: Pharmaceutical Quality System*. Geneva: ICH, 2008.
16. International Council for Harmonisation. *ICH Harmonised Guideline Q11: Development and Manufacture of Drug Substances*. Geneva: ICH, 2012.
17. US Food and Drug Administration. *Guidance for Industry: Liposome Drug Products*. Silver Spring, MD: FDA, 2018.
18. US Food and Drug Administration. *Guidance for Industry: Drug Products, Including Biological Products, that Contain Nanomaterials*. Silver Spring, MD: FDA, 2022.
19. European Medicines Agency. *Reflection Paper on Nanotechnology-Based Medicinal Products for Human Use*. London: EMA, 2011.
20. European Medicines Agency. *Reflection Paper on the Data Requirements for Intravenous Liposomal Products Developed with Reference to an Innovator Liposomal Product*. London: EMA, 2013.

BT-811: Protein Structure and Stability (2 credits)

Refer to the Department of Biotechnology - PhD syllabus

GE-814: Research Ethics (2 credits)

Refer to PhD-Common Courses syllabus

DEPARTMENT OF PHARMACY PRACTICE

Semester – I

PP-711: Advanced Clinical Decision-Making and Precision Pharmacotherapy (2 credits)

Module 1: Clinical Decision-Making Frameworks (6 Hours)

- Clinical reasoning models and diagnostic thinking
- Risk-benefit assessment and decision analysis
- Shared decision-making and patient-centered care

Module 2: Precision Pharmacotherapy (6 Hours)

- Pharmacogenomics and individualized therapy
- Biomarkers and therapeutic drug monitoring
- Dose individualization in special populations

Module 3: Management of Complex Clinical Scenarios (6 Hours)

- Polypharmacy and deprescribing strategies
- Critical care and emergency pharmacotherapy
- Oncology and high-risk medication management

Module 4: Evidence Integration and Clinical Guidelines (6 Hours)

- Evidence-based medicine principles
- Clinical guidelines vs real-world practice
- Case-based discussions and simulations

Recommended Books

1. Brunton LL, Hilal-Dandan R, Knollmann BC, eds. *Goodman & Gilman's The Pharmacological Basis of Therapeutics*. 14th ed. New York: McGraw-Hill; 2023.
2. Koda-Kimble MA, Young LY, Kradjan WA, et al. *Applied Therapeutics: The Clinical Use of Drugs*. 11th ed. Philadelphia: Wolters Kluwer; 2018.
3. DiPiro JT, Talbert RL, Yee GC, et al. *Pharmacotherapy: A Pathophysiologic Approach*. 11th ed. New York: McGraw-Hill; 2020.
4. Atkinson AJ Jr, Huang SM, Lertora JJL, Markey SP. *Principles of Clinical Pharmacology*. 3rd ed. London: Academic Press; 2012.
5. World Health Organization (WHO); National Institute for Health and Care Excellence (NICE); Ministry of Health and Family Welfare (MoHFW), India. Latest clinical treatment guidelines.

PP-712: Pharmacoepidemiology and Real-World Evidence Analytics (2 credits)

Module 1: Advanced Pharmacoepidemiological Study Designs (6 Hours)

- Cohort, case-control, nested case-control designs
- Case-crossover and self-controlled case series
- Pragmatic and adaptive clinical trials
- Comparative effectiveness research

Module 2: Real-World Data Sources and Management (6 Hours)

- Electronic health records (EHR), claims databases, registries
- Data linkage techniques and validation
- Handling missing data and misclassification
- Data standardization (OMOP common data model – overview)

Module 3: Bias, Confounding, and Causal Interpretation (6 Hours)

- Types of bias: selection, information, confounding
- Advanced confounding control methods
- Sensitivity and subgroup analyses
- Interpretation of real-world findings

Module 4: Regulatory and Policy Applications of RWE (6 Hours)

- Signal detection and drug safety surveillance
- Use of RWE in regulatory decisions (global and Indian context)
- Health technology assessment using RWE
- Case studies from national and international settings

Recommended Books

1. Strom BL, Kimmel SE, Hennessy S, eds. *Pharmacoepidemiology*. 6th ed. Chichester: Wiley-Blackwell; 2019.
2. Walker AM. *Pharmacoepidemiology and Therapeutic Risk Management*. Cincinnati: Harvey Whitney Books; 2017.
3. Edlavitch SA, ed. *Real World Health Care Data Analysis: Causal Methods and Implementation Using SAS*. Cary: SAS Institute; 2017.
4. Hulley SB, Cummings SR, Browner WS, Grady DG, Newman TB. *Designing Clinical Research*. 4th ed. Philadelphia: Wolters Kluwer; 2013.
5. Indian Council of Medical Research (ICMR). *National Ethical Guidelines for Biomedical and Health Research Involving Human Participants*. New Delhi: ICMR; Latest edition.

PP-713: Advanced Biostatistics and Data Science for Clinical Research (2 credits)

Module 1: Advanced Biostatistics and Regression Modelling (6 Hours)

- Generalized Linear Models (GLM): logistic, Poisson, and negative binomial regression
- Model diagnostics, goodness-of-fit, and overdispersion
- Survival analysis: Kaplan–Meier estimation, log-rank test, Cox proportional hazards model
- Time-to-event data in clinical research
- Longitudinal data analysis and mixed-effects models

Module 2: Causal Inference in Observational Research (6 Hours)

- Counterfactual framework and causal diagrams (DAGs)
- Confounding and methods of adjustment
- Propensity score methods: matching, stratification, weighting
- Instrumental variable analysis
- Marginal structural models and sensitivity analysis

Module 3: Machine Learning Applications in Healthcare (6 Hours)

- Introduction to supervised and unsupervised learning
- Classification and regression algorithms (decision trees, random forests, SVM)
- Model validation: cross-validation, AUROC, calibration
- Overfitting, bias-variance tradeoff
- Applications in risk prediction, pharmacovigilance, and clinical decision support

Module 4: Reproducible Research and Data Management (6 Hours)

- Programming using R/Python for healthcare analytics
- Data cleaning, transformation, and visualization
- Reproducible workflows (version control, scripts, documentation)
- FAIR data principles (Findable, Accessible, Interoperable, Reusable)
- Ethical considerations in data handling

Recommended Books

1. Rothman KJ, Greenland S, Lash TL. *Modern Epidemiology*. 4th ed. Philadelphia: Wolters Kluwer; 2021.

2. Harrell FE Jr. *Regression Modeling Strategies: With Applications to Linear Models, Logistic and Ordinal Regression, and Survival Analysis*. 2nd ed. Cham: Springer; 2015.
3. James G, Witten D, Hastie T, Tibshirani R. *An Introduction to Statistical Learning: With Applications in R*. 2nd ed. New York: Springer; 2021.
4. Hastie T, Tibshirani R, Friedman J. *The Elements of Statistical Learning: Data Mining, Inference, and Prediction*. 2nd ed. New York: Springer; 2009.
5. Wickham H, Grolemund G. *R for Data Science: Import, Tidy, Transform, Visualize, and Model Data*. 1st ed. Sebastopol: O'Reilly Media; 2017.

GE-714: Research Methodology (2 credits)

Refer to PhD Common Courses syllabus

Semester - II

PP-811: Scientific Writing, Grant Development, and Research Leadership (2 credits)

Module 1: Scientific Writing and Publication (6 Hours)

- Structure of scientific manuscripts (IMRaD)
- Writing for high-impact journals
- Reporting guidelines (CONSORT, STROBE, PRISMA)

Module 2: Grant Writing and Funding Strategies (6 Hours)

- Components of grant proposals
- Budget preparation and justification
- Various funding agencies

Module 3: Research Leadership and Project Management (6 Hours)

- Team science and interdisciplinary collaboration
- Project planning and execution
- Research integrity and authorship ethics

Module 4: Peer Review and Scientific Communication (6 Hours)

- Peer-review process and reviewer comments
- Conference presentations and posters
- Policy briefs and stakeholder communication

Recommended Books

1. Day RA, Gastel B. *How to Write and Publish a Scientific Paper*. 9th ed. Cambridge: Cambridge University Press; 2022.

2. Schimel J. *Writing Science: How to Write Papers That Get Cited and Proposals That Get Funded*. New York: Oxford University Press; 2012.
3. Booth WC, Colomb GG, Williams JM, Bizup J, Fitzgerald WT. *The Craft of Research*. 4th ed. Chicago: University of Chicago Press; 2016.
4. National Academy of Sciences. *On Being a Scientist: A Guide to Responsible Conduct in Research*. 3rd ed. Washington, DC: National Academies Press; 2009.
5. EQUATOR Network. *Enhancing the QUAlity and Transparency Of health Research (Reporting Guidelines)*. Available from: https://www.equator-network.org

PP-812: Advanced Pharmacovigilance and Patient Safety Science (2 credits)

Module 1: Pharmacovigilance Systems and Signal Detection (6 Hours)

- Global PV systems and databases
- Signal detection methods

Module 2: Medication Safety and Error Prevention (6 Hours)

- Types and causes of medication errors
- Human factors engineering

Module 3: Risk Management and Benefit-Risk Assessment (6 Hours)

- Risk minimization strategies
- Benefit-risk evaluation

Module 4: Emerging Trends in Patient Safety (6 Hours)

- AI in pharmacovigilance
- Safety culture and system design

Recommended Books

1. Aronson JK, ed. *Meyler's Side Effects of Drugs: The International Encyclopedia of Adverse Drug Reactions and Interactions*. 16th ed. Amsterdam: Elsevier; 2016.
2. Hartzema AG, Tilson HH, Chan KA. *Pharmacoepidemiology and Therapeutic Risk Management*. Cincinnati: Harvey Whitney Books; 2008.
3. Vincent C. *Patient Safety*. 2nd ed. Chichester: Wiley-Blackwell; 2010.
4. Cohen MR. *Medication Errors*. 2nd ed. Washington, DC: American Pharmacists Association; 2007.
5. Indian Pharmacopoeia Commission. *Pharmacovigilance Programme of India (PvPI) Guidelines*. Ghaziabad: IPC; Latest edition.

PP-813: Health Economics, HTA, and Policy Decision-Making (2 credits)

Module 1: Advanced Economic Evaluation (6 Hours)

- Cost-effectiveness and cost-utility analysis
- Decision analytic modelling

Module 2: Health Technology Assessment (6 Hours)

- HTA frameworks and processes
- Evidence synthesis

Module 3: Policy and Resource Allocation (6 Hours)

- Priority setting in healthcare
- Policy analysis

Module 4: Indian Healthcare Context (6 Hours)

- HTAIn and national programs
- Case studies

Recommended Books

1. Drummond MF, Sculpher MJ, Claxton K, Stoddart GL, Torrance GW. *Methods for the Economic Evaluation of Health Care Programmes*. 4th ed. Oxford: Oxford University Press; 2015.
2. Neumann PJ, Sanders GD, Russell LB, Siegel JE, Ganiats TG. *Cost-Effectiveness in Health and Medicine*. 2nd ed. New York: Oxford University Press; 2016.
3. Briggs A, Claxton K, Sculpher M. *Decision Modelling for Health Economic Evaluation*. Oxford: Oxford University Press; 2006.
4. Bhattacharya J, Hyde T, Tu P. *Health Economics*. 2nd ed. London: Palgrave Macmillan; 2019.
5. Department of Health Research (DHR), Government of India. *Health Technology Assessment in India (HTAIn) Reference Case Guidelines*. New Delhi: DHR; Latest edition.

GE-814: Research Ethics (2 credits)

Refer to PhD Common Courses syllabus

DEPARTMENT OF PHARMACOLOGY AND TOXICOLOGY

Semester - I

PC-711: Mitochondrial Pharmacology in Human Diseases (2 credits)

1. Mitochondria: Structure, function and DNA inheritance
2. Mitochondria control of physiology and Disease, mitochondrial import machinery, subunits of respiratory chain complexes, mtDNA maintenance and expression
3. Mitochondriogenesis and Quality control system, fission and fusion, UPR, chaperons, HSP, LONP1 and ClpP serine protease, Mitophagy
4. Mitochondria as Signalling organelle, mitochondrial dysfunction cross talk with other pathophysiological pathways
5. Mitochondrial bioenergetics, Redox regulation, mitochondrial ROS production
6. Mitochondrial dysfunction in human diseases: Inflammatory diseases, cardiovascular diseases, neurological disorders etc.
7. In vitro and in vivo Methods for studying mitochondrial activity, mitochondrial respiratory Capacity, membrane potential and ROS production
8. Pharmacological modulators targeting Mitochondrial dysfunction, Mitochondrial targeted antioxidants, natural products and other pharmacological interventions.

Suggested reading:

i) Mitochondrial Medicine: Volume I, ISBN: 978-1-4939-2257-4 Edited by Volkmar Weissig, Marvin Edeas
ii) Mitochondria, 2nd Edition, ISBN: 978-0-470-04073-7, Immo E. Scheffler
iii) Mitochondrial Signaling in Health and Disease: 30 (Oxidative Stress and Disease), CRC Press Inc; 1st edition, Enrique Cadenas, Lester Packer, StenOrrenius
iv) The Functions, Disease-Related Dysfunctions, and Therapeutic Targeting of Neuronal Mitochondria (Wiley Series on Neuropharmacology) by V Gribkoff, ISBN-13:978-1118709238 , John Wiley and Sons

PC-712: Epigenetics and Diseases (2 credits)

1. Toxicogenomics, pharmecogenomics, pharmecognetics and personalized medicine.
2. Proteomics in Drug Discovery: Two-dimension gel electrophoresis; in-gel digestion etc.
3. Microarray technology: Hybridization and types of arrays, tilling array, protein arrays.
4. Chromatin structure and functions: The Nucleosome, euchromatin & heterochromatin, regulation and alteration of chromatin higher order structure.
5. Chromatin Immunoprecipitation: Chip on chip technology
6. Epigenomics, Histone modifications: Acetylation, methylation, phosphortylation, ubiquitination, ribosylation etc.
7. Role of histone modifications in diseases in diabetes.
8. Role of histone modifications in cancer.
9. Neurodegenerative diseases.
10. The use of chromatin immunoprecipitation assays in genome-wide analysis of histone modifications.

PC-713: Pharmacological and Toxicological Screening and Assays (2 credits)

1. Role of pharmacology in drug discovery
2. General principles of pharmacological screening: *In silico*, *In vitro* and *In vivo* screening
3. *In vitro* experimentation: Advantages and disadvantages, applications of cell culture for drug screening. Aseptic handling, cell counting and cell viability assays. Tissue isolation, tissue fixation, common fixatives, preparation of single cell suspension, assays such as cell viability, apoptosis vs necrosis, flow cytometry-based assays, PCR, and Western blot
4. *In vivo* Experimentation: Animal ethics, regulations for conducting animal experimentation, the 3 R's concept, and various animal models and their correlations with human situations
5. Zebrafish model to screening pharmaceutical molecules
6. Correlation between in-vitro and in-vivo screening results
7. Drug metabolism and Pharmacokinetic studies: Metabolic stability studies, CYP enzyme-based studies and CaCo-2 cell permeability assay, Pharmacokinetic modelling
8. New Approach Methodologies (NAMs) and Integrated Approaches to Testing and Assessment (IATA): 2D & 3D cell culture, organoids, organ-on-chips, AI/ML-based models, In chemico methods, Omics approaches, Evidence-based Toxicology
9. Biochemical assays.
10. High throughput screening and high content screening, Humanised and transgenic animal models for drug screening.
11. Pharmacogenomics and Personalised Medicine

GE-714: Research Methodology (2 credits)

Refer to PhD-Common Courses syllabus

Semester - II

PC-811: Regulatory Toxicology and Drug Safety Evaluation (2 credits)

1. Concept and development of regulatory toxicity testing models: Bioassays and end- points: Human pharmaceutical products; Exposure characterization; Routes of exposure; ADME profiles.
2. Stages of drug development: Drug laws, FDA, OECD, ICH, Schedule Y; Design of pre- clinical toxicity studies and clinical development, clinical risk/benefit analysis. Safety evaluation of medical devices and biomaterials. Good Laboratory Practices (GLP), issues and implementation.
3. Different methods in toxicity testing: Dose determination, response characterization, NOAEL.
4. MTD and threshold limitations: Hormesis, lower dose extrapolation, in vitro and in vivo correlation, animal to human extrapolation; Flow chart.
5. Mechanism of toxicity: Evaluation across different models: Target organs, cell death, necrosis, apoptosis, oxidative stress, chromosome and DNA damage.

6. Acute and chronic toxicity, genetic toxicity: Types of genetic toxicity testing; Principles of detection; Genotoxicity of marketed drugs, test batteries, Salmonella test, micronucleus test, chromosome aberration test, Comet assay, New-bio assays.
7. Reproductive toxicity: Germ cell toxicant, effect on gonads, Fl generation study. Neonatal toxicity; Transplacental mutagenesis and carcinogenesis.
8. Carcinogenicity, carcinogen identification: Carcinogenesis process, drug induced carcinogenicity, lifetime carcinogenicity bioassays, neonatal mouse models; Short and medium term bioassays, limitations and impacts.
9. Regulations, discovery-development gap: Risk characterization; Management and C
10. Future of regulatory toxicology in drug safety evaluation

PC-812: Precision Therapeutics (2 credits)

1. Fundamentals of Precision Medicine (Precision medicine and Its evolution, Genetic basis of human diseases, population-based vs. Individualized Healthcare, ethical, Legal, and Social Implications (ELSI)
2. Foundations of Precision Medicine (Principles of precision medicine, Importance of biomarkers, Characteristics of ideal biomarkers, Biomarker classifications, Companion diagnostics and regulatory pathways)
3. Biomarker Discovery Strategies (Workflow for biomarker discovery from candidate identification to validation, Challenges in discovery, Quality control and standardization in biomarker research)
4. High-Throughput Technologies and Multi-Omics Integration (Genomics, proteomics, metabolomics, and transcriptomics in biomarker discovery)
5. Computational methodology in precision medicine (AI/ML tools for multi-omics data integration and system pharmacology, Bridging omics data to clinically actionable biomarkers)
6. Clinical Validation and Regulatory Frameworks (Analytical validation vs. clinical validation, Regulatory pathways for biomarkers and companion diagnostics, Ethical challenges)
7. Applications in Precision Therapeutics (Oncology, Neurodegenerative diseases, Infectious diseases etc, Emerging tools eg. CRISPR-based diagnostics, digital pathology, and real-world evidence) Companion Diagnostics and Therapeutic Decision-Making (Role of companion diagnostics in drug development, Co-development of drugs and diagnostics, Health economics)

Suggested reading:

i) Verma M, Barh D eds. Progress and Challenges in Precision Medicine. s.l: Academic Pr; 2017.
ii) Aronson SJ, Rehm HL. Building the foundation for genomics in precision medicine. Nature 2015; 526:336-342.
iii) Deigner H-P, Kohl M eds. Precision medicine: tools and quantitative approaches. First edition. London, United Kingdom: Academic Press; 2018.
iv) Disease C on a F for D a NT of, Council NR. Toward Precision Medicine: Building a Knowledge Network for Biomedical Research and a New Taxonomy of Disease. Washington: National Academies Press; 2012.
v) Dugger SA, Platt A, Goldstein DB. Drug development in the era of precision medicine. Nat Rev Drug Discov 2018;17:183-196.
vi) Friedman AA, Letai A, Fisher DE, et al. Precision medicine for cancer with next-generation functional diagnostics. Nat Rev Cancer 2015;15:74 7-756.
vii) Haendel MA, Chute CG, Robinson PN. Classification, Ontology, and Precision Medicine Phimister EG, ed. N Engl J Med 2018;379:1452-1462.

PC-813: Pharmacological Interventions for Ischemic Brain Injury (2 credits)

1. Pathophysiology of ischemic brain injury, clinical manifestations and laboratory evaluation.

2. Excitotoxicity of ischemic brain injury: Glutamate excitotoxicity, excitatory amino acid (EAA) receptors EAA antagonists. Problems with EAA antagonists.
3. Oxidative stress in ischemic brain injury: FRs measurement and potential of free radical scavengers in brain injury, nitric oxide in ischemic brain injury.
4. Potential neuroprotective approaches for ischemic brain injury: Calpain inhibitors, PARP inhibitors, MAP kinase inhibitors, apoptosis inhibitors etc.
5. Animal models for focal and global ischemia. Neuronal culture and brain slices for testing neuroprotective drugs.

GE-814: Research Ethics (2 credits)

Refer to PhD-Common Courses syllabus

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राष्ट्रीय औषधीय शिक्षा एवं अनुसंधान संस्थान (नाईपर)

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