Semester VI

Course Code	Name of the course		No. of hours per week (L/P)	Credit points
BP601T	Advanced Pharmacognosy (Theory)		3	3
BP602T	Biopharmaceutics and Pharmacokinetics (Theory)		3	3
BP603T	Intellectual Property Rights (Theory)		2	2
BP604T	AI applications in Pharmaceutical Sciences (Theory)		2	2
BP605T	Pharmaceutical Analysis (Theory)		3	3
BP606T	Pharmaceutical Jurisprudence (Theory)		3	3
BP607T AEC*	BP607T AEC1	Green Chemistry	1	1
	BP607T AEC2	Materiovigilance and Hemovigilance		
	BP607T AEC3	Scientific Writing		
	BP607T AEC4	Drug Store and Business Management		
	BP607T AEC5	Career Building in Cultivation of Medicinal Plants		
	BP607T AEC6	Active Pharmaceutical Ingredients and Excipient Sciences		
BP608P	Biopharmaceutics and Pharmacokinetics (Practical)		3	1
BP609P	Pharmaceutical Analysis (Practical)		4	2
BP610P SEC*	BP610P SEC1	Computer-Aided Drug Design	2	1
	BP610P SEC2	Analytical Method Development and Validation		
	BP610P SEC3	Principles of Preclinical Studies		
BP611P VAC*	BP611P VAC1	Professional Skills	2	1
	BP611P VAC2	Process Analytical Technology (PAT) and QbD in Formulation Science		
BP612I	Internship (Mandatory)		8	4
Total			**28**	**26**

* Only 1 course shall be selected from each elective

Course Code	Course Title		Course Type	
BP601T	**Advanced Pharmacognosy (Theory)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
3	3	--	--	45
Maximum Marks	SE		ESE	
75	30		45	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand reverse pharmacology and integrative approaches in natural drug discovery.
2. Apply metabolomics and systems biology tools for quality control and bioactivity evaluation of herbal medicines.
3. Explore modern AI-driven, in-silico, and high-throughput techniques for identification and optimization of natural product leads.
4. Study validation, safety, and development pathways of herbal leads including preclinical and clinical evaluation.
5. Understand legal, ethical, and patenting frameworks related to bioprospecting, traditional knowledge protection, and natural product innovation.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain reverse pharmacology, traditional knowledge databases, and bioprospecting strategies.
2	To analyze herbal drugs using metabolomics, spectral libraries, and chemoinformatics tools.
3	Employ modern in-silico and AI techniques in lead identification and optimization from natural products.
4	Evaluate preclinical safety, pharmacokinetics, and efficacy of bioactive leads.
5	Interpret global IP frameworks and develop strategies for patenting herbal products and protecting traditional knowledge.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Reverse Pharmacology and Integrative Approaches** Reverse pharmacology and integrative approaches from the AYUSH perspective. Ethnopharmacological approach to bioprospecting. Traditional medicine databases: AYUSH Research Portal, ICMR Standards on Indian Medicinal Plants, TKDL, NAPRALERT, Super Natural, etc. Molecular docking and ADMET screening of bioactives. Concept of adjuvant therapy with herbals in metabolic and non-communicable diseases.	6 hours
II	**Metabolomics and Systems Biology** Introduction to metabolomics and its tools: applications of NMR and HRMS in metabolomics, Metabolomics profiling and dereplication studies, Role of metabolomics in quality control, scientific, validation of traditional claims and pharmacological evaluation, Network pharmacology and systems biology approaches to herbal medicine, Significance of spectral libraries and chemoinformatics databases in drug discovery	11 hours
III	**Modern Techniques in Natural Product Discovery** Role of artificial intelligence (AI), Machine learning and big data in Drug discovery from natural Products. Molecular docking, Virtual Screening and Pharmacophore modelling, Use of Genomic and transcriptomic tools in medicinal plant research, High-throughput screening (HTS) and bioautography. .	10 hours
IV	**Validation and Development of Herbal Leads** Bioactivity Guided Fractionation, characterization /Structure Elucidation, Optimization of lead compounds for better efficacy, safety, and stability through SAR and QSAR modelling for semi-synthetic compounds of Salicin, Artemisinin, Piperine, Papaverine and Andrographolides. Preclinical, Clinical Evaluation and New Drug approvals: Testing for toxicity as per OECD guidelines, pharmacokinetics, and bioavailability of herbal products, extracts and lead compounds, assessment of safety and efficacy, clinical trials with or without placebo for clinical endpoints based on assessment of quality of life reporting adverse events if any, filing IND application, NDA submission, Regulatory review and post marketing surveillance.	12 hours
V	**Patenting of Natural Products** Key Terminologies and Concepts: Definitions and distinctions: Patent, Intellectual Property Rights (IPR) Farmers' Rights and Breeders' Rights, Bioprospecting and Biopiracy Patenting Aspects of Natural Products and Traditional Knowledge: Legal frameworks and challenges in patenting natural substances, Traditional Knowledge Digital Library (TKDL) and its role in protecting indigenous knowledge. Role of National Biodiversity Authority in patenting natural products and NAGOYA protocol. Case Studies: Turmeric– U.S. patent on wound healing and its revocation,	6 hours

	Neem– Biopiracy issue and patent cancellation.	

Recommended References (Preferably latest editions)

1. Bhat, S. V., Nagasampagi, B. A. and Sivakumar, M. *Chemistry of Natural Products.* Springer.
2. Gräbley, S. and Thiericke, R. *Drug Discovery from Nature.* Springer.
3. Hanessian, S. *Natural Products in Medicinal Chemistry.* Wiley-VCH.
4. Ikan, R. *Natural Products: A Laboratory Guide.* Academic Press.
5. Kemp, W. *Spectroscopic Methods in Organic Chemistry.* Macmillan.
6. Narayanan, P. *Intellectual Property Law.* Eastern Law House.
7. Sarker, S. D., Latif, Z. and Gray, A. I. *Natural Products: Isolation, Structure Elucidation and History.* Elsevier.

Course Code	Course Title		Course Type	
BP602T	**Biopharmaceutics and Pharmacokinetics (Theory)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
3	3	--	--	45
Maximum Marks	SE		ESE	
75	30		45	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Describe fundamental biopharmaceutics and pharmacokinetic principles governing drug absorption, distribution, metabolism, and excretion.
2. Analyze the physicochemical and biological factors that determine drug bioavailability, protein binding, and elimination pathways.
3. Illustrate compartmental pharmacokinetic models, and their evaluations through application of mathematical equations to calculate key parameters.
4. Design, conduct, and interpret bioavailability, bioequivalence, and in vitro–in vivo correlation studies.
5. Apply pharmacokinetic principles to optimize dosing regimens—including loading and maintenance doses and steady-state kinetics—and utilize software tools to analyze both linear and non-linear drug kinetics.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Interpret fundamental pharmacokinetic and pharmacodynamic principles and apply them to patient-centered clinical scenarios.
2	Evaluate the impact of physicochemical and biological variables on drug absorption, distribution, and protein binding in clinical practice.
3	Differentiate among bioavailability classifications and develop bioequivalence study protocols that comply with international regulatory standards.
4	Solve pharmacokinetic problems using compartment models by employing numerical techniques
5	Design optimal dosing regimens, interpret non-linear pharmacokinetic behaviors, and utilize simulation software for PK/PD analysis.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Introduction to Biopharmaceutics and pharmacokinetics:** Introduction to various Pharmacokinetic parameters (using Plasma drug Concentration vs Time curve) and Pharmacodynamic parameters and drug delivery index. **Absorption**; Mechanisms of drug absorption through GIT, Physicochemical, Biological and Dosage form related factors influencing drug absorption though GIT, methods of Assessment of GIT absorption, **Distribution** Tissue permeability of drugs, binding of drugs, apparent volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs.	10 hours
II	**Elimination (Metabolism and Elimination):** Drug metabolism and basic understanding of metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, non renal routes of drug excretion of drugs **Bioavailability and Bioequivalence:** Definition and Objectives of bioavailability, absolute and relative bioavailability, Introduction to BCS and biopharmaceutical drug disposition classification system, methods of measurement of bioavailability (Plasma data, Urinary excretion data), Protocol for assessment of bioavailability and bioequivalence studies. *in-vitro* drug dissolution methods (test apparatus I-VII), biorelevant dissolution mediums, *in-vitro in-vivo* correlations: Concept and Applications, Biowaivers, Methods of enhancement of bioavailability.	10 hours
III	**Pharmacokinetic Models: Compartment Models:** Definition, Basis of classification, Properties of compartment, Advantages and disadvantages of compartment modelling. Kinetic considerations of One compartment open model. (a). Intravenous Injection (Bolus/rapid) (b). Intravenous infusion and (c) Extra-vascular administration. (with emphasis on Curve Fitting, Wagner –Nelson, Loo Riegelman) **Introduction to non - compartment model: Principles, estimation of PK parameters (AUC, AUMC, MRT, MAT statistical moment theory).**	10 hours
IV	**Multicompartment models:** Multiple dosage regimen: dosing interval, drug accumulation, loading dose, maintenance dose, PK Parameters Kinetic consideration of two compartment open model (a) Intravenous Injection (Bolus/rapid) and (b) Extra vascular administrations (oral administration). Kinetics of multiple dosing, steady state drug levels, calculation of loading and maintenance doses and their clinical significance. Multiple dosage regimen. Introduction to pharmacokinetic consideration of Modified release drug products.	9 hours
V	**Nonlinear Pharmacokinetics:** Introduction, Reasons for Non-linearity, Michaelis-menton method of estimating parameters, Explanation with example of drugs. **Application of PK software:** Introduction of various in -silico methods for calculating various PK parameters.	6 hours
Recommended References (Preferably latest editions) 1. Shargel, L. and Yu, A. B. C. *Applied Biopharmaceutics and Pharmacokinetics.* McGraw-Hill Education.		

2. Gibaldi, M. *Biopharmaceutics and Clinical Pharmacokinetics.* Lea & Febiger.
3. Rowland, M. and Tozer, T. N. *Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications.* Wolters Kluwer.
4. Bonate, P. L. *Pharmacokinetic-Pharmacodynamic Modeling and Simulation.* Springer.
5. Brahmankar, D. M. and Jaiswal, S. B. *Biopharmaceutics and Pharmacokinetics: A Treatise.* Vallabh Prakashan.
6. Eddy, D. M. *Modeling and Simulation in the Medical and Health Sciences.* Springer.

Course Code	Course Title		Course Type	
BP603T	**Intellectual Property Rights (Theory)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
2	2	--	--	30
Maximum Marks	SE		ESE	
50	20		30	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Introduce the fundamental concepts and types of intellectual property (IP) and highlight their importance in the pharmaceutical and healthcare sectors.
2. Understand the procedures and legal frameworks related to patent filing, granting, and protection of intellectual property.
3. Develop awareness of international and national IP laws and treaties, including the TRIPS agreement and Indian Patent Act, and their implications for the pharmaceutical industry.
4. Provide insights into the management and commercialization of IP, including licensing, technology transfer, and joint ventures.
5. Familiarize with common IP infringement issues and remedies, using real-world case studies from the pharmaceutical industry to illustrate key principles.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Understand the basic concepts and significance of intellectual property rights with respect to pharmaceutical industries.
2	Learn the types of intellectual property rights such as patents, copyrights, trademarks, trade secrets.
3	Understand the procedure for patent filing in India and abroad.
4	Understand the key provisions of the Indian Patent Act.
5	Evaluate and understand the strategies for IP management and product commercialization.

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Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	Introduction to Intellectual Property Definition and scope of Intellectual Property (IP), Importance and types of IP: Patents, Trademarks, Copyrights and Trade Secrets, Overview of the origin and progression of intellectual property rights in India and internationally, Role of IP in the pharmaceutical industry	6 hours
II	**Patents – Fundamentals and Process** Definition and objectives of patents, Criteria for patentability such as Novelty/innovations, Non-obviousness, Utility, Types of patents and non-patentable inventions in India, Procedure for filing a patent in India, Rights of a patent holder and term of patent protection	6 hours
III	**Patent Laws and Acts** Overview of Indian Patent Act, 1970 (latest amendments and key provisions under the act), TRIPS Agreement and its implications on the Indian pharmaceutical sector, Compulsory licensing, patent opposition, and revocation, Indian pharmaceutical patents: Case studies.	6 hours
IV	**Other Forms of Intellectual Property** Trademarks, Copyrights, Industrial designs: Definition, importance, registration process**,** Basics and protection in scientific work**,** Importance and legal framework**,** Trade secrets and geographical indications in pharma industry	6 hours
V	**IPR Management and Commercialization** Valuation and strategies for commercialization of intellectual property; processes of technology transfer, licensing agreements, and collaborative ventures; issues related to IP infringement and available legal remedies; management practices of IPR in the pharmaceutical industry supported by relevant case studies.	6 hours

Recommended References (Preferably latest editions):

1. World Intellectual Property Organization. *Introduction to Intellectual Property.* WIPO.
2. Indian IPR. https://ipindia.gov.in/
3. Ahuja, V. K. *Law Relating to Intellectual Property Rights.* LexisNexis.
4. Bouchoux, D. *Intellectual Property.* Cengage Learning.
5. Ganguli, P. *Intellectual Property Rights: Unleashing the Knowledge Economy.* Tata McGraw-Hill.
6. Narayanan, P. *Intellectual Property Law.* Eastern Law House.
7. Ramakrishna, T. *Basic Principles and Acquisition of Intellectual Property Rights.* CIPRA.
8. Sreenivasulu, N. S. *Law Relating to Intellectual Property.* Partridge Publishing.
9. Vaidhyanathan, S. *Intellectual Property: A Very Short Introduction.* Oxford University Press.
10. Wadehra, B. L. *Law Relating to Intellectual Property.* Universal Law Publishing.

Course Code	Course Title		Course Type	
BP604T	AI applications in Pharmaceutical Sciences (Theory)		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
2	2	--	--	30
Maximum Marks	SE		ESE	
50	20		30	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Introduce applications of artificial intelligence and machine learning across major pharmaceutical disciplines.
2. Understand the structured data in natural products, medicinal chemistry, formulation science, and manufacturing
3. Interpret regression and classification models in drug discovery, product performance, and quality monitoring.
4. Build awareness of predictive modeling for pharmaceutical decision-making.
5. Understand multivariate analysis in pharmaceutical analytical techniques.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain how pharmaceutical data from various domains can be structured for machine learning applications.
2	Interpret regression and classification models used in natural products and medicinal chemistry.
3	Analyze predictive modeling approaches in formulation, release, and stability studies.
4	Evaluate AI applications in manufacturing process monitoring and quality prediction.
5	Assess analytical modeling and chemometric applications in pharmaceutical quality control.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**AI in Natural Products & Pharmacognostic Data Modeling** Overview of ML applications in natural products: • Representation of crude drug data (morphological, microscopic, phytochemical, chromatographic features) • Structuring herbal datasets for predictive modeling	6 Hours

	• Classification models for authentication of crude drugs (authentic vs adulterated) • Regression models for prediction of secondary metabolite yield • Application of AI in phytochemical screening and prioritization • Herb-drug interaction prediction using database-driven approaches • Limitations of predictive modeling in natural products.	
II	**AI in Medicinal & Pharmaceutical Chemistry** Overview of the role of AI applications in pharmaceutical chemistry with focus on drug discovery concepts: • Conversion of molecular structures into numerical descriptors (MW, logP, HBD/HBA, TPSA) • Structured chemical datasets and QSAR modeling • Regression and classification models for predicting biological activity (IC_{50}, solubility, ADMET properties), toxicities. • Virtual screening and lead optimization concepts • Limitations of ML models and importance of chemical reasoning	6 Hours
III	**AI in Drug Product Design & Performance Prediction** Overview of AI models across formulation development stages, with emphasis on the applications and limitations: • Overview of dosage form development and formulation variables • Machine learning in formulation optimization and excipient selection • Regression modeling for solubility and bioavailability enhancement • Time-concentration modeling for drug release interpretation • Stability study design and modeling degradation trends • Shelf-life estimation using regression-based approaches • Practical limitations of extrapolation in formulation science	(6 Hours)
IV	**AI in Process Monitoring & Production Systems** Overview of introduces multivariate analysis in pharmaceutical analytical techniques with focus on the different models and their applications: • Digital data acquisition in pharmaceutical production • Critical Quality Attributes (CQAs) and Critical Process Parameters (CPPs)	6 hours

	• Correlation analysis for identifying process variability • Logistic regression models for batch pass/fail prediction • Feature importance in process monitoring, predictive maintenance concepts. Ethical and regulatory considerations in automated decision-making, and limitations of predictive models in manufacturing environments.	
V	**AI in Pharmaceutical Analysis & Chemometrics** Overview of multivariate analysis in pharmaceutical analytical techniques with focus on the different models and their applications: • Introduction to chemometrics and multivariate analytical data • Spectroscopic data modeling (UV/IR interpretation) • Regression analysis in quantitative pharmaceutical analysis • Chromatographic peak modeling and interpretation • Classification models for genuine vs counterfeit detection • Handling noise and variability in analytical datasets • Limitations of AI models in analytical decision-making •	6 Hours

Recommended References *(Preferably latest editions)*:

1. Bakeev, K. A. Process Analytical Technology: Spectroscopic Tools and Implementation Strategies for the Chemical and Pharmaceutical Industries. Wiley.
2. Brown, N. Artificial Intelligence in Drug Discovery. Royal Society of Chemistry.
3. Chavda, V., et al. Bioinformatics Tools for Pharmaceutical Drug Product Development.
4. Gibson, M. Pharmaceutical Preformulation and Formulation. CRC Press.
5. Hanessian, S. Natural Products in Medicinal Chemistry. Wiley.
6. Pais, A., et al. Artificial Intelligence for Drug Product Lifecycle Applications.
7. Schlindwein, W. S. and Gibson, M. Pharmaceutical Quality by Design: A Practical Approach. Wiley.
8. World Health Organization. Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials. WHO Press

Course Code	Course Title		Course Type	
BP605T	**Pharmaceutical Analysis (Theory)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
3	3	--	--	45
Maximum Marks	SE		ESE	
75	30		45	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand the interaction of matter with electromagnetic radiation and its application in spectroscopic methods for pharmaceutical drug analysis.
2. Study the principles, instrumentation, and pharmaceutical applications of electroanalytical techniques such as potentiometry, conductometry, polarography, and amperometry.
3. Understand and apply various chromatographic and electrophoretic separation techniques used for qualitative and quantitative analysis of drugs.
4. Impart knowledge of instrumental methods used for accurate qualitative and quantitative analysis of pharmaceutical substances.
5. Develop the ability to select, optimize, and validate suitable analytical techniques, interpret analytical data.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the theoretical basis of electrochemical methods (potentiometry, conductometry, polarography, amperometry) and spectroscopic techniques (UV-Visible, IR, fluorometry, atomic absorption).
2	Explain the instruments involved in electroanalytical and spectroscopic methods.
3	Describe the principles, instrumentation, and applications of various chromatographic and electrophoretic techniques.
4	Select suitable analytical techniques for specific pharmaceutical analysis requirements.
5	Analyze, interpret, and report analytical data accurately and draw meaningful conclusions.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Electrochemical Methods of analysis** 1. **Potentiometry:** Electrode potential, electrochemical cell, construction and working of reference and indicator electrodes including membrane electrodes, measurement of potential and	10 hours

	pH, potentiometric titrations, methods of detecting end point and Karl Fischer titration. 2. **Conductometry**: Introduction, conductivity cell, conductometric titrations and applications. 3. **Polarography:** Introduction, residual current, migration current, diffusion current and limiting current, DME, polarographic wave, Ilkovic's equation (Statement Only), and applications.	
II	**Spectroscopy** 1. **Fundamentals of Spectroscopy:** Properties of electromagnetic radiation, electromagnetic spectrum. 2. **UV Visible spectroscopy:** Beer and Lambert's law, Derivation and deviations. Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors (Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode). Applications - single and multi component analysis of pharmaceuticals. 3. **IR spectroscopy:** Introduction, fundamental modes of vibrations in poly atomic molecules, factors affecting vibrations, Instrumentation of dispersive Infrared spectrophotometer (including sample handling Techniques) and FTIR. Pharmaceutical applications.	10 hours
III	**Fluorometric Analysis** 1. Theory, luminescence, factors affecting fluorescence, quenching. Instrumentation and pharmaceutical applications. 2. **Flame Photometry and Atomic Absorption Spectrometry:** Theory, nebulisation, flame and flame temperature, interferences, instrumentation and pharmaceutical applications. 3. **Nepheloturbidometry**: Principle, instrumentation and applications.	7 hours
IV	**Introduction to Chromatographic Techniques** 1. Principle, various stationary and mobile phases, diverse development and detection techniques and applications of column, paper and thin layer chromatography. 2. **Ion-exchange chromatography**: Introduction, principles, types of ions exchange resins, factors affecting ion exchange, methodology and applications. 3. **Gel filtration and affinity chromatography**: Principles and applications. 4. **Electrophoresis**: Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications.	8 hours
V	1. **Gas chromatography:** Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications 2. **High performance liquid chromatography:** Introduction, theory, instrumentation, advantages and applications.	10 hours

	3. **HPTLC:** Principle, instrumentation and applications.	

Recommended References *(Preferably latest editions)*:

1. Braun, R. D. *Analytical Chemistry: A Modern Approach to Analytical Science.* McGraw-Hill.
2. Dyer, J. R. *Applications of Absorption Spectroscopy of Organic Molecules.* Prentice Hall.
3. Harvey, D. *Modern Analytical Chemistry.* McGraw-Hill.
4. Sharma, Y. R. *Organic Spectroscopy.* S. Chand.
5. Skoog, D. A., Holler, F. J. and Crouch, S. R. *Principles of Instrumental Analysis.* Cengage Learning.
6. Watson, D. G. *Pharmaceutical Analysis.* Elsevier.

Course Code	Course Title		Course Type	
BP606T	**Pharmaceutical Jurisprudence (Theory)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
3	3	--	--	45
Maximum Marks	SE		ESE	
75	30		45	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand the fundamental principles and scope of pharmaceutical legislations governing drug development, manufacture, distribution, and marketing.
2. Gain comprehensive knowledge of Indian pharmaceutical Acts and Rules, including Drugs and Cosmetics Act, Pharmacy Act, NDPS Act, and related regulations.
3. Learn the roles, responsibilities, and functions of regulatory authorities involved in regulation and control of pharmaceuticals in India.
4. Learn the code of pharmaceutical ethics and legal responsibilities in professional pharmacy practice.
5. Develop the ability to analyse regulatory frameworks, pricing controls, and emerging regulations, and assess their impact on public health, industry compliance, and patient safety.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Demonstrate understanding of major pharmaceutical legislations and explain their relevance in pharmaceutical product development and marketing.
2	Interpret and apply the provisions of various Indian pharmaceutical Acts and laws in real-world scenarios.
3	Identify regulatory bodies such as CDSCO, IPC, and state regulatory authorities, and explain their roles in drug approval, manufacturing, and distribution.
4	Exhibit ethical awareness by applying the code of ethics in professional pharmaceutical practices.
5	Critically analyze regulatory frameworks and assess their impact on public health, industry operations, and compliance requirements.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Drugs and Cosmetics Act, 1940 and its rules 1945:** Objectives, Definitions, Legal definitions of schedules to the Act and Rules, CDSCO guidelines for Import & export of Pharmaceuticals Manufacture of drugs – Prohibition of manufacture and sale of certain drugs, Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.	10 hours
II	**Drugs and Cosmetics Act, 1940 and its rules 1945.** • Detailed study of Schedule G, H, H1, M, N, P, T, U, V, X, Y, Sch F, Part XII B. • Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties • Labeling & packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties. • Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors	10 hours
III	• **Pharmacy Act –1948:** Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations including ER20, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and Penalties • **Medicinal and Toilet Preparation Act –1955**: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Offences and Penalties. • **Narcotic Drugs and Psychotropic substances Act-1985 and Rules**: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic &Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties	8 hours
IV	• **Study of Salient Features of Drugs and Magic Remedies Act and its rules:** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties • **Prevention of Cruelty to animals Act-1960**: Objectives, Definitions, Institutional Animal Ethics Committee, *CCSEA* guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for	8 hours

	experiment, Records, Power to suspend or revoke registration, Offences and Penalties • **National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO)- 2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM).	
V	• **Pharmaceutical Legislations** – A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee • **Code of Pharmaceutical ethics:** Definition, Pharmacist in relation to his job, trade, medical profession and his profession, • Medical Termination of Pregnancy Act • Brief Introduction to Right to Information Act • Introduction New Drugs and Clinical Trials Rules, 2019 and amendments. • Cosmetic rules 2020 • Regulatory guidelines on similar biologics. • Overview of Medical Device Regulations, Guidelines on Probiotics, Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016	9 hours

Recommended References (Preferably latest editions)

1. Government of India. Drugs and Cosmetics Act and Rules. Government of India.
2. Government of India. Drugs and Magic Remedies (Objectionable Advertisements) Act. Government of India.
3. Government of India. Medicinal and Toilet Preparations (Excise Duties) Act. Government of India.
4. Government of India. Narcotic Drugs and Psychotropic Substances Act. Government of India.
5. Government of India. New Drugs and Clinical Trials Rules, 2019. Government of India.
6. Central Drugs Standard Control Organization and Department of Biotechnology. *Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India*. Government of India.

Course Code*	Course Title*	Course Type
BP607T AEC1	Green Chemistry	**Elective**
BP607T AEC2	Materiovigilance and Hemovigilance	
BP607T AEC3	Scientific Writing	
BP607T AEC4	Drug Store and Business Management	
BP607T AEC5	Career Building in Cultivation of Medicinal Plants	
BP607T AEC6	Active Pharmaceutical Ingredients and Excipient Sciences	

Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
1	1	--	--	15

Maximum Marks	SE	ESE
50	20	30

* One course shall be selected from the list
The syllabi for elective subjects are given in the *appendix*

Course Code	Course Title		Course Type	
BP608P	**Biopharmaceutics and Pharmacokinetics (Practical)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
1	--	--	3	45
Maximum Marks	SE		ESE	
50	20		30	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand the dissolution profiles of pharmaceutical formulations using various media and conditions.
2. Apply *in vitro* and *ex vivo* techniques to assess drug absorption, dissolution, and bioavailability.
3. Interpret pharmacokinetic parameters using plasma and urinary excretion data.
4. Establish *in vitro–in vivo correlation* (IVIVC) for drug products based on experimental datasets.
5. Utilize software tools to simulate and analyze pharmacokinetic and pharmacodynamic data.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the fundamental concepts, types, and applications of NDDS in modern therapeutics and precision medicine.
2	Design and prepare advanced drug delivery systems such as orodispersible tablets, bilayer tablets, osmotic systems, microspheres, microcapsules, buccal/sublingual dosage forms, transdermal patches, gastroretentive systems, and lipid-based carriers.
3	Select appropriate excipients and techniques for the development of NDDS considering drug properties, patient needs, and target site requirements.
4	Perform evaluation and quality control tests for novel formulations to ensure efficacy, stability, and patient compliance.
5	Integrate NDDS strategies into precision medicine frameworks to optimize dosing, therapeutic targeting, and individualized treatment plans.

Detailed Syllabus:

List of Practical
1. To calculate MRT from the given data. 2. To assess the effect of protein binding of a drug 3. To report relative bioavailability of given drug product using urinary excretion data 4. To report relative bioavailability of given drug product using plasma data 5. Establish IVIVC from the given *in vitro* and *in vivo* data. 6. To calculate pharmacokinetic parameters of a drug using given plasma level data. 7. To report bioequivalence of drug products using given urinary excretion data administered 8. To calculate absorption rate constant, elimination rate constant and elimination half-life of given excretion data by sigma minus method. 9. To calculate absorption rate constant, elimination rate constant and elimination half-life of the given drug data administered by IV bolus injection represented by one compartment model. 10. To calculate the absorption rate constant by using curve fitting method. 11. To calculate various pharmacokinetic parameters using *in silico* methods.
Recommended References (Preferably latest editions): 1. Bonate, P. L. *Pharmacokinetic-Pharmacodynamic Modeling and Simulation.* Springer. 2. Brahmankar, D. M. and Jaiswal, S. B. *Biopharmaceutics and Pharmacokinetics: A Treatise.* Vallabh Prakashan. 3. Eddy, D. M. *Modeling and Simulation in the Medical and Health Sciences.* Springer. 4. Gibaldi, M. *Biopharmaceutics and Clinical Pharmacokinetics.* Lea & Febiger. 5. Rowland, M. and Tozer, T. N. *Clinical Pharmacokinetics and Pharmacodynamics.* Wolters Kluwer. 6. Shargel, L. and Yu, A. B. C. *Applied Biopharmaceutics and Pharmacokinetics.* McGraw-Hill Education.

Course Code	Course Title		Course Type	
BP609P	**Pharmaceutical Analysis (Practical)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
2	--	--	4	60
Maximum Marks	SE		ESE	
50	20		30	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand the fundamental principles behind various analytical techniques including titrations, spectrophotometry, fluorimetry, flame photometry, and chromatography.
2. Develop proficiency in performing quantitative and qualitative analyses of pharmaceutical compounds using classical and instrumental methods.
3. Learn to operate and maintain laboratory instruments such as potentiometers, conductometers, spectrophotometers, fluorimeters, flame photometers, and chromatographic systems.
4. Apply appropriate analytical techniques for specific analytical challenges and interpretation, including single and multi-component assays, identification of functional groups, and separation of mixtures.
5. Learn good laboratory practices and safety protocols in handling chemicals and operating instruments.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Perform accurate titrations (potentiometric and conductometric) to determine the endpoint of acid-base reactions.
2	Determine absorption maxima, perform assays, and analyze multi-component formulations using spectrophotometric and colorimetric techniques.
3	Identify functional groups in compounds using FTIR spectroscopy and conduct quantitative analysis using fluorimetry and flame photometry.
4	Separate and analyze mixtures of compounds using paper chromatography, thin-layer chromatography (TLC), gas-liquid chromatography (GLC), high-performance liquid chromatography (HPLC), and high-performance thin-layer chromatography (HPTLC).
5	Interpret spectral and chromatographic data to identify compounds and quantify analytes.

Detailed Syllabus:

List of Practical **(Minimum 12 experiments must be performed)**
1. Determination of the endpoint of a acid base titration by potentiometric method. 2. Determination of end point of acid base titrations by conductometry. 3. Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds 4. Assay of APIs by colorimetry. 5. Assay of single component by UV- Spectrophotometer. 6. Simultaneous estimation of multicomponent formulations by UV spectrophotometer. 7. Identification of various functional groups in official compounds by FTIR as per IP. 8. Assay of quinine sulphate by fluorimetry 9. Determination of quenching effect by fluorimetry 10. Assay of sodium chloride by flame photometry 11. Assay of potassium chloride by flame photometry 12. Determination of chlorides and sulphates by nephelo turbidometry 13. Separation of amino acids by paper chromatography 14. Separation of mixture of components by thin layer chromatography 15. Demonstration experiment on GC 16. Determination of official compounds by HPLC (anyone) 17. Demonstration experiment on HPTLC.
Recommended References (Preferably latest editions): 1. Vogel, A.I., Textbook of Quantitative Chemical Analysis. Longman Scientific & Technical. 2. Beckett, A.H., and Stenlake, J.B., Practical Pharmaceutical Chemistry: Part II. Athlone Press. 3. Skoog, D.A., Holler, F.J., and Crouch, S.R., Principles of Instrumental Analysis. Cengage Learning.

Course Code*	Course Title*		Course Type	
BP610P SEC1	Computer-Aided Drug Design		**Elective**	
BP610P SEC2	Analytical Method Development and Validation			
BP610P SEC3	Principles of Preclinical Studies			
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
1	--	--	2	30
Maximum Marks	SE		ESE	
50	20		30	

* One course shall be selected in each elective

Course Code*	Course Title*		Course Type	
BP611P VAC1	Professional Skills		**Elective**	
BP611P VAC2	Process Analytical Technology (PAT) and QbD in Formulation Science			
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
1	--	--	2	30
Maximum Marks	SE		ESE	
50	20		30	

* One course shall be selected from the list
The syllabi for elective subjects are given in the *appendix*

Course Code	Course Title		Course Type
BP612I	**Internship**		**CORE**
Credit	Hours Per Week (L-T-P)*		
	L	T	P
4	--	--	--
Maximum Marks	SE		ESE
100	00		100

* Refer section 22 of Regulation

SEMESTER VI

Course Code	Course Title			Course Type
BP610P SEC1	**Computer Aided Drug Design (Practical)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	--	--	2	30
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Familiarize students with target identification and protein preparation using biological databases and molecular visualization tools.
2. Develop skills in ligand design, optimization, and 3D conformer generation using computational chemistry software.
3. Provide practical understanding of molecular docking and interaction analysis for structure-based drug design.
4. Introduce pharmacophore modelling and QSAR techniques for virtual screening and predictive modelling.
5. Train students in ADMET prediction and molecular dynamics simulations for evaluating drug-likeness and stability of drug–target complexes.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1.	Retrieve and prepare biological targets from protein databases and analyze active sites using molecular modelling tools.
2.	Design and optimize ligand structures and generate energetically stable conformers for computational drug design studies.
3.	Perform molecular docking and analyze drug–target interactions to evaluate ligand binding affinity and stability.
4.	Apply pharmacophore modelling and QSAR methods for virtual screening and prediction of biological activity.
5.	Evaluate drug candidates using ADMET prediction tools and molecular dynamics simulations to assess drug-likeness and complex stability.

Detailed Syllabus

List of Practical

General Instruction on Computational Tools

Open-source computational tools are preferred for teaching and learning purposes. However, institutions may select appropriate software platforms or online resources based on availability, institutional policy, and technical feasibility. The choice of software should enable students to perform the required computational tasks effectively. The specific software used may vary, but the learning outcomes and computational procedures described below must be achieved using suitable tools.

1. Target Identification and Preparation

- Retrieve protein sequence or structural information from publicly available biological databases.
- Prepare the target protein by removing unwanted molecules, correcting structural issues, and adding necessary atoms or charges using appropriate molecular visualization or preparation tools.
- Identify potential binding or active sites using computational methods that analyze structural pockets and cavities.

2. Ligand Design and Optimization

- Design or sketch candidate molecules using suitable molecular drawing tools.
- Convert structures into three-dimensional form and optimize their geometry using computational chemistry methods.
- Generate multiple conformations of the molecule and perform energy minimization to obtain stable structures.

3. Molecular Docking

- Perform docking simulations using computational docking platforms to predict the interaction between ligands and the target protein.
- Examine binding orientations and molecular interactions using visualization tools.
- Rank compounds based on predicted binding affinity and interaction quality.

4. Pharmacophore Modeling

- Identify essential molecular features responsible for biological activity such as hydrogen bond donors/acceptors, hydrophobic regions, and aromatic centers.
- Construct pharmacophore models representing these key features.
- Use these models to screen compound libraries for molecules that match the required feature pattern.

5. QSAR Modeling

- Calculate molecular descriptors that represent structural and physicochemical properties of compounds.
- Develop predictive statistical or machine learning models that relate these descriptors to biological activity.
- Validate models using appropriate validation techniques such as cross-validation and external datasets.

6. ADMET Prediction

- Evaluate pharmacokinetic and toxicity properties computationally, including:
  - Absorption
  - Distribution
  - Metabolism
  - Excretion
  - Toxicity
- Use predictive computational models and online resources to assess drug-likeness and safety profiles.

7. Molecular Dynamics Simulations

- Conduct simulations to study the dynamic behavior of the protein–ligand complex over time.
- Analyze parameters such as structural stability, atomic fluctuations, hydrogen bonding, and interaction persistence.
- Visualize simulation trajectories to understand conformational changes and binding stability.

Recommended References *(Preferably latest edition)*:

1. Leach, A.R., *Molecular Modelling: Principles and Applications*. Harlow: Prentice Hall.
2. Todeschini, R. and Consonni, V., *Molecular Descriptors for Chemoinformatics*. Weinheim: Wiley-VCH.
3. Gupta, S.P., *QSAR and Molecular Modeling*. Berlin: Springer.
4. Jorgensen, W.L., *Efficient Drug Discovery and Development*. Hoboken, NJ: Wiley.
5. Bultinck, P., De Winter, H., Langenaeker, W. and Tollenaere, J.P., *Computational Medicinal Chemistry for Drug Discovery*. New York: Marcel Dekker.
6. Andrew, L.H. and Brown, F.K., *Rational Drug Design: Novel Methodology and Practical Applications*. Washington, DC: American Chemical Society.
7. Ward, S.E. and Davis, A., *The Handbook of Medicinal Chemistry: Principles and Practice*.

Course Code	Course Title			Course Type
BP610P SEC2	**Analytical Method Development and Validation (Practical)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	--	--	2	30
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Provide practical exposure to analytical method development using spectrophotometric, chromatographic, and titrimetric techniques for pharmaceutical analysis.
2. Introduce principles of optimization of analytical parameters such as wavelength, mobile phase composition, column selection, flow rate, temperature, and pH for reliable analysis.
3. Familiarize students with validation requirements of analytical methods as per regulatory guidelines, including assessment of sensitivity, linearity, and specificity.
4. Expose students to advanced chromatographic applications such as dissolution testing, impurity profiling, forced degradation studies, and residual solvent analysis.
5. Bridge analytical theory with industrial and regulatory practices relevant to quality control and quality assurance of pharmaceutical products.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Develop and optimize analytical methods using UV–Visible spectrophotometry, HPLC, GC, and titrimetric techniques for pharmaceutical substances.
2	Construct calibration curves and perform quantitative estimation of APIs and formulations with appropriate analytical validation.
3	Select and optimize chromatographic conditions including column type, mobile phase composition, flow rate, temperature, and detection wavelength.
4	Apply analytical method validation parameters such as LOD, LOQ, and robustness to ensure reliability and regulatory compliance.
5	Conduct stability-indicating and impurity-related studies, including forced degradation, dissolution testing, and residual solvent analysis.

Detailed Syllabus

List of Practical
(Perform any 12 Experiments) 1. Development of a UV-Visible spectrophotometric method for the assay of paracetamol API. Construction of calibration curve for a model API using UV-Visible spectrophotometry. 2. Determination of solid dosage form by using dissolution method. 3. Analytical method development and validation of Atenolol/metformin by using HPLC. 4. Investigation of different columns for HPLC separation of a Multi-component Drug Mixture. 5. Optimization of mobile Phase composition for HPLC analysis of a selected drug. 6. Optimization of Flow rate and temperature in HPLC for paracetamol/ caffeine. 7. Selection of wavelength for spectrophotometric analysis by HPLC of Marketed drugs. 8. Determination of λmax and calibration curve for qualitative analysis of paracetamol. 9. Determination of effect of pH on Retention time in RP-HPLC. 10. Validation of HPLC method : Determination of LOD and LOQ for paracetamol by HPLC 11. Preliminary Investigation of forced Degradation studies on Ibuprofen by HPLC. 12. Method development for related substances of a drug substance using HPLC. 13. Determination of residual solvent analysis for ethanol/acetone in API by using Gas Chromatography. 14. Development of titrimetric method for the assay of marketed drugs(Ascorbic acid/sodium bicarbonate).
Recommended References *(Preferably latest edition)*: 1. Ahuja S, Dong MW, editors. Handbook of pharmaceutical analysis by HPLC. Amsterdam: Elsevier; 2005. 2. Moldoveanu SC. Method development in analytical HPLC. Amsterdam: Elsevier; 2014. 3. Swartz ME, Krull I. Analytical method development and validation. Boca Raton (FL): CRC Press; 2018. 4. Gorog S. Ultraviolet–visible spectrophotometry in pharmaceutical analysis. Boca Raton (FL): CRC Press; 2018. 5. Rehman K, Akash MSH. Essentials of pharmaceutical analysis. Singapore: Springer; 2020. 6. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Q2(R2): Validation of analytical procedures. Geneva: ICH; 2023.

Course Code	Course Title			Course Type
BP610P SEC3	**Principles of Preclinical Studies (Practical)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	--	--	2	30
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Introduce the role and importance of preclinical studies in the drug discovery and development process.
2. Familiarize students with laboratory animal handling, ethical considerations, and experimental protocols used in preclinical research.
3. Explain the principles of pharmacokinetics and toxicology as applied to animal models.
4. Describe the regulatory guidelines and standards governing preclinical research and animal experimentation.
5. Develop skills in analyzing and interpreting preclinical data to support decision-making for clinical trials.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Explain the role and significance of preclinical studies in drug discovery and development.
2	Demonstrate appropriate laboratory animal handling practices in accordance with ethical and regulatory guidelines.
3	Analyze pharmacokinetic parameters obtained from preclinical animal studies.
4	Design and interpret basic toxicological studies to evaluate drug safety.
5	Apply preclinical data in assessing drug candidates for progression to clinical trials.

Detailed Syllabus

List of Practical
(Perform any 12 Experiments) 1. Handling, restraining, and sex differentiation of laboratory animals (demo/video) 2. Calculation of dose for animals based on body surface area 3. Routes of administration: oral, intraperitoneal, subcutaneous (simulation) 4. Observation of behavioral effects using actophotometer/rotarod (if available) 5. Determination of acute toxicity (LD50 concept) – case-based calculation 6. Planning a 28-day sub-acute toxicity study protocol 7. Pharmacokinetic study: Cmax, Tmax, AUC calculation (sample dataset) 8. Observation of histopathological slides from toxicity studies 9. Demonstration of sampling methods – blood, urine (case or video) 10. Writing an animal study protocol using CPCSEA format 11. Identification of organs for toxicity evaluation – liver, kidney, brain 12. Visit to CPCSEA-approved animal house/laboratory 13. Observation of animal behavior – grooming, nesting (case-based) 14. Simulated ethics committee approval process (IAEC) 15. Group activity: Design of a preclinical study for a hypothetical drug
Recommended References *(Preferably latest edition)*: 1. Preclinical and Clinical Research – A Handbook – S. K. Gupta, Jaypee Brothers Medical Publishers 2. Drug Discovery and Clinical Research – B. T. James & M. M. Gupta, CBS Publishers & Distributors 3. Textbook of Preclinical Toxicology – R. K. Goyal, B. S. Shah Prakashan 4. Fundamentals of Experimental Pharmacology – M. N. Ghosh, Hilton & Company 5. Textbook of Pharmacology – S. D. Seth, Elsevier India