B.PHARMACY SYLLABUS (PCI / NEP 2020)

SEMESTER VI

Subject Name: Advanced Pharmacognosy (Theory)

Subject Code: BP601T

UNIT I: Reverse Pharmacology and Integrative Approaches (6 hours)

- 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.

UNIT II: Metabolomics and Systems Biology (11 hours)

- 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.

UNIT III: Modern Techniques in Natural Product Discovery (10 hours)

- 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.

UNIT IV: Validation and Development of Herbal Leads (12 hours)

- 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 and 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.

UNIT V: Patenting of Natural Products (6 hours)

- 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; Neem – Biopiracy issue and patent cancellation.

Subject Name: Biopharmaceutics and Pharmacokinetics (Theory)

Subject Code: BP602T

UNIT I: Introduction to Biopharmaceutics and Pharmacokinetics (10 hours)

- 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 through 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.
- 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.

UNIT II: Bioavailability and Bioequivalence (10 hours)

- 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 (IVIVC): Concept and Applications.
- Biowaivers and Methods of enhancement of bioavailability.

UNIT III: Pharmacokinetic Models (10 hours)

- 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; (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).

UNIT IV: Multiple Dosage Regimens and Two-Compartment Model (9 hours)

- 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.
- Introduction to pharmacokinetic consideration of Modified release drug products.

UNIT V: Nonlinear Pharmacokinetics and PK Software (6 hours)

- Nonlinear Pharmacokinetics: Introduction, Reasons for Non-linearity, Michaelis-Menten method of estimating parameters, Explanation with examples of drugs.
- Application of PK software: Introduction of various in-silico methods for calculating various PK parameters.

Subject Name: Intellectual Property Rights (Theory)

Subject Code: BP603T

UNIT I: Introduction to Intellectual Property (6 hours)

- 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.

UNIT II: Patents – Fundamentals and Process (6 hours)

- Definition and objectives of patents.
- Criteria for patentability: 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.

UNIT III: Patent Laws and Acts (6 hours)

- 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.

UNIT IV: Other Forms of Intellectual Property (6 hours)

- Trademarks, Copyrights, Industrial designs: Definition, importance, registration process, basics and protection in scientific work, importance and legal framework.
- Trade secrets and geographical indications in the pharma industry.

UNIT V: IPR Management and Commercialization (6 hours)

- 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.

Subject Name: AI Applications in Pharmaceutical Sciences (Theory)

Subject Code: BP604T

UNIT I: AI in Natural Products and Pharmacognostic Data Modeling (6 Hours)

- Overview of ML applications in natural products: Representation of crude drug data (morphological, microscopic, phytochemical, chromatographic features); Structuring herbal datasets for predictive modeling.
- 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.

UNIT II: AI in Medicinal and Pharmaceutical Chemistry (6 Hours)

- 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 (IC50, solubility, ADMET properties), toxicities.
- Virtual screening and lead optimization concepts.
- Limitations of ML models and importance of chemical reasoning.

UNIT III: AI in Drug Product Design and Performance Prediction (6 Hours)

- 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.

UNIT IV: AI in Process Monitoring and Production Systems (6 hours)

- Digital data acquisition in pharmaceutical production.
- Critical Quality Attributes (CQAs) and Critical Process Parameters (CPPs).
- Correlation analysis for identifying process variability.
- Logistic regression models for batch pass/fail prediction.
- Feature importance in process monitoring and predictive maintenance concepts.
- Ethical and regulatory considerations in automated decision-making, and limitations of predictive models in manufacturing environments.

UNIT V: AI in Pharmaceutical Analysis and Chemometrics (6 Hours)

- 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.

Subject Name: Pharmaceutical Analysis (Theory)

Subject Code: BP605T

UNIT I: Electrochemical Methods of Analysis (10 hours)

- Potentiometry: Electrode potential, electrochemical cell, construction and working of reference and indicator electrodes including membrane electrodes, measurement of potential and pH, potentiometric titrations, methods of detecting end point and Karl Fischer titration.
- Conductometry: Introduction, conductivity cell, conductometric titrations and applications.
- Polarography: Introduction, residual current, migration current, diffusion current and limiting current, DME, polarographic wave, Ilkovic's equation (Statement Only), and applications.

UNIT II: Spectroscopy (10 hours)

- Fundamentals of Spectroscopy: Properties of electromagnetic radiation, electromagnetic spectrum.
- 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.
- 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.

UNIT III: Fluorometric Analysis, Flame Photometry and Nepheloturbidometry (7 hours)

- Fluorometric Analysis: Theory, luminescence, factors affecting fluorescence, quenching; Instrumentation and pharmaceutical applications.
- Flame Photometry and Atomic Absorption Spectrometry: Theory, nebulisation, flame and flame temperature, interferences, instrumentation and pharmaceutical applications.
- Nepheloturbidometry: Principle, instrumentation and applications.

UNIT IV: Introduction to Chromatographic Techniques (8 hours)

- Principle, various stationary and mobile phases, diverse development and detection techniques and applications of column, paper and thin layer chromatography.
- Ion-exchange chromatography: Introduction, principles, types of ion exchange resins, factors affecting ion exchange, methodology and applications.
- Gel filtration and affinity chromatography: Principles and applications.
- Electrophoresis: Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis and applications.

UNIT V: Gas Chromatography, HPLC and HPTLC (10 hours)

- Gas chromatography: Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications.
- High performance liquid chromatography (HPLC): Introduction, theory, instrumentation, advantages and applications.
- HPTLC: Principle, instrumentation and applications.

Subject Name: Pharmaceutical Jurisprudence (Theory)

Subject Code: BP606T

UNIT I: Drugs and Cosmetics Act, 1940 and Rules 1945 – Part I (10 hours)

- Objectives, Definitions, Legal definitions of schedules to the Act and Rules.
- CDSCO guidelines for Import and 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.

UNIT II: Drugs and Cosmetics Act, 1940 and Rules 1945 – Part II (10 hours)

- 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 and 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.

UNIT III: Pharmacy Act, Medicinal and Toilet Preparations Act and NDPS Act (8 hours)

- 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 and 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.

UNIT IV: Drugs and Magic Remedies Act, Prevention of Cruelty to Animals Act, DPCO and Other Legislations (8 hours)

- 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 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, Ceiling price of scheduled formulations, National List of Essential Medicines (NLEM).
- Pharmaceutical Legislations – A brief review: Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee.

UNIT V: Code of Pharmaceutical Ethics and Newer Regulations (9 hours)

- 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 to 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.

Subject Name: Ability Enhancement Course – Elective (Select ONE): BP607T AEC1: Green Chemistry / 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

Subject Code: BP607T AEC*

UNIT I: Note on Elective (15 Hours (1 Hour per week))

- Only ONE elective course shall be selected from the above six options: Green Chemistry / Materiovigilance and Hemovigilance / Scientific Writing / Drug Store and Business Management / Career Building in Cultivation of Medicinal Plants / Active Pharmaceutical Ingredients and Excipient Sciences.
- The detailed syllabi for these elective courses are provided in the Appendix of the PCI B.Pharmacy Syllabus 2026 (NEP 2020).
- Maximum Marks: 50 (SE: 20 + ESE: 30).

Subject Name: Biopharmaceutics and Pharmacokinetics (Practical)

Subject Code: BP608P

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.

Note:

PCI recommended softwares shall be used for performing experiments.

Subject Name: Pharmaceutical Analysis (Practical)

Subject Code: BP609P

PRACTICAL

(Minimum 12 experiments must be performed)

- 1. Determination of the endpoint of an 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 (any one).
- 17. Demonstration experiment on HPTLC.

Subject Name: Skill Enhancement Course – Elective (Select ONE): BP610P SEC1: Computer-Aided Drug Design / BP610P SEC2: Analytical Method Development and Validation / BP610P SEC3: Principles of Preclinical Studies

Subject Code: BP610P SEC*

PRACTICAL

Only ONE elective course shall be selected from the above three options. The detailed syllabi are provided in the Appendix of the PCI B.Pharmacy Syllabus 2026 (NEP 2020).

Maximum Marks: 50 (SE: 20 + ESE: 30). Hours per week: 2 (Practical only).

- Option 1: BP610P SEC1 – Computer-Aided Drug Design
- Option 2: BP610P SEC2 – Analytical Method Development and Validation
- Option 3: BP610P SEC3 – Principles of Preclinical Studies

Subject Name: Value-Added Course – Elective (Select ONE): BP611P VAC1: Professional Skills / BP611P VAC2: Process Analytical Technology (PAT) and QbD in Formulation Science

Subject Code: BP611P VAC*

PRACTICAL

Only ONE elective course shall be selected from the above two options. The detailed syllabi are provided in the Appendix of the PCI B.Pharmacy Syllabus 2026 (NEP 2020).

Maximum Marks: 50 (SE: 20 + ESE: 30). Hours per week: 2 (Practical only).

- Option 1: BP611P VAC1 – Professional Skills
- Option 2: BP611P VAC2 – Process Analytical Technology (PAT) and QbD in Formulation Science

Subject Name: Internship (Mandatory)

Subject Code: BP612I

PRACTICAL

This is the second and final internship report (first report submitted in Semester IV). Every candidate shall complete a minimum of 240 hours of practical training spread over Semesters IV and VI in a Pharmaceutical/Cosmetics/Medical Devices/Food Industry, or in a Hospital/Community Pharmacy, or any other relevant field as per the prescribed course content.

- Internship placement options include:
  - Pharmaceutical / Cosmetics / Medical Devices / Food Industry
  - Hospital Pharmacy
  - Community Pharmacy
  - Any other relevant field as per prescribed course content
- Evaluation Pattern:
  - Certificate and Report submission: 75 Marks
  - Presentation and Discussion: 25 Marks
  - Total: 100 Marks

Note:

A regular record of attendance in the Internship shall be maintained. This is the Semester VI internship report submission.