B.PHARMACY SYLLABUS (PCI / NEP 2020)

SEMESTER VIII

Subject Name: Ethical Considerations and Translational Applications of AI in Pharmacy (Theory)

Subject Code: BP801T

UNIT I: AI Lifecycle, Validation and Model Auditing (6 hours)

- Overview of AI system lifecycle: data collection, preprocessing, modeling, validation, deployment, and monitoring.
- Importance of data quality in healthcare datasets.
- Training vs testing vs validation datasets; Cross-validation (conceptual understanding).
- Model drift and performance degradation; data leakage in modeling.
- Documentation practices: Documentation and reproducibility.
- Basics of model auditing.

UNIT II: Regulatory Framework and Explainable AI (6 hours)

- Overview of AI in regulatory submissions.
- Explainable AI (XAI) concept; Transparency and interpretability.
- Overview of regulatory guidance on AI (EU AI Act, FDA/CDSCO frameworks).
- Accountability in automated decision systems.
- Risk-based classification of AI systems.

UNIT III: AI in Pharmacy Automation and Supply Chain (6 hours)

- Overview of AI in automated dispensing systems.
- Inventory prediction models.
- Case studies on regression-based demand forecasting and different forecasting methods.
- Medication adherence monitoring systems.
- AI in supply chain risk prediction; Predictive analytics in pharmaceutical logistics.
- Advantages, limitations, legal and privacy considerations of AI in pharmacy automation.

UNIT IV: AI in Public Health and Real-World Data Analytics (6 hours)

- Overview of real-world data sources (EHR, claims, surveillance systems).
- Conceptual knowledge of AI in outbreak prediction and Population-level risk modeling.
- Regression models in epidemiology.
- AI in vaccination forecasting.
- Case studies: AI applications in epidemiological trend analysis (e.g., COVID-19 vaccination hesitancy, diabetes prevalence forecasting, antibiotic resistance trends).

UNIT V: Guided Project – Translational AI in Pharmacy (6 hours)

- Students implement a supervised ML model (regression, logistic regression, or others) using real-world pharmacy data from domains like formulation, pharmacokinetics (PK), ADR detection, quality control (QC), automation, or public health.
- Project steps: Model validation; Analysis of regulatory implications; Identification of ethical risks (e.g., bias, privacy); Presentation of a structured AI implementation plan for peer/faculty review.

- Suggested topics (not exhaustive): ADR prediction system, stability forecasting, demand prediction, QC failure model, disease risk prediction, medication adherence.

Subject Name: Clinical Pharmacotherapeutics (Theory)

Subject Code: BP802T

UNIT I: Cardiovascular and Respiratory Diseases (7 hours)

- Definition, etiopathogenesis, clinical manifestations, overview of management of diseases associated with Ischemic Heart Disease: Hypertension, heart failure, myocardial infarction, hyperlipidaemia, arrhythmia. (5 hours)
- Respiratory System: Asthma, COPD. (2 hours)

UNIT II: Renal and Endocrine Disorders (6 hours)

- Renal System: Acute renal failure, chronic renal failure, renal replacement therapy. (3 hours)
- Endocrine System: Diabetes, thyroid disorders. (3 hours)

UNIT III: Nervous System Disorders (5 hours)

- Definition, etiopathogenesis, clinical manifestations, overview of management of diseases of the Nervous System: Epilepsy, stroke, parkinsonism.

UNIT IV: Gastrointestinal and Musculoskeletal Disorders (5 hours)

- Gastrointestinal System: Peptic ulcer disease, GERD. (2 hours)
- Diseases of bones and joints: Rheumatoid arthritis, osteoarthritis. (3 hours)

UNIT V: Infectious and Hematological Diseases (7 hours)

- Infectious Diseases: Tuberculosis, pneumonia, UTI, malaria, HIV. (4 hours)
- Hematological Diseases: Anaemia. (3 hours)

Subject Name: Industrial Pharmacy and Facility Design (Theory)

Subject Code: BP803T

UNIT I: Regulatory Guidelines, Pilot Plant and Scale-Up (12 hours)

- Regulatory guidelines for formulation development: ICH Q8, QbD and optimization (Fundamental terminologies, process and applications); ICH guidelines of stability testing; Industrial aspects of Product development.
- Pilot Plant and Scale-Up: General considerations including significance of personnel requirements, space requirements, raw materials; Pilot plant scale-up considerations for solids, liquid orals, semi-solids and relevant documentation; SUPAC guidelines; Introduction to platform technology.

UNIT II: Technology Development and Transfer (9 hours)

- WHO guidelines for Technology Transfer (TT): Terminology, technology transfer protocol, quality risk management, Transfer from R&D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials), Documentation, Premises and equipment, qualification and validation, quality control and analytical method transfer.
- TT agencies in India – APCTD, NRDC, TIFAC, BCIL, TBSE/SIDBI.
- TT related documentation – Confidentiality agreement, licensing, MoUs, legal issues.

UNIT III: Facility Considerations – Non-Sterile (9 hours)

- Facility design according to Schedule M for various dosage forms.
- Water purification system: design and operation, storage, distribution, and validation of water systems; Different types of waters; Steam systems and Clean Steam, Compressed air, Vacuum, CIP; Industry standards for water and steam systems.
- Effluent testing facility: Design and significance.
- Layout design for various non-sterile dosage forms (Process flow).
- Cleaning and disinfection protocols, cleaning types (Type A, B and C), Cleaning validation methods and acceptance criteria.

UNIT IV: Facility Considerations – Sterile (9 hours)

- Overview of sterile pharmaceutical manufacturing: layout as per Schedule M and cGMP, clean room concept – Importance of sterility and contamination control, SIP; efficient material and personnel flow to maintain sterility, zoning and segregation.
- Guidelines, standards and Cleanroom classifications from FDA, EMA, WHO and ISO.
- Heating, ventilation and air conditioning system (HVAC): Significance, components, testing (including efficiency and integrity testing of HEPA).
- Parameters for qualification and validation (routine monitoring) of clean area.

UNIT V: Advances in Facility Design (6 hours)

- Modular concept of manufacturing facilities with significance and suitable examples.
- Advances in clean room technology: pass-through chambers, isolators, Modular cleanrooms.
- Automation and robotics in pharmaceutical manufacturing operations.

Subject Name: Pharmaceutical Management (Theory)

Subject Code: BP804T

UNIT I: Introduction to Pharmaceutical Management (6 hours)

- Introduction to management; Overview of Indian and Global pharmaceutical industry.
- Role and responsibilities of a pharmaceutical manager.
- Functions and importance of Key Management Principles: Planning, organizing, leading, controlling.
- Decision-making and Time management.

UNIT II: Marketing Management in Pharmaceuticals (6 hours)

- Definition and uniqueness of pharmaceutical marketing; Pharmaceutical Marketing Overview – Global and Indian Scenario.
- Marketing Mix, 4Ps of Marketing: Product, Price, Place, Promotion.
- Strategic marketing and competitive analysis.
- Pharmaceutical Sales: Role of a medical representative; Digital marketing of pharmaceutical products.
- Ethical considerations in pharmaceutical marketing and promotion; E-pharmacies.

UNIT III: Pharmaceutical Product Management (6 hours)

- Introduction to Pharmaceutical Product Management and role of product management in the pharmaceutical industry.
- Key responsibilities of a pharmaceutical product manager; Product Lifecycle Management.
- Branding and Promotional Strategies in the pharmaceutical sector.
- Importance of market segmentation, targeting, and positioning in product management.
- Market Research and Analysis in the pharmaceutical sector: Techniques for conducting market research.

UNIT IV: Financial Planning and Human Resource Management (6 hours)

- Budgeting, financial forecasting, cost control; Pricing of Pharmaceuticals as per DPCO.
- Importance of human resource management in pharmaceutical organizations.
- Recruitment, selection, and training of pharmaceutical professionals; Performance appraisal and employee motivation.
- Behaviour, Leadership styles and their impact on the pharmaceutical industry.
- Team building and conflict resolution.

UNIT V: Operations and Supply Chain Management in Pharmaceuticals (6 hours)

- Operations Management: Production planning and control in pharmaceutical manufacturing.
- Inventory management and optimization; Lean manufacturing and Six Sigma in the pharmaceutical industry.
- Supply Chain Management: Logistics management and drug distribution channels; Cold chain management and the role of technology in SCM.
- E-commerce and its role in pharmaceutical distribution.
- Risk Management and Sustainability.

Subject Name: Sterile Dosage Forms and Novel Drug Delivery System (Theory)

Subject Code: BP805T

UNIT I: Fundamentals, Polymers and Materials for NDDS (12 hours)

- Limitations of conventional dosage forms (e.g., solubility, permeability, toxicity, first-pass metabolism).
- Classification of NDDS: Controlled Release, Targeted, Stimuli-Responsive (Smart), Chronotherapeutic, Transdermal and Mucosal, Implantable and Injectable Depot Systems, Vesicular, Polymeric, Ocular, Pulmonary, and Nasal Drug Delivery Systems.
- Biodegradable and biocompatible polymers: PLA, PLGA, PCL, chitosan, gelatin.
- Lipids and surfactants: lecithin, phospholipids, Span/Tween, SLNs.
- Inorganic systems: silica, gold nanoparticles, iron oxide, MOFs.
- Excipients in NDDS: GRAS substances, IIG database, regulatory constraints.

UNIT II: Oral and Mucosal Delivery Systems (6 hours)

- Gastro-retentive systems: floating, bioadhesive, expandable systems.
- Colon-targeted systems: pH-triggered, microbially-triggered, time-dependent systems.
- Buccal, nasal, and pulmonary carriers: films, sprays, DPIs, liposomes.
- IVIVC and biorelevant dissolution testing.

UNIT III: Transdermal NDDS (6 hours)

- Introduction to Transdermal drug delivery: Need, advantages, disadvantages, basic structure and components; Formulation aspects including permeation enhancers.
- Long-acting systems: in-situ gels, microspheres, implants, ocular inserts.
- Transdermal and microneedle technologies: iontophoresis, sonophoresis, microneedles.
- Aseptic manufacturing, scale-up challenges, and process analytical tools (PAT).

UNIT IV: Evaluation, Quality, and Translation (6 hours)

- Preformulation and QbD: QTPP, CQAs, CPPs.
- Characterization methods: particle size, zeta potential, SEM/TEM, in-vitro release, permeability assays (PAMPA, Caco-2).
- Non-clinical evaluation: PK/PD modeling, biodistribution, toxicology.
- Regulatory pathways: 505(b)(2), complex generics, ICH Q8–Q10, EMA pathways.
- Nanosystems and precision medicine: Liposomes, niosomes, transferosomes, polymeric nanoparticles, solid-lipid nanoparticles, dendrimers; Precision medicine: definition and scope, evolution from 'one-size-fits-all' to personalized approaches.
- Case studies: Liposomal Amphotericin B, mRNA-Lipid Nanoparticle Vaccines (e.g., COVID-19), Depot Antipsychotic Injections, Transdermal Patch for HRT, Ocular Inserts for Glaucoma, Oral Colon-Targeted Delivery for IBD, Inhalable Insulin for Diabetes, Dendrimers for Targeted Cancer Therapy, Chronotherapeutic Drug Delivery in Hypertension.

UNIT V: Sterile Dosage Forms – Parenteral and Ophthalmic (14 hours)

- Introduction and classification: SVP vs LVP; routes; Advantages/limitations.
- Water for Injection (WFI): Types, preparation, storage/distribution; Pharmacopoeial requirements.
- Formulation components: Vehicles, buffers, co-solvents, surfactants, antioxidants, preservatives, chelators; Isotonicity and osmolality.
- Manufacturing: Aseptic vs terminal sterilisation; filtration; lyophilisation principles; environmental controls. Form Fill Seal and Blow Fill Seal Technology.

- Containers and closures: Glass/Plastic systems; elastomers; selection factors; evaluation and container–closure integrity.
- Ophthalmics: Solutions/suspensions/ointments/gels/inserts; physiological factors (pH, tonicity, viscosity); residence-time enhancers; preservative-free systems (e.g., BFS).
- Quality control and compliance: Sterility tests, LAL/endotoxins, particulate matter, clarity, extractable volume; labelling and documentation; overview of cGMP/cleanrooms and environmental monitoring.

Subject Name: Ability Enhancement Course – Elective (Select ONE): BP806T AEC1: Pharmaceutical Packaging / BP806T AEC2: Supply Chain Management / BP806T AEC3: Industrial Safety and Waste Management / BP806T AEC4: Traditional Healing Practices of India / BP806T AEC5: Futuristic Pharma through AR/VR: Pharma 4.0 / BP806T AEC6: Herbal Cosmetics for Industry Perspective

Subject Code: BP806T AEC*

UNIT I: Note on Elective (30 Hours (2 Hours per week, Theory))

- Only ONE elective course shall be selected from the above six options: Pharmaceutical Packaging / Supply Chain Management / Industrial Safety and Waste Management / Traditional Healing Practices of India / Futuristic Pharma through AR/VR: Pharma 4.0 / Herbal Cosmetics for Industry Perspective.
- 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). Credit: 2.

Subject Name: Pharmaceutical Marketing Skills (Practical)

Subject Code: BP807P

PRACTICAL

- 1. Conduct a comparative study of Indian and global pharmaceutical marketing approaches.
- 2. Study and classify different marketing communication styles in the pharmaceutical industry.
- 3. Design and conduct primary market research on prescription pharmaceutical products and analyze the data.
- 4. Design and conduct primary market research on OTC products and analyze the data.
- 5. Create and deliver a product detailing presentation for healthcare professionals.
- 6. Design a patient education program or presentation for pharmaceutical products targeting consumers.
- 7. Develop and present communication strategies for OTC products for both healthcare professionals and consumers.
- 8. Design a product promotion scheme and create a brand strategy for a pharmaceutical product.
- 9. Develop a sales strategy for a pharmaceutical product focusing on distribution channels and promotional tactics for retailers/distributors.
- 10. Design a mock-up or prototype of an e-commerce website for pharmacy.
- 11. Design a digital marketing campaign for a pharmaceutical or cosmetic product using social media, email marketing, and SEO techniques.
- 12. Create a product positioning statement including the Unique Selling Proposition (USP) for a new pharmaceutical product.

Subject Name: Sterile Dosage Forms and Novel Drug Delivery System (Practical)

Subject Code: BP808P

PRACTICAL

(Minimum 12 experiments must be performed)

- 1. Preparation and evaluation of orodispersible tablets.
- 2. Preparation and evaluation of fast dissolving tablets.
- 3. Preparation and evaluation of bilayer tablets.
- 4. Preparation and evaluation of osmotic tablets.
- 5. Preparation and evaluation of microspheres by coacervation phase separation technique.
- 6. Preparation and evaluation of microcapsules.
- 7. Preparation and evaluation of bioadhesive buccal patches.
- 8. Preparation and evaluation of sublingual tablets.
- 9. Preparation and evaluation of buccal tablets.
- 10. Preparation and evaluation of transdermal patches.
- 11. Preparation and evaluation of floating tablets.
- 12. Preparation and evaluation of gastro retentive drug delivery systems.
- 13. Preparation and evaluation of liposomes.
- 14. Preparation and evaluation of niosomes.
- 15. Preparation and evaluation of nasal spray.
- 16. Preparation and evaluation of a parenteral preparation.
- 17. Evaluation of pharmaceutical waters: Purified and Distilled Water as per IP; review of WFI specifications (conductivity/TOC limits – demo/simulation).

Subject Name: Value-Added Course – Elective (Select ONE): BP809P VAC1: Cleaning Validation / BP809P VAC2: Basic Training in Aseptic Handling Techniques / BP809P VAC3: Impurity Profiling

Subject Code: BP809P VAC*

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). Credit: 1.

- --- BP809P VAC1: Cleaning Validation (Perform any 12 Experiments) ---
- 1. Preparation of a cleaning validation protocol for a tablet machine.
- 2. Calculation of MACO (Maximum Allowable Carry Over).
- 3. Swab sampling technique demonstration using stainless steel surface.
- 4. Rinse sampling technique for equipment residue detection.
- 5. Visual inspection for equipment cleanliness (case photos/videos).
- 6. Preparation of recovery study protocol using a known contaminant.
- 7. Demonstration of Total Organic Carbon (TOC) analysis (video/simulation).
- 8. HPLC method development for residue analysis (demo dataset).
- 9. Interpretation of swab analysis results and comparison with acceptance limits.
- 10. Preparation of cleaning log sheet and checklists.
- 11. Validation of cleaning agents: detergent effectiveness and rinsibility.
- 12. Determining dirty hold time and clean hold time experimentally (conceptual).
- 13. Designing a matrix approach for multi-product equipment.
- 14. Simulated deviation report and CAPA for cleaning failure.
- 15. Preparation of a final cleaning validation summary report.
- --- BP809P VAC2: Basic Training in Aseptic Handling Techniques (10 Experiments) ---
- 1. Gown-up/Gown-down Drill – correct sequencing of coverall, hood, mask, goggles, gloves, and sterile boots.
- 2. Hand-washing Verification – surgical scrub with UV lotion; inspect under UV lamp for missed spots.
- 3. Clean-room Entry and Flow Simulation – air-shower pass, unidirectional walking, and material air-lock transfer.
- 4. LAF Hood Preparation – wipe-down with sporicidal, set airflow, place sterile tools in first-air zone.
- 5. Smoke-pattern Test – visualize HEPA downflow with smoke to confirm laminar, turbulence-free air.
- 6. Aseptic Liquid Transfer – pipette or syringe transfer of TSB between vials without touching non-sterile surfaces.
- 7. Sterile Filtration and Filter Integrity Check – filter a buffer through 0.22 µm unit and perform bubble-point test.
- 8. Mini Media-Fill – fill 20 sterile vials with TSB under LAF, incubate, and record turbidity for 14 days.
- 9. Environmental and Personnel Monitoring – deploy settle/contact plates, take glove-fingertip prints, run an air sampler.
- 10. Cleaning and ATP Validation – full hood wipe-down, then ATP swab pre- and post-clean to verify < 200 RLU residue.
- --- BP809P VAC3: Impurity Profiling (Perform any 12 Experiments) ---
- 1. Identification of organic impurities in bulk drugs using TLC.
- 2. Quantification of impurities using HPLC.
- 3. Determination of residual solvents by GC (as per ICH Q3C).

- 4. UV-spectrophotometric analysis of degradation products.
- 5. Preparation of forced degradation samples (acid/base/hydrolytic).
- 6. Identification of degradation products via IR spectroscopy.
- 7. Extraction and analysis of impurities from finished dosage forms.
- 8. Impurity profiling of marketed paracetamol tablet using HPLC.
- 9. Qualification of impurities as per ICH Q3A/Q3B guidelines.
- 10. Limit test for heavy metals (as per IP).
- 11. Estimation of elemental impurities by ICP-MS or simulated method.
- 12. Determination of related substances in antibiotics (e.g., cephalosporins).
- 13. Use of LC-MS data interpretation for impurity identification (demo/simulated).
- 14. Impurity profiling of herbal products using HPTLC.
- 15. Report preparation on impurity profiling as per regulatory requirements.

Subject Name: Research Project (Continued from Semester VII)

Subject Code: BP810RP

PRACTICAL

The Research Project continues from Semester VII (BP710RP) and is completed in Semester VIII. Each student shall submit the final research project report and present their work at the end of the programme.

- Project work shall involve original research or applied research in any area of pharmaceutical sciences.
- The final project report shall be submitted at the end of Semester VIII.
- Evaluation shall be based on the report, presentation, and viva-voce.
- Evaluation Pattern:
  - Maximum Marks: 150 (SE: 0 + ESE: 150)
  - Credit: 6
- Refer to Section 21 of the PCI NEP 2020 Regulation for detailed guidelines on project work.

Note:

This is the continuation and final submission of the Research Project started in Semester VII (BP710RP). Together, both carry a total of 300 marks (150 each semester) and 12 credits.