# B.PHARMACY SYLLABUS (PCI / NEP 2020)

## SEMESTER VII

### Subject Name: Biostatistics and Research Methodology (Theory)

### Subject Code: BP701T

**UNIT I: Basic Concepts of Biostatistics (9 hours)**

- Definition, meaning and type of variables.
- Data – Meaning and methods of data collection, data preprocessing and cleaning.
- Population and sample, Importance of sampling, Sampling methods: Probability sampling (Random, systematic, stratified, cluster sampling) and Non-probability sampling (Convenience sampling, purposive sampling, snowball sampling).
- Types of statistics – Descriptive statistics and inferential statistics.
- Descriptive statistics – Frequency distribution, measures of central tendency; Measures of dispersion – Range, variance and standard deviation; Concept of degrees of freedom, quartiles, skewness and kurtosis; Diagrammatic representation of frequency distribution.

**UNIT II: Probability and Probability Distributions (9 hours)**

- Probability – Classical probability and statistical probability; Probability of union, intersection and complement of events, conditional probability, marginal probability.
- Probability distributions – Discrete probability distribution (PMF); Continuous probability distribution (PDF); Normal distribution – Meaning and characteristics, parameters, equation for PDF, Standard normal distribution, Z transformation; Binomial and Poisson distributions with pharmaceutical examples.
- Sampling distributions – t distribution (t statistic, degrees of freedom, table of t values, applications); F distribution (F statistic, meaning, table of F values); Chi square distribution (Chi square statistic, meaning, table of chi square values, applications).

**UNIT III: Correlation and Regression Analysis (9 hours)**

- Correlation analysis – Introduction to correlation between two variables, positive and negative correlation; Pearson's Correlation Co-efficient – Definition and formula, assumptions, range, interpretation of sign and magnitude; Spearman's Rank Correlation Co-efficient – Concept and when to use, procedure for calculation; Real life applications in pharmaceutical and health sciences; Multiple correlation – Concept and applications.
- Regression analysis – Concept of regression, dependent and independent variables; Simple linear regression, regression equation (method of least squares), calculation of slope and intercept, co-efficient of determination; Interpretation of output of regression analysis and applications; Relationship between regression co-efficient and correlation co-efficient; Multiple linear regression – Concept and applications, meaning of overfitting and underfitting.

**UNIT IV: Inferential Statistics (12 hours)**

- Statistical estimation – Point estimates and interval estimates of population parameters from sample statistics; Concept of confidence intervals; Confidence intervals for means using t values.
- Hypothesis testing – Concept, steps involved, type I and type II error, sample size and power of the test, p values, applications.

- Parametric tests – t-tests (single sample t test, two independent samples t test, paired t test); ANOVA (one way and two way); Assumptions, procedure and applications; Hypothesis testing in regression analysis and correlation.
- Non-parametric tests – Mann Whitney U test, Wilcoxon Sign Rank test, Kruskal Wallis test, Friedman test, Chi square tests; Assumptions, procedure and applications.

**UNIT V: Research Methodology (6 hours)**

- Research – Meaning, importance and types; Types of research designs; Research methodology – Based on the research question, selection of research design, defining the population and sample, selecting the sample size and sampling method, method of data collection and data analysis.
- Decision tree approach for selection of statistical tests on the basis of research question and type of data.
- Descriptive, Observational, and Experimental research designs – Examples of application.
- Scientific report writing, plagiarism, referencing styles, selection of research journals, abstracting services and databases.
- Screening and Optimization – Concept and experimental designs used for screening and optimization including Plackett Burman design, factorial designs, D-optimal design, sequential simplex design, central composite design and response surface methodology, blocking and confounding in experimental designs.

## Subject Name: Cosmetics and Cosmeceuticals (Theory)

## Subject Code: BP702T

### UNIT I: Classification of Cosmetics and Common Excipients (6 hours)

- Cosmetics and cosmeceuticals – Classification of Cosmetics: Cosmetics and Cosmeceuticals for Skin Care, Hair Care, Oral Care, foot care, body cavities, Decorative Cosmetics, Cleansing cosmetics, Perfumes and Fragrances.
- Types of various dosage forms for Cosmetics.
- Common excipients for cosmetic formulations.

### UNIT II: Skin Cosmetics and Soaps (6 hours)

- Common skin problems (Dry Skin, Oily skin, Pimples and acne, Pigmentation, Prickly heat and Sun burn) and general composition, method for preparation, packing and evaluation of the skin Cosmetics and cosmeceuticals.
- Herbal cosmetics for skin.
- Types of soaps, syndet bars – general composition, method for preparation, packing and evaluation of soaps.
- Introduction to Perfumes and toiletries.

### UNIT III: Hair Cosmetics (6 hours)

- Common Hair problems, Hair Cosmetics and cosmeceuticals.
- Types of shampoos – general composition, method for preparation, packing and evaluation of shampoos.
- Introduction to hair oils, hair serums, conditioners, hair colors, Depilatory and shaving products.
- Herbal hair care products.

### UNIT IV: Oral Cosmetics and Other Cosmetics (6 hours)

- Various problems of oral cavity, Oral Cosmetics and cosmeceuticals – general composition, method for preparation, packing and evaluation of mouthwash and toothpaste.
- Herbal oral care cosmetics.
- Types of Cosmetics for nails, eyes, body odor, lip care and cleansing.
- Intimate hygiene products for males and females.

### UNIT V: Regulatory Framework and Testing (6 hours)

- Role of Regulatory authorities for Cosmetics and cosmeceuticals (CDSCO and FDA).
- Cosmetics Regulations 2020 and role of BIS.
- Role of certifying bodies like ECCERT and COSMOS in herbal cosmetics.
- Labeling requirement of cosmetics and Packaging of cosmetics.
- Testing as per BIS specification and analytical methods (including sensory test, sensitivity test).

## Subject Name: AI in Clinical Applications (Theory)

## Subject Code: BP703T

### UNIT I: AI in Pharmacokinetics and Dose Optimization (6 Hours)

- Review of pharmacokinetic parameters (Cmax, Tmax, AUC, clearance).
- Modeling concentration-time relationships: Linear regression in PK data modeling; Multiple regression for dose adjustment based on patient variables (age, weight, renal function).
- Interpretation of regression coefficients in clinical context.
- Error metrics (RMSE, $R^2$) in PK modeling.
- Limitations of linear modeling in nonlinear pharmacokinetics.

### UNIT II: AI in Drug Safety and Pharmacovigilance (6 Hours)

- Overview of pharmacovigilance systems.
- Structure and data formats from real systems (e.g., FAERS, EudraVigilance).
- Conceptual overview of frequency analysis and signal detection.
- Logistic regression for ADR risk prediction.
- Confusion matrix and clinical performance metrics: Sensitivity, specificity, precision, recall.
- Bias and confounding in observational datasets.

### UNIT III: AI in Personalized Medicine and Risk Stratification (6 Hours)

- Concept of precision medicine.
- Patient covariates and therapeutic response.
- Logistic regression for disease risk prediction.
- Classification of responders vs non-responders.
- Evaluation metrics in healthcare prediction.
- Ethical implications of predictive modeling.

### UNIT IV: AI in Clinical Decision Support and Real-World Data (6 hours)

- Structure of Electronic Health Records (EHR).
- AI in Clinical Decision Support Systems (CDSS).
- Regression models for outcome prediction.
- Classification models for risk scoring.
- Real-world data analytics.
- Limitations of AI in clinical environments: Accountability and interpretability.

### UNIT V: Guided Supervised Learning Project – Pharmaceutical and Clinical Applications (6 Hours)

- Students undertake a guided supervised learning project (individually or in groups) applying regression or classification models to pharmaceutical or clinical datasets.
- Project steps: Identification and definition of a relevant pharmaceutical or clinical problem; Selection of an appropriate publicly available dataset; Identification of predictor variables and outcome variables; Data preprocessing and preparation for analysis; Application of suitable supervised learning methods (e.g., linear regression or logistic regression); Evaluation of model performance using appropriate metrics; Interpretation of results in the context of pharmaceutical or clinical relevance; Discussion of limitations, potential biases, and ethical considerations; Presentation of findings to faculty mentors or peers.
- Suggested project topics (not limited to): Dissolution rate prediction, tablet hardness prediction, stability degradation modelling, quality control batch failure prediction, assay variability modelling, impurity prediction, moisture impact on formulation stability, coating thickness prediction, solubility enhancement

modelling, tablet defect classification, adverse drug reaction (ADR) prediction, therapeutic response prediction using patient datasets, hospital readmission risk prediction, dose requirement prediction using pharmacokinetic data, diabetes risk prediction from health markers, antibiotic treatment success prediction, ICU stay duration prediction, medication adherence analysis, and disease severity classification.

## Subject Name: Modern Analytical Techniques (Theory)

## Subject Code: BP704T

### UNIT I: NMR Spectroscopy and Mass Spectrometry (10 hours)

- Nuclear Magnetic Resonance Spectroscopy: Principles of $^{1}$H-NMR and $^{13}$C-NMR, various solvents used, chemical shift, factors affecting chemical shift, coupling constant, spin–spin coupling, relaxation, instrumentation of FT-NMR and its applications.
- Mass Spectrometry: Principles, fragmentation and its rules, ionization techniques – Electron impact, chemical ionization, MALDI, FAB, API; Analyzers – Time of flight and quadrupole, ion trap; Detectors and applications.

### UNIT II: X-Ray Diffraction and Thermal Analysis (8 hours)

- X-Ray Diffraction Methods: Origin of X-Rays, basic aspects of crystals, X-Ray crystallography, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications.
- Thermal Analysis: Introduction, instrumentation, factors affecting measurements, applications of TGA, DSC (types) and DTA.

### UNIT III: Hyphenated Techniques and Advanced Chromatography (10 hours)

- UPLC and Nano LC: Principle, advantages over LC and applications.
- Principle and applications of hyphenated techniques: GC-MS, LC-MS/MS, ICP-MS.
- Supercritical chromatography and flash chromatography: Principles and applications.

### UNIT IV: Green Analytical Chemistry, Bioanalytical Methods and Immunoassays (12 hours)

- Green Analytical Chemistry: Types of green solvents, various computational tools used to assess the greenness and its applications in sample preparation and analytical method development.
- Bioanalytical Methods: Introduction to bioanalytical method development, extraction of drugs and metabolites from biological fluids – SPE, LLE, PPE; BCS classification, PK-PD interaction, microsomal assays, MTT assay, BA and BE study protocol, biosimilars.
- Radio Immune Assays and ELISA: Importance, various components, principle, different methods, limitations and applications of radio immunoassay and ELISA.

### UNIT V: Microscopy-Based Analytical Techniques (5 hours)

- Principle, instrumentation, and applications of optical microscopy, scanning electron microscopy and transmission electron microscopy.

## Subject Name: Pharmacovigilance (Theory)

## Subject Code: BP705T

### UNIT I: Fundamentals of Pharmacovigilance (10 hours)

- Concept, history, and importance of pharmacovigilance.
- Basic drug classification systems (introductory overview only): ATC classification, ICD.
- Drug-related problems and medication safety.
- Drug safety considerations in special populations: Paediatrics; Geriatrics; Pregnancy and lactation.

### UNIT II: Pharmacovigilance Systems and Regulatory Framework (10 hours)

- Objectives and functions of pharmacovigilance.
- Methods of pharmacovigilance data collection: Spontaneous reporting; Cohort and case-control studies.
- Global pharmacovigilance systems: WHO International Drug Monitoring Programme; Role of CIOMS and major regulatory agencies (e.g., USFDA, EMA).
- Pharmacovigilance Programme of India (PvPI).
- Establishment and role of ADR Monitoring Centres.

### UNIT III: Adverse Drug Reactions (ADRs) (8 hours)

- Classification and types of ADRs.
- Mechanisms and risk factors for ADRs.
- Methods of ADR monitoring, detection, and reporting.
- Assessment of causality, severity, predictability, and preventability of ADRs.
- Management of ADRs.
- Online reporting mechanisms and databases (WHO-ART, VigiBase, Vigiflow, Oracle Argus, OpenVigil software).
- MEDRA (Medical Dictionary for Regulatory Activities).

### UNIT IV: Immunovigilance and Other Disciplines of Pharmacovigilance (7 hours)

- Definition, scope, and significance of immunovigilance, cosmetovigilance, nutraceutical-vigilance, materiovigilance, herbovigilance, ecopharmacovigilance, and hemovigilance.
- Vaccination failure and vaccine pharmacovigilance (vaccinovigilance).
- Overview of adverse events following immunization (AEFIs).
- Immunization safety monitoring systems in India.

### UNIT V: Risk Communication, Evaluation, Management, and ICH Guidelines (10 hours)

- Risk evaluation and management strategies in pharmacovigilance and immunovigilance.
- Communication in drug safety crisis management.
- Communication with regulatory agencies, business partners, and healthcare facilities.
- Analysis of real-world case studies and lessons learnt.
- Emerging trends and challenges in pharmacovigilance and immunovigilance.
- Overview of safety data generation.
- Objectives of ICH guidelines; Expedited and aggregate reporting; Individual Case Safety Reports (ICSRs); Periodic Safety Update Reports (PSURs); Post-approval expedited reporting.
- Good Clinical Practices (GCPs) regulation 2019.

- Application of pharmacogenomics and pharmacometrics in pharmacovigilance.

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## Subject Name: Pharmacy Practice (Theory)

## Subject Code: BP706T

### UNIT I: Introduction to Pharmacy Practice (8 hours)

- Definition, scope and evolution of hospital and clinical pharmacy; Pharmacist's role from dispenser to healthcare provider.
- WHO and FIP guidelines on pharmacy practice; Pharmacy practice regulations in India.
- Role of pharmacy in public health and policymaking; Promoting rational use of medicines; Concepts of Good Pharmacy Practice.
- Pharmacy practice settings: inpatient, outpatient.
- Concept of healthcare delivery system and interprofessional collaboration.
- Primary (PHC), Secondary (CHC), Tertiary (District Hospitals, Medical Colleges) – role of pharmacists at various levels of care.

### UNIT II: Hospital and Community Pharmacy (10 hours)

- Hospital and its Organization: Classification of hospitals, organizational structure of a hospital, healthcare staff involved in hospital services and their functions.
- Hospital Pharmacy and its Organization: Definition, organization structure, location, layout, and staff requirements, responsibilities and functions of hospital pharmacists.
- Pharmacy and Therapeutic Committee: Organization, functions, and policies; drug inclusion into formulary; inpatient and outpatient prescriptions; automatic stop order; emergency drug list preparation.
- Hospital Formulary: Definition, contents, differentiation between hospital formulary and drug list, preparation and revision.
- Drug Distribution System in a Hospital: Drug procurement and inventory control; dispensing of drugs to inpatients; types of drug distribution systems; charging policy and labeling; dispensing of drugs to ambulatory patients; dispensing of controlled drugs; outpatient medication dispensing; NABH standards for medication management.
- Community Pharmacy: Organization and structure of retail and wholesale drug stores; types and design of a drug store; legal requirements for establishment and maintenance; dispensing of proprietary products; maintenance of records; prescription handling, labelling, and patient counselling; OTC medication list; vaccination services.

### UNIT III: Clinical Pharmacy Services (9 hours)

- Introduction to clinical pharmacy and its concept.
- Drug therapy monitoring: Medication chart review; Clinical review; Pharmacist intervention; Ward round participation; Medication history; Pharmaceutical care.
- Drug information services.
- Drug/Medication related problems.
- Drug and poison information services.
- Therapeutic drug monitoring (TDM).

### UNIT IV: Patient-Oriented Services (9 hours)

- Medication Adherence and Non-Adherence: Definition; Factors influencing non-adherence; Pharmacist's role in medication adherence; Monitoring of patient medication adherence; Tools used to assess medication adherence; Strategies to overcome non-adherence.

- Patient Counselling Techniques and Communication Skills: Definition of patient counselling; Steps involved in patient counselling; Communication skills – communication with prescribers and patients; Types of educational materials used in patient counselling; Barriers to effective counselling – types and strategies to overcome barriers.
- Health Screening Services: Definition and importance; Methods for screening: Blood pressure, Blood sugar, Body Mass Index, Lung function test; Role of pharmacist in health screening services.
- Telemedicine.

**UNIT V: Prescribing Guidelines, Essential Drug Concept and Rational Drug Therapy (9 hours)**

- Prescribing Guidelines: Paediatrics, geriatrics, pregnant and lactating women; ISMP guidelines for high risk medicines.
- Essential Drug Concept: WHO definition; Core principles and key features; Procedure involved in adding a drug into the essential drug list.
- Rational Use of Medications: Antibiotics and Antibiotic stewardship program; Injections; OTC drugs; Consequences of irrational drug use; Dose calculations in chemotherapy, renal and hepatic failure patients.

## Subject Name: Regulatory Affairs (Theory)

## Subject Code: BP707T

### UNIT I: Fundamentals of Regulatory Affairs (6 hours)

- Introduction to Drug Regulatory Affairs; Overview of regulatory authorities in India and major international markets (US FDA, EMA, PMDA); Role and responsibilities of Regulatory Affairs Professionals; Organizational structure of regulatory bodies.
- Basic regulatory terminologies: Guidance, Guidelines, Regulations, Laws, Acts.
- Regulatory reference resources: Orange Book, Purple Book, Federal Register, Code of Federal Regulations (CFR).

### UNIT II: Regulatory Requirements in Drug Development (6 hours)

- Drug discovery and development process; Drug development teams and their functions.
- Non-clinical drug development: Pharmacology, Drug metabolism, Toxicology.
- Regulatory documentation: Investigational New Drug (IND) application; Investigator's Brochure (IB); Clinical research protocols; Biostatistics in pharmaceutical product development; Bioequivalence (BE) studies; Data presentation for regulatory submissions.

### UNIT III: Indian Regulatory Framework and Approval Process (6 hours)

- Central Drugs Standard Control Organization (CDSCO) and State Licensing Authorities: Organization and responsibilities; Regulatory requirements for import, manufacture, and sale of pharmaceuticals in India; Certificate of Pharmaceutical Product (COPP).
- Regulatory approval procedure for new drugs in India; Clinical trial regulatory requirements in India.
- Good Clinical Practice (GCP) guidelines and Schedule Y; Innovator and generic drugs; Generic drug product development.
- Phytopharmaceutical regulation by AYUSH and CDSCO.

### UNIT IV: International Regulatory Systems and Global Drug Registration (6 hours)

- Types of regulatory applications: Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA).
- Drug Master Files (DMF), Common Technical Document (CTD), electronic CTD (eCTD), ASEAN CTD (ACTD).
- Registration procedure for Indian drug products in overseas markets.
- Post-approval changes to NDA and ANDA.

### UNIT V: Clinical Trials, Ethics, and Post-Marketing Surveillance (6 hours)

- Clinical research phases (I–IV); Clinical trial documents.
- Institutional Review Board (IRB) and Independent Ethics Committee (IEC): Formation and functions.
- Informed consent process and documentation.
- Good Clinical Practice (GCP) obligations of investigators, sponsors, and monitors.
- Management and monitoring of clinical trials.
- Pharmacovigilance: Safety monitoring during clinical trials and post-marketing.

**Subject Name:** Ability Enhancement Course – Elective (Select ONE): BP708T AEC1: Current Good Manufacturing Practices (cGMP) / BP708T AEC2: Pharmaceutical Automation / BP708T AEC3: Modern Techniques in Cellular Biology / BP708T AEC4: Medical Devices / BP708T AEC5: Transformation of Food Waste into Medicinal Products / BP708T AEC6: Biosimilars, Vaccines and Macromolecules / BP708T AEC7: Precision Medicine

**Subject Code: BP708T AEC***

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

- Only ONE elective course shall be selected from the above seven options: Current Good Manufacturing Practices (cGMP) / Pharmaceutical Automation / Modern Techniques in Cellular Biology / Medical Devices / Transformation of Food Waste into Medicinal Products / Biosimilars, Vaccines and Macromolecules / Precision Medicine.
- 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: Modern Analytical Techniques (Practical)

## Subject Code: BP709P

**PRACTICAL**

*(Minimum 12 experiments must be performed)*

- 1. Interpretation of Proton NMR spectra of known compound (any two).
- 2. Interpretation of Carbon NMR spectra of known compound (any two).
- 3. Interpretation of mass spectrum of known compound (any two).
- 4. Interpretation of X-Ray diffraction spectrum (any one).
- 5. Interpretation of DSC Thermogram (any one).
- 6. Preparation and Evaluation of Green Analytical Solvents.
- 7. Analytical method development by using Green chemistry.
- 8. Quantification of pharmaceuticals in biological fluids using Solid Phase Extraction (SPE).
- 9. Quantification of pharmaceuticals in biological matrix by PPE.
- 10. Quantification of pharmaceuticals in biological matrix by LLE.
- 11. Demonstration of Cell Viability evaluation using MTT Assay.
- 12. Demonstration on residual solvent analysis using GC.
- 13. Assay of drug using HPLC (any two).
- 14. Analysis of drug from biological fluid using HPLC/UV spectroscopy.

## Subject Name: Research Project

## Subject Code: BP710RP

**PRACTICAL**

*The Research Project is a mandatory core component carried out during Semester VII (and continued in Semester VIII as BP810RP). It is an independent, supervised research work undertaken by each student under the guidance of a faculty member.*

- Project work shall involve original research or applied research in any area of pharmaceutical sciences.
- Each student shall submit a research project report at the end of the programme.
- 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:***

*The Research Project (BP710RP) in Semester VII is continued as BP810RP in Semester VIII. Both form part of the same continuous research project.*