Semester VII

Course Code	Name of the course		No. of hours per week (L/P)	Credit points
BP701T	Biostatistics Research methodology (Theory)		3	3
BP702T	Cosmetics and Cosmeceuticals (Theory)		2	2
BP703T	AI in Clinical applications (Theory)		2	2
BP704T	Modern Analytical Techniques (Theory)		3	3
BP705T	Pharmacovigilance (Theory)		3	3
BP706T	Pharmacy Practice (Theory)		3	3
BP707T	Regulatory Affairs (Theory)		2	2
BP708T AEC	BP708T AEC1	Current Good Manufacturing Practices (cGMP)	1	1
	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 & Macromolecules		
BP709P	Modern Analytical Techniques (Practical)		3	1
BP710RP	Research Project		-	6
Total			**22**	**26**

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

Course Code	Course Title			Course Type
BP701T	**Biostatistics and Research Methodology (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. Introduce the fundamental concepts of biostatistics including types of variables, data collection methods, sampling techniques, and descriptive statistical measures used in pharmaceutical and biomedical research.
2. Develop understanding of probability theory, probability distributions, and sampling distributions used in the analysis of biological and pharmaceutical data.
3. Explain the principles of correlation and regression analysis for studying relationships between variables and predicting outcomes in pharmaceutical and healthcare datasets.
4. Provide knowledge of inferential statistical methods including estimation, confidence intervals, hypothesis testing, parametric and non-parametric tests, and analysis of variance.
5. Familiarize students with research methodology, experimental design, and scientific reporting practices relevant to pharmaceutical research and data interpretation.

Course Outcomes (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the basic concepts of biostatistics including variables, sampling methods, descriptive statistics, and graphical representation of biomedical data.
2	Apply probability concepts and probability distributions (binomial, Poisson, normal, t, F, and chi-square distributions) in pharmaceutical and healthcare data analysis.
3	Analyze relationships between variables using correlation and regression techniques and interpret their applications in pharmaceutical research.
4	Perform inferential statistical analysis including estimation, confidence intervals, hypothesis testing, ANOVA, and non-parametric tests for research decision-making.
5	Design and evaluate research studies by selecting appropriate research designs, sampling techniques, and statistical methods, and demonstrate competence in scientific reporting and ethical research practices.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Basic concepts of biostatistics** 1. 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 and non-probability sampling o Probability sampling - Random, systematic, stratified, cluster sampling o Non-probability sampling - Convenience sampling, purposive sampling, snowball sampling Types of statistics - Descriptive statistics and inferential statistics Descriptive statistics – Meaning and types of 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	**9 hours**
II	**Probability and probability distributions** 1. Probability and probability distributions- Classical probability and statistical probability Probability of union, intersection and complement of events, conditional probability, marginal probability 2. Probability distributions- Meaning of a probability distribution Discrete probability distribution- Meaning and examples of discrete probability distribution, meaning of PMF Continuous probability distribution – Meaning and examples of normally distributed data, meaning of PDF • Normal distribution – Meaning and characteristics of a normal distribution, parameters of a normal distribution, equation for PDF of a normal distribution. Pharmaceutical examples of data which can be modelled with Poisson Normal distribution. • Standard normal distribution, Z transformation, reading the table of Z values Problems based on standard normal distribution, binomial and Poisson distributions 3. Sampling distributions – Meaning of sampling distributions • t distribution – the t statistic, equation for calculating t statistic, meaning of t distribution, meaning of degrees of freedom and their relevance to t distribution, reading and interpreting table of t values, applications of t distribution • F distribution – the F statistic, equation for calculating F statistic, meaning of F distribution, reading and interpreting table of F values • Chi square distribution – the Chi square statistic, meaning of chi square distribution, reading and interpreting the table of chi square values, applications of chi square distribution.	**9 hours**

III	**Correlation and regression analysis** **1.** Correlation analysis – Introduction to the concept of correlation between two variables, positive and negative correlation, no correlation, examples of positive, negative and no correlation Measurement of correlation - • Pearson's Correlation Co-efficient – Definition and formula, assumptions, range of Pearson's correlation co-efficient, interpretation of sign and magnitude • Spearman's Rank Correlation Co- efficient – Concept and when to use, procedure for calculation Spearman's Rank Correlation Co-efficient. Real life applications in pharmaceutical and health sciences Problems on calculation of these two types of correlation co-efficient, use of scatter plot Multiple correlation – Concept and applications. **2.** Regression analysis – Concept of regression, dependent and independent variables in regression analysis, simple linear regression, simple linear regression equation (method of least squares), calculation of slope and intercept, co-efficient of determination, interpretation of output of regression analysis, applications of regression analysis. Relationship between regression co-efficient and correlation co-efficient Problems on simple linear regression analysis for predicting values of dependent variables (pharmaceutical examples) Multiple linear regression-Concept and applications, meaning of overfitting and underfitting.	**9 hours**
IV	**Inferential statistics** 1. Statistical estimation – Point estimates and interval estimates of population parameters from sample statistics Concept of confidence intervals. Confidence intervals for means using t values. Problems on generating confidence intervals **2.** Hypothesis testing – Concept, steps involved, type I and type II error, sample size and power of the test, p values, applications of hypothesis testing 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 (case studies using t tests and ANOVA) 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 (problems on non-parametric tests)	**12 hours**
V	**Research methodology** 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.	**6 hours**

	Decision tree approach for selection of statistical tests on the basis of research question and type of data Descriptive research design – Examples of application Observational research design – Examples of application Experimental research design – 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.	

Recommended References (Preferably latest editions)

1. Bolton, S. *Pharmaceutical Statistics: Practical and Clinical Applications.* Marcel Dekker.
2. Daniel, W. W. *Biostatistics: A Foundation for Analysis in the Health Sciences.* Wiley.
3. Montgomery, D. C. *Design and Analysis of Experiments.* Wiley.

Course Code	Course Title		Course Type	
BP702T	**Cosmetics and Cosmeceuticals (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. Recognize the fundamental concepts and classification of cosmetics and cosmeceutical formulations and their packaging and testing.
2. Develop knowledge of some common dermatological, hair, and oral care issues and their respective cosmetic products.
3. Develop an understanding of herbal cosmetics and their principles of formulation.
4. Learn regulatory guidelines, labeling protocols, and packaging regulations for cosmetics and cosmeceuticals.
5. Study the recent trends of research in artificial intelligence (AI) in customized skincare and cosmetic innovation.

Course Outcomes (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Classify cosmetics and cosmeceuticals based on application and dosage forms, and outline the role of formulation excipients.
2	Describe the formulation, preparation, packaging, and evaluation of cosmetics for skin, hair, and oral care, including herbal products.
3	Demonstrate knowledge of formulation and quality assessment of commonly used cosmetic products such as shampoos, soaps, lotions, and decorative cosmetics.
4	Identify the functional roles of cosmetic ingredients in managing skin, hair, and oral conditions.
5	Explain the roles of regulatory bodies and labeling standards, and discuss the integration of AI in personalized cosmetic formulation and virtual applications.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	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.	6 hours
II	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.	6 hours
III	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.	6 hours
IV	Various problems of oral cavity, Oral Cosmetics, and cosmeceuticals: general composition, method for preparation, packing and evaluation of mouth wash 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.	6 hours
V	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).	6 hours

Recommended References (Preferably latest editions)

1. Baki, G. and Alexander, K. S. *Introduction to Cosmetic Formulation and Technology.* Wiley.
2. Barel, A. O., Paye, M. and Maibach, H. I. *Handbook of Cosmetic Science and Technology.* CRC Press.
3. Benson, H. A. E. and Watkinson, A. C. *Cosmetic Formulation: Principles and Practice.* CRC Press.
4. Chisvert, A. and Salvador, A. *Cosmetic Formulation of Skin, Hair and Nails.* Wiley.
5. Dweck, A. C. and Santos, P. F. *Formulating Natural Cosmetics.* Allured Publishing.
6. Matsumoto, M. *Cosmetic Science and Technology.* Elsevier.
7. Rosen, M. R. *Harry's Cosmeticology.* Chemical Publishing.

Course Code	Course Title			Course Type
BP703T	**AI in Clinical applications (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 AI applications in pharmacology, pharmacokinetics, and drug safety.
2. Enable students to apply supervised ML models to clinical and pharmacovigilance datasets.
3. Develop interpretation skills for predictive modeling in healthcare.
4. Build understanding of real-world healthcare data analytics.
5. Promote responsible and ethical AI usage in patient care.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the applications of AI & ML in pharmacokinetics, pharmacodynamics, and clinical decision-making.
2	Apply regression and classification models to analyze clinical, pharmacokinetic, and pharmacovigilance datasets.
3	Interpret predictive model outputs for adverse drug reactions, therapeutic response, and clinical risk assessment.
4	Evaluate the performance of machine learning models using healthcare metrics such as accuracy, sensitivity, specificity, precision, recall, and RMSE.
5	Analyze real-world healthcare datasets and assess the ethical and practical implications of AI-based clinical decision support systems.

Unit No.	Topics	No. of Lectures
I	**AI in Pharmacokinetics & Dose Optimization** • 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	6 Hours
II	**AI in Drug Safety & Pharmacovigilance** • 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	6 Hours
III	**AI in Personalized Medicine & Risk Stratification** • 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	6 Hours
IV	**AI in Clinical Decision Support & Real-World Data** • 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	6 hours

	• Limitations of AI in clinical environments • Accountability and interpretabilit	
V	**Guided Supervised Learning Project – Pharmaceutical and Clinical Applications** Students will undertake a guided supervised learning project (individually or in groups) applying regression or classification models to pharmaceutical or clinical datasets. The project should include the following 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.	6 Hours

Recommended References (Preferably latest editions)

1. Aggarwal, C. C. and Reddy, C. K. *Healthcare Data Analytics.* CRC Press.
2. Bonate, P. L. *Pharmacokinetic–Pharmacodynamic Modeling and Simulation.* Springer.
3. Campbell, M. J., Machin, D. and Walters, S. J. *Medical Statistics: A Textbook for the Health Sciences.* Wiley-Blackwell.
4. Schmidt, S. and Derendorf, H. *Applied Pharmacometrics.* Springer.
5. Steyerberg, E. W. *Clinical Prediction Models: A Practical Approach to Development, Validation, and Updating.* Springer.
6. Strom, B. L., Kimmel, S. E. and Hennessy, S. *Pharmacoepidemiology.* Wiley-Blackwell.

Course Code	Course Title		Course Type	
BP704T	**Modern Analytical Techniques (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. Introduce advanced instrumental techniques used in pharmaceutical analysis,.
2. Provide conceptual understanding of modern separation and hyphenated analytical techniques.
3. Familiarize students with principles and applications of green analytical chemistry and sustainable analytical method development.
4. Explain the fundamentals of bioanalytical methods and immunoassays.
5. Introduce microscopy-based analytical techniques and highlight their role in structural characterization and pharmaceutical research.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Apply the principle of Mass and NMR spectra in the structural elucidation of organic compounds.
2	Determine the physical nature of the drugs and excipients using thermal studies, X ray crystallographic techniques and microscopy based analytical techniques.
3	Apply the basic knowledge on radio immune assays in carrying out the immunological studies.
4	Understand the theoretical and practical's aspects of the latest hyphenated Chromatographic techniques used for analysis of drugs.
5	Apply green analytical chemistry techniques for environmental sustainability.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	1. **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. 2. **Mass Spectrometry:** Principles, fragmentation and its rules, ionization techniques –	10 hours

	Electron impact, chemical ionization, MALDI, FAB, API, analyzers – Time of flight and quadrupole, ion trap, detectors and applications.	
II	1. **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. 2. **Thermal Analysis:** Introduction, instrumentation, factors affecting measurements, applications of TGA, DSC (types) and DTA.	08 hours
III	1. UPLC and Nano LC: Principle, advantages over LC and applications. 2. Principle and applications of hyphenated techniques: GC-MS, LC-MS/MS, ICP-MS. 3. Supercritical chromatography and flash chromatography: principles and applications.	10 hours
IV	1. **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. 2. **Bio-analytical 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 & BE study protocol, biosimilars. 3. **Radio Immune Assays and ELISA:** Importance, various components, principle, different methods, limitations and applications of radio immunoassay and ELISA.	12 hours
V	1. **Microscopy-Based Analytical Techniques:** Principle, instrumentation, and applications of optical microscopy, scanning electron microscopy and transmission electron microscopy.	5 hours

Recommended References (Preferably latest editions)

1. Brown, M. E. *Introduction to Thermal Analysis: Techniques and Applications.* Springer.
2. Cullity, B. D. and Stock, S. R. *Elements of X-Ray Diffraction.* Prentice Hall.
3. Dong, M. W. *Modern HPLC for Practicing Scientists.* Wiley.
4. Friebolin, H. *Basic One- and Two-Dimensional NMR Spectroscopy.* Wiley.
5. Niessen, W. M. A. *Liquid Chromatography–Mass Spectrometry.* CRC Press.
6. Poole, C. F. *The Essence of Chromatography.* Elsevier.
7. Silverstein, R. M., Webster, F. X., Kiemle, D. J. and Bryce, D. L. *Spectrometric Identification of Organic Compounds.* Wiley.
8. Skoog, D. A., Holler, F. J. and Crouch, S. R. *Principles of Instrumental Analysis.* Cengage Learning.

Course Code	Course Title		Course Type	
BP705T	**Pharmacovigilance (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 principles, scope, and importance of pharmacovigilance in ensuring drug safety and patient care.
2. Familiarize students with the classification of adverse drug reactions and the methods used for their detection, assessment, monitoring, and prevention within healthcare systems.
3. Explain the concepts and significance of immunovigilance in monitoring and managing adverse events following immunization.
4. Learn national and international regulatory frameworks, guidelines, and reporting systems related to pharmacovigilance and immunovigilance.
5. Analyze pharmacovigilance data and apply risk management strategies to enhance medication and vaccine safety.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the core concepts, objectives, and significance of pharmacovigilance and immunovigilance.
2	Interpret and analyze national and global regulatory frameworks related to drug and vaccine safety.
3	Identify, document, and report ADRs and AEFIs using appropriate pharmacovigilance systems.
4	Evaluate pharmacovigilance data to detect trends, safety signals, and risk factors associated with medicinal products.
5	Propose and implement risk management strategies aimed at improving patient safety and public health outcomes.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Fundamentals of Pharmacovigilance** a) Concept, history, and importance of pharmacovigilance b) Basic drug classification systems (introductory overview only): c) ATC classification, ICD • ATC system • ICD d) Drug-related problems and medication safety e) Drug safety considerations in special populations: • Paediatrics • Geriatrics • Pregnancy and lactation	10 hours
II	**Pharmacovigilance Systems and Regulatory Framework** a) Objectives and functions of pharmacovigilance b) Methods of pharmacovigilance data collection: • Spontaneous reporting • Cohort and case-control studies c) Global pharmacovigilance systems: • WHO International Drug Monitoring Programme • Role of CIOMS and major regulatory agencies (e.g., USFDA, EMA) d) Pharmacovigilance Programme of India (PvPI) e) Establishment and role of ADR Monitoring Centres	10 hours
III	**Adverse Drug Reactions (ADRs)** a) Classification and types of ADRs b) Mechanisms and risk factors for ADRs c) Methods of ADR monitoring, detection, and reporting d) Assessment of causality, severity, predictability, and preventability of ADRs e) Management of ADRs f) Online reporting mechanisms and databases (WHO-ART, VigiBase, Vigiflow, Oracle Argus, OpenVigil software). g) MEDRA	8 hours
IV	**Immunovigilance and Other Disciplines of Pharmacovigilance** a) Definition, scope, and significance of immunovigilance, cosmetovigilance, nutraceutical-vigilance, materiovigilance, herbovigilance, ecopharmacovigilance, and hemovigilance b) Vaccination failure and vaccine pharmacovigilance (vaccinovigilance) c) Overview of adverse events following immunization (AEFIs) d) Immunization safety monitoring systems in India	7 hours
V	**Risk Communication, Evaluation, Management, and ICH Guidelines** a) Risk evaluation and management strategies in pharmacovigilance	10 hours

	and immunovigilance b) Communication in drug safety crisis management c) Communication with regulatory agencies, business partners, and healthcare facilities d) Analysis of real-world case studies and lessons learnt e) Emerging trends and challenges in pharmacovigilance and immunovigilance f) Overview of safety data generation g) Objectives of ICH guidelines h) Expedited and aggregate reporting i) Individual Case Safety Reports (ICSRs) j) Periodic Safety Update Reports (PSURs) k) Post-approval expedited reporting l) Good Clinical Practices (GCPs) regulation 2019 m) Application of pharmacogenomics and pharmacometrics in pharmacovigilance.	

Recommended References (Preferably latest editions)

1. Andrews, E. B. and Moore, N. *Mann's Pharmacovigilance.* Wiley Blackwell.
2. Cobert, B. *Cobert's Manual of Drug Safety and Pharmacovigilance.* World Scientific Publishing.
3. Jose, J., Cox, A. R. and Paudyal, V. *Principles and Practice of Pharmacovigilance and Drug Safety.* Springer.
4. Strom, B. L., Kimmel, S. E. and Hennessy, S. *Textbook of Pharmacoepidemiology.* Wiley.
5. Talbot, J. and Waller, P. *Stephens' Detection of New Adverse Drug Reactions.* Wiley.
6. Waller, P. and Harrison-Woolrych, M. *An Introduction to Pharmacovigilance.* Wiley Blackwell.

Course Code	Course Title		Course Type	
BP706T	**Pharmacy Practice (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 evolution, scope, and various roles of pharmacists in healthcare delivery systems.
2. Describe the structure and functions of hospital and community pharmacy, including drug distribution systems and regulatory standards.
3. Demonstrate knowledge of clinical pharmacy services and their application in drug therapy monitoring and patient care.
4. Develop skills in patient counseling, medication adherence strategies, and basic health screening services.
5. Apply prescribing guidelines, essential drug concepts, and principles of rational drug use to ensure safe and effective pharmacotherapy.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Describe the evolution, scope, and settings of pharmacy practice, including roles of pharmacists in various levels of healthcare.
2	Explain the organization and functions of hospital and community pharmacies, including drug distribution systems and regulatory standards.
3	Demonstrate clinical pharmacy services such as drug therapy monitoring, drug information, and handling medication-related problems.
4	Apply patient-oriented services like medication adherence strategies, patient counseling, and communication techniques.
5	Interpret and apply prescribing guidelines, essential drug concepts, and principles of rational drug use for optimal pharmacotherapy.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Introduction to Pharmacy Practice** 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.	8 hours
II	**Hospital and Community Pharmacy** **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 of hospital formulary, contents of hospital formulary, differentiation between hospital formulary and drug list, preparation and revision of hospital formulary **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 in hospital settings **Community Pharmacy** Organization and structure of retail and wholesale drug stores, types and design of a drug store, legal requirements for establishment and maintenance of a drug store, dispensing of proprietary products, maintenance of records of retail and wholesale drug stores, prescription handling, labelling, and patient counselling, introduction, definition, sale, and OTC medication list, vaccination services	10 hours

III	**Clinical Pharmacy Services** • Introduction to clinical pharmacy and its concept • Drug therapy monitoring o Medication chart review o Clinical review o Pharmacist intervention o Ward round participation o Medication history o Pharmaceutical care • Drug information services • Drug/Medication related problems • Drug and poison information services • Therapeutic drug monitoring (TDM)	9 hours
IV	**Patient-Oriented Services** **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	9 hours
V	**Prescribing Guidelines, Essential Drug Concept and Rational Drug Therapy** **Prescribing Guidelines** Pediatrics, 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 • Antibiotic stewardship program Injections OTC drugs Consequences of irrational drug use. • Dose calculations in chemotherapy, renal and hepatic failure	9 hours

	patients.	

Recommended References (Preferably latest editions)

1. Hassan, W. E. *Hospital Pharmacy.* Lea & Febiger.
2. Harman, R. J. *Handbook of Pharmacy – Health Care.* Pharmaceutical Press.
3. Merchant, S. H. and Qadry, J. S. *A Textbook of Hospital Pharmacy.* CBS Publishers & Distributors.
4. Parmar, N. S. *Health Education and Community Pharmacy.* CBS Publishers & Distributors.
5. Parthasarathi, G., Hansen, K. N. and Nahata, M. C. *A Textbook of Clinical Pharmacy Practice.* Universities Press.
6. Shargel, L. *Comprehensive Pharmacy Review.* Lippincott Williams & Wilkins.

Course Code	Course Title		Course Type	
BP707T	Regulatory Affairs (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. Understand the drug discovery and development process.
2. Identify key regulatory authorities and their roles in drug regulation.
3. Describe the regulatory approval processes in India and international markets.
4. Understand the documentation and registration procedures for drug products.
5. Describe the laws and guidelines governing the pharmaceutical industry.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Describe the fundamental concepts and organizational structures of regulatory affairs and global regulatory authorities governing pharmaceutical products.
2	Describe the drug discovery and development process, including preclinical, clinical, and regulatory documentation requirements.
3	Summarize the regulatory framework, approval procedures, and legal requirements for pharmaceuticals in India.
4	Compare regulatory approval processes and submission formats across major international markets.
5	Understand clinical trial requirements, ethics committee roles, informed consent, GCP guidelines, and pharmacovigilance requirements.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Fundamentals of Regulatory Affairs** 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).	6 hours
II	**Regulatory Requirements in Drug Development** • 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.	6 hours
III	**Indian Regulatory Framework and Approval Process** • 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, phytopharmaceutical regulations, Good Clinical Practice (GCP) guidelines and Schedule Y, Innovator and generic drugs, Generic drug product development • Phytopharmaceutical regulation by AYUSH and CDSCO.	6 hours
IV	**International Regulatory Systems & Global Drug Registration:** • 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.	6 hours

V	**Clinical Trials, Ethics, and Post-Marketing Surveillance:** • 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,	6 hours

Recommended References (Preferably latest editions)

1. Berry, I. R. and Martin, R. P. *The Pharmaceutical Regulatory Process.* Informa Healthcare.
2. Gallin, J. I. and Ognibene, F. P. *Principles and Practice of Clinical Research.* Academic Press.
3. Guarino, R. A. *New Drug Approval Process: Accelerating Global Registrations.* CRC Press.
4. Ng, R. *Drugs: From Discovery to Approval.* Wiley.
5. Pisano, D. J. and Mantus, D. S. *Textbook of FDA Regulatory Affairs.* Informa Healthcare.
6. Weinberg, S. *Guidebook for Drug Regulatory Submissions.* Wiley.

Course Code*	Course Title*			Course Type	
BP708T AEC1	Current Good Manufacturing Practices (cGMP)			**Elective**	
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 & Macromolecules				
BP708T AEC7	Precision Medicine				
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	
BP709P	**Modern Analytical Techniques (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. Provide practical training in interpretation of advanced instrumental data used for structural and physicochemical characterization.
2. Introduce quantitative analytical techniques using modern separation methods, such as UHPLC and HPLC, for the estimation of pharmaceutical substances.
3. Familiarize students with the principles and practice of green analytical chemistry, including preparation of green solvents and development of environmentally sustainable analytical methods.
4. Develop understanding of bioanalytical sample preparation techniques for pharmaceutical analysis in biological matrices, including solid phase extraction, liquid–liquid extraction, and protein precipitation.
5. Learn applied pharmaceutical analysis and methods including cell viability assays, residual solvent analysis, and estimation of drugs from biological fluids.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Analyze and interpret proton NMR, carbon NMR, mass spectra, X-Ray diffraction patterns, and DSC thermograms to characterize pharmaceutical compounds.
2	Perform quantitative analysis of official pharmaceutical compounds using UHPLC.
3	Design and assess the suitability of green analytical solvents for pharmaceutical applications, promoting sustainability.
4	Construct a comprehensive protocol for bioavailability and bioequivalence studies adhering to USFDA regulatory standards.
5	Employ appropriate extraction techniques (SPE, PPE, LLE) for the accurate quantification of pharmaceuticals in biological fluids and matrices and explain and execute the MTT assay for evaluating cell viability in a laboratory setting.

Detailed Sllabus:

List of Practicals **(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.
Recommended References (Preferably latest editions) 1. Beckett, A. H. and Stenlake, J. B. *Practical Pharmaceutical Chemistry.* CBS Publishers & Distributors. 2. Brittain, H. G. *Analytical Profiles of Drug Substances and Excipients.* Elsevier. 3. Kemp, W. *Organic Spectroscopy.* Palgrave Macmillan. 4. Munson, J. W. *Pharmaceutical Analysis: Modern Methods.* Marcel Dekker. 5. Sharma, Y. R. *Organic Spectroscopy.* S. Chand. 6. Silverstein, R. M., Webster, F. X., Kiemle, D. J. and Bryce, D. L. *Spectrometric Identification of Organic Compounds.* Wiley. 7. Willard, H. H., Merritt, L. L., Dean, J. A. and Settle, F. A. *Instrumental Methods of Analysis.* Brooks/Cole. 8. *Indian Pharmacopoeia.* Indian Pharmacopoeia Commission.

Course Code	Course Title		Course Type	
BP710RP	**Research Project**		**CORE**	
Credit	Hours Per Week (L-T-P)*			Max. Hours.
	L	T	P	
6	--	--	--	--
Maximum Marks	SE		ESE	
150	0		150	

* Refer section 21 of regulation.

Semester VIII

Course Code	Name of the course		No. of hours per week (L/P)	Credit points
BP801T	Ethical Considerations and Translational Applications of AI in Pharmacy (Theory)		2	2
BP802T	Clinical Pharmacotherapeutics (Theory)		2	2
BP803T	Industrial Pharmacy and Facility Design (Theory)		3	3
BP804T	Pharmaceutical Management (Theory)		2	2
BP805T	Sterile Dosage Forms and Novel Drug Delivery System (Theory)		3	3
BP806T AEC*	BP806T AEC1	Pharmaceutical Packaging	2	2
	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		
BP807P	Pharmaceutical Marketing Skills (Practical)		2	1
BP808P	Sterile Dosage Forms and Novel Drug Delivery System (Practical)		4	2
BP809P VAC*	BP809P VAC1	Cleaning Validation	2	1
	BP809P VAC2	Basic Training in Aseptic Handling Techniques		
	BP809P VAC3	Impurity Profiling		
BP810RP	Research Project		-	6
Total			**22**	**24**

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

Course Code	Course Title		Course Type	
BP801T	**Ethical Considerations and Translational Applications of AI in Pharmacy (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:

1. Introduce the lifecycle of artificial intelligence systems used in pharmaceutical and healthcare applications, including data management, model development, validation, and deployment.
2. Provide an understanding of model validation, auditing procedures, and documentation practices required for reliable and reproducible AI systems.
3. Familiarize students with regulatory, governance, and ethical frameworks guiding the implementation of AI in pharmaceutical and healthcare environments.
4. Explore applications of artificial intelligence in pharmacy automation, supply chain management, and public health data analytics.
5. Develop practical understanding of AI implementation in pharmaceutical and healthcare domains through case studies and guided project work.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the lifecycle of AI systems in pharmaceutical settings.
2	Evaluate model performance, bias, and validation requirements.
3	Discuss regulatory and governance frameworks applicable to AI in pharmacy.
4	Analyze AI applications in automation and public health analytics.
5	Evaluate ethical considerations in AI applications for pharmaceutical sciences and healthcare

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**AI Lifecycle, Validation & Model Auditing** • 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	6 hours
II	**Regulatory Framework & Explainable AI** • 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	6 hours
III	**AI in in Pharmacy Automation & Supply Chain** • Overview of AI in automated dispensing systems • Inventory prediction models • Case studies on regression-based demand forecasting, different forecasting methods • Medication adherence monitoring systems • AI in supply chain risk prediction • Predictive analytics in pharmaceutical logistics • Advantages, limitations, legal & privacy considerations of AI in pharmacy automation.	6 hours
IV	**AI in in Public Health & Real-World Data Analytics**	6 hours

	• Overview of real-world data sources (EHR, claims, surveillance systems) • Conceptual knowledge of AI in outbreak prediction, 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 etc.)	
V	**Guided Project - Translational AI in Pharmacy** 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. They validate the model, analyze regulatory implications, identify ethical risks (e.g., bias, privacy), and present 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	6 hours

Recommended References (Preferably latest editions)

1. Germanakos, P. *Human-Centered AI: An Illustrated Scientific Quest.*
2. Matheny, M., et al. *Artificial Intelligence in Health Care: The Hope, the Hype, the Promise, the Peril.* National Academy of Medicine.
3. Mittal, M. and Bhushan, B. *Generative AI in Healthcare: Concepts, Methodologies, Tools, and Applications.*
4. Steyerberg, E. W. *Clinical Prediction Models: A Practical Approach to Development, Validation, and Updating.* Springer.
5. Steyerberg, E. W. *Practical Predictive Analytics and Decisioning Systems for Medicine.* Academic Pres

Course Code	Course Title		Course Type	
BP802T	**Clinical Pharmacotherapeutics (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. Explain the pathophysiology and clinical manifestations of selected disease conditions and their relevance to drug therapy.
2. Provide an understanding of the pharmacological and therapeutic approaches used in the management of these diseases.
3. Develop the ability to design individualized therapeutic plans based on diagnosis and patient characteristics.
4. Enable identification of patient-specific parameters required for initiating, monitoring, and modifying drug therapy.
5. Familiarize students with evidence-based therapeutic guidelines and non-pharmacological approaches in disease management.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Understand the subjective and objective parameters, risk factors for common disease conditions
2	Describe the general therapeutic approach in management of selected diseases
3	Identify the patient-specific parameters relevant in initiating the drug therapy
4	Discuss the rationale for drug therapy of the selected disease
5	Understand the methods of non-pharmacological management.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
	Definition, etiopathogenesis, clinical manifestations, overview of management of the diseases associated with	
I	**Ischemic Heart Disease** Hypertension, heart failure, myocardial infarction, hyperlipidaemia, arrhythmia	5 hours

II	**Respiratory System**: Asthma, COPD	2 hours
III	**Renal System**: acute renal failure, chronic renal failure, renal replacement therapy	3 hours
IV	**Endocrine System:** diabetes, thyroid disorders	3 hours
V	**Nervous System:** epilepsy, stroke, parkinsonism	5 hours
VI	**Gastrointestinal System:** peptic ulcer disease, GERD	2 hours
VII	**Diseases of bones and joints:** rheumatoid arthritis, osteoarthritis	3 hours
VII	**Infectious Diseases:** tuberculosis, pneumonia, UTI, malaria, HIV	4 hours
IX	**Hematological Diseases:** Anemia	3 hours

Recommended References (Preferably latest editions)

1. Bauer, L. A. *Applied Clinical Pharmacokinetics.* McGraw-Hill Education.
2. DiPiro, J. T., Yee, G. C., Posey, L. M., Haines, S. T., Nolin, T. D. and Ellingrod, V. *Pharmacotherapy: A Pathophysiologic Approach.* McGraw-Hill Education.
3. Herfindal, E. T. and Gourley, D. R. *Clinical Pharmacy and Therapeutics.* Williams & Wilkins.
4. Walker, R. and Whittlesea, C. *Clinical Pharmacy and Therapeutics.* Elsevier.
5. Zeind, C. S. and Carvalho, M. G. *Applied Therapeutics: The Clinical Use of Drugs.* Wolters Kluwer.

Course Code	Course Title		Course Type	
BP803T	**Industrial Pharmacy and Facility Design (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. Introduce regulatory guidelines such as ICH, WHO, Schedule M, cGMP, and SUPAC governing pharmaceutical formulation development, stability testing, and scale-up processes.
2. Develop an understanding of industrial product development processes including pilot plant operations, scale-up considerations, and platform technologies used in pharmaceutical manufacturing.
3. Explain the principles and procedures involved in technology transfer from research and development to commercial production, including documentation, quality risk management, and regulatory compliance.
4. Introduce the design and operational requirements of pharmaceutical facilities for sterile and non-sterile manufacturing, including layout planning, utilities, and contamination control systems.
5. Familiarize students with modern pharmaceutical facility design concepts such as modular cleanrooms, isolators, automation, and advanced contamination control technologies to ensure product quality and regulatory compliance.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Interpret regulatory guidelines (ICH, WHO, Schedule M, SUPAC) relevant to pharmaceutical product development, stability studies, and manufacturing processes.
2	Explain pilot plant operations and scale-up strategies for the development of solid, liquid, and semi-solid pharmaceutical dosage forms.
3	Describe the processes, documentation, and quality management principles involved in technology transfer from R&D to manufacturing.
4	Design and evaluate facility layouts and utility systems for sterile and non-sterile pharmaceutical manufacturing in accordance with cGMP and global cleanroom standards.
5	Assess modern pharmaceutical facility design approaches, including modular cleanrooms, automation, and validation systems, to ensure efficient and compliant manufacturing operation

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**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	12 hours
II	**Technology development and transfer:** 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 equipments, 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	9 hours
III	**Facility Considerations: Non sterile** 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,	9 hours
IV	**Facility considerations: Sterile** 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.	9 hours
V	**Advances in facility design** Modular concept of manufacturing facilities with significance and suitable examples, Advances in clean room technology: pass- through chambers,	6 hours

	isolators, Modular cleanrooms Automation and robotics in pharmaceutical manufacturing operations.	

Recommended References (Preferably latest editions)

1. Akers, M. J. *Sterile Product Development: Formulation, Process and Regulatory Considerations.* CRC Press.
2. Beg, S., Abbas, M. Z. and Hossain, M. A. *Pharmaceutical Quality by Design: A Practical Approach.* Academic Press.
3. Bunn, G. *Pharmaceutical Production Facilities: Design and Applications.* CRC Press.
4. Francke, R. M. and Meissner, H. *Cleaning Validation: Practical Compliance Solutions for Pharmaceutical Manufacturing.* CRC Press.
5. Gad, S. C. *Pharmaceutical Manufacturing Handbook: Production and Processes.* Wiley.
6. Levin, M. *Pharmaceutical Process Scale-Up.* CRC Press.
7. McCormick, K. *Pharmaceutical Facility Design.* CRC Press.
8. Nally, J. D. *Good Manufacturing Practices for Pharmaceuticals.* CRC Press.
9. Sandle, T. *Advanced Cleanroom Technology.* Wiley-Blackwell.
10. Steinborn, L. *GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers.* CRC Press.
11. Teasdale, A., Elder, D. and Greenwood, R. W. *ICH Quality Guidelines: An Implementation Guide.* Wiley.
12. Whyte, W. *Cleanroom Technology: Fundamentals of Design, Testing and Operation.* Wiley-Blackwell.

Course Code	Course Title		Course Type	
BP804T	**Pharmaceutical Management (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. Gain a deep understanding of the pharmaceutical sector, including the development, production, and distribution of pharmaceutical products.
2. Familiarize with the global and local pharmaceutical landscape, trends, regulations, and the competitive environment.
3. Learn how to formulate and implement effective business strategies specific to the pharmaceutical industry.
4. Analyze the dynamics of pharmaceutical marketing, product life cycles, and strategic decision-making processes.
5. Understand the principles and practices of marketing pharmaceutical products, including branding, pricing, distribution, and promotion.
6.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Demonstrate a comprehensive understanding of the pharmaceutical industry, including drug development, regulatory processes, manufacturing, and distribution.
2	Understand the role of pharmaceutical companies in healthcare and their impact on society at large.
3	Apply strategic management principles to solve complex issues in the pharmaceutical industry, including market entry, competitive advantage, and business growth strategies.
4	Formulate and evaluate strategic business plans for pharmaceutical companies, considering global and local market dynamics.
5	Develop and implement pharmaceutical marketing strategies that align with both business goals and regulatory guidelines. Apply advanced sales and marketing techniques tailored to the pharmaceutical industry, focusing on product positioning, customer segmentation, and digital marketing.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Introduction to Pharmaceutical Management** Introduction to management. Overview of Indian & 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.	6 hours
II	**Marketing Management in Pharmaceuticals** Definition and uniqueness of pharmaceutical marketing, Pharmaceutical Marketing Overview; Global & Indian Scenario, Marketing Mix, 4 Ps 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	6 hours
III	**Pharmaceutical Product Management** Introduction to Pharmaceutical Product Management, role of product management in the pharmaceutical industry, Key responsibilities of a pharmaceutical product manager, Product Lifecycle Management, Branding and Promotional Strategies in pharmaceutical sector, Importance of market segmentation, targeting, and positioning in product management, Market Research and Analysis in pharmaceutical sector: Techniques for conducting market research.	6 hours
IV	**Financial planning and Human Resource Management** 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.	6 hours
V	**Operations & Supply Chain Management in Pharmaceuticals** 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.	6 hours

Recommended References (Preferably latest editions)

Dessler, G. *Human Resource Management.* Pearson.
Drucker, P. F. *Principles of Management.* Harper Business.
Joseph, A. S. *Pharmaceutical Management and Marketing.* CBS Publishers & Distributors.
Pandey, I. M. *Financial Management.* Vikas Publishing House.

5. Stevenson, W. J. *Operations Management.* McGraw-Hill Education.
6. Kotler, P. and Keller, K. L. *Marketing Management.* Pearson Education.
7. Kotler, P., Kartajaya, H. and Setiawan, I. *Marketing 6.0: The Future Is Immersive.* Wiley.
8. Nandy, S. *Strategic Pharmaceutical Marketing Management in Growth Markets.* CRC Press.
9. Smith, M. C., Kolassa, E. M., Perkins, G. and Siecker, B. *Pharmaceutical Marketing: Principles, Environment, and Practice.* Pharmaceutical Products Press

Course Code	Course Title		Course Type	
BP805T	**Sterile Dosage Form and Novel Drug Delivery System (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 scientific and technological foundations of advanced and novel drug delivery systems, including their classification, design rationale, materials, and formulation development challenges.
2. Examine the role of polymers, lipids, and excipients in formulating biodegradable, targeted, and controlled-release drug delivery systems.
3. Study specialized drug delivery routes such as oral, mucosal, transdermal, ocular, parenteral and drug carriers including and their impact on therapeutic efficacy.
4. Apply principles of Quality by Design (QbD), preclinical evaluation, and regulatory science to assess NDDS development and clinical translation.
5. Explore the emerging field of precision medicine, including its genetic, molecular, and technological underpinnings relevant to pharmacy.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Classify and explain the different types of NDDS and describe their need in overcoming limitations of conventional drug delivery.
2	Identify appropriate pharmaceutical ingredients for designing site-specific or controlled-release delivery systems.
3	Design oral, mucosal, parenteral, and transdermal NDDS, and evaluate their mechanisms and formulation parameters.

4	Apply QbD principles and preclinical evaluation tools to assess NDDS quality and safety.
5	Demonstrate an understanding of the scope, principles, and challenges of precision medicine in modern pharmacotherapy.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Fundamentals, Polymers & Materials for NDDS** 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	12 hours
II	**Oral and Mucosal Delivery Systems** 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.	6 hours
III	**Transdermal NDDS** 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, micro needles Aseptic manufacturing, scale-up challenges, and process analytical tools (PAT)	6 hours
IV	**Evaluation, Quality, and Translation** 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 Case studies: Liposomal Amphotericin B for Fungal Infections, mRNA-Lipid Nanoparticle Vaccines (e.g., COVID-19 Vaccines), Depot Antipsychotic Injections (e.g., Risperidone Microspheres),	6 hours

	Transdermal Patch for Hormone Replacement Therapy, Ocular Inserts for Glaucoma Management, Oral Colon-Targeted Delivery for Inflammatory Bowel Disease, Inhalable Insulin for Diabetes Mellitus, Dendrimers for Targeted Cancer Therapy, Chronotherapeutic Drug Delivery in Hypertension. 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	
V	**a. Sterile Dosage Forms (Parenteral & Ophthalmic) Introduction & 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 & osmolality. **Manufacturing:** Aseptic vs terminal sterilisation; filtration **lyophilisation** principles; environmental controls. **Containers & closures:** Glass/Plastic systems; elastomers; selection factors; evaluation & container– closure integrity. Form fill Seal and Blow Fill Seal Technology **Ophthalmics:** Solutions/suspensions/ointments/gels/inserts physiological factors (pH, tonicity, viscosity); residence-time enhancers preservative-free systems (e.g., BFS). **Quality control & compliance:** Sterility tests, **LAL**/endotoxins particulate matter, clarity, extractable volume; labelling & documentation; overview of **cGMP/cleanrooms** and environmenta monitoring.	14 hours

Recommended References *(Preferably latest editions):*

Aulton, M. E. and Taylor, K. *Aulton's Pharmaceutics: The Design and Manufacture of Medicines.* Elsevier.
Banga, A. K. *Transdermal and Intradermal Delivery of Therapeutic Agents.* CRC Press.
Dash, A. K. and Cudworth, G. C. *Therapeutic Proteins and Peptides: Formulation, Processing and Delivery Systems.* CRC Press.
Jain, N. K. *Drug Delivery Systems.* CBS Publishers & Distributors.
Kreuter, J. *Colloidal Drug Delivery Systems.* CRC Press.
Martin, A., Sinko, P. J. and Singh, Y. *Martin's Physical Pharmacy and Pharmaceutical Sciences.* Lippincott Williams & Wilkins.
Torchilin, V. P. *Nanoparticulates as Drug Carriers.* Imperial College Press.
Remington. *The Science and Practice of Pharmacy.* Pharmaceutical Press.

Course Code*	Course Title*			Course Type
BP806T AEC1	Pharmaceutical Packaging			**Elective**
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			
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
2	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	
BP807P	**Pharmaceutical Marketing Skills (Practical)**		Core	
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 students to the fundamentals of pharmaceutical marketing, focusing on the industry-specific strategies and tactics.
2. Gain insight into the stages of a pharmaceutical product's lifecycle, from development to commercialization.
3. Discuss the critical role of regulations, ethical considerations, and compliance issues in marketing pharmaceutical products.
4. Equip students with skills to design marketing strategies for pharmaceutical products, considering various market segments and stakeholder needs.
5. Introduce various sales techniques and communication skills needed to build relationships with healthcare professionals and other stakeholders.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Understand the dynamics of the pharmaceutical market and the various factors that influence sales, including consumer behavior, competition, and regulatory environment.
2	Design and implement effective marketing strategies for pharmaceutical products, tailored to specific market needs and target audiences.
3	Demonstrate knowledge of the ethical and legal considerations in pharmaceutical marketing and how to ensure compliance with industry standards and regulations.
4	Implement digital marketing strategies, such as social media campaigns, search engine optimization (SEO), and online advertisements, to promote pharmaceutical products.
5	Develop and demonstrate strong interpersonal and communication skills, necessary for building relationships with healthcare professionals, patients, and other stakeholders in the pharmaceutical industry.

Detailed Syllabus

List of 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.
Recommended References *(Preferably latest editions)*: 1. Crompton, J. L. and Lamb, C. W. *Marketing Government and Social Services.* Wiley. 2. Herger, M. *Pharma Marketing Excellence: Strategy, Tactics and Implementation.* CRC Press. 3. Jain, S. K. *Pharmaceutical Marketing Management.* CBS Publishers & Distributors. 4. Kotler, P. and Keller, K. L. *Marketing Management.* Pearson. 5. Kotler, P., Shalowitz, J. and Stevens, R. J. *Strategic Marketing for Health Care Organizations.* Jossey-Bass. 6. Malhotra, N. K. *Marketing Research: An Applied Orientation.* Pearson. 7. Panda, T. K. *Sales and Distribution Management.* Oxford University Press. 8. Porter, M. E. *Competitive Strategy: Techniques for Analyzing Industries and Competitors.* Free Press. 9. Smith, M. C. *Pharmaceutical Marketing: Strategy and Cases.* Pharmaceutical Products Press.

Course Code	Course Title		Course Type	
BP808P	**Sterile Dosage Form and Novel Drug Delivery System (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. Provide a comprehensive understanding of the concepts, design principles, and technological advancements in novel drug delivery systems (NDDS) and their application in precision medicine.
2. Develop proficiency in the formulation, preparation, and evaluation of various advanced dosage forms for site-specific and controlled drug delivery.
3. Impart knowledge on biopharmaceutical and pharmacokinetic considerations influencing NDDS for improved therapeutic outcomes.
4. Introduce students to the role of NDDS in personalized/precision medicine, focusing on patient-specific drug delivery strategies.
5. Equip students with skills to critically evaluate formulation performance using appropriate experimental, analytical, and regulatory approaches.

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.
3	Select appropriate excipients and techniques for the development of NDDS.
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
(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 & Distilled Water as per IP; review of WFI specifications (conductivity/ TOC limits-demo / simulation).
Recommended References *(Preferably latest editions)*: 1. Allen, L. V., Popovich, N. G. and Ansel, H. C. *Pharmaceutical Dosage Forms and Drug Delivery Systems.* Lippincott Williams & Wilkins. 2. Ansel, H. C., Allen, L. V. and Popovich, N. G. *Pharmaceutical Calculations.* Wolters Kluwer. 3. Banker, G. S. and Rhodes, C. T. *Modern Pharmaceutics.* CRC Press. 4. Chien, Y. W. *Novel Drug Delivery Systems.* CRC Press. 5. Jain, N. K. *Controlled and Novel Drug Delivery Systems.* CBS Publishers & Distributors. 6. Lachman, L., Lieberman, H. A. and Kanig, J. L. *The Theory and Practice of Industrial Pharmacy.* CBS Publishers & Distributors. 7. Sinko, P. J. *Martin's Physical Pharmacy and Pharmaceutical Sciences.* Lippincott Williams & Wilkins. 8. Swarbrick, J. and Boylan, J. C. *Encyclopedia of Pharmaceutical Technology.* CRC Press. 9. *Indian Pharmacopoeia.* Indian Pharmacopoeia Commission.

Course Code*	Course Title*		Course Type	
BP809P VAC1	Cleaning Validation		**Elective**	
BP809P VAC2	Basic Training in Aseptic Handling Techniques			
BP809P VAC3	Impurity Profiling			
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*

		SEC3			
	Elective 5	BP611P VAC1	Professional Skills	Practical	VAC
		BP611P VAC2	Process Analytical Technology (PAT) and QbD in Formulation Science	Practical	VAC
VII	Elective 6	BP708T AEC1	Current Good Manufacturing Practices (cGMP)	Theory	AEC
		BP708T AEC2	Pharmaceutical Automation	Theory	AEC
		BP708T AEC3	Modern Techniques in Cellular Biology	Theory	AEC
		BP708T AEC4	Medical Devices	Theory	AEC
		BP708T AEC5	Transformation of Food Waste into Medicinal Products	Theory	AEC
		BP708T AEC6	Biosimilars, Vaccines & Macromolecules	Theory	AEC
		BP708T AEC7	Precision Medicine	Theory	AEC
VIII	Elective 7	BP806T AEC1	Pharmaceutical Packaging	Theory	AEC
		BP806T AEC2	Supply Chain Management	Theory	AEC
		BP806T AEC3	Industrial Safety and Waste Management	Theory	AEC
		BP806T AEC4	Traditional Healing Practices of India	Theory	AEC
		BP806T AEC5	Futuristic Pharma through AR/VR: Pharma 4.0	Theory	AEC
		BP806T AEC6	Herbal Cosmetics for Industry Perspective	Theory	AEC
	Elective 8	BP809P VAC1	Cleaning Validation	Practical	VAC

Detailed Syllabus

List of Practical
1. Identify Critical Quality Attributes (CQAs) – Brainstorm and list five tablet CQAs (hardness, dissolution, etc.) and link each to patient safety or efficacy. 2. Ishikawa (Fish-Bone) Diagram – Draw a cause-and-effect diagram for poor tablet dissolution, categorising factors into Materials, Methods, Machines and Manpower. 3. Blend-Uniformity by NIR Probe – Collect in-line near-infrared spectra during 10 min of blender operation and plot real-time API concentration trends. 4. Moisture Tracking with NIR – Use a portable NIR gun to measure LOD in wet granules every 2 min, stopping when the plot hits the 3 % target. 5. Mini DoE for Granulation – Run a 2^2 design varying impeller speed and granulation time; measure granule mean size and create main-effects plots. 6. Real-Time Release Test (RTRT) – Set up an at-line NIR hardness prediction model, test 20 tablets, and compare predicted vs. actual hardness. 7. Control Chart of Particle Size (FBRM) – Stream Focused Beam Reflectance data during milling; plot $\bar{X}$ and R for d_{50} and decide if the process is in control. 8. Multivariate Calibration Model – Build a partial-least-squares (PLS) model correlating NIR spectra to drug content; report R^2 and RMSEP. 9. FMEA Risk-Priority Number – Score severity, occurrence and detectability for three high-risk process variables; rank them by RPN and suggest mitigation. 10. PAT Model Verification Batch – Run the optimised process, capture PAT data, and confirm that all CQAs meet specification without end-product testing.
Recommended References *(Preferably latest edition)*: 1. Bakeev KA, editor. Process Analytical Technology: Spectroscopic Tools and Implementation Strategies for the Chemical and Pharmaceutical Industries. 2nd ed. Chichester: Wiley; 2010. 2. Rathore AS, Winkle H. Quality by Design for Biopharmaceuticals. 2nd ed. Hoboken: Wiley; 2019. 3. Kourti T, Bakeev K. Process Analytical Technology: Theory and Applications. 1st ed. Oxford: Butterworth-Heinemann; 2022. 4. Patil AS, Rane VP. Practical Implementation of Quality by Design (QbD) for Pharmaceutical Product Development. 1st ed. Amsterdam: Elsevier; 2019.

SEMESTER VII

Course Code	Course Title			Course Type
BP708T AEC1	**cGMP (Theory)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	1	--	--	15
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Explain the structure, purpose, and implementation of Standard Operating Procedures (SOPs) in pharmaceutical operations.
2. Develop understanding of training and development systems, including training needs assessment and evaluation methods used in the pharmaceutical industry.
3. Describe the principles of current Good Manufacturing Practices (cGMP) and key regulatory guidelines relevant to pharmaceutical quality assurance.
4. Examine core pharmaceutical quality systems such as Quality Management Systems (QMS), CAPA, deviation management, and non-conformance handling.
5. Understand procedures for managing customer complaints, investigating quality issues, and ensuring product safety and regulatory compliance.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Understand the structure of SOPs, its writing and approval system, Importance of training, development, training needs identification and evaluation.
2	Understand the major FDA guidelines (regulated and semi regulated markets) and its understanding.
3	Impart knowledge on manufacturing assurance, analytical assurance, engineering assurance etc, and handling systems for non-conformances.
4	Procedures used to investigate market complaints and its closure.
5	Impart knowledge on preparing for the regulatory audits, reports handling and drafting of compliance report, with certain understanding of Do's and Don'ts during the audits.

Detailed Syllabus

Unit No.	Topics	No. of Lectures
I	**Standard Operating Procedures (SOP), Systems for Training & Development in Pharmaceuticals** • Introduction to SOPs, SOP on SOP, Contents of a standard SOP, Writing a good SOP, Distribution and control of SOPs. • Introduction to Training and development, Training needs identification, Training and evaluation.	3 hours
II	**A comprehensive review of cGMP and various important FDA guidelines** • List of major guidelines referred in pharmaceuticals • Effectively reading and understanding the guidelines	3 hours
III	**Important Quality Assurance and cGMP systems adopted in Pharmaceuticals** • Introduction to Quality Management Systems (QMS), Manufacturing Assurance, Analytical Assurance, Developments Quality Assurance, Engineering Assurance. • Concepts of corrective and preventive actions (CAPA), Deviations and Incidents handling. Handling of non-conforming materials	3 hours
IV	**Handling of Customer Complaints** • Introduction to complaints, Types of complaints • Understanding Manufacturing defects and Quality issues • Handling and investigation of customer complaints	3 hours
V	**Regulatory Audits** • Introduction to audits and Types of audits. • Preparation for a successful audit, Audit teams and internal audits. • Handling of FDA inspections: FDA observations, Compliance and replying to an audit report.	3 hours

Recommended References *(Preferably latest edition)*:

1. Good Manufacturing Practices for Pharmaceuticals – Joseph D. Nally, CRC Press
2. Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials (Vol. 1 & 2) – World Health Organization (WHO), WHO Press
3. Guidance for Industry: Quality Systems Approach to Pharmaceutical CGMP Regulations – U.S. FDA, CDER/CDRH Guidance Document
4. Pharmaceutical Production and Packaging Technologies – Michael J. Groves, CRC Press
5. Pharmaceutical Quality by Design: A Practical Approach – Walkiria S. Schlindwein & Mark Gibson, Wiley
6. Government of India, Ministry of Health and Family Welfare (2023) Drugs and Cosmetics Rules, 1945: Amendment introducing revised Schedule M – Good Manufacturing Practices. Gazette of India, Notification G.S.R. 922(E), 28 December.

Course Code	Course Title			Course Type
BP708T AEC2	**Pharmaceutical Automation (Theory)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	1	--	--	15
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Introduce the fundamental concepts of automation technologies used in the pharmaceutical industry.
2. Explain the application of automated systems in pharmaceutical manufacturing, quality control, and packaging operations.
3. Describe the principles of process instrumentation, SCADA, PLC, and robotics in pharmaceutical production environments.
4. Develop understanding of laboratory automation systems including LIMS and Process Analytical Technology (PAT).
5. Examine regulatory considerations and emerging trends in pharmaceutical automation and digital manufacturing.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the principles and advantages of automation in pharmaceutical processes.
2	Identify and describe various automated systems used in production and quality control.
3	Apply knowledge of instrumentation and control systems like SCADA and PLC in pharma environments.
4	Analyze the role of automation in enhancing data integrity, regulatory compliance, and productivity.
5	Evaluate new trends like Industry 4.0, IoT, and AI applications in pharmaceutical automation.

Detailed Syllabus

Unit No.	Topics	No. of Lectures
I	**Introduction to Automation in Pharmaceuticals** • Definition and scope of automation in pharmaceutical industry • Importance and benefits: accuracy, efficiency, cost-effectiveness, compliance • Types of automation: fixed, programmable, flexible • Application areas: production, packaging, quality control, warehousing • Challenges and limitations of automation	3 hours
II	**Automated Manufacturing Systems** • Principles of automated tablet compression, capsule filling, liquid filling, and coating machines • PLC-based machinery in granulation and drying • Robotics in sterile product manufacturing (isolators, RABS) • Continuous manufacturing vs. batch processing • Automation in aseptic processing and lyophilization	3 hours
III	**Process Control and Instrumentation** • Sensors and transducers: temperature, pressure, flow, pH, conductivity • Introduction to SCADA (Supervisory Control and Data Acquisition) systems • Distributed Control Systems (DCS) in pharma • Process Analytical Technology (PAT) – definition and applications • Basics of automation programming (ladder diagrams, logic gates – overview only)	3 hours
IV	**Quality Control and Laboratory Automation** • Automation in analytical laboratories: HPLC, UV, FTIR, dissolution testers • Laboratory Information Management System (LIMS) • Integration of instruments with software and data loggers • Automated sampling and testing methods • Role of AI/ML in predictive quality assurance	3 hours
V	**Regulatory Aspects and Emerging Trends** • Regulatory expectations: USFDA, WHO, EMA on automation & electronic systems • 21 CFR Part 11 – electronic records and signatures • Data integrity and ALCOA • Emerging trends: IoT, Industry 4.0, cloud-based manufacturing, AI in pharma • Case studies: automated systems in top pharma companies	3 hours

Recommended References *(Preferably latest edition)*:

1. Automation and Control in the Pharmaceutical Industry by Burton H. Sage, CRC Press
2. Pharmaceutical Engineering by K. Sambamurthy, New Age International Publishers
3. Process Automation Handbook by Jonathan Love, Springer-Verlag London Ltd.
4. Industrial Automation and Robotics by Mikell P. Groover, Pearson Education
5. Instrumentation and Process Control by Terry L.M. Bartelt, Cengage Learning
6. Good Automated Manufacturing Practice (GAMP 5 Guide) by ISPE (International Society for Pharmaceutical Engineering), ISPE Publications
7. Pharmaceutical Manufacturing Handbook: Production and Processes by Shayne Cox Gad, Wiley-Interscience

Course Code	Course Title			Course Type
BP708T AEC3	**Modern Techniques in Cellular Biology (Theory)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	1	--	--	15
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Learn the basics of five key cell-biology tools: CRISPR editing, flow cytometry, live-cell imaging, single-cell RNA-seq, and advanced fluorescence microscopy.
2. Plan good experiments by picking the right reagents, controls, and settings for each technique.
3. Get hands-on practice using at least one workflow from every unit.
4. Read and understand the data these methods produce—plots, images, and gene-expression maps.
5. Apply the methods responsibly by considering safety, ethics, and real-world biomedical uses.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Explain key principles of CRISPR editing, flow cytometry/FACS, live-cell imaging, single-cell RNA-seq, and advanced fluorescence microscopy.
2	Design and carry out one basic protocol for each technique (e.g., gRNA design, four-colour FACS run, 12-h time-lapse capture, scRNA-seq data import, confocal Z-stack acquisition).
3	Interpret the resulting data by creating clear plots, images, or cluster maps and extracting at least one biological conclusion from each.
4	Choose the right technique for a given cellular-biology question and justify the choice with brief technical and practical reasoning.
5	Apply essential safety, ethical, and data-quality guidelines while performing and reporting every experiment

Detailed Syllabus

Unit No.	Topics	No. of Lectures
I	**CRISPR & Genome Editing** CRISPR-Cas9 mechanics, guide-RNA design and DNA repair outcomes, contrasts knock-outs, knock-ins and base-editing, and shows how dCas9 fusions enable gene activation or repression. Students compare delivery routes—plasmid, ribonucleoprotein, viral and lipid-nanoparticle—then	3 hours

	evaluate off-target detection strategies before a mini-lab in which they design a gRNA and screen predicted off-targets.	
II	**Flow Cytometry & Cell Sorting** Learners review flow-cytometer fluidics, optics and fluorochrome chemistry, interpret forward/side scatter plots for cell size and granularity, and build multi-colour antibody panels with compensation. They perform cell-cycle, apoptosis and immunophenotyping assays, study FACS sorting logic and viability checks, and finish with a hands-on run of a four-colour immunophenotyping panel.	3 hours
III	**Live-Cell Imaging** This unit covers phase-contrast, DIC and fluorescence time-lapse microscopy, stressing environmental control through on-stage incubators and microfluidic perfusion. Students deploy fluorescent reporters such as GFP fusions and calcium biosensors to track motility, division and signalling, learn to minimise phototoxicity and manage large image datasets, then conduct a 12-hour GFP-cell time-lapse demo.	3 hours
IV	**Single-Cell RNA-Seq & Multi-Omics** Participants examine single-cell isolation by droplets, microwells or FACS, walk through barcoding, library preparation and sequencing, and run a basic bioinformatics pipeline for quality control, normalisation, clustering and UMAP/t-SNE visualisation. They identify cell types, trajectories and rare populations, glimpse CITE-seq and spatial transcriptomics, and explore a public scRNA-seq dataset in R/Python during a workshop.	3 hours
V	**Advanced Fluorescence & Super-Resolution Microscopy** Confocal and two-photon fundamentals, followed by super-resolution strategies—STED, SIM and PALM/STORM—plus functional techniques such as FRET, FRAP and FLIM for probing protein interactions and dynamics. Learners plan multiplexed staining with spectral imaging, discuss clinical applications including FISH and diagnostic immunofluorescence, and acquire and process a confocal z-stack in a practical sessions.	3 hours

Recommended References *(Preferably latest edition)*:

1. Brown TA. Gene Cloning and DNA Analysis: An Introduction. 8th ed. Hoboken: Wiley-Blackwell; 2023.
2. Ormerod MG. Flow Cytometry: A Practical Approach. 4th ed. Oxford: Oxford University Press; 2014.
3. Goldman RD, Swedlow JR, editors. Live Cell Imaging: A Laboratory Manual. 2nd ed. Cold Spring Harbor: CSHL Press; 2010.
4. Tang F, Van Oudenaarden A, editors. Single-Cell RNA Sequencing: Methods and Protocols. 2nd ed. New York: Humana Press; 2021.

Course Code	Course Title			Course Type
BP708T AEC4	**Medical Devices (Theory)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	1	--	--	15

Maximum Marks	SE	ESE
50	20	30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand the Evolution and Regulatory Landscape: Gain insights into the history, market trends, and regulatory frameworks governing medical devices in India and globally.
2. Master Design and Biocompatibility Principles: Learn the principles of medical device design, selection of materials, and the importance of biocompatibility in device development.
3. Implement Quality Systems in Manufacturing: Understand the application of Good Manufacturing Practices (GMP), quality assurance, and risk management in medical device production.
4. Navigate Regulatory Affairs for Global Market Access: Acquire knowledge of regulatory requirements and strategies for medical device approval and post-market surveillance in various regions.
5. Explore Emerging Technologies in Biomedical Engineering: Investigate the integration of electronics, sensors, and software in medical devices, and address ethical considerations in their development and use.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Analyze Market Trends and Regulatory Policies: Assess the evolution of the medical device industry and the impact of regulatory frameworks on market dynamics across regions.
2	Design Safe, Effective, and Compliant Medical Devices: Apply design principles, emerging technologies (sensors, electronics, software), and appropriate biomaterials to develop medical devices that ensure safety, efficacy, biocompatibility, and functionality.
3	Implement Quality and Risk Management Systems: Apply ISO 13485 standards, risk management processes, and ethical principles to ensure quality, safety, and responsible device development.
4	Navigate Global Regulatory Pathways: Understand and apply regulatory approval processes for medical devices in India, the US, the EU, and other regions.
5	Develop Post-Market Surveillance Strategies: Design and implement strategies to monitor performance, safety, and compliance of medical devices after market launch.

Detailed Syllabus

Unit No.	Topics	No. of Lectures
I	**Introduction to Medical Devices:** History and Overview of Medical Device Industry and evolving market Trends 1. (India + WW) 2. GOI's initiatives and National Medical Device Policy. 3. Regulatory frameworks (CDSCO; State FDA; USFDA; EU-CE, etc.) 4. Medical device design and development process 5. Definition and Classification of Medical Devices (India; US; EU)	3 hours
II	**Medical Device Design, Biomaterials and Biocompatibility:** 1. Medical Device Design principles and methodologies, safety analysis 2. Properties and selection of materials & biomaterials for devices 3. Tissue engineering and regenerative medicine 4. Biocompatibility Testing and Standards (ISO 10993)	3 hours
III	**Manufacturing and Quality Systems: (based on ISO 13485 Fifth Sch of IMDR 2017)** 1. Good Manufacturing Practices (GMP) & Infrastructure requirements 2. Quality assurance and quality control in Medical Devices 3. Supply chain management (warehousing distribution) 4. Risk Management (ISO 14971)	3 hours
IV	**Regulatory Affairs, Regulatory strategies for global market access** 1. Medical device regulations and standards (IMDR 2017) 2. Understanding Regional Differences in Regulatory Pathways 3. Regulatory submissions and approvals (India) 4. Post-market surveillance and vigilance (India) 5. Global Regulatory Requirements (USFDA, CE Mark, etc.) 6. Case Studies of Global Regulatory Challenges	3 hours
V	**Biomedical Engineering; Instrumentation: Emerging Technologies** 1. Principles of biomedical sensors and transducers 2. Medical imaging techniques (X-ray, CT, MRI, ultrasound) 3. Telemedicine and remote monitoring 4. Integration of Electronics and Software in Medical Devices 5. Wearable Devices and Remote Monitoring 6. Ethical issues in device development and use	3 hours

Recommended References *(Preferably latest edition)*:

1. Ramakrishna, S., Mayer, J., Wintermantel, E., Leong, K. W. Biomedical Materials and Devices. Springer, Singapore.
2. Enderle, J. D., Bronzino, J. D., Blanchard, S. M. Introduction to Biomedical Engineering. Academic Press (Elsevier).

3. Bronzino, J. D., Peterson, D. R. (Eds.) The Biomedical Engineering Handbook. CRC Press, Taylor & Francis.
4. Ratner, B. D., Hoffman, A. S., Schoen, F. J., Lemons, J. E. Biomaterials Science: An Introduction to Materials in Medicine. Academic Press (Elsevier).
5. Walsh, S. T. Medical Device Technologies: A Systems Based Overview Using Engineering Standards. Academic Press (Elsevier).
6. FDA / CDSCO. Medical Device Regulations and Regulatory Affairs. Government Publications (USFDA / Government of India).
7. Sharma, S. K. Medical Device Design and Development. McGraw-Hill Education.
8. Bhat, S., Kotian, S. Biomedical Instrumentation. PHI Learning Pvt. Ltd.
9. Webster, J. G. (Ed.) Medical Instrumentation: Application and Design. Wiley India.
10. ISO / BIS. Quality Management Systems for Medical Devices (ISO 13485 & ISO 14971). International Organization for Standardization.
11. Fitzpatrick, R., et al. Ethics and Regulation of Medical Devices. Oxford University Press.
12. Panchal, H., Patel, D. Regulatory Affairs for Medical Devices. PharmaMed Press.

Course Code	Course Title			Course Type
BP708T AEC5	**Transformation of Food Waste into Medicinal Products (Theory)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	1	--	--	15
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Explain the sources, environmental impacts, and regulatory aspects of food waste.
2. Describe sustainable principles and technologies used in food waste management.
3. Explore methods for converting food waste into value-added products.
4. Discuss the recovery of bioactive compounds from food waste and their potential applications.
5. Introduce the use of artificial intelligence and digital technologies in food waste management and resource optimization.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Identify types, sources, impacts, and regulations related to food waste.
2	Apply principles and sustainable technologies for effective food waste management.
3	Explain the conversion of food waste into biofuels, biopolymers, and other value-added products.
4	Assess bioactive compounds derived from food waste and their industrial and health applications.
5	Understand the role of AI, IoT, and blockchain in smart food waste management systems.

Detailed Syllabus

Unit No.	Topics	No. of Lectures
I	**Introduction to Food Waste** Food waste: Definition, Types, Sources, Causes, Problems, Impacts Advantages, Challenges, Solutions and Future directions Indian and International regulations for food waste management	3 hours
II	**Sustainable Management of Food Waste** Principles of Food waste Management Technologies and Processes: Thermo-chemical Processes, Biological Processes, Green extraction, Pyrolytic and Enzymatic techniques	4 hours
III	**Byproducts from Food Waste** Production of Biohydrogen, Biogas, Organic acids, Vermicompost, and Biopolymers	3 hours
IV	**Bioactive Compounds from Food Waste** Antimicrobial, Antioxidants, Anti-inflammatory agents, Antibiotics, Prebiotics, Nutritional Supplements, Cosmetics and Biopolymers 3D printed medicines: Customized dosages and Scaffolds	3 hours
V	**Role of AI in Food waste management** Machine learning, Internet of Things (IoT) and Blockchain	2 hours

Recommended References *(Preferably latest edition)*:

1. Ranjna Sirohi et al., 2025. Sustainable Technologies for Food Waste Management. Taylor and Francis Group.
2. Monika Thakur et al., 2020. Sustainable Food Waste Mangement: Concepts and Innovations. Ist ed., Springer.
3. Arvanitoyannis, 2013. Waste management for food industries. Food Science and Technology International series.

Course Code	Course Title			Course Type
BP708T AEC6	**Bio-similars, Vaccines and Macromolecule Sciences (Theory)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	1	--	--	15
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Introduce the fundamental concepts of biological macromolecules, biosimilars, and modern vaccine technologies used in pharmaceutical biotechnology.
2. Explain the physicochemical and functional characterization methods used for the analysis and comparability assessment of biologics and biosimilars.
3. Develop understanding of upstream and downstream manufacturing processes involved in the production of biopharmaceuticals and vaccines.
4. Describe quality control, stability testing, and immunogenicity assessment procedures applied to biologics and vaccine products.
5. Familiarize students with regulatory frameworks and approval pathways governing biosimilars and vaccines in India and global markets.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Describe the structure and therapeutic roles of biological macromolecules, biosimilars and vaccines.
2	Apply analytical methodologies for characterization and bioequivalence assessment.
3	Understand upstream and downstream processing and formulation protocols.
4	Understand quality control, stability testing, and immunogenicity assessment methods used for ensuring the safety and efficacy of biologics and vaccines.
5	Assess regulatory compliance requirements across the product lifecycle.

Detailed Syllabus

Unit No.	Topics	No. of Lectures
I	**Introduction to Biosimilars, Vaccines and Macromolecules** • Classes: Monoclonal antibodies (mAbs), cytokines, insulin, growth factors; primary/secondary/tertiary structures. • Biosimilars: Definition, rationale, types (e.g., erythropoietin, filgrastim). • Vaccines: Generations (live, subunit, viral vector, mRNA); adjuvants and delivery systems.	3 hours

	• Industry landscape: Blockbuster biologics (Humira, Keytruda), Indian biosimilar market.	
II	**Characterization Methodologies** • Physicochemical: SDS-PAGE, SEC-HPLC, peptide mapping, mass spectrometry. • Glycosylation analysis: N-linked glycans (HILIC, lectin arrays). • Functional assays: Cell-based potency, binding ELISA, ADCC. • Comparability for biosimilars: Fingerprinting (ICH Q5E).	3 hours
III	**Manufacturing Protocols** • Upstream: Cell line development (CHO, HEK), bioreactors, media optimization. • Downstream: Harvesting, chromatography (affinity, ion-exchange), viral clearance. • Fill-finish: Lyophilization, aseptic processing, cold chain. • Process analytical technology (PAT) in biologics.	3 hours
IV	**Quality Control and Stability Protocols** • Release testing: Host cell proteins (HCP), DNA, sterility, endotoxin (LAL). • Stability: ICH Q5C for biologics; subvisible particles, aggregation. • Immunogenicity assessment: ADA assays, neutralizing antibodies. • Vaccine QC: Potency, identity, safety (animal models).	3 hours
V	**Regulatory Compliances and Case Studies** • Global: USFDA 351(k) biosimilar pathway, EMA guidelines, WHO prequalification. • India: CDSCO Biosimilar Guidelines 2021, DCGI vaccine approvals. • Documentation: BLA/CMC modules, PK/PD comparability studies. • Case studies: COVID-19 mRNA vaccines (Pfizer), Indian trastuzumab biosimilars.	3 hours

Recommended References *(Preferably latest edition)*:

1. Genomic and Precision Medicine by Geoffrey S. Ginsburg & Huntington F. Willard
2. Genomics and Personalized Medicine by Michael Snyder
3. Deep Medicine by Eric Topol

Course Code	Course Title			Course Type
BP708T AEC7	**Precision Medicine (Theory)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	1	--	--	15
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Introduce the fundamental concepts, scope, and evolution of precision medicine and its relevance to modern pharmacy practice.
2. Provide an understanding of pharmacogenomics and the role of genetic variability in drug response, safety, and efficacy.
3. Explain the importance of biomarkers, targeted therapies, and companion diagnostics in personalized treatment strategies.
4. Introduce the emerging technologies such as artificial intelligence, big data analytics, and electronic health records in precision medicine.
5. Develop awareness of regulatory frameworks, ethical considerations, and clinical implementation challenges associated with genomic-based therapies.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Define precision medicine and explain its evolution from conventional therapy to personalized healthcare approaches, highlighting the role of pharmacists and interdisciplinary collaboration.
2	Describe basic human genetics and pharmacogenomic principles, and interpret genotype–phenotype relationships affecting drug response and adverse drug reactions.
3	Analyze the role of genetic polymorphisms (e.g., CYP450 enzymes) and utilize pharmacogenomic resources and databases such as PharmGKB and CPIC in clinical decision-making.
4	Classify biomarkers and evaluate their role in targeted therapies and companion diagnostics, with reference to real-world clinical case studies as targeted nanocarriers, antibody–drug conjugates, and smart delivery systems
5	Define precision medicine and explain its evolution from conventional therapy to personalized healthcare approaches, highlighting the role of pharmacists and interdisciplinary collaboration.

Detailed Syllabus

Unit No.	Topics	No. of Lectures
I	**Introduction to Precision Medicine and Its Relevance to Pharmacy** Definition and scope of precision medicine Evolution from "one-size-fits-all" to personalized approaches Key components: genomics, epigenetics, environmental factors, lifestyle Role of pharmacists in precision medicine Interdisciplinary nature (clinicians, bioinformaticians, pharmacologists)	3 hours
II	**Pharmacogenomics in Drug Response and Safety** Basic human genetics relevant to pharmacy Genotype-phenotype relationships Genetic polymorphisms: CYP450 enzymes (CYP2D6, CYP2C9, etc.) FDA drug labelling and pharmacogenomic biomarkers Tools/databases: AlphaGenome, PharmGKB, CPIC, SNPedia	3 hours
III	**Biomarkers, Targeted Therapy, and Companion Diagnostics** Types of biomarkers: predictive, prognostic, diagnostic Role of biomarkers in targeted therapy Companion diagnostics: regulatory approval and clinical application Case study: Trastuzumab and HER2 testing in breast cancer Lab-on-chip and biosensor technologies Targeted nano-delivery in oncology Antibody-drug conjugates (ADCs) Smart delivery systems (stimuli-responsive biosensors)	4 hours
IV	**Technology, AI, and Big Data in Precision Medicine** Role of AI, machine learning, and data analytics in precision medicine Electronic Health Records (EHRs), clinical decision support systems Integration of genomic data with patient profiles Examples of AI-driven drug discovery Data security and interoperability	2 hours
V	**Regulatory, Ethical, and Clinical Implementation** Regulatory guidelines (US FDA, EMA, CDSCO) for genomic-based therapies Clinical trial design for precision drugs Cost-effectiveness and access in low-resource settings Ethical issues: genetic testing, informed consent, data ownership Future of pharmacy practice in the precision medicine era	3 hours

Recommended References *(Preferably latest edition)*:

1. Genomic and Precision Medicine (3rd Edition) by Geoffrey S. Ginsburg & Huntington F. Willard
2. Genomics and Personalized Medicine by Michael Snyder
3. Deep Medicine by Eric Topol

SEMESTER VIII

Course Code	Course Title			Course Type
BP806T AEC1	**Pharmaceutical Packaging (Theory)**			Elective
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:

1. Provide students with a comprehensive understanding of pharmaceutical packaging, its principles, materials, processes, and regulatory aspects.
2. Equip students with knowledge of the selection, design, and development of packaging materials for various dosage forms.
3. Educate students on the interaction between packaging and formulation, quality control, and advances in pharmaceutical packaging.
4. Train students in assessing packaging materials for pharmaceutical products in compliance with regulatory guidelines.
5. Prepare students for future roles in pharmaceutical manufacturing, quality assurance, and packaging development.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Understand the purpose and function of packaging in pharmaceuticals, including primary, secondary, and tertiary packaging.
2	Identify and evaluate the materials used in pharmaceutical packaging and their interactions with dosage forms.
3	Design and select appropriate packaging materials during product development.
4	Apply quality control and regulatory principles to packaging processes.
5	Recognize advancements in packaging technology, including child-resistant packaging, tamper-evident packaging, and automation.

Detailed Syllabus

Unit No.	Topics	No. of Lectures
I	**General Information on Packaging** 1. Introduction: Purpose of packaging, selection of the ideal package (primary, secondary and tertiary), hazards encountered by the package, various types of inner and outer packages, selection of a suitable package.	6 hours

	2. Packaging materials: Detailed study with regard to composition packaging characteristics, advantages, economics and limitations of various packaging materials with special emphasis on glass, plastics, metals and rubber. 3. Child resistant package, Tamper Evident Packaging, Anti-Counterfeit Packaging, Environmental considerations of packaging (Recycling).	
II	**Pharmaceutical Packaging – Design and Development** 1. Selection and Design of Packaging during Product Development Process (Parameters). 2. Packaging Process: Significance of Strip, Blister, Pouch Packaging, advantages, economics and limitation, Packing machinery and recent advances, films employed in Packing (Video based learning).	6 hours
III	**Formulation Packaging Interaction** 1. Polymer Chemistry Science and Stability Aspects 2. Extractable and Leachables 3. Methods to study formulation packaging interaction 4. Suitability considerations for pharmaceutical packaging	6 hours
IV	**Quality Assurance, Control and Regulatory Aspects** 1. Total Quality management, Good Manufacturing Practice, Quality Risk Management related to Packaging Department, Specification Testing and Shelf-life testing as per Pharmacopoeial Guidelines for Packaging Material in-process and finished Package Products. 2. Standard Operating Procedures (SOPs)/Documentation for Solid/Semi-Solid/Liquid/Parenteral Formulation Packaging. Packaging waste and Waste policies for packaging materials,	6 hours
V	**Advances in Pharmaceutical Packaging** 1. Labelling- Types of label (including Bar code, Hologram, RF, structured program, in- mould and decorative labelling) – Use of Software, Legal requirements of Labelling, packaging inserts and outserts. Adhesives and Machinery Employed for Labelling - Pharmacy Accessory Label Printers (PALP), Concept of paperless labelling 2. Logistics Packaging - Block Chain Technology in Supply Traceability, Transparency and Credibility. Review on Automated Packaging System for Oral Solids (Auto-Print), Oral Liquid (Fluidose), and overwrapping (PABS).	6 hours

Recommended References *(Preferably latest edition)*:

1. Brody, A. L., Marsh, K. S. The Wiley Encyclopedia of Packaging Technology. John Wiley & Sons, New York, USA.
2. Lachman, L., Lieberman, H. A., Kanig, J. L. The Theory and Practice of Industrial Pharmacy. Lea & Febiger, Philadelphia, USA.
3. KacChesney, T. C. Packaging of Cosmetics and Toiletries. Newness-Butterworth, London, UK.
4. Allen, L. V. Jr. Remington: The Science and Practice of Pharmacy. Mack Publishing Company, Easton, USA.
5. Bauer, E. J. Pharmaceutical Packaging Handbook. CRC Press / Informa Healthcare Ltd, USA.

6. Dean, D. A., Evans, E. R., Hall, I. H. (Eds.) Pharmaceutical Packaging Technology. CRC Press, USA.
7. Lockhart, H., Paine, F. A. Packaging of Pharmaceuticals & Healthcare Products. Chapman & Hall, UK.
8. Harburn, K. Quality Control of Packaging Materials in the Pharmaceutical Industry. CRC Press, USA.

Course Code	Course Title			Course Type
BP806T AEC2	**Supply Chain Management (Theory)**			Elective
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. Understand and apply key SCM concepts and frameworks.
2. Analyze and optimize supply chain processes using industry-standard models.
3. Evaluate the impact of digital technologies and sustainability on supply chains.
4. Develop strategies for risk management and resilience in supply chains.
5. Implement best practices for procurement, logistics, and inventory management.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Analyze and design efficient supply chains.
2	Implement effective procurement and supplier management strategies.
3	Optimize logistics and distribution networks
4	Leverage technology for supply chain innovation.
5	Develop sustainable and resilient supply chain practices and importance of cold chain management.

Detailed Syllabus

Unit No.	Topics	No. of Lectures
I	**Introduction to Supply Chain Management** ○ Introduction to SCM: Definition, scope, Importance of SCM, in global business, Key components and stakeholders, Supply Chain Strategies, Process and barriers of supply chain management. ○ Supply Chain Models: SCOR Model (Plan, Source, Make, Deliver, Return) CSCMP Supply Chain Process Standards. ○ Supply Chain Network Design, Facility location and layout, Transportation planning. ○ Supply Chain Performance Metrics, Key Performance Indicators (KPIs) ○ Performance measurement tools ○ Case Study: SCM in Practice with Real-world examples	6 hours

II	**Procurement and Supplier Management** o Procurement Fundamentals, Role of procurement in SCM, sourcing strategies o Supplier selection criteria, supplier performance evaluation, Collaboration and communication. o Global Sourcing, Challenges and opportunities, Cultural considerations, Legal and ethical issues o E-Procurement, Electronic procurement systems, Benefits and challenges o Case Study: Procurement Excellence, Best practices.	6 hours
III	**Logistics and Distribution Management** o Logistics Fundamentals, Definition and scope, Importance in SCM o Transportation Management, Modes of transportation, Routing and scheduling, Freight cost analysis o Inventory Management of pharmaceuticals, Inventory types and functions, Inventory control techniques, Economic Order Quantity (EOQ) o Introduction to warehouse functions, Management and Distribution channels and distribution strategies for vaccines and biologicals. o Case Study: Logistics and transportation Optimization process, Knowledge and skill sets needed for optimization.	6 hours
IV	**Technology and Innovation in SCM** o Information Technology in SCM, Role of IT in SCM planning and operations management for pharmaceuticals. o Enterprise Resource Planning (ERP) systems, operations 6system, Supply Chain Management Softwares. o Big Data and Analytics, Importance of data in SCM. o Artificial Intelligence and Machine Learning, AI/ML applications in SCM, smart logistics. o Demand forecasting, Autonomous vehicles o Security and transparency with special emphasis to cybersecurity.	6 hours
V	**Sustainability and Risk Management in SCM** o Sustainable Supply Chain Management, Green logistics, Circular economy Environmental impact assessment. o Ethical Sourcing, Fair trade practices, Labor standards, Supplier audits. o Risk Management in SCM, Risk identification and assessment, Risk mitigation strategies, Crisis management with special emphasis to Pharmaceutical products. o Regulatory Compliance, International trade regulations, Customs and import/export laws, Compliance standards. o Cold chain management, its need, challenges and opportunities in Pharmaceutical products. o Case Study: Risk and Sustainability Challenges	6 hours

Recommended References *(Preferably latest edition)*:

1. Chopra, S., & Meindl, P. (2019). Supply Chain Management: Strategy, Planning, and Operation (7th ed.). Pearson.
2. Christopher, M. (2016). Logistics & Supply Chain Management (5th ed.). Pearson.
3. Lambert, D. M., & Cooper, M. C. (2000). Issues in Supply Chain Management. Industrial Marketing Management, 29(1), 65-83.
4. Coyle, Bardi, Longley, The Management of Business Logistics- A Supply Chain Perspective, Thompson Press, 2006.

Course Code	Course Title			Course Type
BP806T AEC3	**Industrial Safety and Waste Management (Theory)**			Elective
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. Explain the principles of industrial safety and accident prevention in pharmaceutical industries.
2. Analyze workplace hazards and apply risk management strategies for ensuring safe industrial operations.
3. Describe the types of industrial waste generated in pharmaceutical industries and their environmental impacts.
4. Familiarize students with waste treatment technologies and regulatory frameworks governing industrial waste management.
5. Promote understanding of sustainable waste management practices in accordance with national and international environmental standards.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Identify hazards in industrial settings and apply preventive safety measures.
2	Conduct risk assessments and implement control strategies for workplace safety.
3	Classify and manage different types of industrial waste generated in pharmaceutical sectors.
4	Apply suitable treatment and disposal methods for hazardous and non-hazardous waste.
5	Interpret and follow safety and environmental regulations applicable to industrial practices.

Detailed Syllabus

Unit No.	Topics	No. of Lectures
I	**Introduction to Industrial Safety** • Importance of industrial safety in pharmaceutical and chemical industries • Types of industrial hazards: physical, chemical, biological, mechanical, electrical • Accident prevention techniques • Safety signs, symbols, and personal protective equipment (PPE)	6 hours

	• OSHA guidelines and ISO safety standards	
II	**Risk Assessment and Hazard Management** • Hazard identification methods (HAZOP, FMEA) • Risk analysis and evaluation • Safety audit and checklist • Fire hazards and fire-fighting systems • Role of safety officer and disaster management planning	6 hours
III	**Waste Management – Fundamentals** • Classification of industrial waste: hazardous, non-hazardous, solid, liquid • Sources of pharmaceutical and chemical waste • Waste minimization strategies • Recycling, reuse, and resource recovery Environmental impact assessment (EIA) basics	6 hours
IV	**Waste Treatment Technologies** • Physical, chemical, and biological methods of waste treatment • Treatment of effluents, emissions, and solid waste • Common Effluent Treatment Plants (CETP) • Biomedical waste disposal and rules (BMW Rules – India) • Guidelines from CPCB, WHO, and MOEFCC	6 hours
V	**Regulatory and Sustainable Practices** • Environmental Protection Act, Factories Act, Hazardous Waste Rules • Good Manufacturing Practices (GMP) related to waste and safety • International guidelines: US EPA, EU regulations, WHO • Sustainable development goals (SDGs) related to waste and health • Case studies of safe and green pharma manufacturing	6 hours

Recommended References *(Preferably latest edition)*:

1. Industrial Safety Management by L.M. Deshmukh, McGraw-Hill Education
2. Waste Management Practices: Municipal, Hazardous, and Industrial by John Pichtel, CRC Press
3. Safety, Health and Environment for Engineers and Scientists by Michel W. First, John Wiley & Sons
4. Industrial Waste Management Handbook by Kanti L. Shah, McGraw-Hill Education
5. Biomedical Waste Management in India by Sunil Kumar, Elsevier

Course Code	Course Title			Course Type
BP806T AEC4	**Traditional Healing Practices of India (Theory)**			Elective
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 historical background of Indian traditional medicine systems.
2. Explain the core principles and diagnostic approaches of Ayurveda, Siddha, Unani, Naturopathy, and Homeopathy.
3. Examine tribal and folk healing traditions and their role in community healthcare practices.
4. Explore the cultural, spiritual, and religious dimensions associated with traditional healing systems.
5. Promote understanding of the scientific validation and policy-level integration of traditional medical knowledge.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Understand the foundational concepts and history of traditional healing systems in India.
2	Explore the various regional healing practices and their sociocultural relevance.
3	Analyse the integration of traditional and modern healthcare systems.
4	Develop a critical appreciation of indigenous knowledge systems in health and healing.
5	Encourage scientific validation and policy-level integration of traditional health knowledge

Detailed Syllabus

Unit No.	Topics	No. of Lectures
I	Introduction to Traditional Medicine, Definition and scope of traditional healing Historical evolution of traditional medicine in India Indigenous knowledge systems and oral traditions Health and disease in Indian philosophical thought Integrating Traditional Healing with Modern Medicine What is a traditional healing practice. Traditional healing practice in India. Socio-Scientific Validation and Knowledge Integration Preservation of Socio-Cultural Health Knowledge Ethnoveterinary Empowerment and Rural Health Equity	6 hours
II	Basic principles: Ayurveda, Panchamahabhuta, Tridosha, Dhatu, Mala Diagnosis and treatment: Pulse diagnosis, Panchakarma, Rasayana, Nadi Parikshan, Marma therapy, Chiropathic treatment, Materia medica (Dravyaguna) and formulation (Rasa Shastra) Current relevance and institutionalization (AYUSH) The study seeks to integrate traditional healing practices into contemporary healthcare systems. Contemporary usage and debates Fostering Transdisciplinary Collaboration Economic Viability and Grassroots Entrepreneurship	6 hours
III	**Siddha and Unani Systems**: Siddha: Origin, principles, and therapeutic techniques Unani: Greek-Arabic foundations, four humors, pharmacopoeia Role in South Indian and Indo-Islamic medical heritage Role of traditional healing practice in homeopathy and naturopathy Role of traditional healing practice in homeopathy and naturopathy Development and acceptance in India Role of traditional healing practice in homeopathy and naturopathy Development and acceptance in India	6 hours
IV	**Folk and Tribal Healing Practices:** Holistic approach to the traditional system, natural methods of healing practices, and cultural significance of the traditional system of medicine. Difference between Indian traditional system of medicine and traditional Chinese medicinal system. Regional practices: Snake stones, ritual healing, herbal knowledge Role of healers: Vaidya, Ojha, Bhopa, Bonesetters, Dai (traditional midwives) Ethnomedicine and ethnobotany: Case studies from North East of India, Chhattisgarh, Himalaya etc. Multidisciplinary longitudinal study to comprehensively document, scientifically validate, and integrate traditional healing systems	6 hours
V	**Spiritual and Religious Healing:** Role of Yoga, Pranayama, and meditation Healing through Mantras, rituals, and astrology	6 hours

	Use of temples and sacred groves in mental health and well-being Computational studies will complement laboratory investigations by revealing molecular interactions and mechanisms of action, thereby providing scientific rigor to traditional claims. Legal and policy frameworks (AYUSH, WHO recognition) Role of NGOs and community health programs Challenges in validation, standardization, and commercialization Case studies of integration in rural/urban healthcare Protection of Intellectual Property and Cultural Sovereignty Documentation of Indigenous Knowledge System (IKS). Prevention of the Traditional system of medicine.	

Recommended References *(Preferably latest edition)*:

1. The Roots of Ayurveda: Selections from Sanskrit Medical Writings – Dominik Wujastyk, Penguin Classics
2. Indian Medicine in the Classical Age – D. N. Jha, Munshiram Manoharlal Publishers
3. A History of Indian Medical Literature – Gerrit Jan Meulenbeld, Egbert Forsten Publishing
4. The Ayurveda Encyclopedia: Natural Secrets to Healing, Prevention, and Longevity – Swami Sadashiva Tirtha, Ayurvedic Holistic Center Press
5. The Science of Medicine and Surgery in Ancient India – K. R. Srikantha Murthy, Chaukhambha Orientalia
6. Traditional Knowledge System in India – Kapil Kapoor, Indian Institute of Advanced Study
7. Folk Medicine and Culture in Tribal India – P. C. Joshi, Rawat Publications
8. Encyclopaedia of Indian Medicine: Volumes on Ayurveda, Siddha, Unani & Folk Traditions – K. L. Sharma, Deep & Deep Publications

Course Code	Course Title			Course Type
BP806T AEC5	**Futuristic Pharma Through Augmented Reality and Virtual Reality (AR/VR): Pharma 4.0 (Theory)**			Elective
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 of Augmented Reality (AR) and Virtual Reality (VR) technologies and their applications in the pharmaceutical sector.
2. Provide hands-on exposure to AR/VR tools used in pharmaceutical manufacturing, training, simulation, and patient education.
3. Develop skills in utilizing immersive technologies for pharmaceutical research, formulation development, and scientific communication.
4. Explore the integration of Pharma 4.0 technologies, including AI, IoT, and AR/VR, in smart pharmaceutical manufacturing and regulatory compliance.
5. Familiarize students with emerging immersive solutions in the pharmaceutical industry that support quality assurance, training, and regulatory standards.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Explain the core principles of Pharma 4.0 and distinguish immersive technologies (AR, VR, MR, XR) and their components relevant to pharmaceutical applications.
2	Demonstrate hands-on proficiency in using AR/VR hardware and software tools to create basic immersive pharmaceutical experiences.
3	Apply AR/VR technologies in drug discovery, molecular modeling, and collaborative virtual research environments.
4	Design AR/VR training simulations and SOP overlays for pharmaceutical manufacturing, GMP practices, and quality control.
5	Develop and present immersive pharma solutions that meet compliance standards, validation protocols, and Pharma 4.0 integration needs.

Detailed Syllabus

Unit No.	Topics	Hours
I	**Introduction to AR/VR and Tools** 1. Understanding AR and VR: Concepts, Tools, and Devices	6 hours

	• Hands-on demo of Google Cardboard, Oculus, or similar headsets • Difference between AR, VR, and Mixed Reality (MR) 2. Exploring AR/VR Platforms for Life Sciences • Overview of software: Unity 3D, Vuforia, WebAR, JigSpace, ARKit • Demo of existing pharma-related AR/VR apps (e.g., Human Anatomy VR)	
II	**AR/VR in Pharmaceutical Education and Training** • Use of apps for visualizing drug-receptor interaction • Virtual dissection and interactive physiology • Simulated tablet compression and coating machines • Training modules on aseptic techniques using VR • Counseling Patients in a Virtual Pharmacy Setup • Use of avatars and scenarios for OTC counseling, prescription explanation • Emphasis on communication and empathy in virtual settings	6 hours
III	**AR/VR in Manufacturing and Pharma 4.0** Digital Twin Concept & Virtual Plant Walkthrough • Create mock layouts of pharma production plants in AR • Navigate a cleanroom and observe equipment placement virtually Smart Maintenance and SOP Training via AR Integrating AR with Sensors and QR-based Inventory • Real-world temperature/humidity sensors • Live monitoring of warehousing systems Pharma 4.0 Compliance and Regulatory Perspectives • Virtual audit readiness • Documentation and equipment validation trails using AR mock-ups	6 hours
IV	**AR/VR for Patient-Centric Applications** Patient Leaflets and Drug Delivery Tutorials • Creating content showing how to use inhalers, injectables, or devices • Overlay content on medicine boxes or instruction cards AR/VR for Mental Health, Pain, and Rehabilitation Therapy • Case studies: VR for phobia therapy, chronic pain, relaxation therapy Digital Adherence Tools with AR Guidance • Real-time AR reminders linked to prescription schedules • AI avatars for personalized patient nudges	6 hours
V	**Project-Based Integration and Evaluation** Mini Project: Create an AR/VR-Based Solution • Example: VR tour of GMP plant, AR-based patient education module • Demo Unity or online tools like CoSpaces / ZapWorks	6 hours

Recommended References *(Preferably latest edition)*:

1. Schmalstieg D, Hollerer T. Augmented Reality: Principles and Practice. 1st ed. Boston: Addison-Wesley Professional; 2016.
2. Craig AB. Understanding Augmented Reality: Concepts and Applications. 2nd ed. Burlington: Morgan Kaufmann; 2018.
3. Umeda B, Thompson KK, editors. Virtual and Augmented Reality in Medical and Pharmaceutical Applications. 1st ed. Cambridge: Elsevier; 2022.
4. Huang Y, Jiang P, editors. Digital Twin-Driven Smart Manufacturing. 1st ed. Amsterdam: Elsevier; 2020.

Course Code	Course Title			Course Type
BP806T AEC6	**Herbal Cosmetics for Industry Perspectives (Theory)**			Elective
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 fundamentals of the herbal cosmetics industry and its scope in the global market.
2. Develop an entrepreneurial mindset for innovation and business development in herbal cosmetic products.
3. Build competence in financial planning, business management, and marketing strategies relevant to herbal cosmetic enterprises.
4. Familiarize students with legal and regulatory frameworks governing the manufacture and marketing of herbal cosmetic products.
5. Develop skills in quality assurance, safety evaluation, and standardization of herbal cosmetic formulations.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Know about the materials, capital and infrastructural requirements along with understanding the fundamentals of Entrepreneurship
2	Understand the specifications and importance of adhering to Good Manufacturing Practices (GMP)
3	Know the guidelines and testing requirements for ensuring quality and safety of herbal cosmetics.
4	Acquire knowledge about legal and regulatory requirements for manufacturing and import of herbal cosmetics. Also the labelling requirements and regulations for advertising. With emphasis on the Drugs and Cosmetics Act (1940) and rules (1945) of India. Along with the regulatory approval process and their registration in Indian and international markets.
5	Know about the materials, capital and infrastructural requirements along with understanding the fundamentals of Entrepreneurship

Detailed Syllabus

Unit No.	Topics	No. of Lectures
I	**Introduction to the requirements for an herbal cosmetics industry** Market trends, worldwide trade and consumer demand for herbal cosmetics. Advantages and challenges of the herbal cosmetics industry. Requirements for factory location, premises, plant layout and infrastructure and materials.	6 hours
II	**Fundamentals of Entrepreneurship** Characteristics and skills of successful entrepreneurs. Types of entrepreneurship: product, process, and quality testing entrepreneurship. Developing Entrepreneurial mind-set. Case studies Success Stories of some successful herbal cosmetic brands (e.g., Forest Essentials, Biotique, Khadi Naturals) **Steps involved in setting up a start-up:** • Identifying gaps in the herbal cosmetics market • Business plan development for a herbal cosmetic product • SWOT analysis for herbal cosmetics start-ups • Technical, financial, and market feasibility study • Planning for scalability and sustainability	6 hours
III	**Financial Management and Marketing Strategies** Budgeting and cost estimation. Sources of finance: loans, grants, angel investors, venture capital. Government schemes (STARTUP INDIA) and support for MSMEs and herbal industries. Overview on branding essentials – positioning and brand identity. Distribution channels: retail, e-commerce, exports. Digital marketing: social media, Search Engine Optimization (SEO) influencer marketing	6 hours
IV	**Legal and Regulatory Framework** Licensing and registration for herbal cosmetics as per the Drugs and Cosmetics Act (1940) and rules (1945) of India. The role of CDSCO, AYUSH ministry, FSSAI, ISO, GMP in the herbal cosmetics industry Labelling and packaging norms (Schedule S and role of Bureau of Indian Standards –BIS) Advertising regulation for herbal cosmetics IP rights: patents, trademarks, and protection of herbal knowledge	8 hours
V	**Quality and safety evaluation of herbal cosmetics** Importance of quality assurance in herbal cosmetics. Key safety concerns (contamination, allergens, microbial growth). Quality evaluation of herbal raw material. **Product-Specific Quality Parameters -** Quality standards for creams, lotions, shampoos, oils, face packs, etc. Specific marker compounds and their quantification in herbal products. **Toxicological and Safety Evaluation:** *In vitro* and *in vivo* safety testing (skin irritation, sensitization, eye irritation). Patch testing, Draize test, and OECD	4 hours

	guidelines. Use of alternative non-animal testing methods (3D skin models, in silico models)	

Recommended References *(Preferably latest edition)*:

1. Barel, A. O., Paye, M., Maibach, H. I. (Eds.) Handbook of Cosmetic Science and Technology. CRC Press, Taylor & Francis.
2. Nema, R. K., Rathore, K. S. Herbal Cosmetics: Formulation, Characterization and Standardization. CBS Publishers & Distributors, New Delhi, India.
3. Mitsui, T. (Ed.) New Cosmetic Science. Elsevier Science, Amsterdam, Netherlands.
4. Barel, A. O., Paye, M., Maibach, H. I. Cosmetic Dermatology. CRC Press, Taylor & Francis.
5. Rosen, M. R. (Ed.) Delivery System Handbook for Personal Care and Cosmetic Products. William Andrew Publishing (Elsevier).
6. Draize, J. H. Dermal Toxicology and Safety Evaluation of Cosmetics. Academic Press, USA.
7. OECD. Guidelines for the Testing of Chemicals: Skin and Eye Irritation/Sensitization. OECD Publishing, Paris, France.
8. Mukherjee, P. K. Quality Control and Evaluation of Herbal Drugs. Elsevier, New Delhi, India.
9. Forestier, J. P. Cosmetic Microbiology. Taylor & Francis, USA.
10. WHO. Quality Control Methods for Herbal Materials. World Health Organization, Geneva, Switzerland.

SEMESTER VIII

Course Code	Course Title			Course Type
BP809P VAC1	**Cleaning 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:

1. To understand the importance of cleaning validation in pharmaceutical manufacturing.
2. To familiarize students with the regulatory requirements for cleaning validation.
3. To teach methods for residue detection and the development of cleaning protocols.
4. To explore different analytical techniques used in cleaning validation.
5. To develop skills in writing cleaning validation reports and ensuring compliance.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Explain the purpose and importance of cleaning validation.
2	Develop cleaning validation protocols and methods for pharmaceutical equipment.
3	Understand and apply residue detection techniques such as HPLC and TOC.
4	Evaluate cleaning effectiveness and compliance with regulatory standards.
5	Prepare detailed cleaning validation reports and perform revalidation when necessary.

Detailed Syllabus

List of Practical
(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

Recommended References *(Preferably latest edition)*:

1. Cleaning Validation: A Practical Approach – David M. Blenkinsopp & Roy T. Harvey, CRC Press
2. Cleaning Validation in Pharmaceutical Manufacturing – Trevor Deeks, CRC Press
3. Pharmaceutical Cleaning Validation: The Basics – Andrew Walsh, Interpharm Press
4. Cleaning and Cleaning Validation: Volume 1 – Syed Imtiaz Haider, Informa Healthcare
5. Validation of Cleaning Processes in Pharmaceuticals and Biopharmaceuticals – Jeanne Moldenhauer, DHI Publishing
6. Pharmaceutical Equipment Cleaning: Fundamentals, Applications and Validations – Gail Sofer, CRC Press

Course Code	Course Title			Course Type
BP809P VAC2	**Basic Training in Aseptic Handling Techniques (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:

1. Understand aseptic principles that prevent microbial contamination in clean-room work.
2. Learn correct gowning and hand-hygiene steps for ISO-classified areas.
3. Practise safe techniques for setting up laminar-airflow hoods and transferring sterile materials.
4. Carry out routine monitoring of surfaces, air, and personnel to verify sterility.
5. Document procedures accurately to meet GMP and audit requirements.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Explain the key concepts of asepsis, clean-room classifications, and contamination control.
2	Demonstrate full sterile gown-up and hand-wash without contamination spots.
3	Set up and operate a laminar-airflow workstation and perform aseptic liquid transfers with no spills.
4	Complete a mini media-fill that meets sterility acceptance criteria (> 95 % clear vials).
5	Record and interpret environmental and personnel monitoring data, flagging any values above action limits.

Detailed Syllabus

List of Practical
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 & 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 & 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 & Personnel Monitoring – deploy settle/contact plates, take glove-fingertip prints, run an air sampler.
10. Cleaning & ATP Validation – full hood wipe-down, then ATP swab pre- and post-clean to verify < 200 RLU residue.

Recommended References *(Preferably latest edition)*:

1. Akers J, Moldenhauer J, editors. Aseptic Processing: A Review of Current Industry Practice. 2nd ed. Boca Raton: CRC Press; 2022.
2. Smith C. Sterile Drug Products: Formulation, Packaging, Manufacturing, and Quality. 2nd ed. New York: Springer; 2020.
3. Vanderhaegen B. Cleanroom Design: Concepts and Practice. 3rd ed. London: Wiley; 2019.
4. Sandle T. Cleanroom Microbiology. 1st ed. Boca Raton: CRC Press; 2021.

Course Code	Course Title			Course Type
BP809P VAC3	**Impurity Profiling (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:

1. To understand the types and sources of impurities in pharmaceutical substances.
2. To learn the techniques used for detection, isolation, and quantification of impurities.
3. To study regulatory guidelines for impurity profiling (ICH, USFDA, EMA).
4. To develop skills in interpreting impurity data and analytical validation.
5. To apply impurity profiling in drug development, stability studies, and quality control.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Explain the principles and significance of impurity profiling in pharmaceutical analysis.
2	Identify methods for detection and quantification of organic, inorganic, and residual impurities.
3	Follow ICH and pharmacopeial guidelines for impurity limits and documentation.
4	Perform impurity analysis using HPLC, GC, UV, and IR techniques.
5	Evaluate and interpret impurity data for regulatory submissions and quality assurance.

Detailed Syllabus

List of Practical
(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

Recommended References *(Preferably latest edition)*:

1. Gorog, S. Impurities Evaluation of Pharmaceuticals. Marcel Dekker Inc., USA.
2. Teasdale, A. ICH Quality Guidelines: An Implementation Guide. John Wiley & Sons, USA.
3. Kar, A. Pharmaceutical Analysis. New Age International Publishers, New Delhi, India.
4. Connors, K. A. A Textbook of Pharmaceutical Analysis. Wiley India Pvt. Ltd., New Delhi, India.
5. Ahuja, S. Handbook of Isolation and Characterization of Impurities in Pharmaceuticals. Academic Press (Elsevier), USA.
6. Chamberlain, J. The Analysis of Drugs in Biological Fluids. CRC Press, USA.

Appendix II-Laboratory Specifications

1. Requirements of Laboratory Specifications

Sl No.	Particular	Details
1.	Lab Size	Total area: 75 Sq. mts including preparation room Capacity: 20–30 students + 1or 2 faculty
2.	Zoning (recommended)	1. Working benches (students) 2. Instructor/demo area 3. Instrument and balance zone 4. Fuming chamber (Chemistry Lab) and exhaust zone 5. Wash and drainage zone 6. Circulation
3. Floor Design and Specifications (Material): Acid- and alkali-resistant vitrified tiles/stone (heavy duty) or Epoxy resin flooring (chemical resistant, seamless)		
	Floor Specifications	1. Thickness: ≥10 mm (tiles) / 2–3 mm epoxy 2. Finish: Matt / anti-skid 3. Chemical resistance: Acids, alkalis, solvents, salts 4. Skirting:100–150 mm epoxy or tile skirting (covered)
	Sink and Drainage Layout	One sink per six students Sink material: Chemical Resistant with acid-resistant valves
	Drainage System	Separate lab drainage line (Discharge should be suitably treated for minimizing the Environmental impact)
4. Modular Furniture Layout		
	Student Working Benches	Type: Island benches Surfaces should be sufficiently chemical resistant
	Side Wall Benches	For instruments, reagent prep, drying
	Storage	Separate flammable storage cabinet (recommended)
5. Fuming Chamber (Fume Hood) Mandatory for Synthetic Chemistry Lab		
	Quantity	Minimum one
6. Exhaust and Ventilation System		
	General Ventilation	Wall-mounted exhaust fans Labs should be well ventilated.
	Exhaust Fans	Should be placed in every lab. Acid-resistant coating Placed near fuming chamber zone
7. Lighting and Electrical (Brief)		
	Lighting	300–500 lux at bench level Emergency lighting near exits Arrangement of sufficient lighting at the work benches in HAP and Pharmacognosy Lab.
	Electrical	Sufficient number of combination sockets on side benches:

		On benches sufficient number of electrical sockets (Earthing mandatory)
8. Preparation Room (Between Two Labs)		
	Location and Purpose	Preparation room with minimum 10 sq.mt area Each laboratory should have a preparation room. However, one preparation room may be shared by two laboratories if it is located between them and both belong to the same department used for Solution preparation, Reagent storage, Sample weighing
	Design Features	Central working bench Storage cabinets (lockable) Balance table (anti-vibration) Exhaust fan Chemical-resistant floor and walls (same specs as lab)
	Access	Door from both labs (controlled access) if shared.
9. Safety Provisions (Must-Have)		
		First aid box Material Safety Data Sheet (MSDS) display Proper signage Emergency eye wash and safety shower (near wet and fume hood zones) (Desirable) Fire Extinguisher (Dry Powder Type) Provision of Double Door Access (Every Laboratory)
10.	**Balance Room**	A closed balance room is desirable for housing high-sensitivity balances to prevent disturbances caused by airflow.
11.	**Gas Connection**	A gas connection is essential in the Pharmaceutical Chemistry, Pharmacognosy, and Pharmaceutics laboratories. One Bunsen burner may be shared by two students during practical sessions.

2. Department wise List of Minimum laboratory required for the B. Pharm as per NEP2020.

Sl No	Department	Laboratory Name	Area Requirement
1	Pharmaceutics	1. Fundamental Pharmaceutics Lab 2. Advanced Formulation Development Lab 3. Pharmaceutical Biotechnology and Microbiology lab (Including Aseptic Room)	75 Sq. mts including preparation room with minimum 10 sq.mt area Each laboratory should have a preparation room. However, one preparation room may be shared by two laboratories if it is located between them and both belong to the same department.
2	Pharmaceutical Chemistry	1. Inorganic and Analytical Chemistry 2. Synthetic Chemistry 3. Biochemistry and Biomedical Chemistry	
3	Pharmacology	1. Human Anatomy and Physiology 2. Pharmacology	
4	Pharmacognosy	1. Pharmacognosy Lab	

5	Research Lab	75 Sq. mts
6	Central Instrumentation Lab	80 Sq.mts with A/C Air purifier (desirable)
7	Machine Room	75-100 Sq.mts
8	Computer Lab	75 Sq mts
9	Store-I	100 Sq.mts
10	Store-II (For Inflammable chemicals)	20 Sq.mts

3. Department wise List of Minimum laboratory required for the B. Pharm as per NEP2020 and D. Pharm

Sl No	Department	Laboratory Name	Area Requirement
1	Pharmaceutics	1. Fundamental Pharmaceutics Lab 2. Advanced Formulation Development Lab 3. Pharmaceutical Biotechnology and Microbiology lab (Including Aseptic Room)	75 Sq. mts including preparation room with minimum 10 sq.mt area Each laboratory should have a preparation room. However, one preparation room may be shared by two laboratories if it is located between them and both belong to the same department.
2	Pharmaceutical Chemistry	1. Inorganic and Analytical Chemistry 2. Synthetic Chemistry 3. Biochemistry and Biomedical Chemistry	
3	Pharmacology	1. Human Anatomy and Physiology 2. Pharmacology 3. Social Pharmacy Lab	
4	Pharmacognosy	1. Pharmacognosy Lab	
5	Research Lab		75 Sq. mts
6	Central Instrumentation Laboratory		80 Sq.mts with A/C Air purifier (desirable)
7	Machine Room		75-100 Sq.mts
8	Computer Laboratory		75 Sq mts
9	Running Model Community Pharmacy		80 Sq. mts (Including 10 Sq. mt for Drug Information Centre & 10 Sq. mt. for Patient Counseling)
10	Store-I		100 Sq.mts
11	Store-II (For Inflammable chemicals)		20 Sq.mts

4. Laboratory Equipment and Apparatus

4.1. Pharmaceutics:

Sl. No	Instrument Name	Quantity
1.	Antibiotic Zone reader	1
2.	Autoclave	1

3.	Binocular Microscope (With Phase Contrast)	1
4.	BOD Incubator	1
5.	Buchner Funnels (Small, medium, large)	5 each
6.	Bulk Density & Tapped density Apparatus	2
7.	Burette & Burette stand	10 each
8.	Capsule counter	1
9.	Centrifuge (minimum 4000 rpm)	1
10.	Compound Microscope with movable stage	15
11.	Culture Tubes	30
12.	Deep freezer (Desirable)	1
13.	Desiccator (Glass/PVC)	5
14.	Digital Balance (min. 10mg)	4
15.	Digital Colony Counter	1
16.	Digital Melting point Apparatus	2
17.	Digital pH meter	3
18.	Digital Vernier calliper (Desirable)	4
19.	Distillation Unit	2
20.	Electronic Water Bath 12 Holes	3
21.	ELISA Reader and Kits (Desirable)	1
22.	Eye Piece Micrometer	10
23.	Franz Diffusion Cell (Desirable)	5
24.	Hardness Test apparatus (Monsanto & Pfizer)	2 each
25.	Heating Mantle (500ml)	10
26.	High Speed Homogenizer with RPM Controller and Display	5
27.	Hot Air Oven	3
28.	Hot Plate	4
29.	Glass Petri Plates/Casting Plates	10
30.	Incinerator	1
31.	Incubator (Desirable)	1
32.	Lab Fermenter (Desirable)	1
33.	Laminar Air Flow	1
34.	Magnetic Stirrer (500 ml) with Temperature Control	12
35.	Mechanical stirrer with propeller type agitator	2
36.	Mechanical Stirrer with Speed Regulator	8
37.	Membrane Filtration Unit	2
38.	Micro-centrifuge	1
39.	Micropipettes (1-10 µL, 10-100 µL, 100–1000 µL)	1 set
40.	Microscope with digital camera eyepiece (Desirable)	1
41.	Mortar & Pestle (Glass)	10
42.	Mortar Pestle (Porcelain)	20
43.	Ointment slab	10
44.	Ointment spatula	10
45.	Orbital Shaker Incubator	1

46.	Orbital Shaker/Flask Shaker (6 flask holding capacity) (Desirable)	2
47.	Ostwald viscometer	15
48.	Personnel Protection Equipment (Complete Set) (Desirable)	Adequate
49.	Petri Plates	30
50.	Platinum Inoculating Loop	30
51.	Pycnometer (Specific gravity Bottle)	30
52.	Refrigerated centrifuge	1
53.	Refrigerator	1
54.	Standard sieves, sieve no. 8, 10, 12,22,24, 44, 66, 80 (as per BIS standards)	1 Set
55.	Separating Funnel	10
56.	Spirit Lamps (Desirable)	10
57.	Stage micrometer	10
58.	Stalagmometer	15
59.	Sterility Testing Unit	1
60.	Stopwatch	5
61.	Suppository Mold	20
62.	Tablet counter	1
63.	Thermometer (Upto 300'C)	20
64.	Sonicator	1
65.	Vaccum Filtration Unit (Filtration Unit and Vaccum Pump)	2
66.	Vortex Shaker	2
67.	Water Bath (Copper)	10

4.2. Pharmaceutics Chemistry

Sl. No	Instrument Name	Quantity
1.	Boiling point apparatus (Desirable)	2
2.	Bomb Calorimeter (Desirable)	1
3.	Burette	60
4.	Centrifuge (12–16 tube capacity)	1
5.	Clinical Thermometer	10
6.	Digital Colorimeter	2
7.	Compound Microscope	5
8.	Digital potentiometer	1
9.	Desiccator	4
10.	Digital balance (10mg sensitivity)	3
11.	Digital Conductivity meter	1
12.	Digital Flame Photometer	1
13.	Digital Fluorimeter	1
14.	Digital pH meter	3
15.	Double door Refrigerator	2
16.	Fluoride ion meter (Desirable)	1
17.	Distillation Assembly (Glass)	1
18.	Double Distillation Assembly (Glass)	1

19.	Distillation Assembly (Steel- Wall Mounted))	1
20.	Fume hood	1
21.	Glass filtration assembly with 5 micron membrane filter	1
22.	Arsenic Test Apparatus (Gutzeit) apparatus	20
23.	Heating mantle (1000ml)	10
24.	Heating mantle (500 ml)	10
25.	Homogenizer	1
26.	Hot air oven	3
27.	Hot Plate	5
28.	Incubator (37°C) (Desirable)	1
29.	Ion exchanger	1
30.	Laboratory Microwave Oven (Desirable)	1
31.	Digital Melting Point apparatus	2
32.	Melting point apparatus (analog)	5
33.	Laboratory Thermometer	10
34.	Micropipettes (1-10 µL, 10-100 µL, 100–1000 µL)	1 set
35.	Magnetic stirrer with thermostat (1000ml)	5
36.	Magnetic stirrer with thermostat (500ml)	5
37.	Morter and pestle (500ml)	5
38.	Morter and pestle (Glass-250ml)	10
39.	Nessler cylinder	20 pairs
40.	Reflux flask and condenser double / triple necked	20
41.	Reflux flask and condenser single necked	20
42.	Sahli's Hemoglobinometer	15
43.	Soxhlet Apparatus (500mL)	2
44.	Stopwatch	10
45.	Vaccum pump	3
46.	TLC chamber	5
47.	UV cabinet	1
48.	Vortex Mixer (Desirable)	1
49.	Water bath with thermostat (6 holes)	3

4.3. Pharmacology:

Sl. No	Instrument Name	Quantity
1.	Adult CPR Manikin	2
2.	AED Trainer (Automated External Defibrillator) non-shocking version	1
3.	AED Trainer (Training Pads)	10
4.	Ambu Bag (Bag-Valve-Mask Resuscitator)	2
5.	Digital balance (10 mg sensitivity)	1
6.	Aneroid sphygmomanometer	5
7.	Arm Mannequin (Training Arm Model)	2
8.	Autoclave	1
9.	Barrier Devices	1
10.	Bio safety Cabinet (Class II) (Desirable)	1

11.	Biohazard Sharps Container	5
12.	Biohazard Waste Bag	1
13.	BMI Chart	Adequate
14.	Bones (set of spare bones)	1 set
15.	Centrifuge	1
16.	Charts for different organs, systems, tissues	Adequate
17.	Charts for family planning devices, contraception (birth control) methods, etc.	One for each
18.	Clinical thermometer (Digital)	10
19.	Clinical thermometer (Mercury)	10
20.	CO2 Incubator (Desirable)	1
21.	Colorimeter	1
22.	Compound Microscope	20
23.	Contraceptive devices including contraceptive pills (different types), male condom, female condom, diaphragm, copper-T, vaginal ring,	1 set
24.	Different Wound Dressing Materials	Adequate
25.	Digital blood pressure monitor	5
26.	Digital Glucometer with Test Strips	5
27.	Digital Hemoglobinometer with Test Strips	5
28.	Electrocardiograph (ECG Machine) (Desirable)	1
29.	Eye Occluder	10
30.	First Aid Kit	5
31.	Gauze Pads	20
32.	Hemocytometer (Neubauer's Chamber) with RBC/WBC Dilution Pipette	15
33.	Health promotion material (Charts, Pamphlets)	Adequate
34.	Hematology Analyzer (Desirable)	1
35.	Histopathological slides from toxicity studies	Adequate
36.	Homogenizer	2
37.	Hot plate	2
38.	Immunization chart	Adequate
39.	Incubator	1
40.	Infant/Child CPR Mannequin (Desirable)	1
41.	Infrared Thermometer	2
42.	Kneeling Pads	1
43.	Leaflet on lifestyle modifications for disease prevention.	Adequate
44.	Magnetic stirrer with hot plate	2
45.	Magnifying glass	10
46.	Masked patient reports (if available)/ theoretical case studies (at least one for each disease - anaemia, thalassemia, haemophilia, leprosy, gout, hypertension and ischemic heart disease, IBD, peptic ulcer, jaundice, hepatitis, typhoid, asthma, tuberculosis, diabetes, and thyroid disorders)	3 per diseases
47.	Measuring Tape	5
48.	Mechanical mixer	2

49.	Mercury sphygmomanometer	10
50.	Micropipettes (various ranges)	1 set
51.	Model for each organ system	1 Model for each organ system
52.	Mortar and pestle	5
53.	Peak Flow meter	10
54.	Pen torch	10
55.	Permanent Slides for various tissues (Epithelial tissue, Connective tissue, Muscle tissue, and Nervous tissue)	At least 30
56.	Personal Protective Equipment (PPE)	2
57.	pH meter	1
58.	Pocket Mask (CPR Mask)	2
59.	Pregnancy detection kit.	1 unit
60.	Pulse Oximeter	10
61.	Reflex hammer	10
62.	Refrigerator	1
63.	Sahli's Haemoglobinometer	20
64.	Skeleton	1
65.	Snellen Chart	2
66.	Specimen for various organs	15
67.	Spirometer	5
68.	Spirometer (digital)	1
69.	Stadiometer	2
70.	Stethoscope	15
71.	Stopwatch	10
72.	Student Organ Bath Complete Set up [Organ Bath assembly Single/Double unit, Sherrington Rotating Drum, Aretor, Different types of lever (Simple lever, Frontal writing lever, Starling's heart lever, Universal lever), Fulcrum, Stylus, Different types of Cannula (Arterial cannula, Venus cannula, Tracheal cannula), Clamp] **(For demonstration)**	2 set
73.	Suturing Practice Kit inclusing suturing pad (i.e. Surgical scissors, Tissue forceps, Suture needles, Suture thread, suturing pads)	10 sets
74.	Tuning fork (128 Hz)	10
75.	Two-point discriminator	5
76.	Vaccine Carrier (Desirable)	2
77.	Vortex mixer	1
78.	Water bath (at least 6 holes)	2
79.	Weighing Scale (Weighing balance upto 150 kg)	2
80.	Westergren Stand and Tube	15
81.	Wintrobe Tube and Stand	15
82.	Digital urine analyzer (Desirable)	1

4.4. Pharmacognosy

Sl. No	Instrument Name	Quantity
1.	Angle of Repose Apparatus (Desirable)	1
2.	Autoclave	1
3.	BOD incubator	1
4.	Buchner Funnel with Vacuum Pump	1
5.	Burette	30
6.	Camera lucida	10
7.	Centrifuge	1
8.	Clevenger apparatus (500ml;1L)	2sets each
9.	Column for chromatography	5 different size
10.	Compound Microscope	20
11.	Culture Bottles	10
12.	Culture flask	10
13.	Culture tubes	30
14.	Cutter Mill	1
15.	Desiccator	1
16.	Digital balance	1
17.	Digital microscope (Desirable)	1
18.	Double distillation unit (Desirable)	1
19.	Eyepiece/Ocular micrometer	20
20.	Germination Chamber (Desirable)	1
21.	Heating mantle	10
22.	Homogenizer	1
23.	Hot air oven	1
24.	Hydrometer Cylinder (Desirable)	5
25.	Liebig Condenser	15
26.	Magnetic Stirrer with hot plate	5
27.	Magnifying lens	30
28.	Micropipettes (1-10 µL, 10-100 µL, 100–1000 µL)	1 set
29.	Microtome (Desirable)	1
30.	Moisture balance	1
31.	Mortar and Pestle	15
32.	Muffle furnace	1
33.	pH meter	1
34.	Power Blender (Desirable)	1
35.	Projection microscope	2
36.	Pycnometer	5
37.	Reflux apparatus (Full setup)	15
38.	Refrigerator	1
39.	Rotary vaccum evaporator (Desirable)	1
40.	Separating funnel (250ml;500ml)	5 sets each
41.	Separating funnel (250ml;500ml)	5 sets each
42.	Sieve sets (40-60 mesh)	2 sets

43.	Silica crucible	10
44.	Simple distillation unit	1
45.	Soxhlet apparatus (Full set) (500ml; 1L)	2 sets each
46.	Spirit Lamp	30
47.	Stage micrometer	15
48.	Stereo microscope	2
49.	Sterility testing unit	1
50.	Stop watch / timer	2
51.	Test tube rack (10 slot)	5
52.	Thermometer (300 Centigrade)	15
53.	TLC chamber	10
54.	TLC glass slides	30
55.	TLC spreader	5
56.	TLC Spray bottle	5
57.	Tongs	15
58.	Sonicator	1
59.	UV Chamber (254 & 366 nm) (Desirable)	1
60.	Vernier Caliper (Desirable)	5
61.	Water bath (6holes)	2
62.	Weighing bottles with lid (Desirable)	15

4.5. Central Instrumentation Laboratory

Sl. No	Instrument Name	Quantity
1.	Autoanalyzer/Semi-autoanalyzer (Desirable)	1
2.	Conductivity Meter	1
3.	Cooling Sonicator (Desirable)	1
4.	Digital balance (1 mg sensitivity)	1
5.	Digital pH meter	1
6.	Disintegration Test Apparatus	1
7.	Dissolution test Apparatus	1
8.	Fluorimeter	1
9.	Friability Test Apparatus	1
10.	FTIR (Desirable)	1
11.	Gel Electrophoresis Unit (Desirable)	1
12.	High Performance Rotational Viscometer	1
13.	HPLC	1
14.	HPTLC (Desirable)	1
15.	Lyophilizer (Desirable)	1
16.	Refractometer	1
17.	Solid Phase Extraction apparatus (Desirable)	1
18.	Texture analyzer (Desirable)	1
19.	UV spectrophotometer	1
20.	UV Transilluminator (For Gel Electrophoresis) (Desirable)	1
21.	RT- PCR (Essential before the commencement of fifth semester)	1

4.6. Machine Room

Sl. No	Instrument Name	Quantity
1.	All-purpose equipment with all accessories (*)	1
2.	Ampoule filling and sealing machine (Jet Burner) (Desirable)	1
3.	Ampoule washing machine (Desirable)	1
4.	Ball mill (*)	1
5.	Bottle Sealing Machine	1
6.	Bottle washing Machine	1
7.	Coating pan machine (*)	1
8.	Collapsible tube - Filling and Sealing	1
9.	Double cone blender (*)	1
10.	Granulator machine	1
11.	Liquid Filling Machine	1
12.	Ointment filling machine (Desirable)	1
13.	Rotary Tablet Punching Machine (min 8 Station)	1
14.	Sieve shaker	1
15.	Stability Chamber	1
16.	Tray Dryer	1
17.	Fluidize Bed Dryer (Desirable)	1
18.	Spray Dryer (Desirable)	1
19.	Rotary Flash Evaporator (Desirable)	1
20.	Twin Screw Extruder (Desirable)	1
21.	**Note (*):** Either the marked instruments or the All-purpose equipment with all accessories must be procured.	

- Desirable instruments listed may be procured by the institute or accessed through collaboration/MoU with research centers or interdisciplinary institutions.

- The requirements specified herein apply to institutions offering the B. Pharm programme under the NEP 2020 syllabus. Institutions conducting more than one programme may share the common facilities, infrastructure, laboratories, equipment's, and other resources between the programmes, provided that such sharing complies with the norms and standards prescribed by the Pharmacy Council of India (PCI) and is adequate for all programmes.



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