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SEMESTER VII

B.PHARM

NEW SYLLABUS

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PHARMACY COUNCIL OF INDIA

6395596959, 8006781759

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.

PHARMACY INDIA

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 hour

	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 hour
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 hour
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 hour
V	1. **Microscopy-Based Analytical Techniques:** Principle, instrumentation, and applications of optical microscopy, scanning electron microscopy and transmission electron microscopy.	5 hour

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 hour
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 hour
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 hour
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 hour
V	**Risk Communication, Evaluation, Management, and ICH Guidelines** a) Risk evaluation and management strategies in pharmacovigilance	10 hour

	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 hour
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 hour

III	**Clinical Pharmacy Services**
	• Introduction to clinical pharmacy and its concept
	• Drug therapy monitoring
	  ○ Medication chart review
	  ○ Clinical review
	  ○ Pharmacist intervention
	  ○ Ward round participation
	  ○ Medication history
	  ○ Pharmaceutical care
	• Drug information services
	• Drug/Medication related problems
	• Drug and poison information services
	• Therapeutic drug monitoring (TDM)
		9 hour

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 hour
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 hour

	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.**

PHARMACY INDIA

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 hour
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 hour
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 hour
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 hour

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 hour

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. Sethi, P. D. *Quantitative Analysis of Drugs in Pharmaceutical Formulations.* CBS Publishers & Distributors. 6. Sharma, B. K. *Instrumental Methods of Chemical Analysis.* Goel Publishing House. 7. Sharma, Y. R. *Organic Spectroscopy.* S. Chand. 8. Silverstein, R. M., Webster, F. X., Kiemle, D. J. and Bryce, D. L. *Spectrometric Identification of Organic Compounds.* Wiley. 9. Willard, H. H., Merritt, L. L., Dean, J. A. and Settle, F. A. *Instrumental Methods of Analysis.* Brooks/Cole. 10. *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.

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