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** • 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.)	6 hours
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 Readings:

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)

1. Dessler, G. *Human Resource Management.* Pearson.
2. Drucker, P. F. *Principles of Management.* Harper Business.
3. Joseph, A. S. *Pharmaceutical Management and Marketing.* CBS Publishers & Distributors.
4. 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** 1. Limitations of conventional dosage forms (e.g., solubility, permeability, toxicity, first-pass metabolism) 2. 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 3. Biodegradable and biocompatible polymers: PLA, PLGA, PCL, chitosan, gelatin 4. Lipids and surfactants: lecithin, phospholipids, Span/Tween, SLNs 5. Inorganic systems: silica, gold nanoparticles, iron oxide, MOFs 6. Excipients in NDDS: GRAS substances, IIG database, regulatory constraints	12 hours
II	**Oral and Mucosal Delivery Systems** 1. Gastro-retentive systems: floating, bioadhesive, expandable systems 2. Colon-targeted systems: pH-triggered, microbially-triggered, time-dependent systems 3. Buccal, nasal, and pulmonary carriers: films, sprays, DPIs, liposomes 4. IVIVC and biorelevant dissolution testing.	6 hours
III	**Transdermal NDDS** 1. Introduction to Transdermal drug delivery: Need, advantages disadvantages, basic structure and components. Formulation aspects including permeation enhancers. 2. Long-acting systems: in-situ gels, microspheres, implants, ocular inserts 3. 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** 1. Preformulation and QbD: QTPP, CQAs, CPPs 2. Characterization methods: particle size, zeta potential, SEM/TEM, in-vitro release, permeability assays (PAMPA, Caco-2) 3. Non-clinical evaluation: PK/PD modeling, biodistribution, toxicology 4. Regulatory pathways: 505(b)(2), complex generics, ICH Q8–Q10, EMA pathways 5. 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. 6. Nanosystems and precision medicine a) Liposomes, niosomes, transferosomes, polymeric nanoparticles, solid-lipid nanoparticles, dendrimers. b) 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 environmental monitoring.	14 hours

Recommended References *(Preferably latest editions):*

1. Aulton, M. E. and Taylor, K. *Aulton's Pharmaceutics: The Design and Manufacture of Medicines.* Elsevier.
2. Banga, A. K. *Transdermal and Intradermal Delivery of Therapeutic Agents.* CRC Press.
3. Dash, A. K. and Cudworth, G. C. *Therapeutic Proteins and Peptides: Formulation, Processing and Delivery Systems.* CRC Press.
4. Jain, N. K. *Drug Delivery Systems.* CBS Publishers & Distributors.
5. Kreuter, J. *Colloidal Drug Delivery Systems.* CRC Press.
6. Martin, A., Sinko, P. J. and Singh, Y. *Martin's Physical Pharmacy and Pharmaceutical Sciences.* Lippincott Williams & Wilkins.
7. Torchilin, V. P. *Nanoparticulates as Drug Carriers.* Imperial College Press.
8. 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*

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 • 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)	6 hours
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
05	**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	6 hours

	for factory location, premises, plant layout and infrastructure and materials.	
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 guidelines. Use of alternative non-animal testing methods (3D skin models, in silico models)	4 hours

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. Sharma, P. P. Cosmetics: Formulation, Manufacturing and Quality Control. Vandana Publications, New Delhi, India.

5. Barel, A. O., Paye, M., Maibach, H. I. Cosmetic Dermatology. CRC Press, Taylor & Francis.
6. Rosen, M. R. (Ed.) Delivery System Handbook for Personal Care and Cosmetic Products. William Andrew Publishing (Elsevier).
7. Draize, J. H. Dermal Toxicology and Safety Evaluation of Cosmetics. Academic Press, USA.
8. OECD. Guidelines for the Testing of Chemicals: Skin and Eye Irritation/Sensitization. OECD Publishing, Paris, France.
9. Mukherjee, P. K. Quality Control and Evaluation of Herbal Drugs. Elsevier, New Delhi, India.
10. Forestier, J. P. Cosmetic Microbiology. Taylor & Francis, USA.
11. 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. Sethi, P. D. Quantitative Analysis of Drugs in Pharmaceutical Formulations. CBS Publishers & Distributors, New Delhi, India.
7. Chamberlain, J. The Analysis of Drugs in Biological Fluids. CRC Press, USA.