As Per NEP2020

SEMESTER VIII

B.PHARM

NEW SYLLABUS

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Semester VIII

Course Code	Name of the course		No. of hours per week (L/P)	Credit points
BP801T	Ethical Considerations and Translational Applications of AI in Pharmacy (Theory)		2	2
BP802T	Clinical Pharmacotherapeutics (Theory)		2	2
BP803T	Industrial Pharmacy and Facility Design (Theory)		3	3
BP804T	Pharmaceutical Management (Theory)		2	2
BP805T	Sterile Dosage Forms and Novel Drug Delivery System (Theory)		3	3
BP806T AEC*	BP806T AEC1	Pharmaceutical Packaging	2	2
	BP806T AEC2	Supply Chain Management		
	BP806T AEC3	Industrial Safety and Waste Management		
	BP806T AEC4	Traditional Healing Practices of India		
	BP806T AEC5	Futuristic Pharma through AR/VR: Pharma 4.0		
	BP806T AEC6	Herbal Cosmetics for Industry Perspective		
BP807P	Pharmaceutical Marketing Skills (Practical)		2	1
BP808P	Sterile Dosage Forms and Novel Drug Delivery System (Practical)		4	2
BP809P VAC*	BP809P VAC1	Cleaning Validation	2	1
	BP809P VAC2	Basic Training in Aseptic Handling Techniques		
	BP809P VAC3	Impurity Profiling		
BP810RP	Research Project		-	6
Total			**22**	**24**

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

Course Code	Course Title		Course Type	
BP801T	**Ethical Considerations and Translational Applications of AI in Pharmacy (Theory)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
2	2	--	--	30
Maximum Marks	SE		ESE	
50	20		30	

COURSE OBJECTIVES:

The objectives of this course are:

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

COURSE OUTCOMES (CO):

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

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**AI Lifecycle, Validation & Model Auditing** • Overview of AI system lifecycle: data collection, preprocessing, modeling, validation, deployment, and monitoring • Importance of data quality in healthcare datasets • Training vs testing vs validation datasets • Cross-validation (conceptual understanding) • Model drift and performance degradation, data leakage in modeling • Documentation practices: Documentation and reproducibility • Basics of model auditing	6 hours
II	**Regulatory Framework & Explainable AI** • Overview of AI in regulatory submissions • Explainable AI (XAI) concept • Transparency and interpretability • Overview of regulatory guidance on AI (EU AI Act, FDA/ CDSCO frameworks) • Accountability in automated decision systems • Risk-based classification of AI systems	6 hours
III	**AI in in Pharmacy Automation & Supply Chain** • Overview of AI in automated dispensing systems • Inventory prediction models • Case studies on regression-based demand forecasting, different forecasting methods • Medication adherence monitoring systems • AI in supply chain risk prediction • Predictive analytics in pharmaceutical logistics • Advantages, limitations, legal & privacy considerations of AI in pharmacy automation.	6 hours
IV	**AI in in Public Health & Real-World Data Analytics**	6

	• Overview of real-world data sources (EHR, claims, surveillance systems) • Conceptual knowledge of AI in outbreak prediction, Population-level risk modeling • Regression models in epidemiology • AI in vaccination forecasting • Case studies: AI applications in epidemiological trend analysis (e.g. COVID-19 vaccination hesitancy, diabetes prevalence forecasting, antibiotic resistance trends etc.)	
V	**Guided Project - Translational AI in Pharmacy** Students implement a supervised ML model (regression, logistic regression, or others) using real-world pharmacy data from domains like formulation, pharmacokinetics (PK), ADR detection, quality control (QC), automation, or public health. They validate the model, analyze regulatory implications, identify ethical risks (e.g., bias, privacy), and present a structured AI implementation plan for peer/faculty review. Suggested topics (not exhaustive): ADR prediction system, stability forecasting, demand prediction, QC failure model, disease risk prediction, medication adherence	6

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. 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*

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