DR. A.P.J. ABDUL KALAM TECHNICAL UNIVERSITY, UTTAR PRADESH, LUCKNOW

EVALUATION SCHEME & SYLLABUS

BACHELOR OF PHARMACY

I, II, III & IV Year

On PCI Guidelines

(EFFECTIVE FROM THE SESSION: 2026-27)

GRADUATE ATTRIBUTES (GA's)

Graduate Attributes (GAs) represent the key competencies and professional qualities expected from every pharmacy graduate, irrespective of the program such as D.Pharm, B.Pharm,Pharm.D or M.Pharm. While the level of mastery may vary, these attributes remain common and guide the overall outcomes of pharmacy education.

1. **Pharmaceutical Knowledge Proficiency**

– Strong grounding in core and applied pharmaceutical sciences and practice.

2. **Scientific and Analytical Thinking**

– Ability to critically analyze data, processes, and clinical information.

3. **Ethical and Professional Integrity**

– Commitment to ethical conduct, patient safety, and regulatory compliance.

4. **Patient-Centered Orientation**

– Sensitivity to patient needs, cultural diversity, and healthcare outcomes.

5. **Industry and Practice Readiness**

– Preparedness for roles in industry, hospitals, community pharmacy, research, and regulation.

6. **Digital and Technological Awareness**

– Familiarity with AI, data analytics, automation, and modern pharmaceutical technologies.

7. **Effective Communication Skills**

– Clear, empathetic, and professional interaction across healthcare settings.

8. **Teamwork and Leadership Skills**

– Ability to collaborate, lead, and contribute constructively in teams.

9. **Innovation and Problem-Solving Mindset**

– Capability to identify problems and develop practical, evidence-based solutions.

10. **Lifelong Learning Orientation**

– Motivation for continuous professional development and higher education.

PROGRAMME EDUCATIONAL OBJECTIVES

The Bachelor of Pharmacy (B. Pharm) programme aims to prepare graduates with strong knowledge of pharmaceutical sciences, practical skills, professional ethics, and a commitment to patient care and public health. The graduates of the programme are expected to achieve the following Programme Educational Objectives (PEOs):

PEO 1: Apply fundamental knowledge of pharmaceutical sciences to work effectively in pharmacy practice, pharmaceutical industry, research, and related healthcare fields.

PEO 2: Demonstrate practical skills in drug formulation, manufacturing, pharmaceutical analysis, quality control, and pharmacy practice.

PEO 3: Use scientific reasoning and problem-solving skills to address challenges related to medicines, drug development, and patient care.

PEO 4: Practice pharmacy with ethical responsibility, good communication, teamwork, and concern for patient safety and public health.

PEO 5: Pursue continuous learning and professional development to keep pace with advances in pharmaceutical sciences and healthcare.

PROGRAMME OUTCOMES (POs)

Bachelor of Pharmacy (B. Pharm)

PO1. Pharmacy Knowledge

Apply comprehensive knowledge of pharmaceutical sciences, biomedical sciences, pharmacology, pharmacognosy, pharmaceutical chemistry, pharmacy practice, and manufacturing processes to understand drug actions, disease mechanisms, and therapeutic interventions and solve professional problems across diverse pharmacy domains.

PO2. Problem Analysis, Critical Thinking and Evidence-Based Decision Making

Identify, formulate, analyze, and interpret complex pharmaceutical problems using principles of scientific inquiry, critical thinking, biostatistics, and evidence-based reasoning to arrive at defensible solutions and informed decision-making.

PO3. Pharmaceutical Skills & Practice

Demonstrate proficiency in formulation development, analysis, quality assurance, pharmacovigilance, clinical pharmacotherapy, and pharmacy practice through laboratory work, simulations, internships, and experiential learning.

PO4. Modern Tools, AI & Digital Competence

Select, apply, and evaluate modern pharmaceutical tools, analytical instruments, digital technologies, artificial intelligence, machine learning, and computational techniques with awareness of their limitations and ethical use.

PO5. Research & Innovation

Design and conduct basic research, analyze data, interpret results, and contribute to innovation through research projects, startup initiatives, and problem-based learning relevant to industry, healthcare, and society.

PO6. Professional Ethics & Human Values

Apply ethical principles, professional integrity, regulatory frameworks, intellectual property rights, and universal human values while addressing professional, legal, and societal responsibilities in pharmacy practice.

PO7. Communication & Interpersonal Skills

Communicate effectively with patients, healthcare professionals, industry personnel, and society through clear documentation, reports, presentations, counseling, teamwork, and interdisciplinary collaboration.

PO8. Leadership, Management & Entrepreneurship

Demonstrate leadership, teamwork, planning, and managerial skills in pharmaceutical organizations, healthcare systems, quality systems, and entrepreneurial ventures, including innovation and startup ecosystems.

PO9. Pharmacist & Society

Evaluate public health, patient safety, legal, and societal issues related to pharmacy practice and contribute responsibly to healthcare delivery, rational use of medicines, and improvement of community health outcomes.

PO10. Environment and sustainability:

Recognize and address the environmental impact of pharmaceutical manufacturing, use, and disposal, and promote environmentally responsible practices, green pharmacy principles, and sustainable healthcare aligned with the United Nation's Sustainable Development Goals (SDGs).

PO11. Life-Long Learning & Professional Development

Recognize the need for continuous learning and demonstrate the ability to engage in selfdirected, life-long learning to adapt to technological advancements, evolving healthcare needs, and professional growth.

Semester I

Course Code	Name of the Course	No. of hours/week (L/P)	Continuous Mode (Marks)	Sessional Exam (Marks)	Sessional Duration	Internal Total	End Semester Marks	End Sem Exam Duration	Total Marks	Credit points
BP101T	Basics of Python Programming for Pharmaceutical Sciences (Theory)	2	10	10	1 Hr	20	30	1.5 Hr	50	2
BP102T	General Pharmacy (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP103T	Healthcare Psychology and Communication Skills (Theory)	1	10	10	1 Hr	20	30	1.5 Hr	50	1
BP104T	Human Anatomy, Physiology and Pathophysiology I (Theory)	4	20	20	1 Hr	40	60	3 Hr	100	4
BP105T	Introduction to Pharmacognosy (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP106T	Pharmaceutical Inorganic and Analytical Chemistry (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP107P	General Pharmacy (Practical)	3	10	10	3 Hr	20	30	3 Hr	50	1
BP108P	Healthcare Psychology and Communication Skills (Practical)	2	10	10	3 Hr	20	30	3Hr	50	1
BP109P	Human Anatomy, Physiology and Pathophysiology I (Practical)	3	10	10	3 Hr	20	30	3 Hr	50	1
BP110P	Introduction to Pharmacognosy (Practical)	3	10	10	3 Hr	20	30	3 Hr	50	1
BP111P	Pharmaceutical Inorganic and Analytical Chemistry (Practical)	3	10	10	3 Hr	20	30	3 Hr	50	1
Total		**30**	**135**	**135**	**21 Hr**	**270**	**405**	**27**	**675**	**21**

Course Code	Course Title			Course Type
BP101T	**Basics of Python Programming for Pharmaceutical Sciences (Theory)**			Core
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
2	2	--	--	30
Maximum Marks	SE			ESE
50	20			30

Course Objectives:

The objectives of this course are to:

1. Introduce the fundamentals of Python programming for pharmaceutical sciences.
2. Develop basic programming skills using control structures, functions, and data structures.
3. Provide knowledge of data handling techniques for structured dataset management.
4. Familiarize students with data analysis tools such as NumPy and Pandas for healthcare datasets.
5. Enable students to visualize and interpret pharmaceutical data.

Course Outcomes (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the fundamentals of Python programming, including variables, data types, operators, and libraries.
2	Analyze program logic using control structures and functions.
3	Organize, manipulate, and retrieve data using data structures and file handling techniques.
4	Analyze pharmaceutical datasets using Python libraries.
5	Visualize and interpret pharmaceutical data using graphical tools.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Introduction to Python programming** • Installing Python and an Integrated Development Environment (IDE) [Jupyter Notebook, PyCharm, VS Code etc.], Advantages of IDEs over text editors. • Python variables and data types (integers, floats, strings, booleans), Type casting and basic operators (arithmetic, comparison, logical), Input and output operations.	6 Hours

	• Basic string operations and manipulation techniques. Introduction to standard libraries and third-party libraries, installing and uninstalling libraries.	
II	**Control Structures & Functions** • Conditional statements (if, if-else, if-elif-else), nested conditions • Loops (for loop, while loop). • Break and continue statements. • Defining and calling functions, passing arguments and returning values. • Writing modular programs for simple pharmaceutical applications- dosage calculation and BMI calculation.	6 hours
III	**Data Structures & File Handling** • Lists, tuples, and dictionaries. • Indexing and slicing lists, basic operations on lists and dictionaries, string manipulation techniques. • Introduction to NumPy arrays, basic operations using NumPy (array creation, arithmetic operations). • Reading and writing CSV files. • Understanding structured healthcare datasets. • Importing small pharmaceutical datasets and performing basic data access and manipulation tasks.	6 hours
IV	**Data Handling with Pandas** • Introduction to Pandas library. • Pandas Series and DataFrame structures. • Reading CSV and Excel files-PK study datasets and ADR reports • Inspecting datasets using functions such as head (), tail (), info (), and describe (). • Data cleaning techniques and handling missing values. • Filtering and selecting data based on conditions. • Grouping data and performing aggregation functions.	6 Hours
V	**Data Visualization with Matplotlib** • Introduction to Matplotlib. • Creating line plots, histograms, scatter plots, and box plots. • Labeling axes, titles, and legends. • Create plots and visualize pharmaceutical datasets - concentration-time curves for oral and IV administration, ADR reporting rates across drugs, dissolution profiles. • Scientific interpretation of plots.	6 Hours

Recommended References *(Preferably Latest Editions)*:

1. Weiss, C.J., 2017. *Scientific Computing for Chemists with Python*. Available at: https://weisscharlesj.github.io/SciCompforChemists/notebooks/introduction/intro.html
2. Perkovic, L., 2015. *Introduction to Computing Using Python: An Application Development Focus*. 2nd ed. Hoboken: Wiley.
3. Sweigart, A., 2025. *Automate the Boring Stuff with Python*. 3rd ed. Available at: https://automatetheboringstuff.com/
4. W3Schools, n.d. *Python Tutorial*. Available at: https://www.w3schools.com/python/
5. Datasets for Education and Research:
   Mentors and students can access healthcare datasets from sources such as Kaggle (healthcare records), government agencies (healthdata.gov, WHO, https://www.data.gov.in/), and clinical trial registries (https://ctri.nic.in/, https://clinicaltrials.gov/). *Always use data responsibly*.

Course Code	Course Title			Course Type
BP102T	**General Pharmacy (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. Provide knowledge about evolution and development of Pharmacy profession in India and the growth of the Pharmaceutical Industries over the years.
2. Provide understanding of different types of pharmacopoeias and other official books in maintaining the standards of medicines.
3. Provide knowledge about the basic pharmaceutical calculations used in dispensing and compounding.
4. Understand the role of active pharmaceutical ingredients and pharmaceutical excipients in drug formulations
5. Impart basic knowledge about formulation and preparation of Various solid, liquid and semisolid dosage forms

Course Outcomes (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Describe the history and evolution of the pharmacy profession, including pharmacopeial practices and prescription handling.
2	Perform accurate pharmaceutical calculations required in the formulation and preparation of various types of dosage forms.
3	Explain the properties and functions of active pharmaceutical ingredients (APIs) and excipients and demonstrate the methods of preparation of solid dosage forms.
4	Illustrate the formulation principles of liquid dosage forms by analyzing the role of APIs and excipients involved.
5	Compare and evaluate the formulation of semisolid dosage forms based on the characteristics of APIs, excipients, and preparation methods.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Introduction to the Profession of Pharmacy** • History of the Profession of Pharmacy in India: In relation to pharmacy education, pharmaceutical industries and organizations– evolution, development and milestones. • Scope of the Pharmacy Profession: Role and responsibilities of pharmacists in retail/community pharmacy, hospital and clinical pharmacy, and industrial pharmacy including research and development. • Pharmacopoeias: Introduction to IP, BP, USP, BPC, International Pharmacopoeia, other pharmacopoeias and the National Formulary of India; structure and content of the Indian Pharmacopoeia; study of one model IP monograph. • Introduction to Prescription: Structure and format/parts of prescription, handling of prescriptions, Latin terminology related to prescriptions.	9 hours
II	**Pharmaceutical Calculations** • Metric system of weights and measures; calculations based on alligation, proof spirit, isotonic solutions, dilute solutions (percentage and ratio) and geometric dilution; scientific notation of units and measures. • Posology: Definition and dose calculation based on age, body weight and body surface area. • Introduction to Dosage Forms: Routes of administration and classification of dosage forms. • Introduction to Active Pharmaceutical Ingredients and Excipients: Definition, ideal characteristics and importance.	9 hours
III	**Solid Dosage Forms** • Powders: Classification, advantages and disadvantages; dusting powders, effervescent powders, efflorescent powders, hygroscopic powders and eutectic mixtures; introduction to excipients and methods of preparation. • Tablets: Definition, types of tablets including moulded tablets and pills with examples; advantages and disadvantages; introduction to excipients and methods of preparation. • Capsules: Definition, types of capsules, advantages and disadvantages, capsule sizes; introduction to excipients and methods of preparation.	9 hours
IV	**Monophasic and Biphasic Liquids** • For internal use – aromatic waters, syrups, elixirs and linctus (definition and preparation).	9 hours

	• For external use and body cavities – liniments, lotions, throat paints, applications, gargles, mouthwashes, enemas, eye drops, ear drops, nasal drops and tinctures with examples. • Study of official preparations; introduction to excipients and methods of preparation. • Suspensions- Definition and types (flocculated and deflocculated), advantages and disadvantages, formulation excipients and general methods of preparation. • Emulsions- Definition and types, emulsifying agents, tests for identification of types of emulsions, formulation excipients and general methods of preparation.	
V	**Semisolid Dosage Forms** • Definitions, classification, advantages and disadvantages, ointment bases and other excipients used in semisolid dosage forms; general methods of preparation of ointments, pastes, creams and gels. • Suppositories / Pessaries: Definition, types of suppositories, advantages and disadvantages, formulation excipients used in suppositories, properties of ideal suppository bases, types of suppository bases, displacement value and general method of preparation.	9 hours

Recommended References *(Preferably Latest Editions)*:

1. Ansel, H.C., Allen, L.V. and Popovich, N.G., *Pharmaceutical Dosage Forms and Drug Delivery Systems*. Lippincott Williams & Wilkins, New Delhi.
2. Carter, S.J., *Cooper and Gunn's Dispensing for Pharmaceutical Students*. CBS Publishers, New Delhi.
3. Indian Pharmacopoeia Commission, *Indian Pharmacopoeia*. Ghaziabad.
4. Indian Pharmacopoeia Commission, National Formulary of India. Ghaziabad, India.
5. British Pharmacopoeia Commission, *British Pharmacopoeia*. London.
6. United States Pharmacopeial Convention, *United States Pharmacopeia (USP ~~N~~F)*. Rockville, Maryland, USA.
7. Lachman, L., Lieberman, H.A. and Kanig, J.L., *The Theory and Practice of Industrial Pharmacy*. Lea & Febiger, University of Michigan.
8. Gennaro, A.R., *Remington: The Science and Practice of Pharmacy*. Lippincott Williams & Wilkins, New Delhi.
9. Rawlins, E.A., *Bentley's Textbook of Pharmaceutics*. Elsevier Health Sciences, USA.
10. Nieloud, F. and Marti-Mestres, G., *Pharmaceutical Emulsions and Suspensions*. Marcel Dekker Inc., New York.

Course Code	Course Title			Course Type
BP103T	**Healthcare Psychology and Communication Skills (Theory)**			**Core**
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	1	--	--	15
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Introduce the fundamental concepts and branches of psychology relevant to healthcare.
2. Help students understand human behavior, development, and psychological responses to illness.
3. Develop awareness of common psychological disorders and coping mechanisms in healthcare contexts.
4. Equip students with effective health communication skills for clinical and community settings.
5. Promote professional interaction with patients, caregivers, and healthcare teams through ethical and empathetic communication.

Course Outcomes (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the fundamental concepts of psychology and their relevance in healthcare settings.
2	Describe the stages of human development, personality traits, and behavioral responses associated with illness and recovery.
3	Apply effective communication models and techniques in clinical and interdisciplinary healthcare scenarios.
4	Demonstrate professional communication skills including active listening, empathetic interaction, and accurate clinical documentation.
5	Analyze psychological and behavioral interventions that promote mental health, treatment adherence, and stigma reduction.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Introduction to Psychology in Healthcare** Definition, scope, and relevance of psychology in health sciences. Branches of psychology with healthcare relevance: clinical, health, behavioural, and developmental psychology. Sensation, perception, and attention in clinical assessment. Learning and memory: reinforcement in health behaviour change. Emotion and motivation: theories and implications in health contexts.	3 hours
II	**Developmental and Behavioural Psychology** Human developmental stages and healthcare needs. Personality theories and patient interaction styles. Psychological factors affecting illness perception and recovery. Common psychological disorders in healthcare: anxiety, depression, and somatization. Coping strategies, resilience, and stress management techniques.	3
III	**Foundations of Health Communication** Elements and models of communication in healthcare. Types of communication: interpersonal, group, mass, and telehealth communication. Barriers to effective communication in clinical settings. Active listening, questioning techniques, and empathy. Culturally appropriate and inclusive communication.	3
IV	**Professional Communication in Healthcare Settings** Communication with patients, caregivers, and interdisciplinary teams. Delivering difficult news and handling emotionally charged situations. Legal and ethical issues in health communication (confidentiality, consent). Writing patient records, reports, and discharge summaries. Use of technology and digital communication tools in healthcare services.	3
V	**Health Psychology and Behavioural Interventions** Health belief models and illness behaviour. Psychosomatic illnesses and the mind–body connection. Behaviour change theories (e.g., CBT, TTM) in treatment adherence. Psychological first aid and crisis communication. Mental health promotion and stigma reduction through communication.	3

Recommended References *(Preferably Latest Editions)*:

1. Feldman, R.S., Understanding Psychology. McGraw-Hill Education, New York.
2. Taylor, S.E., Health Psychology. McGraw-Hill Education, New York.
3. Hargie, O., The Handbook of Communication Skills. Routledge, London.

4. Nevid, J.S., Rathus, S.A. and Greene, B., Psychology and the Challenges of Life: Adjustment and Growth. Wiley, New York.
5. Atkinson, R.L., Atkinson, R.C., Smith, E.E., Bem, D.J. and Nolen-Hoeksema, S., Introduction to Psychology. Wadsworth Publishing, Belmont.
6. Kumar, A., Communication Skills for Health Professionals. Jaypee Brothers Medical Publishers, New Delhi.
7. Park, K., Park's Textbook of Preventive and Social Medicine. Banarsidas Bhanot Publishers, Jabalpur.

Course Code	Course Title			Course Type
BP104T	**Human Anatomy, Physiology and Pathophysiology I (Theory)**			**Core**
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
4	4	--	--	60
Maximum Marks	SE			ESE
100	40			60

COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand the structural organization of the human body from cells to systems.
2. Comprehend physiological functions of various body systems and the principles of homeostasis.
3. Learn the cellular basis of disease including injury, adaptation, and inflammation.
4. Recognize common pathological conditions related to skin, bones, joints, blood, cardiovascular system, and special senses.
5. Establish the groundwork for clinical interpretation of symptoms and disease mechanisms relevant to pharmacy and therapeutics.

Course Outcomes (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the fundamental concepts of Human Anatomy, Physiology and Pathophysiology.
2	Explain the gross morphology, structure and functions of various organs of the human body.
3	Understand the etiology and pathogenesis of diseases/disorders associated with integumentary system, peripheral nervous system and cardiovascular system
4	Understand the basic mechanism behind inflammation
5	Identify and differentiate the various tissues and organs of different systems of human body.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Introduction to human body** Cellular and tissue level of organization. Definition and scope of anatomy, physiology and pathophysiology. Levels of structural organization and body systems, basic life processes,	12 hours

	homeostasis, basic anatomical terminologies. Structure and functions of cell, transport across cell membrane, cell division, cell junctions. General principles of cell communication, forms of intracellular signaling- a) Contact-dependent, b) Paracrine, c) Synaptic, d) Endocrine Classification of tissues, structure, location and functions of epithelial, muscular and nervous and connective tissues. **Basic principles of cell injury and adaptation** Components and types of feedback systems, causes of cellular injury, pathogenesis (cell membrane damage, mitochondrial damage, ribosome damage and nuclear damage), morphology of cell injury – adaptive changes (atrophy, hypertrophy, hyperplasia, metaplasia, dysplasia), cell swelling, intra cellular accumulation and cell death. Definitions of commonly used relevant medical terminologies.	
II	**Integumentary system and wound healing** Structure and functions of skin. Skin disorders: Psoriasis and dermatitis and pathophysiology of Leprosy. Basic principles of wound healing. **Skeletal system and joints** Divisions of skeletal system, types of bones, salient features and functions of bones of axial and appendicular skeletal system. Organization of skeletal muscle, physiology of muscle contraction, neuromuscular junction. Structural and functional classification of joints. **Diseases of bones and joints** Pathophysiology of rheumatoid arthritis, osteoporosis and gout.	12 hours
III	**Body fluids, blood and lymphatic system** Body fluids, composition and functions of blood, hemopoiesis, formation of haemoglobin, mechanisms of coagulation, blood grouping, Rh factors and transfusion. Lymphatic organs and tissues, lymphatic vessels, lymph formation, circulation and functions of lymphatic system. **Basic mechanism of inflammation and repair** Introduction, classification and pathophysiology of inflammation, mediators of inflammation. **Haematological diseases** Pathophysiology of iron deficiency, megaloblastic anaemia (Vit B12 and folic acid), sickle cell anaemia, Thalassemia, hereditary acquired anaemia and haemophilia.	12 hours
IV	**Peripheral nervous system** Classification of peripheral nervous system: structure and functions of sympathetic and parasympathetic nervous system. Origin and functions of spinal and cranial nerves. **Special senses** Structure and functions of eye, ear, nose and tongue. Pathophysiology	12 hours

	of special sense disorders- glaucoma, cataract, myopia, otitis externa, otitis media, vertigo and anosmia	
V	**Cardiovascular system** Anatomy of heart, blood circulation, blood vessels, structure and functions of artery, vein and capillaries, elements of conduction system of heart and heartbeat, its regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of blood pressure, pulse, electrocardiogram. Pathophysiology of hypertension, cardiac arrhythmias, congestive heart failure, ischemic heart disease (angina, myocardial infarction, atherosclerosis and coronary artery disease).	12 hours

Recommended References *(Preferably Latest Editions)*:

1. Sembulingam, K. and Sembulingam, P., *Essentials of Medical Physiology*. Jaypee Brothers Medical Publishers, New Delhi.
2. Guyton, A.C. and Hall, J.E., *Textbook of Medical Physiology*. Elsevier Saunders, Philadelphia, USA.
3. Tortora, G.J. and Grabowski, S.R., *Principles of Anatomy and Physiology*. Wiley, Palmetto, GA, USA.
4. Kumar, V., Cotran, R.S. and Robbins, S.L., *Basic Pathology*. W.B. Saunders Company, Philadelphia.

Course Code	Course Title			Course Type
BP105T	**Introduction to Pharmacognosy (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. Explain the origin, history, and classification of natural drugs.
2. Understand cultivation and conservation methods for medicinal plants.
3. Study quality control and evaluation of crude drugs.
4. Study primary and secondary metabolites with their therapeutic relevance
5. Introduce traditional systems of medicine and phyto-therapeutic agents.

COURSE OUTCOMES (CO)

CO No.	Upon successful completion of this course, the students will be able to:
1	Describe the historical development, classification, and scope of Pharmacognosy.
2	Explain cultivation, processing, and conservation techniques for medicinal plants.
3	Apply quality evaluation methods to crude drugs using organoleptic, microscopic, and chemical parameters.
4	Identify primary and secondary metabolites with their therapeutic relevance.
5	Recognize traditional systems of medicine and commonly used phyto-therapeutic agents.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Fundamentals of Pharmacognosy** (a) Definition, history, present status, scope and development of pharmacognosy. (b) **Sources of drugs:** Plants, animals, microbial, marine, mineral and plant tissue culture. (c) **Historical milestones in drug discovery:** Morphine, quinine, aspirin, warfarin, penicillin, cephalosporin, taxol and artemisinin. (d) **Introduction to different herbal / traditional pharmacopoeias:** Indian Pharmacopoeia, British Herbal Pharmacopoeia, United States Pharmacopeia– Herbal Medicines and Dietary Supplements, Ayurvedic Pharmacopoeia of India, Unani Pharmacopoeia of India and American Herbal Pharmacopoeia. (e) **Official and non-official; codified and non-codified drugs.** Classification of crude drugs: alphabetical, morphological, taxonomical, chemical, pharmacological	10 hours

	and chemotaxonomic classification along with their merits and limitations.	
	(e) **Official and non-official; codified and non-codified drugs.** Classification of crude drugs: alphabetical, morphological, taxonomical, chemical, pharmacological and chemotaxonomic classification along with their merits and limitations.	
II	**Cultivation, Collection, Processing and Storage of Drugs of Natural Origin** Methods of plant cultivation and Good Agricultural and Collection Practices (WHO / GAP / GCP guidelines) for medicinal plants. Factors influencing cultivation, collection and storage of medicinal plants. Plant hormones and their applications in cultivation of medicinal plants. Application of polyploidy, mutation and hybridization concepts with reference to secondary metabolites. Ex-situ and in-situ conservation and strategies for value addition of medicinal plants. Role of eco-pharmacognosy in sustainable conservation of endangered medicinal plants such as kutki and chirata.	8 hours
III	**Quality Control of Drugs of Natural Origin (WHO Guidelines)** Adulteration of drugs of natural origin. Evaluation of drugs using organoleptic, microscopic (qualitative and quantitative), physical, chemical and biological methods. Physicochemical parameters: extractive values, moisture content, foreign organic matter, ash values, bitterness value, foaming index, haemolytic potential, swelling index, viscosity, optical rotation, refractive index, acid value and saponification value. DNA barcoding.	8 hours
IV	**Introduction to Metabolites of Plant Origin** Definition and general properties of plant metabolites. Primary and secondary metabolites such as carbohydrates, proteins, lipids, alkaloids, glycosides, flavonoids, tannins, terpenoids, volatile oils and resins. **Traditional Systems of Medicine** Basic principles of treatment of diseases in different systems of medicine including AYUSH and TCM. Types of dosage forms in AYUSH medicines. Role of pharmacognosy in allopathy and traditional systems of medicine such as AYUSH and TCM.	12 hours
V	**Phyto-therapeutic Agents** Biological source, major constituents and uses of the following classes of drugs: • Adaptogens and Immunomodulators: Ashwagandha, Tulsi, Amla • Hepatoprotectives: Milk thistle, Kutki • Cardiovascular drugs: Garlic, Arjuna • Antidiabetics: Gymnema, Fenugreek • Anti-inflammatory and analgesics: Turmeric, Boswellia • CNS drugs: Brahmi • Antimicrobial and antivirals: Giloy, Neem, Andrographis • Gastrointestinal drugs: Psyllium • Dermatological agents: Aloe • Drugs used in women's health: Chasteberry, Shatavari • Respiratory drugs: Vasaka	7 hours

Recommended References (*Preferably latest editions*):

1. Evans, W.C., *Trease and Evans Pharmacognosy*. 16th ed. London: W.B. Saunders & Co., 2009.
2. Tyler, V.E., Brady, L.R. and Robbers, J.E., *Pharmacognosy*. 9th ed. Philadelphia: Lea & Febiger, 1988.
3. Wallis, T.E., *Textbook of Pharmacognosy*. London: J. & A. Churchill Ltd.
4. World Health Organization (2002) *WHO traditional medicine strategy 2002–2005*. Geneva: World Health Organization
5. World Health Organization (1998) *Quality control methods for medicinal plant materials*. Geneva: World Health Organization.
6. World Health Organization (2003) *WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants*. Geneva: World Health Organization.

Course Code	Course Title			Course Type
BP106T	**Pharmaceutical Inorganic and Analytical Chemistry (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 importance of errors, impurities in pharmaceuticals.
2. Comprehend the principles of buffer systems.
3. Develop skills in performing and interpreting limit tests and titrimetric analysis.
4. Emphasize the importance of inorganic compounds and radiopharmaceuticals in Pharmacy
5. Explain synthesis and analysis of inorganic compounds/products of pharmaceutical importance

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Identify sources and types of errors in pharmaceutical analysis, and impurities products
2	Apply concepts of acid-base chemistry, buffer systems with importance of electrolytes
3	Describe and differentiate various analytical techniques used in pharmaceutical analysis, including titrimetric methods, and their specific applications in quality assessment.
4	Analyze the properties, mechanisms, and therapeutic uses of gastrointestinal agents, radiopharmaceuticals, expectorants, antidotes, and other pharmaceutical compounds, illustrating their roles in therapy and safety considerations.
5	Describe the drugs used in expectorants, emetics, haemintics, poison and antidote and astringents.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Introduction to pharmaceutical analysis** Different techniques of analysis, Methods of expressing strength of solutions, Primary and secondary standards with examples. **Errors** Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures. **Impurities** Definition, types, contents and regulatory importance. Sources and types of impurities in Pharmaceuticals, limit tests for chloride, sulphate, iron, arsenic, lead, heavy metals, and modified limit test for chloride and sulphate.	7 hours
II	**Acid-Base Chemistry and Buffer Systems in Pharmacy** Definition of acids, bases, buffers, pH Scale and its significance, Buffer equation, calculation of pH for Buffer solution. Isotonicity and its application in IV Fluids and Ophthalmic Solutions. **Major extra and intracellular electrolytes** Functions of major physiological ions, Electrolytes used in the replacement therapy: Sodium chloride*, Potassium chloride, Calcium chloride and Oral Rehydration Salt (ORS), Physiological acid base balance.	8 hours
III	**Acid base titrations** Theories of acid base indicators, classification of acid base titrations. Preparation and standardization of titrants viz. hydrochloric acid and sodium hydroxide. Theory involved in titrations of strong, weak, and very weak acids and bases, neutralization curves. Assay of Ammonium hydroxide. **Non-aqueous titrations** Types of solvents used, acidimetric and alkalimetric titration using non-aqueous solvents. Preparation and standardization of acidic and basic titrants. Estimation of weakly acidic and basic substances using non-aqueous titrants, estimation of Sodium benzoate. **Precipitation titrations and gravimetry** Principle and steps involved in gravimetric analysis, Mohr's method, Volhard's, Modified Volhard's, Fajans method. Estimation of barium sulphate by gravimetry. **Complexometric titrations** Classification, metal ion indicators, masking and demasking reagents, preparation and standardization of disodium EDTA. Estimation of Magnesium sulphate and Calcium gluconate*.	14 hours

	Redox titrations Concepts of oxidation and reduction, Types of redox titrations viz. Permanganometry, Cerimetry, Iodimetry, Iodometry and titrations with potassium iodate.	
IV	**Gastrointestinal agents** Acidifiers: Sodium acid phosphate and Dilute Hydrochloric acid. Antacids: Ideal properties of antacids, combinations of antacids, Sodium bicarbonate*, Aluminium hydroxide gel*. Agents promote bowel movements: Magnesium hydroxide, Sodium orthophosphate, Sodium Potassium tartrate and magnesium trisilicate. Antimicrobials: Mechanism, classification, Potassium permanganate, Boric acid, Hydrogen peroxide*, Chlorinated lime*, Iodine and its preparations. **Radiopharmaceuticals** Basics of radioactivity, applications of radioisotopes of Sodium Iodide I-131, Technetium-99m, Cobalt-60, Phosphorus-32 including safe handling, storage, and disposal of radiopharmaceuticals, adhering to regulatory guidelines for safety.	10 hours
V	**Miscellaneous Compounds** Expectorants: Potassium iodide, Ammonium chloride*. Emetics: Copper sulphate*, Sodium potassium tartrate. Haematinics: Ferrous sulphate*, Ferrous gluconate. Poison and Antidote: Definition, classification of antidotes, Sodium thiosulphate	06 hours

Recommended References (*Preferably latest editions*):

1. Bentley, R. and Driver, J., *Bentley and Driver's Textbook of Pharmaceutical Chemistry*. Oxford: Oxford University Press.
2. Vogel, A.I., *Vogel's Textbook of Quantitative Chemical Analysis*. Essex: Pearson Education Limited.
3. Beckett, A.H. and Stenlake, J.B., *Practical Pharmaceutical Chemistry*. Part I & II. London: The Athlone Press, University of London.
4. Schroff, M.L., *Inorganic Pharmaceutical Chemistry*. New Delhi: Oxford Book Company.
5. Indian Pharmacopoeia Commission, *Indian Pharmacopoeia*. Ghaziabad, India.

Course Code	Course Title			Course Type
BP107P	**General Pharmacy (Practical)**			**Core**
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	--	--	3	45
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Familiarize students with essential pharmaceutical calculations including dilution, concentration, and allegation methods required for accurate formulation of dosage forms.
2. Impart practical skills in the preparation of official and non-official dosage forms such as solutions, syrups, powders, granules, suppositories, semisolids, gargles, and mouthwashes in accordance with pharmacopeial standards.
3. Develop understanding of formulation principles related to selection of ingredients, dosage form design, stability, and patient acceptability.
4. Train students in the application of pharmacopoeial specifications (IP, BPC, WHO) during compounding, labeling, and evaluation of pharmaceutical preparations.
5. Enhance hands-on competency and professional confidence required for dispensing practice and pharmaceutical compounding in hospital and community pharmacy settings.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Perform accurate pharmaceutical calculations using dilution and allegation principles for the preparation of various dosage forms.
2	Prepare and dispense liquid dosage forms such as solutions, syrups, gargles, and mouthwashes following official pharmacopeial procedures.
3	Formulate solid dosage forms including powders, divided powders, dusting powders, and effervescent granules as per standard guidelines.
4	Prepare semisolid and specialized dosage forms such as ointments, liniments, and suppositories using appropriate bases and techniques.
5	Compile and evaluate a compendium of marketed dosage forms, demonstrating compliance with pharmacopeial standards, labeling requirements, and patient-centric considerations

Detailed Syllabus:

List of practical
1. Pharmaceutical Calculations Solutions based on allegation and dilution methods **2. Solutions** a) Strong solution of ammonium acetate – IP b) Cresol with soap solution – IP c) Lugol's solution – BPC **3. Syrups** a) Simple Syrup – IP **4. Powders & Granules** a) ORS powder – WHO b) Effervescent granules – IP c) Dusting powder – IP d) Divided powders – IP **5. Suppositories** a) Glycerogelatin suppository – BPC b) Cocoa butter suppository – IP c) Zinc Oxide suppository – IP **6. Semisolids** a) Sulphur ointment – IP b) Non-staining iodine ointment with methyl salicylate – BPC **7. Gargles & Mouthwashes** a) Iodine gargle – BPC b) Chlorhexidine mouthwash – IP ***Note:*** *a) Preparation of compendia of dosage forms (marketed products), is recommended.* *b) Any other practical relevant to the syllabus can be introduced.* *c) Minimum 12 experiments must be performed covering all dosage forms.*
Recommended References (*Preferably latest editions*): 1. Carter, S.J., *Cooper and Gunn's Dispensing for Pharmaceutical Students*. 12th ed. New Delhi: CBS Publishers. 2. Indian Pharmacopoeia Commission, *Indian Pharmacopoeia*, Vol. I. Ghaziabad: IPC. 3. United States Pharmacopeial Convention, *United States Pharmacopeia National Formulary (USP–NF)*. Rockville, MD, USA. 4. British Pharmacopoeia Commission, *British Pharmacopoeia Codex*. London: The Stationery Office. 5. World Health Organization, *Oral Rehydration Salts (ORS) Formulation Guidelines*. Geneva: WHO.

Course Code	Course Title			Course Type
BP108P	**Healthcare Psychology and Communication 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:

1. To develop effective communication skills essential for diverse clinical and community health scenarios.
2. To enhance empathetic interaction through role plays, simulations, and reflective practices.
3. To promote collaborative learning and peer feedback in communication-based tasks.
4. To encourage application of psychological principles in real-life healthcare contexts.
5. To build confidence in delivering health education and awareness activities in community settings.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Demonstrate patient-centered communication through role plays and clinical simulations.
2	Analyze healthcare communication challenges using case study discussions.
3	Practice reflective listening, paraphrasing, and team-based communication strategies.
4	Design and deliver effective health education messages for the community.
5	Reflect on personal emotional growth and improvement in communication competencies.

Detailed Syllabus:

List of practical
1. **Role Plays and Simulations** Counselling a patient with chronic illness Breaking bad news in a clinical setting Empathetic listening in crisis response

2. **Case Study Discussions**
   Mental health cases in primary care
   Impact of miscommunication in healthcare errors
3. **Peer-to-Peer Practice Sessions**
   Reflective listening and paraphrasing
   Effective team communication and decision-making
4. **Community Engagement Tasks**
   Designing IEC materials for public health awareness
   Conducting mock health education sessions
5. **Journaling & Self-Reflection Logs**
   Weekly reflection on emotional responses during care simulations
   Growth in communication skill development over the semester

Recommended References (*Preferably latest editions*):

1. Morgan, C.T. and King, R.A., *Introduction to Psychology*. New York: McGraw-Hill.
2. Taylor, S.E., *Health Psychology*. New York: McGraw-Hill Education.
3. Hargie, O., *Skilled Interpersonal Communication: Research, Theory and Practice*. London: Routledge.
4. Balzer-Riley, J., *Communication in Nursing and Healthcare*. Boston: Pearson.
5. Weinman, J., Petrie, K.J. and Moss-Morris, R., *The Psychology of Health and Illness*. London: Routledge.

Course Code	Course Title			Course Type
BP109P	**Human Anatomy, Physiology and Pathophysiology I (Practical)**			Core
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	--	--	3	45
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Provide fundamental knowledge of the structure and functions of various organ systems of the human body.
2. Understand the mechanisms of homeostasis and their role in maintaining normal physiological functions.
3. Introduce the basic concepts of pathophysiology and the causes of diseases affecting different organ systems.
4. E-producing agents.
5. Lay the foundation for understanding clinical conditions through the study of functional alterations in organs and systems.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the principles, applications, and experimental use of microscopy techniques, and perform basic laboratory experiments related to the nervous system and special senses.
2	Describe the gross morphology, microscopic structure, and coordinated functioning of major human organs and organ systems, emphasizing their roles in maintaining normal physiology.
3	Estimate and interpret key hematological parameters, and explain the mechanisms of homeostasis along with related physiological and pathological disorders.
4	Discuss the etiology and pathogenesis of selected disease states, linking structural and functional changes to clinical manifestations.
5	Identify and explain common diseases with respect to their signs and symptoms, risk factors, diagnostic methods, preventive measures, treatment strategies, and possible complications.

Detailed Syllabus:

List of practical
(Minimum 12 experiments must be performed) Practical HAPP allows the verification of physiological processes discussed in theory classes through experiments on living tissues, simulated videos, models and charts. 1. Study of compound microscopes. 2. Microscopic study of epithelial and connective tissue. 3. Microscopic study of muscular and nervous tissue. 4. Identification of axial bones. 5. Identification of appendicular bones. 6. Introduction to hemocytometry. 7. Demonstration of total blood count by cell analyser. 8. Enumeration and interpretation of white blood cell (WBC) count, differential count. 9. Enumeration and interpretation of total red blood corpuscles (RBC) count. 10. Determination of bleeding time and clotting time. 11. Estimation and interpretation of hemoglobin content. 12. Determination of blood group. 13. Determination and interpretation of erythrocyte sedimentation rate (ESR). 14. Determination of pulse rate, heart rate and blood pressure. 15. Recording and interpretation of ECG. 16. To study the cardiovascular system and integumentary system. 17. Case studies/files of patients with anaemia, thalassemia, haemophilia, leprosy, gout, hypertension and ischemic heart disease.
Recommended References *(Preferably latest editions)*: 1. Wilson, K.J.W., *Anatomy and Physiology in Health and Illness*. New York: Churchill Livingstone. 2. Guyton, A.C. and Hall, J.E., *Textbook of Medical Physiology*. Philadelphia: Elsevier. 3. Tortora, G.J. and Grabowski, S.R., *Principles of Anatomy and Physiology*. New York: Wiley.

Course Code	Course Title			Course Type
BP110P	**Introduction to Pharmacognosy (Practical)**			**Core**
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	--	--	3	45
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Identify medicinal plants and crude drugs using morphological and microscopical characters.
2. Analyze powdered drugs and perform quantitative microscopy.
3. Evaluate crude drugs using physicochemical parameters.
4. Introduce standardization and quality control of herbal materials.
5. Collect medicinal plants and prepare voucher specimens.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Identify medicinal plants and crude drugs using morphological and microscopical characters.
2	Analyze powdered drugs microscopically to identify diagnostic cell contents.
3	Perform quantitative microscopy for stomatal and vein parameters.
4	Evaluate quality and purity of crude drugs using physicochemical parameters.
5	Collect medicinal plants and prepare voucher specimens during field visits.

Detailed Syllabus:

List of practices
(Minimum 12 experiments must be performed) 1. Morphological study of medicinal plants (as mentioned in Unit V Theory). 2. Organoleptic evaluation and powder microscopical characters of the following drugs: Tulsi and Ashwagandha. 3. Organoleptic evaluation and powder microscopical characters of the following drugs: Amla and Arjuna. 4. Organoleptic evaluation and powder microscopical characters of the following drugs: Turmeric and Psyllium husk.

5. Organoleptic evaluation and powder microscopical characters of the following drugs: Brahmi and Fenugreek.
6. Determination of moisture content of crude drugs.
7. Determination of swelling index and foaming index of crude drugs.
8. Determination of stomatal number and stomatal index of leaf.
9. Determination of vein islet and vein termination number of leaf.
10. Determination of ash value and extractive values of crude drugs.
11. Determination of foreign organic matter of crude drugs.
12. Determination of dimensions of calcium oxalate crystals and phloem fibers by eyepiece micrometry.
13. Determination of dimensions of starch grains by eyepiece micrometer.
14. Experiential learning-based experiments involving collection, identification of medicinal plant material, preparation of voucher specimens and excursion visits to medicinal plant garden.

Recommended References *(Preferably Latest Editions)*:

1. Evans, W.C., 2009. *Trease and Evans Pharmacognosy*. 16th ed. London: W.B. Saunders & Co.
2. Tyler, V.E., Brady, L.R. and Robbers, J.E., 1988. *Pharmacognosy*. 9th ed. Philadelphia: Lea & Febiger.
3. Wallis, T.E., *Textbook of Pharmacognosy*. London: J. & A. Churchill Ltd.

Course Code	Course Title			Course Type
BP111P	**Pharmaceutical Inorganic and Analytical Chemistry (Practical)**			**Core**
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	--	--	3	45
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Gain practical knowledge on various volumetric titration techniques.
2. Learn the principles of volumetric analysis.
3. Study the preparation and assessment of inorganic compounds.
4. Determine the assay of various inorganic compounds in pharmaceutical use.
5. Develop analytical skill for the qualitative and quantitative analysis of various inorganic compounds.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Perform limit tests to detect and identify impurities in pharmaceutical substances.
2	Prepare various pharmaceutical inorganic compounds following standard procedures.
3	Analyze the significance of quality control in pharmaceutical products and raw materials.
4	Demonstrate proficiency in titrimetric analysis using different volumetric techniques.
5	Competence in applying analytical skills to qualitative and quantitative data.

Detailed Syllabus:

List of practical
1. **Limit tests (Any 4 Experiments)** a. Limit test and modified limit test for Chloride as per Indian Pharmacopoeia b. Limit test and modified limit test for sulphate as per Indian Pharmacopoeia c. Limit test for Iron d. Limit test for Lead e. Limit test for arsenic 2. **Preparation of inorganic pharmaceuticals (Any 3 Experiments)** a. Preparation of Aluminium hydroxide b. Preparation of potash alum c. Preparation of ferrous sulphate d. Preparation of Magnesium sulphate from magnesium hydroxide or magnesium carbonate

3. **Test for Purity (Any 2 Experiments)** a. Assessment of swelling power of bentonite as per Indian Pharmacopoeia b. Evaluation of acid neutralizing capacity of aluminum hydroxide gel c. Determination of potassium iodate and iodine in potassium Iodide
4. **Assay of the following inorganic compounds including standardization of titrant (Any 5 Experiments)** a. Assay of ammonium chloride by acid base titration, b. Assay of Ferrous sulphate by Cerimetry, c. Assay of Copper sulphate by Iodometry, d. Assay of Calcium gluconate by Complexometry, e. Assay of Hydrogen peroxide by Permanganometry, f. Assay of Sodium benzoate by non-aqueous titration, g. Assay of Sodium Chloride by precipitation titration (Modified Volhard's method)

Recommended References *(Preferably Latest Editions)*:

1. Bentley, R. and Driver, J., *Bentley and Driver's Textbook of Pharmaceutical Chemistry*. Oxford: Oxford University Press.
2. Vogel, A.I., *Vogel's Textbook of Quantitative Chemical Analysis*. Essex: Pearson Education Limited.
3. Beckett, A.H. and Stenlake, J.B., *Practical Pharmaceutical Chemistry*. Part I & II. London: The Athlone Press, University of London.
4. Kennedy, J.H., *Analytical Chemistry: Principles*. New York: Saunders College Publishing.
5. Schroff, M.L., *Inorganic Pharmaceutical Chemistry*. New Delhi: Oxford Book Company.
6. Indian Pharmacopoeia Commission, *Indian Pharmacopoeia*. Ghaziabad, India.

Semester II

Course Code	Name of the Course	No. of hours/week (L/P)	Continuous Mode (Marks)	Sessional Exam (Marks)	Sessional Duration	Internal Total	End Semester Marks	Exam Duration	Total Marks	Credit points
BP201T	Applied Biostatistics and Data Analytics for Pharmaceutical Sciences (Theory)	2	10	10	1 Hr	20	30	1.5 Hr	50	2
BP202T	Biochemistry (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP203T	Human Anatomy, Physiology and Pathophysiology II (Theory)	4	20	20	1 Hr	40	60	3 Hr	100	4
BP204T	Pharmaceutical Organic Chemistry (Theory)	4	20	20	1 Hr	40	60	3 Hr	100	4
BP205T	Pharmacognosy and Phytochemistry (Theory)	4	20	20	1 Hr	40	60	3 Hr	100	4
BP206T	Physical Pharmaceutics (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP207P	Biochemistry (Practical)	3	10	10	3 Hr	20	30	3 Hr	50	1
BP208P	Human Anatomy, Physiology and Pathophysiology II (Practical)	3	10	10	3 Hr	20	30	3 Hr	50	1
BP209P	Pharmaceutical Organic Chemistry (Practical)	3	10	10	3 Hr	20	30	3 Hr	50	1
BP210P	Pharmacognosy and Phytochemistry (Practical)	3	10	10	3 Hr	20	30	3 Hr	50	1
BP211P	Physical Pharmaceutics (Practical)	3	10	10	3 Hr	20	30	3 Hr	50	1
BP212P	SEC* – Elective 1 (Practical)	2	10	10	3 Hr	20	30	3 Hr	50	1
Total		**37**	**160**	**160**	**24 Hr**	**320**	**480**	**32.5 Hr**	**800**	**26**

* Only one elective course shall be selected

The syllabi for elective subjects are given in the APPENDIX

Course Code	Course Title			Course Type
BP201T	**Applied Biostatistics and Data Analytics for Pharmaceutical Sciences (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 fundamental statistical concepts relevant to pharmaceutical sciences.
2. Develop the ability to interpret clinical and experimental data scientifically.
3. Apply statistical methods for analyzing pharmaceutical and biomedical data.
4. Demonstrate the use of Python-based tools for statistical analysis and data handling.
5. Recognize the role of statistical analysis in evidence-based decision making and machine learning applications in healthcare.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Classify pharmaceutical data using appropriate descriptive statistics.
2	Apply probability concepts and statistical distributions in clinical and pharmaceutical contexts.
3	Perform sampling and hypothesis testing for decision-making in research.
4	Analyze correlation and regression relationships in pharmaceutical datasets.
5	Demonstrate statistical analysis using Python and interpret outputs appropriately.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Descriptive Statistics** • Types of data in pharmaceutical sciences (nominal, ordinal, interval, ratio) • Sources of data in pharmacy: clinical trials, pharmacovigilance, quality control, PK studies • Measures of central tendency: mean, median, mode, their calculation and interpretation	6 hours

	• Measures of dispersion (range, variance, standard deviation) and their interpretation using pharmaceutical data • Skewness and understanding distribution shape in biological measurements • Perform descriptive statistical analysis using Python libraries such as NumPy and Pandas, with focus on Interpretation of results	
II	**Probability & Statistical Distributions in Healthcare** • Basic probability concepts and laws (addition and multiplication rules), conditional probability and its interpretation • Bayes' theorem and its application in clinical decision-making • Concept of random variables (discrete and continuous) • Normal distribution and its importance in biological and pharmaceutical measurements, • Binomial distribution demonstrating applications in clinical trial outcomes • Poisson distribution for modeling rare events such as adverse drug reactions • Graphical visualization of these probability distributions using Python	6 hours
III	**Sampling & Statistical Inference** • Population versus sample, sampling techniques used in clinical research, Sampling error and bias • Conceptual understanding of the Central Limit Theorem • Confidence intervals and their interpretation • Hypothesis testing framework (null and alternative hypotheses) • Type I and Type II errors, p-value and statistical significance • Demonstration, calculation and interpretation of these parameters using python with pharmaceutical data	6 hours
IV	**Basics of Correlation & Regression** Conceptual understanding of the following concepts with emphasis on their interpretation- • correlation and Pearson correlation coefficients • Interpretation of positive and negative correlations • Scatter plots and trend visualization using pharmaceutical data such as dose-response relationships • Simple linear regression concept, interpretation of regression coefficients • Introduction to odds ratio and its application in clinical risk analysis	6 hours
V	**Statistical Analysis Using Python – Case based learning** • Demonstration of descriptive statistics, correlation analysis and linear regression using Python libraries- SciPy / Statsmodels / Scikit-learn on pharmaceutical datasets • Interpretation of the output summaries and p-values • Preparation of statistical reports	6 hours

Recommended References *(Preferably Latest Editions)*:

1. Lane, D.M., Introduction to Statistics. Houston: Rice University. Available at: https://onlinestatbook.com/2/index.html
2. Walters, S.J., Campbell, M.J. and Machin, D., Medical Statistics: A Textbook for the Health Sciences. Hoboken, NJ: Wiley-Blackwell.
3. Rowe, P., Essential Statistics for the Pharmaceutical Sciences. London: Pharmaceutical Press.
4. Bolton, S. and Bon, C., Pharmaceutical Statistics: Practical and Clinical Applications. New York: Informa Healthcare.
5. De Muth, J.E., Basic Statistics and Pharmaceutical Statistical Applications. Boca Raton, FL: CRC Press.

Course Code	Course Title			Course Type
BP202T	**Biochemistry (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. Know about enzymology and various tests in clinical chemistry
2. Understand the biochemical pathways and clinical relevance of carbohydrate, lipid and protein metabolism.
3. Describe energetics and biological oxidation.
4. Explain aminoacid and protein metabolism
5. Understand Nucleic acid metabolism and genetic information.

Course Outcomes (CO):

CO No.	Upon successful completion of this course, the students will be able to:
CO1	Explain the principles of enzymology and various tests in clinical chemistry
CO2	Describe the classification, the classification, structure, and functions of major biomolecules such as carbohydrates, lipids, proteins, nucleic acids, enzymes, and vitamins.
CO3	Explain the principles of bioenergetics, biological oxidation, and the overview of metabolic pathways of biomolecules, along with their clinical significance.
CO4	Understand metabolism of lipid and its significance.
CO5	Understand metabolism of proteins & its significance and monitoring of metabolic and organ-specific disorders.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Enzymology** a. Introduction, properties, nomenclature, and IUB classification of enzymes and coenzymes. Enzyme kinetics (Michaelis plot, Lineweaver – Burk plot). Enzyme inhibitors with examples. Regulation of enzymes: enzyme induction and repression, allosteric enzyme regulation.	10

	Therapeutic and diagnostic application of enzymes and isoenzymes. Factors affecting enzyme activity. Digestion, absorption function of dietary Macro and Micronutrients, including Vitamins and Minerals, Biochemical functions of vitamins and associated diseases. b. Clinical Chemistry: Liver function tests (routinely performed tests based on liver function). Renal function tests (routinely performed tests based on kidney function, ELISA test)	
II	a. Introduction about biomolecules – Introduction of carbohydrate, lipids, nucleic acids, amino acids and proteins. b. Bioenergetics: Concept of free energy; relationship between free energy, enthalpy, and entropy; redox potential; energy-rich compounds (ATP, GTP, etc.) and their biological significance. c. Carbohydrate Metabolism and their role in diabetes mellitus: Overview and significance of major pathways: Glycolysis, Citric Acid Cycle (TCA), Gluconeogenesis, Hexose Monophosphate (HMP) shunt, and Glycogen metabolism; regulation of blood glucose levels; metabolic adaptations during fed state, fasting, and prolonged starvation; metabolic derangements in diabetes mellitus and related disorders. d. Biological Oxidation: Electron Transport Chain (ETC), oxidative phosphorylation, and mechanisms of ATP synthesis; regulation and clinical implications of mitochondrial dysfunction and oxidative stress.	10
III	**Lipid metabolism** a. Classification, functions, and properties of lipids and lipoproteins (HDL, LDL, VLDL, chylomicrons) b. β-oxidation and de-novo synthesis of fatty acids: Ketone bodies: synthesis, utilization, and clinical significance c. Biological significance of cholesterol, lipid profile, and its clinical significance d. Disorders associated with lipid metabolism: Hyperlipidaemias and hypercholesterolemia, lipid storage diseases, atherosclerosis, fatty liver disease, and obesity	7
IV	**Amino acids and protein metabolism** a. Classification and Biological Functions: Classification and physiological roles of amino acids. Structure and functions of proteins and plasma proteins b. General Metabolism of Amino Acids: Transamination, oxidative and non-oxidative deamination, decarboxylation. Urea cycle – nitrogen disposal and detoxification. Fate of carbon skeletons of amino acids (glucogenic vs ketogenic). c. Catabolism of Specific Amino Acids and Related Disorders: Catabolism of phenylalanine and tyrosine and their metabolic disorders	10

	(Phenylketonuria, Albinism, Alkaptonuria, Tyrosinemia) and Inborn errors of branched chain and aromatic amino acids d. Biochemical significance of neurotransmitters and hormones derived from amino acids: 5-HT (serotonin), melatonin, dopamine, noradrenaline, adrenaline e. Catabolism of heme and related disorders (jaundice).	
V	**Nucleic acid metabolism and genetic information transfer** a. Nucleotide Metabolism and their related disorders: Biosynthesis of purine and pyrimidine nucleotides. Catabolism of purine nucleotides (uric acid formation). Clinical significance of Hyperuricemia and Gout. b. Genome Structure and Central Dogma: Organization of the mammalian genome. Introduction to DNA replication, Transcription, and Translation. c. Genetic Code and Regulation of Protein Synthesis: Properties of the genetic code: Inhibitors of transcription and translation (antibiotics, toxins) d. DNA Repair and Related Disorders: DNA damage types, Repair mechanisms. Overview of clinical disorders associated with faulty DNA repair.	8

Recommended References *(Preferably latest editions)*:

1. Nelson, D.L., Cox, M.M. and Hoskins, A., *Lehninger Principles of Biochemistry*. New York: W.H. Freeman.
2. Kennelly, P.J., Rodwell, V.W., Bender, D.A., Botham, K.M. and Weil, P.A., *Harper's Illustrated Biochemistry*. New York: McGraw-Hill Education.
3. Murray, R.K., Bender, D.A., Botham, K.M., Kennelly, P.J., Rodwell, V.W. and Weil, P.A., *Harper's Biochemistry*. New York: McGraw-Hill.
4. Voet, D. and Voet, J.G., *Biochemistry*. New York: John Wiley & Sons.
5. Devlin, T.M., *Textbook of Biochemistry with Clinical Correlations*. New York: Wiley-Liss.
6. Satyanarayana, U. and Chakrapani, U., *Biochemistry*. Kolkata: Books and Allied (P) Ltd.
7. Stryer, L., *Biochemistry*. New York: W.H. Freeman.

Course Code	Course Title			Course Type
BP203T	**Human Anatomy, Physiology and Pathophysiology II (Theory)**			Core
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
4	4	--	--	60
Maximum Marks	SE			ESE
100	40			60

COURSE OBJECTIVES

The objectives of this course are to:

1. Understand the anatomy and physiology of major body systems.
2. Learn mechanisms of neurological, gastrointestinal, respiratory, renal, endocrine, and reproductive functions.
3. Identify common pathophysiological conditions affecting each organ system.
4. Correlate structural and functional abnormalities with disease symptoms.
5. Equip students with foundational knowledge for interpreting disease processes and planning rational pharmacotherapy.

Course Outcomes (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Describe the structural organization of the nervous, gastrointestinal, respiratory, urinary, endocrine and reproductive systems.
2	Explain the physiological mechanisms that regulate the functions of nervous, endocrine and reproductive systems.
3	Illustrate the etiology and development of common diseases affecting different organ systems including cancer.
4	Analyze the pathophysiological alterations associated with disorders of the nervous, gastrointestinal, respiratory, renal and endocrine systems.
5	Interpret clinical manifestations and case findings related to organ system dysfunctions.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Nervous System** a) Organization of nervous system, neuron, neuroglia, classification and properties of nerve fibre, electrophysiology, action potential, nerve impulse, receptors, synapse and neurotransmitters. Central nervous system: Meninges, ventricles of brain and cerebrospinal fluid. Structure and functions of brain (cerebrum, brain stem and cerebellum), spinal cord (gross structure, functions of afferent and efferent nerve tracts, reflex activity). b) Pathophysiology of epilepsy, Parkinson's disease, stroke, migraine, depression, schizophrenia, Alzheimer's disease and meningitis.	14
II	**Gastrointestinal System** a) Anatomy of GI tract with special reference to anatomy and functions of stomach (acid production in the stomach and its regulation through parasympathetic nervous system; role of pepsin in protein digestion). Anatomy and functions of small intestine and large intestine. Anatomy and functions of salivary glands, pancreas and liver. Movements of GIT, digestion and absorption of nutrients. b) Pathophysiology of inflammatory bowel diseases, peptic ulcer, jaundice, hepatitis, typhoid and alcoholic and non alcoholic fatty liver disease	12
III	a) **Respiratory System** Anatomy of respiratory system with special reference to anatomy of lungs. Mechanism of respiration and regulation of respiration. Lung volumes and capacities, transport of respiratory gases, artificial respiration and resuscitation methods. b) Pathophysiology of asthma, chronic obstructive pulmonary diseases and tuberculosis. c) **Urinary System** Anatomy of urinary tract with special reference to anatomy of kidney and nephrons. Functions of kidney and urinary tract. Physiology of urine formation, micturition reflex and role of kidneys in acid ~~b~~ase balance. Role of Renin Angitensin Aldosterone System in kidney. d) Pathophysiology of acute and chronic renal failure and urinary tract infections.	12
IV	**Endocrine System** a) Classification of hormones and mechanism of hormone action. Structure and functions of pituitary gland, thyroid gland, parathyroid gland, adrenal gland, pancreas, pineal gland and thymus. b) Pathophysiology of diabetes, hypothyroidism, hyperthyroidism, goitre and polycystic ovary syndrome.	10

V	**Reproductive System and Cancer** a) Anatomy of male and female reproductive system. Functions of male and female reproductive system, sex hormones, physiology of menstruation, fertilization, spermatogenesis, oogenesis, pregnancy and parturition. b) Pathophysiology of sexually transmitted diseases: AIDS, syphilis and gonorrhea. c) Etiology and pathogenesis of cancer.	12

Recommended References *(Preferably latest editions)*:

1. Wilson, K.J.W., *Ross and Wilson Anatomy and Physiology in Health and Illness*. Churchill Livingstone, New York.
2. Tortora, G.J. and Grabowski, S.R., *Principles of Anatomy and Physiology*. Palmetto, GA, U.S.A.
3. Guyton, A.C. and Hall, J.E., *Textbook of Medical Physiology*. Elsevier.
4. Chatterjee, C.C., *Human Physiology (Vol. I & II)*. Academic Publishers, Kolkata.
5. Mohan, H., *Textbook of Pathology*. Jaypee Publishers.
6. Porth, C.M., *Pathophysiology: Concepts of Altered Health States*. Lippincott Williams & Wilkins.
7. Kumar, V., Abbas, A.K., Aster, J.C. and Deyrup, A.T., *Robbins and Kumar Basic Pathology*. Elsevier.

Course Code	Course Title			Course Type
BP204T	**Pharmaceutical Organic Chemistry (Theory)**			Core
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
4	4	--	--	60
Maximum Marks	SE			ESE
100	40			60

COURSE OBJECTIVES

The objectives of this course are to:

1. Develop a clear understanding of the chemistry of saturated hydrocarbons.
2. Study the chemistry and reactions of unsaturated hydrocarbons.
3. Understand the chemistry and reaction mechanisms of alkyl halides.
4. Explain the chemistry of aromatic hydrocarbons and their derivatives.
5. Provide an understanding of carbonyl compounds and fundamental organic reaction mechanisms relevant to pharmaceuticals.

Course Outcomes (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Describe the chemical reactions and mechanisms of aliphatic saturated hydrocarbons.
2	Explain the reactions and mechanisms of aliphatic unsaturated hydrocarbons.
3	Understand nucleophilic substitution and elimination reactions of alkyl halides.
4	Explain electrophilic aromatic substitution reactions and the effect of substituents.
5	Apply knowledge of carbonyl compounds and reaction mechanisms in pharmaceutical chemistry.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Aliphatic Saturated Hydrocarbons –** **Alkanes** • Methods of preparation: Wurtz reaction, Kolbe's reaction, Clemmensen reduction, Wolff –Kishner reduction • Chemical reactions of alkanes • Mechanism of free radical substitution (halogenation) • Pharmaceutical applications of alkanes: Liquid paraffin, soft paraffin, hard paraffin **Cycloalkanes** • Baeyer's strain theory and its limitations • Coulson–Moffitt modification • Sachse–Mohr theory	12
II	**Aliphatic Unsaturated Hydrocarbons – -** **Alkenes** • Methods of preparation: o Dehydration of alcohols o Dehydrohalogenation of alkyl halides o Dehalogenation of vicinal dihalides o Wittig reaction • Chemical reactions of alkenes • Mechanism of electrophilic addition reactions • Markovnikov's and anti-Markovnikov's rule • Ozonolysis **Conjugated Dienes** • Stability of conjugated dienes • Mechanism of Diels –Alder reaction Electrophilic and free radical addition reactions • 1,2- and 1,4-addition reactions	12
III	**Alkyl Halides** • Nucleophilic substitution reactions: **SN1 and SN2** o Mechanism, kinetics, substrate structure, solvent effect, stereochemistry • Elimination reactions: **E1 and E2** o Mechanism, kinetics, substrate structure, solvent effect, stereochemistry • Zaitsev's (Saytzeff's) rule with examples • Comparison of substitution vs elimination reactions	12

IV	**: Benzene and Its Derivatives – -** • IUPAC nomenclature of mono- and di-substituted benzene derivatives • Structure of benzene • Molecular orbital picture and resonance • Aromaticity and Hückel's rule • Electrophilic aromatic substitution reactions: o Nitration o Halogenation o Friedel–Crafts alkylation and its limitations o Friedel–Crafts acylation o Sulphonation and desulphonation • Effect of substituents on reactivity and orientation	12
V	**Carbonyl Compounds -** **Aldehydes and Ketones** • Preparation and properties of carbonyl compounds • Nucleophilic addition reactions • Aldol condensation and crossed aldol condensation • Cannizzaro and crossed Cannizzaro reactions • Benzoin and Perkin condensation • Oxidation and reduction reactions • Pharmaceutical applications of carbonyl compounds: Chloral, Paraldehyde, Ketoprofen	12

Recommended References *(Preferably latest editions)*:

1. Morrison, R.T., Boyd, R.N. and Bhattacharjee, S.K., *Organic Chemistry*. Pearson Education India.
2. Finar, I.L., *Organic Chemistry, Vol. I*. Pearson Books.
3. Bahl, B.S. and Bahl, A., *Textbook of Organic Chemistry*. S. Chand & Company.
4. Furniss, B.S., *Vogel's Textbook of Practical Organic Chemistry*.

Course Code	Course Title			Course Type
BP205T	**Pharmacognosy and Phytochemistry (Theory)**			Core
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
4	4	--	--	60
Maximum Marks	SE			ESE
100	40			60

COURSE OBJECTIVES

The objectives of this course are to:

1. Understand major metabolic pathways and the biogenetic origin of primary and secondary phytoconstituents, including the use of modern tools for pathway studies.
2. Study and interpret the pharmacognostic features of crude drugs containing primary metabolites such as carbohydrates, proteins/enzymes, and lipids.
3. Study and interpret the pharmacognostic features of crude drugs containing secondary metabolites such as alkaloids, glycosides, tannins, resins, volatile oils, flavonoids, phenolics, and terpenoids.
4. Impart knowledge of conventional and modern extraction techniques and enable selection of appropriate extraction methods.
5. Develop competency in isolation, identification, characterization, and quality evaluation of medicinal plants and botanicals.

Course Outcomes (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Describe biosynthetic pathways and genetic tools involved in phytoconstituent production.
2	Classify and explain drugs containing primary and secondary metabolites.
3	Apply traditional and modern extraction and isolation methods.
4	Explain qualitative and quantitative analysis of plant metabolites.
5	Evaluate identity, purity, and quality of herbal raw materials.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Metabolic Pathways and Biogenetic Studies –** Brief study of basic metabolic pathways and biosynthesis of secondary metabolites including: • Shikimic acid pathway • Acetate pathway • Amino acid pathways Utilization of radioactive isotopes in biogenetic studies. Introduction to pathway prediction tools and modern genetic tools such as **CRISPR/Cas9**.	10
II	**Primary Metabolites –** **General classification and identification tests** **Pharmacognostic study** (biological source, distribution, identifying characters, chemical constituents, specific tests, therapeutic uses, and commercial applications) of: **Carbohydrates:** • Acacia, • Agar • Tragacanth • Honey **Proteins and Enzymes:** • Gelatin • Casein • Proteolytic enzymes: Papain, Bromelain, Serratiopeptidase, Urokinase, Streptokinase, Pepsin **Lipids (Waxes, Fats, Fixed Oils):** • Castor oil • Olive oil • Cocoa butter • Wool fat • Beeswax	12
III	**Secondary Metabolites –** **General classification and identification tests** **Pharmacognostic study** (biological source, distribution, cultivation of underlined drugs, identifying characters, chemical constituents, specific tests, therapeutic uses, and commercial applications) of: **Alkaloids:** • Vinca • Rauwolfia	12

	• Opium **Volatile Oils:** • Lemongrass • Clove • Cinnamon • Fennel **Tannins:** • Myrobalans • Catechu • Pomegranate **Resins:** • Guggul • Asafoetida **Glycosides:** • Senna • Liquorice • Digitalis **Phenylpropanoids and Flavonoids:** • Green Tea • Ginkgo • Flax seed **Iridoids, Other Terpenoids and Naphthoquinones:** • Gentian • Artemisia	
IV	**Extraction Methods for Medicinal Plants –** **Conventional Methods of Extraction:** • Infusion • Decoction • Digestion • Maceration • Percolation • Reflux • Distillation • Soxhlet extraction • Successive solvent extraction **Modern Methods of Extraction:** • Supercritical fluid extraction • Microwave-assisted extraction • Ultrasonic-assisted extraction • Enzyme-assisted extraction • Pressurized liquid extraction	12
V	**Overview of Isolation, Identification and Characterization Techniques –**	14

	Separation and Isolation Techniques: • Planar chromatography • Column chromatography • Preparative TLC • Flash chromatography **Identification Techniques:** • Phytochemical tests • Chromatographic techniques • Spectroscopic techniques Fingerprinting of medicinal plants using **TLC/HPTLC**. Types and significance of **markers (phytochemical reference standards)**. Screening and analysis of major metabolites: • Alkaloids • Glycosides • Saponins • Tannins • Resins • Flavonoids • Phenolics • Steroids	

Recommended References *(Preferably latest editions)*:

1. Dewick, P.M., *Medicinal Natural Products: A Biosynthetic Approach*. John Wiley & Sons.
2. Evans, W.C., *Trease and Evans' Pharmacognosy*. W.B. Saunders & Co., London.

Course Code	Course Title			Course Type
BP206T	**Physical Pharmaceutics (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. Provide a comprehensive understanding of the theory and principles of pharmaceutical processes and unit operations involved in drug manufacturing.
2. Impart knowledge of physicochemical phenomena such as solubility, dissolution, interfacial phenomena, rheology, and micromeritics relevant to dosage form design.
3. Develop understanding of colloidal and coarse dispersions, including suspensions and emulsions, and their pharmaceutical applications.
4. Familiarize students with rheological and micromeritic properties of powders and dispersions and their role in formulation development and evaluation.
5. Build a strong foundation for formulation development, process optimization, and quality control of pharmaceutical dosage forms.

Course Outcomes (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain and interpret the fundamental principles governing pharmaceutical manufacturing processes and unit operations.
2	Analyze physicochemical properties of drugs and excipients and correlate them with formulation stability, quality, and performance.
3	Apply concepts of interfacial phenomena, colloids, and dispersions in the design and evaluation of pharmaceutical dosage forms.
4	Evaluate and optimize pharmaceutical processes by controlling variables related to rheology, micromeritics, and dispersion systems.
5	Demonstrate foundational competency required for advanced studies in formulation development, industrial pharmacy, and pharmaceutical research.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Solubility distribution phenomenon & buffers** Solubility expression, Solute solvent interactions, Solubility of liquid and liquids, Solubility of solids and liquids, Solubility of Gas in Liquids, Raoult's Law. Factors affecting solubility, Measurement of saturation Solubility, Effect of pH on solubility, Partition Coefficient – Measurement and significance, Critical Solution Temperature and Applications. Introduction to buffers, Buffers in pharmaceutical and biological system, pH determination methos (Electrometry and colorimetry). Buffer equation / Factor influencing the pH of buffer solutions, Factor influencing Buffer capacity, General procedure for preparing buffers, Indicators.	9
II	**Interfacial phenomenon** Liquid interface: Surface and interfacial tension, surface free energy, Measurement of surface and interfacial tension, Spreading coefficient, surface active agent, HLB, detergency, types of monolayers at liquid surface. Adsorption at solid interface, Liquid Interface (contact angle, activated charcoal and Wetting). Adsorption of surface-active agents. Electric properties of interface / Electric double layer, Nernst and zeta potential effect of electrolytes	8
III	**Colloidal and Coarse Dispersion** Colloidal dispersions: Types of colloidal dispersions (Lyophobic, Lyophilic, Association colloids), Optical properties of colloids, Kinetic properties of colloids, Electrical properties of colloids, Size and shape of colloidal systems, Stability of colloidal system (peptization and protective action), Application of Colloidal System. Coarse Dispersions: Suspensions, stokes law (Theory of sedimentation), Effect of Brownian movement / Sedimentation of flocculated particles, sedimentation parameters. Flocculation and controlled structure flocculation. Theories of emulsification and stabilization (DLVO Theory, Monomolecular adsorption, Multimolecular adsorption, Film formation, Solid particle adsorption). Physical instabilities of emulsions (creaming, coalescence and breaking, and phase inversion).	12
IV	**Rheological studies** Newtonian systems and non-Newtonian systems. Thixotropy – measurement / Bulges and spurs. Negative thixotropy, Determination of rheological properties (Viscometers / single and multi-point). Viscoelasticity, psycho-rheology. Applications of rheology in pharm	8

V	**Micromeritics** Particle size and size distribution, Particle Shape and Surface area: Methods for determination and significance. Flow properties of powders: determination, significance and methods of enhancement. Advanced flow properties of powers (Powder flow tester).	8

Recommended References *(Preferably latest editions)*:

1. Sinko, P.J., *Martin's Physical Pharmacy and Pharmaceutical Sciences*.
2. Allen, L.V. and McPherson, T.B., *Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems*.
3. Adejare, A., *Remington: The Science and Practice of Pharmacy*.
4. Aulton, M.E. and Taylor, K.M.G., *Aulton Pharmaceutics: The Design and Manufacture of Medicines*. Elsevier.
5. Lachman, L. and Libbermann, H.A., *The Theory and Practice of Industrial Pharmacy*.
6. Mendham, J., Denney, R.C., Barnes, J.D. and Thomas, M.J.K., *Vogel's Textbook of Quantitative Chemical Analysis*.

Myers, D., *Surfaces, Interfaces, and Colloids: Principles and Applications*.

Ladisch, M.R., *Rheology of Fluid and Semisolid Foods*. Springer.

Course Code	Course Title			Course Type
BP207P	**Biochemistry (Practical)**			Core
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	--	--	3	45
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES

The objectives of this course are:

1. To develop skills to identify and differentiate carbohydrates and proteins through classical qualitative biochemical tests.
2. To apply biochemical techniques for analysis of pathological conditions using urine and blood samples.
3. To perform estimations of clinically important biomolecules such as glucose, cholesterol, urea, creatinine, uric acid, and proteins in biological fluids.
4. To demonstrate enzymatic activity and study factors affecting enzyme function, including substrate concentration and temperature.
5. To interpret biochemical results and correlate them with clinical conditions such as diabetes, renal dysfunction, and lipid disorders.

Course Outcomes (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Identify proteins and carbohydrates using qualitative biochemical tests and explain their physiological relevance.
2	Detect normal and abnormal constituents in urine and interpret their diagnostic significance.
3	Estimate and interpret levels of glucose, cholesterol, urea, creatinine, uric acid, and serum proteins, and correlate results with clinical conditions.
4	Demonstrate enzyme–substrate reactions and evaluate the effect of temperature and substrate concentration on enzymatic activity.
5	Analyze, record, and report biochemical results accurately and relate practical findings to theoretical knowledge and clinical application.

Detailed Syllabus:

List of practical
(Minimum 12experiments must be performed) 1. Identification tests for proteins (Albumin and Casein). 2. Qualitative analysis of carbohydrates* (Glucose, Fructose, Lactose, Sucrose, and Starch). 3. Qualitative analysis of urine for normal and abnormal constituents. 4. Estimation of blood glucose. 5. Estimation of total cholesterol and HDL cholesterol. 6. Estimation of urea, creatinine, and uric acid in serum. 7. Estimation of serum total protein and albumin. 8. Study of enzymatic hydrolysis of starch. 9. Study of the effect of temperature on salivary amylase activity. 10. Study of the effect of substrate concentration on salivary amylase activity. 11. Estimation of hemoglobin in blood by Sahli's method / Cyanmethemoglobin method. 12. Estimation of serum bilirubin (total and direct bilirubin). 13. Estimation of glycogen content 14. Estimation of SGOT and SGPT
Recommended References *(Preferably latest editions)*: 1. Plummer, D. T. *An Introduction to Practical Biochemistry.* McGraw-Hill, New York. 2. Wilson, K., and Walker, J. *Principles and Techniques of Biochemistry and Molecular Biology.* Cambridge University Press. 3. Varley, H., Gowenlock, A. H., Bell, M., and Bell, J. L. *Varley's Practical Clinical Biochemistry.* Heinemann Medical Books. 4. Burtis, C. A., Ashwood, E. R., and Bruns, D. E. *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics.* Elsevier. 5. Rodwell, V. W., Bender, D. A., Botham, K. M., Kennelly, P. J., and Weil, P. A. *Harper's Illustrated Biochemistry.* McGraw-Hill. 6. Freifelder, D. *Essential Molecular Biology: A Practical Approach.* Oxford University Press.

Course Code	Course Title			Course Type
BP208P	**Human Anatomy, Physiology and Pathophysiology II (Practical)**			Core
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	--	--	3	45
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES

The objectives of this course are to:

1. Provide foundational knowledge of the structure and functions of major organ systems of the human body.
2. Develop understanding of physiological mechanisms responsible for maintenance of homeostasis.
3. Explain the pathophysiology of diseases affecting different organ systems.
4. E
5. Build a strong base for clinical learning through the study of functional and structural changes in disease states.

Course Outcomes (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the gross morphology, structures, and functions of various organs and organ systems of the human body.
2	Demonstrate basic emergency response procedures such as cardiopulmonary resuscitation (CPR).
3	Describe the etiology and pathogenesis of selected disease states.
4	Identify signs and symptoms, risk factors, diagnostic methods, prevention, treatment strategies, and complications of diseases.
5	Understand coordinated working patterns of different organs of each system and perform experiments related to special senses and nervous system.

Detailed Syllabus:

List of practical
(Minimum of 12 experiments must be performed) Practical HAPP allows the verification of physiological processes discussed in theory classes through experiments on living tissues, simulated videos, models, and charts. 1. Study of nervous system using specimens and models. 2. Study of respiratory system using models. 3. Study of gastrointestinal system using models. 4. Study of reproductive system using models. 5. Demonstration of general neurological examination. 6. Demonstration of function of olfactory nerve. 7. Examination of different types of taste. 8. Demonstration of visual acuity. 9. Demonstration of reflex activity. 10. Recording of body temperature. 11. Determination of tidal volume and vital capacity. 12. Recording of body mass index (BMI). 13. Study of family planning devices and pregnancy diagnosis tests. 14. Understanding pathophysiology of IBD, peptic ulcer, jaundice, hepatitis, typhoid, asthma, tuberculosis, diabetes, and thyroid disorders through case files / case reports. 15. Hands-on training in cardiopulmonary resuscitation (CPR).
Recommended References *(Preferably latest editions)*: 1. Wilson, K. J. W., and Waugh, A. *Anatomy and Physiology in Health and Illness.* Churchill Livingstone, New York. 2. Best, C. H., and Taylor, N. B. *The Physiological Basis of Medical Practice.* Williams & Wilkins, Baltimore. 3. Guyton, A. C., and Hall, J. E. *Textbook of Medical Physiology.* Elsevier / W.B. Saunders, Philadelphia. 4. Tortora, G. J., and Grabowski, S. R. *Principles of Anatomy and Physiology.* John Wiley & Sons. 5. Brunton, L., Chabner, B., and Knollmann, B. *Goodman & Gilman's The Pharmacological Basis of Therapeutics.* McGraw-Hill, New York. 6. Colledge, N. R., Walker, B. R., and Ralston, S. H. *Davidson's Principles and Practice of Medicine.* Churchill Livingstone, London.

Course Code	Course Title			Course Type
BP209P	**Pharmaceutical Organic Chemistry (Practical)**			Core
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	--	--	3	45
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES

The objectives of this course are to:

1. Understand and follow essential laboratory safety protocols for handling chemicals, glassware, and equipment.
2. Identify and analyze organic compounds through their physical properties and functional group reactivity.
3. Apply ball-and-stick molecular models to visualize and interpret the structure of organic compounds.
4. Perform purification techniques such as crystallization to isolate and refine organic substances.
5. Synthesize simple organic compounds and their derivatives using standard laboratory methods.

Course Outcomes (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Recall and outline the preliminary qualitative tests used for identifying water-insoluble and immiscible organic compounds.
2	Understand the synthesis methods for preparing simple organic compounds and their derivatives.
3	Apply crystallization techniques to purify organic compounds effectively.
4	Analyze experimentally to detect elements and functional groups to identify unknown organic compounds.
5	Interpret and analyze organic compounds through systematic qualitative analysis to confirm their chemical nature.

Detailed Syllabus:

List of practical
(Minimum 12 experiments to be performed) 1. **Systematic qualitative analysis of minimum of five water-insoluble or water-immiscible unknown organic compounds from different chemical classes:** a. Preliminary tests: Color, odour, Solubility tests, test for aromaticity, test for saturation/unsaturation etc. b. Detection of elements such as nitrogen, sulphur and halogens by Lassaigne's test c. Determination of Functional group tests such as phenols, amides, amines, carboxylic acids, aldehydes and ketones, alcohols, esters, aromatic and halogenated hydrocarbons and nitro compounds. d. Preparation of the derivatives and confirmation of the unknown organic compound by melting point / boiling point. 2. **Building Molecular Models:** Students will use ball-and-stick models to create structures of molecules and understand their shapes and bonding. 3. **Crystallization Method** Students will learn how to purify three organic compounds using the crystallization technique.
Recommended References *(Preferably latest editions)*: 1. Furniss, B. S., Hannaford, A. J., Smith, P. W. G. and Tatchell, A. R. *Vogel's Textbook of Practical Organic Chemistry.* Longman Scientific & Technical, London. 2. Mann, F. G. and Saunders, B. C. *Practical Organic Chemistry.* Pearson Education. 3. Shriner, R. L., Hermann, C. K. F., Morrill, T. C., Curtin, D. Y. and Fuson, R. C. *The Systematic Identification of Organic Compounds.* John Wiley & Sons. 4. Vogel, A. I. *Elementary Practical Organic Chemistry.* Longman Group Ltd. 5. Pavia, D. L., Lampman, G. M., Kriz, G. S. and Engel, R. *Introduction to Organic Laboratory Techniques.* Cengage Learning.

Course Code	Course Title			Course Type
BP210P	**Pharmacognosy and Phytochemistry (Practical)**			Core
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	--	--	3	45
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES

The objectives of this course are to:

1. Perform chemical tests for the identification of gums, resins, oils, fats, waxes, and unorganized drugs.
2. Examine crude drugs using transverse section and powder microscopy for correct identification.
3. Apply suitable extraction techniques and study their effect on yield of crude extracts.
4. Isolate and identify important phytoconstituents and volatile oils using standard procedures.
5. Evaluate herbal raw materials collected from field/market sources as per Pharmacopoeial standards.

Course Outcomes (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Identify unorganized crude drugs using specific chemical tests.
2	Analyze organized crude drugs through microscopy and powder analysis.
3	Select and perform appropriate extraction methods for herbal drugs.
4	Isolate and characterize phytoconstituents using laboratory techniques and TLC.
5	Assess and compare the quality and purity of herbal raw materials with official standards.

Detailed Syllabus:

List of practical
(Minimum 12 experiments must be performed) 1. Chemical tests for identification of Agar, Acacia, Tragacanth, Honey. 2. Chemical tests for identification of Castor oil, Olive oil, Wool fat, Beeswax. 3. Chemical tests for identification of Asafoetida, Catechu, Aloe. 4. Transverse section and powder microscopy of a vinca leaf. 5. Transverse section and powder microscopy of a cinnamon bark. 6. Transverse section and powder microscopy of a fennel fruit. 7. Transverse section and powder microscopy of a clove flower bud. 8. Transverse section and powder microscopy of a Tulsi stem. 9. Transverse section and powder microscopy of a Liquorice roots. 10. Study of effect on different extraction techniques on yield of crude extract (maceration, decoction, soxhlation). 11. Isolation of volatile oil and it's TLC. 12. Isolation of caffeine from tea. 13. Isolation of Hesperidin from lemon peel. 14. Isolation of Glycyrhizin from liquorice roots. 15. Isolation of Pectin from orange peel. 16. Experiential learning-based experiment involving evaluation and comparison of field/market collected herbal raw materials with Pharmacopoeial standards.
Recommended References *(Preferably latest editions)*: 1. Trease, G. E. and Evans, W. C. *Pharmacognosy.* Elsevier. 2. Harborne, J. B. *Phytochemical Methods: A Guide to Modern Techniques of Plant Analysis.* Springer. 3. Wallis, T. E. *Textbook of Pharmacognosy.* CBS Publishers & Distributors, New Delhi. 4. Tyler, V. E., Brady, L. R. and Robbers, J. E. *Pharmacognosy.* Lea & Febiger.

Course Code	Course Title			Course Type
BP211P	**Physical Pharmaceutics (Practical)**			Core
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	--	--	3	45
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES

The objectives of this course are to:

1. Introduce basic laboratory techniques for determining physicochemical properties such as surface tension, viscosity, and density in pharmaceutical systems.
2. Develop understanding of interfacial phenomena and surfactant behavior, including micelles, critical micellar concentration (CMC), and HLB in formulation design.
3. Train students in evaluating disperse systems through sedimentation studies and the effect of suspending agents.
4. Provide practical experience in powder characterization, including particle size distribution, density, flow properties, porosity, and the role of glidants.
5. Develop skills in determining solubility, partition coefficient, buffer capacity, and related equilibria relevant to drug formulation.

Course Outcomes (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Demonstrate practical knowledge of principles and procedures involved in measuring surface tension, viscosity, density, and related physical properties using standard laboratory apparatus.
2	Determine and interpret surfactant-related parameters such as CMC and HLB and explain their significance in formulation stability and performance.
3	Conduct experiments and analyze results related to sedimentation volume and evaluate the influence of type and concentration of suspending agents on dispersion stability.
4	Evaluate micromeritic and flow properties of powders by determining particle size distribution, bulk density, tapped density, Hausner ratio, Carr's index, angle of repose, true density, and porosity, and interpret the effect of glidants.
5	Perform and assess experiments on solubility, partition coefficient, critical solution temperature, adsorption studies, and buffer capacity, and apply findings to formulation decisions.

Detailed Syllabus:

List of practical
(Minimum 12 experiments must be performed) 1. Determination of surface tension of given liquids by drop count method and drop weight method. 2. Determination of critical micellar concentration (CMC) of surfactants. 3. Determination of viscosity of liquids using Ostwald's viscometer and Brookfield viscometer. 4. Determination of HLB value of a surfactant. 5. Calculation of isotonicity by different methods (Sodium Chloride Equivalent Method). 6. Determination of particle size and particle size distribution using sieving method. 7. Determination of particle size and particle size distribution using microscopic method. 8. Determination of densities and derived properties of powders (bulk density, tapped density, Hausner ratio, Carr's compressibility index), true density, and porosity. 9. Determination of angle of repose and influence of glidants on angle of repose. 10. Determination of solubility of a drug at different pH/buffer systems at room temperature. 11. Determination of partition coefficient of a drug in n-octanol and water system. 12. Determination of partition coefficient of a drug in benzene and water system. 13. Determination of critical solution temperature and composition of phenol ~~w~~ater system. 14. Determination of specific surface area of charcoal by adsorption of acetic acid on activated charcoal. 15. Determination of buffer capacity at various stages of titration of a weak acid against a strong base and determination of pKa. ***Note:*** Compare the values of various physicochemical properties with marketed formulations wherever possible.
Recommended References *(Preferably latest editions)* :' 1. Sinko, P. J. *Martin's Physical Pharmacy and Pharmaceutical Sciences.* Lippincott Williams & Wilkins. 2. Aulton, M. E. and Taylor, K. M. G. *Aulton's Pharmaceutics: The Design and Manufacture of Medicines.* Elsevier. 3. Lachman, L., Lieberman, H. A. and Kanig, J. L. *The Theory and Practice of Industrial Pharmacy.* CBS Publishers & Distributors. 4. Allen, L. V., Popovich, N. G. and Ansel, H. C. *Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems.* Lippincott Williams & Wilkins. 5. Cooper, S. J. and Gunn, C. *Cooper and Gunn's Tutorial Pharmacy.* CBS Publishers & Distributors.

Course Code*	Course Title*		Course Type	
BP212P SEC1	Communication Skills		Elective	
BP212P SEC2	Mental Well-Being, Stress & Conflict Management			
BP212P SEC3	Fundamentals of Computer Operations			
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	--	--	2	30
Maximum Marks	SE	ESE		
50	20	30		

* Only 1 elective course shall be selected

The syllabi for elective subjects are given in the APPENDIX

Semester III**

Course Code	Name of the Course	No. of hours/week (L/P)	Continuous Mode (Marks)	Sessional Exam (Marks)	Sessional Duration	Internal Total	End Semester Marks	Exam Duration	Total Marks	Credit points
BP301T	Introduction to Machine Learning in Pharmaceutical Sciences (Theory)	2	10	10	1 Hr	20	30	1.5 Hr	50	2
BP302T	Environmental Science (Theory)	1	10	10	1 Hr	20	30	1.5 Hr	50	1
BP303T	Ethics and Universal Human Values (Theory)	1	10	10	1 Hr	20	30	1.5 Hr	50	1
BP304T	General Pharmacology (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP305T	Heterocyclic Compounds and Stereochemistry (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP306T	Pharmaceutical Dosage Forms I (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP307T	Pharmaceutical Engineering (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP308T	Pharmaceutical Microbiology (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP309P	General Pharmacology (Practical)	4	10	10	4 Hr	20	30	4 Hr	50	2
BP310P	Heterocyclic Compounds and Stereochemistry (Practical)	4	10	10	4 Hr	20	30	4 Hr	50	2
BP311P	Pharmaceutical Dosage Forms I (Practical)	3	10	10	3 Hr	20	30	3 Hr	50	1
BP312P	AEC* – Elective 2 (Practical)	2	10	10	3 Hr	20	30	3 Hr	50	1
Total		**32**	**145**	**145**	**22 Hr**	**360**	**435**	**28.5 Hr**	**725**	**25**

* Only 1 elective course shall be selected
The syllabi for elective subjects are given in the APPENDIX
**The lateral entry students taking admission directly to second year shall compulsorily appear for and pass the subjects, Healthcare Psychology and Communication Skills (Theory and Practical) and Basics of Python Programming for Pharmaceutical Sciences (Theory) during the Third Semester.

Course Code	Course Title			Course Type
BP301T	**Introduction to Machine Learning in Pharmaceutical Sciences (Theory)**			Core
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
2	2	--	--	30
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Introduce the fundamental concepts of Artificial Intelligence, Machine Learning, and Data Science and their relevance to pharmaceutical sciences.
2. Develop conceptual understanding of machine learning workflows, including model building, training testing strategies, and evaluation.
3. Explain the principles and applications of regression models for predicting continuous outcomes in pharmaceutical and healthcare data.
4. Familiarize students with classification and tree-based models used for clinical prediction and decision-making.
5. Introduce unsupervised learning techniques and demonstrate their applications in pattern recognition and healthcare data analysis.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the basic concepts of artificial intelligence and machine learning, including types of learning and model development.
2	Apply regression models to analyze pharmaceutical data and interpret model outputs and performance metrics.
3	Analyze classification models for predicting categorical clinical outcomes using evaluation measures such as accuracy, sensitivity, and ROC –AUC.
4	Interpret tree-based and ensemble learning models for decision-making in pharmaceutical and healthcare applications.
5	Utilize unsupervised learning techniques such as clustering to identify patterns in healthcare and pharmaceutical datasets.

Detailed Syllabus:-

Unit No.	Topics	No. of Lectures
I	**Foundations of Machine Learning** Definition and scope of Artificial Intelligence, Machine Learning, and Data Science • Types of machine learning: supervised, unsupervised, and reinforcement learning • Features and labels, training data and testing data • Concept of model building and prediction • Train-test split, overfitting and underfitting • Conceptual explanation of bias-variance trade-off • Overview of the basic ML workflow	6 Hours
II	**Regression Models in Healthcare** Overview of the concepts in predictive modeling for continuous outcomes, with emphasis on interpretation of outputs, and applications in pharmaceutical sciences. • Linear regression and multiple linear regression • Model coefficients and their interpretation • Residuals and goodness-of-fit • Performance metrics such as Mean Squared Error (MSE), Root Mean Squared Error (RMSE), R^2 score • Implementation of regression models on pharmaceutical data (e.g. dose ~~r~~esponse relationships, predicting drug dissolution rates, estimating PK parameters), and demonstration of predictive modeling using python libraries such as sklearn	6 Hours
III	**Classification Models in Clinical Applications** Overview of the following ML models used for categorical prediction, with emphasis on conceptual understanding, interpretation of outputs and applications in pharmaceutical sciences. • Logistic regression • Probability output and threshold selection • Confusion matrix • Accuracy, sensitivity, specificity, precision, recall • Intuitive understanding of ROC curve and AUC, and k-Nearest Neighbors • Demonstration of predictive modeling using pharmaceutical and clinical examples such as predicting adverse drug reactions, disease risk prediction, binary therapeutic outcome modeling.	6 Hours

IV	**Tree-Based Models & Ensemble Learning** Overview of the following ML models with emphasis on intuitive and conceptual understanding. • Decision Trees (structure and splitting criteria), interpretation of decision paths and feature importance • Random Forest, overview of ensemble concept • Advantages and limitations of tree-based models • Demonstration of these models for pharmaceutical and clinical applications such as ADR risk stratification, Patient classification, Predicting treatment outcomes etc.	6 hours
V	**Unsupervised Learning & Practical Case Studies** Overview of the unsupervised learning with emphasis on intuitive and conceptual understanding of pattern recognition and clustering, and their applications in pharmaceutical sciences. • Concept of unsupervised learning • Clustering overview, K-means clustering, choosing number of clusters, Interpreting cluster outputs • Mini-case study integrating regression, classification, or clustering on healthcare datasets to demonstrate Patient segmentation, and drug grouping based on properties.	6 Hours

Recommended References *(Preferably latest editions)*:

1. James, G., Witten, D., Hastie, T. and Tibshirani, R. *An Introduction to Statistical Learning with Applications in Python.* Springer. Available at: statlearning.com.
2. Simon, G. J. and Aliferis, C. *Artificial Intelligence and Machine Learning in Health Care and Medical Sciences: Best Practices and Pitfalls.* Springer.
3. Brown, N. *Artificial Intelligence in Drug Discovery.* Royal Society of Chemistry.
4. Walters, S. J., Campbell, M. J. and Machin, D. *Medical Statistics: A Textbook for the Health Sciences.* Wiley-Blackwell.
5. Géron, A. *Hands-On Machine Learning with Scikit-Learn, Keras and TensorFlow.* O'Reilly Media.

Course Code	Course Title			Course Type
BP302T	**Environmental Sciences (Theory)**			Core
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	1	--	--	15
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Explain the environmental challenges and disaster risks relevant to human health and pharmaceutical activities.
2. Demonstrate knowledge of waste management protocols and legal guidelines for pharmaceutical and biomedical waste handling.
3. Apply technical understanding of effluent and sewage treatment technologies used in the pharmaceutical sector.
4. Assess the ecological impact of APIs and recommend mitigation strategies for pollution control.
5. Explain sustainable practices and energy-efficient operations within pharmaceutical industries.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Understand the basic concepts of environmental pollution, its types, causes, and disaster management strategies.
2	Identify and categorize different types of pharmaceutical and biomedical waste generated in the healthcare and pharmaceutical sectors.
3	Describe the design and operation of Effluent Treatment Plants (ETPs), Sewage Treatment Plants (STPs), and water purification systems in pharma settings.
4	Analyze the environmental risks posed by pharmaceutical manufacturing, APIs, and dosage forms.
5	Recognize the importance of sustainability and green pharmacy practices in the pharmaceutical industry.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Environmental Pollution** • Definition, scope, and importance of environmental studies • Types, causes, effects, and control measures of Air, water, soil, noise, and nuclear pollution • Solid waste and hazardous waste management in pharmaceuticals • Role of pharmacists in conservation and sustainable use of resources	3 Hours
II	**Pharmaceutical Waste and Effluent Management** • Types of pharmaceutical waste: chemical, expired drugs, packaging, biomedical waste • Biomedical Waste Management Rules (2016) and CPCB guidelines • Effluent Treatment Plant (ETP) design and functioning • Water purification methods in pharmaceutical settings (RO, UV, distillation, filtration)	3 Hours
III	**Environmental Impact of the Pharmaceutical Industry** • Sources of pollution in pharmaceutical manufacturing • Types of pharmaceutical waste: solid, liquid, and gaseous • Environmental risks of active pharmaceutical ingredients (APIs) and its dosage forms. Impact of pharmaceutical residues on ecosystems and human health	3 Hours
IV	**Sustainability in the Pharmaceutical Sector** • Principles of sustainable development in pharma • Principles and Practices of Green pharmacy • Energy conservation and resource optimization.	3 Hours
V	**Government Policies, Compliance, and Practical Exposure** • Environmental laws: o Environment (Protection) Act, 1986 o Water (Prevention and Control of Pollution) Act • National Green Tribunal (NGT) and regulatory bodies (CPCB, SPCB) • Government initiatives: o Swachh Bharat Abhiyan o River rejuvenation program- Namami Gange Programme o Jal Jeevan Mission • ISO-14000	3 Hours

Recommended References *(Preferably latest editions)*:

1. Bharucha, E. *Environmental Studies.* University Grants Commission, New Delhi.
2. Rajagopalan, R. *Environmental Studies.* Oxford University Press.
3. Joseph, B. *Environmental Studies.* Tata McGraw Hill.

Course Code	Course Title		Course Type	
BP303T	**Ethics and Universal Human Values (Theory)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
1	1	--	--	15
Maximum Marks	SE		ESE	
50	20		30	

COURSE OBJECTIVES:

The objectives of this course are:

1. Understand the concept, definition, scope, and need of Value Education in personal, social, and professional life.
2. Develop self-exploration, positive attitude, confidence, and ethical sensitivity as foundations of value-based living.
3. Comprehend the co-existence of Self (I) and Body and establish harmony between physical and psychological aspects.
4. Analyze the importance of family, society, and relationships in promoting mutual respect, trust, and cooperation.
5. Appreciate the concept of harmony in nature and existence, leading to sustainable and responsible human conduct.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the principles, content, and process of Value Education and apply ethical values in day-to-day life.
2	Demonstrate self-awareness, right understanding, confidence, and clarity about happiness and prosperity through self-exploration.
3	Distinguish between the needs and activities of the Self and the Body and establish harmony between them.
4	Apply values such as respect, affection, kindness, gratitude, and love to maintain harmony in family and society.
5	Interpret the concept of harmony in nature and holistic existence, recognizing the four orders of nature and the comprehensive human goal.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Introduction to Value Education** 1. Concept, definition, and need for value education. 2. Content and process of value education. 3. Application of human values in everyday life.	3 Hours

II	**Self-Exploration and Human Aspirations** 1. Self-exploration as a means of value education. 2. Development of positive attitude and self-confidence. 3. Right understanding of happiness and prosperity.	3 Hours
III	**Harmony in the Human Being** 1. Human being as more than just the physical body. 2. Harmony between the Self ('I') and the Body. 3. Understanding the coexistence of the Self and the Body.	3 Hours
IV	**Harmony in the Individual and Society** 1. Understanding the needs of the Self and the needs of the Body. 2. Activities of the Self and activities of the Body. 3. Family as the basic unit of human interaction and the role of values in relationships. 4. Foundations of respect in relationships: affection, kindness, guidance, reverence, glory, gratitude, and love.	3 Hours
V	**Harmony in Society and Nature** 1. Comprehensive human goal: the five dimensions of human endeavour. 2. Harmony in nature and the four orders in nature. 3. Holistic perception of harmony in existence.	3 Hours

Recommended References *(Preferably latest editions)*:

1. Tripathi, A. N. *Human Values.* New Age International Publishers, New Delhi.
2. Gaur, R. R., Asthana, R. and Bagaria, G. P. *A Foundation Course in Human Values and Professional Ethics.* Excel Books, New Delhi.
3. Gaur, R. R., Asthana, R. and Bagaria, G. P. *Teachers' Manual for A Foundation Course in Human Values and Professional Ethics.* Excel Books, New Delhi.
4. Raghavan, V. *Universal Human Values.* Excel Books.
5. Gaur, R. R., Sangal, R. and Bagaria, G. P. *Human Values and Professional Ethics.* Excel Books.
6. Govindarajan, M., Natarajan, S. and Senthil Kumar, V. S. *Engineering Ethics.* Prentice Hall India.
7. Velasquez, M. G. *Business Ethics: Concepts and Cases.* Pearson Education.

Course Code	Course Title			Course Type
BP304T	**General Pharmacology (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:

1. To provide a foundational understanding of the history of pharmacology, focusing on the evolution of drug discovery and development.
2. Introducing the concepts of pharmacodynamics and pharmacokinetics, helping students understand the mechanisms of drug action, absorption, distribution, metabolism, and excretion.
3. To familiarize students with the principles behind new drug development, including preclinical testing, drug screening methods, and safety pharmacology.
4. To enable students to learn about toxicity testing, ensuring they understand different methods of evaluating drug safety and the regulatory guidelines involved in toxicity assessment.
5. To prepare students for understanding the pharmacology of different therapeutic drug classes, by applying basic pharmacological knowledge to current trends in drug development and screening.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Relate the fundamental principles of pharmacodynamics and pharmacokinetics of drugs actions on the human body.
2	Illustrate the processes involved in the drug metabolism, toxicity, and safety evaluation to relate their significance in the preclinical development of new drugs.
3	Apply the knowledge of pharmacological principles to efficacy, toxicity, and safety evaluation of new drug candidates.
4	Assess the ethical and scientific principles underlying drug safety, efficacy, and toxicity testing
5	Appraise the recent trends in pharmacology.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Introduction to Pharmacology** **a)** Definition, historical perspectives, branches of pharmacology and their scope, drug, nature and sources of drugs, International Classification of Diseases (ICD) and International Non-proprietary Names (INN) for drugs **b)** Concept of generic medicines, essential drugs and rational drug use (RDU). Indian Government's initiatives to promote these concepts. **c)** Routes of drug administration along with their advantages and disadvantages.	08 Hours
II	**Pharmacokinetics** **a)** Drug absorption, mechanisms of drug absorption, membrane transporters, bioavailability, bioequivalence, factors affecting drug absorption. **b)** Drug distribution in different compartments, volume of distribution, storage sites, plasma protein binding and its therapeutic importance. **c)** Drug biotransformation, microsomal, non- microsomal metabolism and cytochrome P450 enzyme system, phase I and II reactions, first-pass metabolism, entero-hepatic cycling, concept of prodrugs. **d)** Drug excretion and its kinetics.	07 Hours
III	**Pharmacodynamics** **a)** Types drug action and mechanisms of drug action, dose response relationship. **b)** Receptor theories, structure of receptors, classification and regulation of receptors, spare receptors. Concept of agonist, inverse agonist, partial agonist and antagonist. **c)** Signal transduction mechanisms of receptors. **d)** Factors modifying drug action including the concepts of tachyphylaxis, idiosyncrasy, drug tolerance, dependence, addiction, and the combined effect of drugs (Additive effect & Synergism). **e)** Adverse drug reactions (ADR) and types of ADRs. **f)** Drug interaction, types, pharmacokinetic and pharmacodynamic drug-drug interactions.	10 Hours
IV	**Overview of drug discovery and evaluation of new drug** **a)** Brief discussion on drug discovery and preclinical evaluation of new drugs. **b)** Human relevant screening techniques: Reconstructed human epidermis, organ-on- Chip model, skin irritancy test by reconstructed corneal epithelium, skin corrosivity testing by Direct	12 Hours

	Peptide Reactivity Assay. **c)** Advantages and disadvantages of *in vitro* and *in silico* Pharmacological screening and evaluation **Recent trends in pharmacology** **a)** Chronopharmacology: Introduction, biological clock, types of rhythms, hormones, diseases and drugs affected by circadian rhythm. Introduction to chrono kinetics and importance of chronotherapeutic and future scope. **b)** Introduction, general principles, applications and scope of Pharmacogenomics, Gene therapy, Biosimilars and Precision medicine.	
V	**Toxicology** **a)** Introduction to toxicology and its branches. Classification of poisons based on actions and lethal doses, types of antidotes. **b)** General principles of treatment of acute poisoning include heavy metal poisoning. Management of poisoning. **c)** Definition and basic knowledge of preclinical toxicity testing-acute toxicity, sub-acute toxicity, combined chronic and carcinogenicity testing as per OECD norms. **d)** Basic understanding of principles of genotoxicity and teratogenicity as per OECD guidelines. **e)** Definition and concepts of safety pharmacology as per ICH and OECD guidelines.	8 Hours

Recommended References *(Preferably latest editions)*:

1. Brunton, L., Hilal-Dandan, R. and Knollmann, B. *Goodman and Gilman's The Pharmacological Basis of Therapeutics.* McGraw-Hill Education.
2. Rang, H. P., Dale, M. M., Ritter, J. M., Flower, R. J. and Henderson, G. *Rang and Dale's Pharmacology.* Elsevier.
3. Katzung, B. G. and Trevor, A. J. *Basic and Clinical Pharmacology.* McGraw-Hill Education.
4. Whalen, K. and Finkel, R. *Lippincott's Illustrated Reviews: Pharmacology.* Wolters Kluwer.
5. Tripathi, K. D. *Essentials of Medical Pharmacology.* Jaypee Brothers Medical Publishers.

Course Code	Course Title		Course Type	
BP305T	**Heterocyclic Compounds and Stereo Chemistry (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 Chemistry of Carboxylic acids, Phenols, Amines and Polynuclear Aromatic hydrocarbons
2. Explain the concepts of optical isomerism and their pharmaceutical significance.
3. Explain the concepts of Geometrical isomerism and their pharmaceutical significance
4. Know about IUPAC nomenclature and Chemistry of heterocycles
5. Equip students with knowledge of organic reaction mechanisms and their applications in drug synthesis.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Recall and outline methods for the preparation and chemical reactions of various organic compounds.
2	Explain the acidity and basicity of organic compounds and recognize the medicinal relevance of polynuclear hydrocarbons and heterocyclic compounds.
3	Illustrate the concepts of stereoisomerism with appropriate examples.
4	Classify, name, and interpret the structures and chemistry of heterocyclic compounds.
5	Describe and analyze the synthesis, chemical behaviour, and applications of heterocyclic and polynuclear hydrocarbon compounds.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Chemistry of Carboxylic acids, Phenols, Amines and Polynuclear Aromatic hydrocarbons** 1. **Aliphatic and aromatic carboxylic acids** • Methods to prepare carboxylic acids (Oxidation of alcohols, carbonation of Grignard reagent, Kolbe-Schmidt reaction) • Study of acidity of carboxylic acids and effect of substituents on acidity • Study of chemical reactions of carboxylic acids [Mechanism of nucleophilic acyl substitution, Decarboxylation and Hell-Volhard-Zelinsky reaction]. Pharmaceutical applications of aromatic carboxylic acids (Benzoic acid, Salicylic acid, Acetyl Salicylic acid) 2. **Aliphatic and aromatic amines** • Methods to prepare amines (Reduction of nitro compound, reduction of nitriles and Hofmann degradation of amides) • Study of basicity of amines and effect of substituents on basicity • Study of mechanism and synthetic applications of diazonium salts including Sandmeyer's and azo-dye coupling reaction 3. **Alcohols and Phenols** • Classification of alcohols, methods to prepare alcohols (oxymercuration - demercuration, reduction of carbonyl compounds) • Acidity of alcohols and Phenols including effect of substituent on acidity • Definition of phenols, method to prepare phenols by cumene process. Comparison of the acidity of phenol vs alcohol • Study of mechanism of chemical reactions of phenols (Reimer-Tiemann reaction, halogenation and nitration of phenols). Pharmaceutical applications of alcohols and phenols (Glycerin, Thymol, Paracetamol) 4. **Chemistry of polynuclear hydrocarbons** Definition, and classification of polynuclear aromatic hydrocarbons, Study of synthesis (Haworth synthesis) and mechanism of electrophilic aromatic substitution reactions of naphthalene, phenanthrene and anthracene and medicinal uses of drugs containing Naphthalene (Propranolol, Naphazoline) and Phenanthrene (Morphine, Codeine).	15 Hours
II	**Optical isomerism** • Definition of stereoisomerism and types of stereoisomerism with examples • Definition with examples for optical activity, origin of chirality, elements of symmetry, chiral and achiral molecules, enantiomerism, diastereoisomerism and meso compounds • Study of configuration including D & L system, sequence rules, R & S system. Medicinal importance of optical isomers with examples • Racemic mixture and resolution of racemic mixtures	7 Hours

III	**Geometrical isomerism** • Nomenclature of geometrical isomers (Cis & Trans, E & Z, Syn & Anti system) • Conformational isomerism and its analysis in ethane, butane and cyclohexane • Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity in biphenyl compounds	6 Hours
IV	**Chemistry of five membered heterocycles** • IUPAC nomenclature and classification of heterocyclic compounds as per the Hansch- Widman system • Relative aromaticity and reactivity of pyrrole, furan and thiophene • Study of synthesis of pyrrole (Paal – Knorr synthesis), furan (Feist-Bénary reaction), thiophene (Hinsberg synthesis) and Mechanism of Electrophilic substitution reactions of pyrrole, furan and thiophene • Medicinal uses of drugs containing pyrrole (Ethosuximide, procyclidine), furan (Furosemide, Nitrofurazone) and thiophene (Cephaloridine, Clopidogrel)	10 Hours
V	**Chemistry of other heterocycles** • Study of nomenclature of fused heterocyclic compounds, synthesis for pyrazole (Knorr synthesis), imidazole (Debus-Radziszewski reaction), pyridine (The Hantzsch synthesis), quinoline (The Skraup synthesis) and Electrophilic aromatic substitution reactions of pyrazole and imidazole • Chemical structures of Indole, pyrimidine, benzimidazole, purine, azepine, pyrazole, oxazole, Phenothiazine, benzotriazole, quinoxaline • Basicity of imidazole, pyridine and quinolone • Medicinal uses of any two drugs containing pyrazole (Sildenafil, Celecoxib), imidazole (Metronidazole, Pilocarpine), pyridine (Isoniazid, Chlorpheniramine), quinoline (Chloroquine, Ciprofloxacin), indole (Indomethacin, Reserpine), benzimidazole (Albendazole, Mebendazole) pyrimidine (Fluorouracil, Sulphadiazine), purine (Mercaptopurine, Thioguanine), azepine (Diazepam, Loxapine) heterocycles	07 Hours

Recommended References *(Preferably latest editions)*:

1. Finar, I. L. *Organic Chemistry, Vol. 1.* Pearson Education.
2. Finar, I. L. *Organic Chemistry: Stereochemistry and Natural Products, Vol. 2.* Pearson Education.
3. Smith, M. B. and March, J. *March's Advanced Organic Chemistry: Reactions, Mechanisms and Structure.* Wiley.
4. Bahl, B. S. and Bahl, A. *Textbook of Organic Chemistry.* S. Chand.
5. Nadendla, R. R. *Pharmaceutical Organic Chemistry: Heterocyclic and Natural Products.* Vallabh Prakashan.
6. Gilchrist, T. L. *Heterocyclic Chemistry.* Prentice Hall.
7. Eliel, E. L. and Wilen, S. H. *Stereochemistry of Organic Compounds.* Wiley.

Course Code	Course Title			Course Type
BP306T	**Pharmaceutical Dosage Forms I (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 fundamentals of dosage form development, including pre-formulation studies, drug excipient compatibility, and stability considerations as per ICH guidelines.
2. Acquire knowledge of formulation and manufacturing of compressed solid dosage forms, including tablets and coated tablets, along with quality control and packaging.
3. Develop competence in the formulation and evaluation of finely divided and filled solid dosage forms, such as powders, granules, and hard and soft gelatin capsules.
4. Understand the principles and formulation strategies of modified-release solid dosage forms, including sustained-release and controlled-release systems.
5. Gain knowledge of microencapsulation techniques, their applications, advantages, limitations, and evaluation of microcapsules in pharmaceutical products.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Describe pre-formulation principles and evaluate key physicochemical parameters critical to solid dosage-form development.
2	Apply formulation and manufacturing processes and perform quality control tests for tablets, including coated tablets, and troubleshoot common formulation and processing defects.
3	Formulate and evaluate finely divided and filled solid dosage forms such as medicated powders, granules, hard capsules, and soft gelatin capsules using appropriate materials, equipment, and quality control procedures.
4	Design and evaluate modified-release solid dosage forms by selecting suitable polymers and mechanisms to achieve sustained and controlled drug release.
5	Analyze various microencapsulation methods, select suitable techniques for specific drug-delivery needs, and evaluate microcapsules based on physicochemical and performance parameters.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Fundamentals of Dosage Form Development:** Pre-formulation studies: concept, need, and parameters including solubility, pKa, physical nature (amorphous and crystalline), polymorphism, particle size and shape, and powder flow parameters. Drug–excipient compatibility studies. Packaging selection for various dosage forms. Drug product and container-closure interaction. Introduction to stability guidelines of new drug substances and products (ICH Q1).	07 Hours
II	**Compressed Solids:** **Tablets** Excipients (roles and examples); tooling (types and specifications); manufacturing methods and equipment; tablet defects and remedies; in-process quality control (IPQC); finished-product tests; packaging. **Tablet Coating** Types of coating (sugar, film, compression, enteric); need, advantages, and limitations; polymers, process specifications, and equipment; coating defects; quality control of coated tablets.	12 Hours
III	**Finely Divided and Filled Solids:** Medicated powders and granules: formulation considerations, manufacturing processes (mixing, granulation), quality control, and packaging. Gelatin and non-gelatin shells: composition, empty shell manufacturing, quality control, and capsule sizes. Hard gelatin capsules: formulation design; filling methods (manual, semi-automatic, automatic); IPQC and finished-product tests; packaging. Soft gelatin capsules: shell composition and plasticizers; fill materials; manufacturing methods (rotary die and others); defects; quality control and stability.	12 Hours
IV	**Modified-Release Solids:** Types of tablets: sustained-release and controlled-release tablets. Concept, need, advantages, and disadvantages. Formulation design and drug-release mechanisms. Polymers used for sustained and controlled release. Evaluation of modified-release dosage forms.	07 Hours
V	**Microencapsulation:** Concept, need, advantages, and disadvantages. Methods of microencapsulation: spray drying, spray congealing, extrusion and spheronisation, fluidized bed coating, and phase-separation coacervation. Evaluation of microcapsules.	07 Hours

Recommended References *(Preferably latest editions)*:

1. Allen, L. V., Popovich, N. G. and Ansel, H. C. *Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems.* Lippincott Williams & Wilkins.
2. Aulton, M. E. and Taylor, K. M. G. *Aulton's Pharmaceutics: The Design and Manufacture of Medicines.* Elsevier.
3. Lachman, L., Lieberman, H. A. and Kanig, J. L. *The Theory and Practice of Industrial Pharmacy.* CBS Publishers & Distributors.
4. Troy, D. B. and Beringer, P. *Remington: The Science and Practice of Pharmacy.* Pharmaceutical Press.
5. Robinson, J. R. and Lee, V. H. L. *Controlled Drug Delivery: Fundamentals and Applications.* CRC Press.
6. Sinko, P. J. *Martin's Physical Pharmacy and Pharmaceutical Sciences.* Lippincott Williams & Wilkins.
7. *Indian Pharmacopoeia.* Indian Pharmacopoeia Commission.
8. *United States Pharmacopeia.* United States Pharmacopeial Convention.
9. *British Pharmacopoeia.* British Pharmacopoeia Commission.

Course Code	Course Title		Course Type	
BP307T	**Pharmaceutical Engineering (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. Provide fundamental knowledge of pharmaceutical engineering principles and common unit operations involved in solid and liquid pharmaceutical manufacturing.
2. Develop an understanding of thermal operations such as drying, evaporation, distillation, and heat transfer used in pharmaceutical processing.
3. Introduce material handling systems, corrosion control, and waste management practices relevant to pharmaceutical plants.
4. Explain the principles of fluid flow and flow measurement used in pharmaceutical process equipment.
5. Develop knowledge of the design, construction, working principles, and pharmaceutical applications of engineering equipment used in the pharmaceutical industry.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the principles and pharmaceutical applications of unit operations such as size reduction, mixing, size separation, and fluid flow.
2	Identify and describe the construction, working, and utility of various pharmaceutical engineering equipment.
3	Compare and evaluate different thermal processes such as drying, evaporation, distillation, and heat transfer based on operational efficiency.
4	Apply principles of safe and efficient material handling and understand the impact of corrosion and waste management in pharmaceutical industries.
5	Examine the relevance of contemporary technological trends such as PAT and automation for enhancing pharmaceutical manufacturing processes.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Unit operations associated with solids** Principle, construction, working, advantages and disadvantages and Pharmaceutical applications of size reduction, size separation and mixing equipment	12 Hours
II	**Unit operations associated with liquids** Principle, construction, working, advantages and disadvantages and Pharmaceutical applications of filtration, crystallization and centrifugation equipment	12 Hours
III	**Unit operations associated with heat transfer** Principle, construction, working, advantages and disadvantages and Pharmaceutical applications of evaporation, drying, distillation and Heat transfer equipment	12 Hours
IV	**Materials and material handling** Introduction to material handling equipment and techniques, Conveyors, hoists, and automated guided vehicles (AGVs), Storage systems: bins, silos in warehouses, Safety considerations in material handling and waste management. Types of corrosion and their impact on pharmaceutical processes and environment	05 Hours
V	**Flow of fluids** Types and measurement of flow**,** manometers, Reynolds number and its significance, Bernoulli's theorem and its applications, Orifice meter, Venturimeter, Pitot tube and Rotometer.	04 Hours

Recommended References (Preferably latest editions):

1. Banker, G. S. *Pharmaceutical Engineering.* Marcel Dekker.
2. Sambamurthy, K. *Introduction to Pharmaceutical Engineering.* New Age International.
3. Kennedy, T. F. *Good Design Practices for GMP Pharmaceutical Facilities.* CRC Press.
4. Banker, G. S. and Rhodes, C. T. *Modern Pharmaceutics.* CRC Press.
5. Hickey, A. J. *Pharmaceutical Process Engineering.* CRC Press.
6. Cole, G. C. *Pharmaceutical Facilities: Design, Layouts and Validation.* CRC Press.
7. Bertch, F. J. *Fundamentals of Modern Pharmaceutical Process Engineering.* Academic Press.
8. Chase, A. G. *Environmental Management in the Pharmaceutical Industry.* Springer.
9. Bunn, G. *Pharmaceutical Production Facilities: Design and Applications.* CRC Press.

Course Code	Course Title			Course Type
BP308T	**Pharmaceutical Microbiology (Theory)**			Core
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
3	3	--	--	45
Maximum Marks	SE			ESE
75	30			45

COURSE OBJECTIVES:

The objectives of this course are to:

1. Introduce the fundamental concepts of microbiology and its relevance to pharmaceutical sciences.
2. Provide insights into the industrial application of microorganisms in the manufacture of pharmaceutical products.
3. Provide knowledge Good Manufacturing Practices (GMP) related to microbial contamination control.
4. Provide understanding in microbial evaluation techniques such as sterility testing, microbial limit tests, and microbial assay.
5. Familiarize students with sterilization technologies, microbial spoilage control, and in vitro cell culture techniques for pharmaceutical research and quality assurance.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the basic concepts of microbiology and the role of microorganisms in pharmaceuticals.
2	Identify and differentiate microorganisms using staining and biochemical techniques.
3	Evaluate microbial contamination sources and apply GMP-based strategies for contamination control.
4	Describe microbial spoilage mechanisms and select appropriate disinfectants, antiseptics, or preservatives.
5	Compare various sterilization methods and assess their effectiveness and validation parameters and perform microbial limit and sterility tests in compliance with pharmacopeial guidelines.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Introduction and role of microorganisms in pharmaceutical industry** • Fundamentals of microbiology: Microorganisms and medicines, Introduction to various microorganisms, Microbial cultivation, isolation and enumeration. Pharmaceutical importance of microorganisms. • Introduction to Microscope (Compound and Electron Microscope) • Identification of bacteria using staining techniques (simple, Gram's &Acid-fast staining) and biochemical tests (IMViC). • Antibiotics produced by microbiology (Production and uses streptomycin, cephalosporin)	09 Hours
II	**Evaluation of microbiological contamination** • Sources and types of microbial contaminant • Control of microbial contamination during manufacture of Nonsterile dosage forms and sterile dosage forms (including Aseptic area), control of Atmosphere, Water, Raw material, Facility, Packaging, Equipment • Microbiological spoilage of pharmaceuticals, Factors affecting microbial spoilage of pharmaceuticals. • Introduction to Fermentation, types and fermenters.	09 Hours
III	**Microbial control and evaluation** Designing of aseptic area. Laminar flow equipment's, clean area classification, Biological Safety Level categories. Methods of prevention. Disinfectants, antiseptics, and preservatives, and their evaluation, Factors affecting the antimicrobial activity of disinfectants	09 Hours
IV	**Sterilization procedures, assurance and evaluation** • Physical, chemical, gaseous, radiation and mechanical methods of sterilization, Advances sterilization technologies, Evaluation of efficiency of sterilization; Validation of sterilization procedures and Sterility indicators. • Sterility assurance, Bioburden determination, Modelling in predicting microbial growth and death, Test for bacteriostatic, bactericidal activity	09 Hours
V	**Microbiological quality control** • Microbial limit tests and Microbial assay (antibiotics, vitamins and amino acids) • Sterility testing of products according to IP, BP and USP • Methods for monitoring Water and Air Quality In vitro cell cultures, general procedure for cell culture, Application of cell cultures in pharmaceutical industry and research	09 Hours

Recommended References *(Preferably latest editions):*

1. Pelczar, M. J., Chan, E. C. S. and Krieg, N. R. *Microbiology: Concepts and Applications.* McGraw-Hill.
2. Prescott, L. M., Harley, J. P. and Klein, D. A. *Microbiology.* McGraw-Hill.
3. Hugo, W. B. and Russell, A. D. *Pharmaceutical Microbiology.* Blackwell Science.
4. Waites, M. J., Morgan, N. L., Rockey, J. S. and Higton, G. *Industrial Microbiology: An Introduction.* Blackwell Science.
5. Denyer, S. P., Hodges, N. A. and Gorman, S. P. *Hugo and Russell's Pharmaceutical Microbiology.* Wiley-Blackwell.
6. Atlas, R. M. *Handbook of Microbiological Media.* CRC Press.
7. Sandle, T. *Pharmaceutical Microbiology: Essentials for Quality Assurance and Quality Control.* Elsevier.
8. Sutton, S. V. W. *Microbiology in Pharmaceutical Manufacturing.* PDA/DHI Publishing.

Course Code	Course Title			Course Type
BP309P	**General Pharmacology (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. Understand the historical and foundational aspects of experimental pharmacology
2. Develop knowledge and practical awareness of ethical and regulatory standards in laboratory animal care and use, as outlined in CCSEA guidelines
3. Acquire skills in pharmacological data acquisition and analysis
4. Interpret and construct dose-response curves (DRCs) and calculate and interpret pharmacological indices such as LD50, threshold and ceiling dose, slope of DRC, and

5. Calculate the pharmacokinetic parameters and analyse the roles of pharmacokinetic parameters in the drug effects, and dosing schedule.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Identify and describe the pharmacological actions of drugs on different physiological systems and understand their therapeutic relevance.
2	Design basic pharmacological experiments and analyze the results to determine drug efficacy and safety.
3	Apply the knowledge of drug mechanisms and interactions to predict clinical outcomes.
4	Develop skills for documentation, data collection, and report preparation of experimental pharmacological investigations.
5	Understand the importance of pharmacology in drug development, clinical research, and its application in medical practice

Detailed Syllabus:

List of practical
(Minimum 12 experiments must be performed) 1. To describe the contributions of renowned pharmacologists and their discoveries based on pharmacological experiments (Any 5 Noble Laureates whose research contributed to the development of Pharmacology). 2. To study various laboratory safety precautions, hazards, personal hygiene, commonly used tools, devices and instruments in experimental pharmacology. 3. To study common experimental animals including transgenic animals along with their applications in the pharmacological experiments in current drug discovery paradigm. 4. To study concept of 6Rs along with the maintenance and experimentation on laboratory animals as per the CCSEA guidelines. 5. To demonstrate collection/isolation of DNA and RNA using computer simulations and audiovisual aids. 6. To study important anaesthetics and euthanasia procedures for experimental animals. 7. To demonstrate different routes drug administration using computer simulation and understand the significance of each route along with the maximum administrable dose. 8. To study preparation of different types of physiological salt solutions (PSS), cell culture media and to understand the role of each ingredient used in PSS preparation. 9. To study the instrumentation used for isolated tissue experiments (students organ bath assembly) and recent development in recording of the responses of isolated tissues. 10. To record the dose response curve of any two agonists on suitable isolated tissue preparation using computer simulation experiment. 11. To study the potentiating effect of physostigmine on DRC of acetyl choline through interactive computer simulation. 12. To study antagonizing effect of d-tubocurarine on the DRCs of acetylcholine through interactive computer simulation. 13. To determine of PD2 of given agonists using isolated tissue preparation using computer simulation experiment. 14. To study and determine various pharmacokinetic parameters (Cmax, Tmax, Ke, t½, Vd, Clt, AUC, AUMC) from given hypothetical data. 15. To estimate LD_{50} using hypothetical data through computer-simulated experimentation (as per OECD 425 guideline) using software. 16. Software based quantification of micronucleus test and chromosomal aberration test 17. Software based prediction of teratogenicity. 18. Use of UV-Spectrophotometer for studying drug-protein interactions.
Recommended References *(Preferably latest editions)*: 1. Ghosh, M. N. *Fundamentals of Experimental Pharmacology.* Hilton & Company, Kolkata. 2. Kulkarni, S. K. *Handbook of Experimental Pharmacology.* Vallabh Prakashan. 3. Goyal, R. K. *Practical Pharmacology.* B. S. Shah Prakashan. *4.* Organisation for Economic Co-operation and Development. *OECD Guidelines for the Testing of Chemicals.* *5.* International Council for Harmonisation. *ICH Guideline S7A: Safety Pharmacology Studies for Human Pharmaceuticals.* 6. International Council for Harmonisation. *ICH Guideline S7B: Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization.*

Course Code	Course Title		Course Type	
BP310P	**Heterocyclic Compounds and Stereo Chemistry (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. Understand basic laboratory safety rules and learn how to handle chemicals and glassware properly.
2. Gain hands-on experience in preparing, purifying, and identifying organic compounds.
3. Learn practical techniques to separate components of binary organic mixtures.
4. Learn digital tools for drawing chemical structures and Chemical Reactions.
5. Determine molecular properties of aromatic organic and heterocyclic compounds

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Draw organic compound structures using chemical drawing tools.
2	Explain and apply techniques for purification and characterization of organic compounds.
3	Synthesize organic compounds through practical laboratory methods.
4	Analyze and separate binary organic mixtures using suitable experimental techniques.
5	Determine molecular properties of aromatic organic and heterocyclic compounds.

Detailed Syllabus:

List of practical
(Minimum 12 experiments must be performed) 1. Prepare, purify and characterize melting point, recrystallization following organic compounds (Minimum of 04 aromatic and any two heterocyclic compounds with different chemical reactions) a. Benzanilide/phenyl benzoate/acetanilide from aniline/ phenol by acetylation/acylation reaction. b. 2,4,6-Tribromo aniline from aniline/*para* bromo acetanilide from Acetanilide by halogenation (Bromination) reaction. c. 5-Nitro salicylic acid from salicylic acid / *meta* di-nitro benzene from nitro benzene by nitration reaction. d. Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis

reaction.

e. 1-Phenyl-azo-2-napthol from aniline by diazotization and coupling reactions.
f. Synthesis of 2,4,6- trinitrophenol by nitration reaction
g. Synthesis of 3,5-dimethyl pyrazole from acetylacetone.
h. Synthesis of benzimidazole from ortho phenylene diamine
i. Preparation of benzophenone oxime.

2. Qualitative analysis of binary mixture of organic compounds (any two) (Acid + Neutral and Base + Neutral).
3. To draw and visualize 3D structures, calculate molecular properties and to draw Chemical reactions using software tools

Recommended References *(Preferably latest editions)*:

1. Furniss, B. S., Hannaford, A. J., Smith, P. W. G. and Tatchell, A. R. *Vogel's Textbook of Practical Organic Chemistry.* Pearson Education.
2. Mann, F. G. and Saunders, B. C. *Practical Organic Chemistry.* Pearson Education.
3. Pavia, D. L., Lampman, G. M. and Kriz, G. S. *Introduction to Organic Laboratory Techniques: A Small Scale Approach.* Brooks/Cole.

Course Code	Course Title		Course Type	
BP311P	**Pharmaceutical Dosage Forms I (Practical)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
1	--	--	3	45
Maximum Marks	SE		ESE	
50	20		30	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Provide understanding on preformulation principles and evaluation of key parameters for drugs, excipients, and dosage forms.
2. Provide understanding of drug excipient compatibility testing during formulation development.
3. Provide hands-on experience in manufacturing processes and evaluation for solid dosage forms.
4. Provide hands-on experience in manufacturing processes and evaluation for sustained/controlled-release dosage forms and microcapsules.
5. Provide fundamentals of packaging material evaluation.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Conduct preformulation studies to evaluate physicochemical properties of drugs and excipients relevant to dosage form development.
2	Assess drug–excipient compatibility using appropriate experimental techniques during formulation development.
3	Formulate and evaluate solid dosage forms, including tablets and capsules, using suitable manufacturing methods.
4	Formulate and evaluate modified-release dosage forms and microcapsules using appropriate formulation and coating techniques.
5	Evaluate pharmaceutical packaging materials and understand their role in ensuring product stability and quality.

Detailed Syllabus:

List of practical
(Minimum 12 experiments must be performed) 1. Preformulation study of any drug/excipient as per pharmacopoeia. 2. Evaluation of powder flow properties for tablet blends. 3. Evaluation of effect of lubricating agents on powder flow properties. 4. Preparation and evaluation of tablets by direct compression.

5. Preparation and evaluation of tablets by dry granulation.
6. Preparation and evaluation of tablets by wet granulation.
7. Quality control of marketed tablets (IR, coated, enteric-coated).
8. Preparation and evaluation of coated tablets.
9. Comparison of dissolution profiles of marketed preparations.
10. Preparation and evaluation of hard-/non-gelatin capsules (fill weight, disintegration).
11. Virtual demonstration: hard-gelatin shell and soft-gel manufacturing (with overview of aseptic line/isolator).
12. Evaluation of packaging materials: primary and secondary/tertiary.
13. Preparation and evaluation of sustained-release tablets.
14. Preparation and evaluation of enteric-coated tablets.

Recommended References (Preferably latest editions):

1. Aulton, M. E. *Aulton's Pharmaceutics: The Science of Dosage Form Design.* Elsevier.
2. Lachman, L., Lieberman, H. A. and Kanig, J. L. *The Theory and Practice of Industrial Pharmacy.* CBS Publishers & Distributors.
3. Troy, D. B. and Beringer, P. *Remington: The Science and Practice of Pharmacy.* Pharmaceutical Press.
4. Gibson, M. *Pharmaceutical Preformulation and Formulation.* CRC Press.
5. Robinson, J. R. and Lee, V. H. L. *Controlled Drug Delivery: Fundamentals and Applications.* CRC Press.
6. *Indian Pharmacopoeia.* Indian Pharmacopoeia Commission.

Course Code*	Course Title*		Course Type
BP312P AEC1	Nutraceuticals and Functional Foods		Elective
BP312P AEC2	Food Analysis		
BP312P AEC3	Yoga and Life Sciences		
Credit	Hours Per Week (L-T-P)		
	L	T	P
1	--	--	1
Maximum Marks	SE		ESE
50	20		30

* Only 1 elective course shall be selected
The syllabi for elective subjects are given in the APPENDIX

Semester IV**

Course Code	Name of the Course	No. of hours/week (L/P)	Continuous Mode (Marks)	Sessional Exam (Marks)	Sessional Duration	Internal Total	End Semester Marks	Exam Duration	Total Marks	Credit points
BP401T	Herbal Drug Technology (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP402T	Medicinal Chemistry (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP403T	Pharmaceutical Biotechnology (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP404T	Social Pharmacy and Public Health (Theory)	2	10	10	1 Hr	20	30	1.5 Hr	50	2
BP405T	Systemic Pharmacology I (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP406P	Herbal Drug Technology (Practical)	3	10	10	3 Hr	20	30	3 Hr	50	1
BP407P	Medicinal Chemistry (Practical)	3	10	10	3 Hr	20	30	3 Hr	50	1
BP408P	Pharmaceutical Biotechnology (Practical)	3	10	10	3 Hr	20	30	3 Hr	50	1
BP409P	Social Pharmacy and Public Health (Practical)	2	10	10	3 Hr	20	30	3 Hr	50	1
BP410P	Systemic Pharmacology I (Practical)	3	10	10	3 Hr	20	30	3 Hr	50	1
BP411I	Internship (Mandatory)	8	Refer Section 22 of the ordinance	–	–	–	100	4 Hr	100	4
Total		**28**	**120**	**120**	**20 Hr**	**240**	**460**	**28.5**	**700**	**23**

**The lateral entry students taking admission directly to second year shall compulsorily appear for and pass the Applied Biostatistics and Data Analytics for Pharmaceutical Sciences (Theory) subject examination in the Fourth Semester.

Course Code	Course Title			Course Type
BP401T	**Herbal Drug Technology (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 and apply plant tissue culture techniques and related approaches for biomass and secondary metabolite production.
2. Introduce biomanufacturing concepts in herbal drug technology, including plant-based production systems and edible vaccines.
3. Develop skills in the preparation and optimization of standardized herbal extracts using metabolite analysis and TLC fingerprinting.
4. Study the formulation of herbal products using standardized extracts in conventional and novel dosage forms.
5. Understand quality control, standardization, regulatory guidelines, and interaction studies for safe herbal drug development.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Demonstrate tissue culture applications for herbal drug production and edible vaccines.
2	Summarize the concept of standardized extracts and incorporate them in herbal formulations and cosmetics.
3	Apply analytical methods for quality control of herbal preparations.
4	Analyze herb–drug/food interactions and their clinical significance.
5	Interpret national regulatory provisions and global standards related to herbal drug development.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Plant Tissue Culture and Standardized Extracts:** **Plant tissue culture as an alternative source of medicine:** • Historical development • Types of cultures • Nutritional requirements • Growth and maintenance of callus and suspension culture • Role of elicitation, genetic transformation, biotransformation, precursor feeding, and somaclonal variation in biomass and secondary metabolite production **Introduction to biomanufacturing:** • Medicinal plant–based biomanufacturing • Utilising plant factories in obtaining valuable ingredients for food, pharmaceutical, and cosmetic industries • Examples: **Shikonin and Paclitaxel** • Oral vaccines in healthcare **Optimization and production of standardized extracts of medicinal plants:** Strategies for preparation of desired quality extracts by optimizing and adjusting bioactives ensuring quality using analysis of metabolites and TLC fingerprints of the following: • Aqueous and hydro-alcoholic extracts of **Ashwagandha, Shatavari, Licorice, Neem, and Haritaki** • Flavonoid-rich fraction of **Sweet lime peel** • Terpenoid-rich fraction of **Bacopa** • Phenol-rich fraction of **Green Tea** • Steroid-rich fraction of **Tribulus** • Alkaloid-rich fraction of **Vasaka**	10 Hours

II	**Herbal Formulations, Excipients and Cosmetics:**
	Herbal formulations:
	• Conventional herbal formulations: syrups, mixtures, powders, capsules, tablets, creams, ointments
	• Novel dosage forms: phytosomes (phytocomplexes), liposomes, nanoformulations
	• Composition, preparation, and characterization using standardized extracts and bioactives
	Herbal cosmetics:
	• Sources and description of raw materials of herbal origin as active agents in skincare, hair care, and oral hygiene products
	• Applications in skincare, hair care, and oral hygiene products such as:
	  ○ Sunscreen-lotion/gel
	  ○ Hair oil, shampoo, herbal dye
	  ○ Herbal mouthwash, chewing gums, candies, gargles
	• Face serums and herbal face packs
	Excipients of Natural origin
	• Colorants, sweeteners, binders, diluents
		10 Hours

	• Viscosity builders, disintegrants • Flavors and perfumes • Protective agents, waxes, bleaching agents and antioxidants	
III	**Quality Control and Standardisation of Herbal Medicines:** • WHO, AYUSH, and EU guidelines on quality control, stability, and shelf life studies of herbal medicines • Approaches for standardisation and quality control of botanicals and formulations • Testing methods and regulatory considerations • Role of DNA fingerprint and molecular markers such as **rbcL, matK, and SCAR** in quality control • **Forensic pharmacognosy:** Role in identification of illicit herbal drugs (e.g., **Cannabis, Opium**)	7 Hours
IV	**Herb–Drug / Food / Herb Interactions:** • General introduction to interactions and role of ADME, Cytochrome P450, and P-gp • **Herb–drug interactions:** o St. John's Wort with warfarin o Ginkgo biloba with aspirin • **Herb–food interactions:** o Licorice with salty foods o Turmeric with fats o Green tea with iron-rich foods • **Herb–herb interactions:** o Ephedra with Ginseng o Chamomile with Valerian • Adverse reactions related to plants and foods such as allergy, intolerance, and toxicity	10 Hours
V	**Regulatory Requirements of Herbal Drugs and Botanicals:** **Regulatory framework in India for Herbal and ASU medicines:** a) Role of regulatory bodies b) ASU DTAB (Ayurveda, Siddha, and Unani Drugs Technical Advisory Board) c) ASU DCC (Drugs Consultative Committee for ASU drugs) d) Schedule T – GMP requirements for ASU drugs e) Schedule E1 – Poisonous drugs listed under AYUSH f) Drugs and Cosmetics Act – Regulatory provisions relevant to herbal/ASU medicines, procedures for registration, trade, and export g) Concept of **Phytopharmaceuticals** and **Ayush Aahara** in bridging Indian traditional knowledge with modern science.	8 Hours

Recommended References (Preferably latest editions):

1. Waldesch, F. G. *Herbal Medicinal Products.* CRC Press.
2. *Indian Herbal Pharmacopoeia.* Indian Drug Manufacturers' Association.
3. World Health Organization. *Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants.*
4. *Drugs and Cosmetics Act and Rules (India).* Government of India.

Course Code	Course Title			Course Type
BP402T	**Medicinal Chemistry (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. Develop a comprehensive understanding of the fundamental principles of medicinal chemistry, including physicochemical properties, drug metabolism, and prodrug concepts.
2. Classify and describe the chemical structures, therapeutic uses, and structure activity relationships of drugs acting on the autonomic and cardiovascular systems.
3. Apply the principles of structure activity relationships (SAR) to explain and predict the pharmacological activity.
4. Understand the synthetic pathways of drugs, emphasizing important reaction steps and chemical transformations.
5. Analyze the relationship between drug structure and pharmacological activity in relation to therapeutic efficacy and safety.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Relate the physicochemical properties of drug molecules to their biological activity and pharmacokinetic behavior.
2	Categorize drugs affecting the autonomic nervous system and predict their therapeutic outcomes.
3	Analyze and interpret the structure-activity relationships of selected drug classes (e.g., beta-blockers, local anesthetics, thiazide diuretics, NSAIDs) to optimize drug design.
4	Outline the synthetic routes of selected drugs, identifying key intermediates and reactions involved in their preparation.
5	Correlate the chemical structure of drugs with their therapeutic uses and potential adverse effects. Apply the knowledge of medicinal chemistry principles to understand and potentially contribute to the drug discovery and development process.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
	Study of the development of the following classes of drugs, Chemical Classification, Structure, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and Synthesis of selected drugs as superscripted (*)	
I	**Fundamentals of Medicinal Chemistry** • **Introduction:** History and scope of medicinal chemistry • **Physicochemical properties in relation to biological action:** Ionization, solubility, partition coefficient, hydrogen bonding, Chelation, Bioisosterism and protein binding • **Drug metabolism:** Phase I & II reactions	7 hours
II	**Drugs Acting on the Autonomic Nervous System** 1. **Adrenergic or Sympathomimetic agents:** Nor-epinephrine, Epinephrine, Phenylephrine*, Dopamine, Methyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline, Salbutamol*, Bitolterol, Naphazoline, Oxymetazoline and Xylometazoline, Hydroxyamphetamine, Pseudoephedrine, Propylhexedrine, Metaraminol. 2. **Anti-adrenergic or Sympatholytic agents:** Tolazoline*, Phentolamine, Phenoxybenzamine, Prazosin, Dihydroergotamine, Propranolol*, Metibranolol, Atenolol, Betazolol, Bisoprolol, Esmolol, Metoprolol, Labetalol, Carvedilol. SAR of beta adrenergic blockers. 3. **Cholinergic or Parasympathomimetic agents:** Acetylcholine, Carbachol*, Bethanechol, Methacholine, Pilocarpine, Physostigmine, Neostigmine, Pyridostigmine, Edrophonium chloride, Tacrine hydrochloride, Ambenonium chloride, Isofluorphate, Echothiophate iodide, Parathione, Malathion. Pralidoxime chloride. **4. Anti-Cholinergic or Parasympatholytic agents:** Atropine, Hyoscyamine, Scopolamine, Homatropine, Ipratropium*, Tropicamide, Cyclopentolate, Clidinium Glycopyrrolate, Dicyclomine*, Methantheline, Propantheline, Benztropine mesylate, Orphenadrine, Biperidine, Procyclidine, Tridihexethyl, Isopropamide, Ethopropazine, SAR of cholinergic blockers. 5. **Local anesthetic agents:** Cocaine, Hexylcaine, Meprylcaine, Cyclomethycaine, Piperocaine. Benzocaine, Butamben, Procaine*, Butacaine, Propoxycaine, Tetracaine, Benoxinate, Lignocaine, Mepivacaine, Prilocaine, Etidocaine, Phenacaine, Diperodon, Dibucaine.* SAR of Local anesthetics.	15 hours
III	**Drugs Acting on the Cardiovascular System** 1. **Anti-anginals:** Amyl nitrite, Nitroglycerin, Pentaerythritol, Isosorbide dinitrite*, Dipyridamole, Verapamil, Bepridil	09 hours

	hydrochloride, Diltiazem, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine. **2. Anti-hypertensives:** Timolol, Captopril, Lisinopril, Enalapril, Benazepril, Quinapril, Methyldopate,* Clonidine, Guanethidine, Guanabenz, Sodium nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine. **3. Drugs to treat Congestive Heart Failure (CHF):** Digoxin, Digitoxin, Nesiritide, Bosentan,Tezosentan. **4. Anti-arrhythmics (Class I – IV):** Quinidine sulphate, Procainamide, Disopyramide*, Phenytoin, Lidocaine, Tocainide, Mexiletine, Lorcainide, Amiodarone, Sotalol.	
IV	**Drugs acting on blood and Renal System** **1. Antihyperlipidemic Agents:** Fenofibrate*, Lovastatin, Cholesteramine and Cholestipol **2. Coagulants and Anti-Coagulants:** Menadione, Acetomenadione, Warfarin, Anisindione, clopidogrel. 3. **Diuretics:** Acetazolamide*, Methazolamide, Dichlorphenamide, Chlorthiazide, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide, Furosemide*, Bumetanide, Ethacrynic acid, Spironolactone, Triamterene, Amiloride. Mannitol. SAR of Thiazides.	06 hours
V	**Autacoids and related drugs** **1. Antihistamines** **a. H1– antagonists:** Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines, Clemastine, Diphenylphyraline, Tripelenamine, Chlorcyclizine, Meclizine, Buclizine, Chlorpheniramine, Triprolidine, Phenindamine, Promethazine*, Trimeprazine, Cyproheptadine, Azatidine, Astemizole, Loratadine, Cetirizine, Levocetrizine Cromolyn. **b. H2-antagonists:** Cimetidine*, Famotidine, Ranitidine. **2. Gastric Proton pump inhibitors:** Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole **Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), Antipyretics:** Sodium salicylate, Aspirin, Diflunisal, Mefenamic acid*, Niflumic acid, Meclofenamate, Indomethacin, Sulindac, Tolmetin, Zomepirac, Diclofenac, Ketorolac, Ibuprofen*, Naproxen, Piroxicam, Phenacetin, Acetaminophen, Antipyrine, Phenylbutazone, Celecoxib, Etoricoxib, SAR of representative agents by class.	08 hours

Recommended References (Preferably latest editions):

1. Lemke, T. L., Williams, D. A. and Roche, V. F. *Foye's Principles of Medicinal Chemistry.* Lippincott Williams & Wilkins.
2. Beale, J. M., Thomas, J. T. and Duckett, M. H. *Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry.* Lippincott Williams & Wilkins.
3. Abraham, D. J. and Griffin, J. L. *Burger's Medicinal Chemistry and Drug Discovery.* Wiley.
4. Patrick, G. L. *An Introduction to Medicinal Chemistry.* Oxford University Press.
5. Kar, A. *Medicinal Chemistry.* New Age International.
6. Li, J. J. and Welch, W. M. *Modern Drug Synthesis.* Wiley.
7. Lednicer, D. *The Organic Chemistry of Drug Synthesis.* Wiley.
8. Furniss, B. S., Hannaford, A. J., Smith, P. W. G. and Tatchell, A. R. *Vogel's Textbook of Practical Organic Chemistry.* Pearson Education.
9. Brunton, L., Hilal-Dandan, R. and Knollmann, B. *Goodman and Gilman's The Pharmacological Basis of Therapeutics.* McGraw-Hill Education.
10. Williams, D. A. Foye's Principles of Medicinal Chemistry. Lippincott Williams & Wilkins.

Course Code	Course Title			Course Type
BP403T	**Pharmaceutical Biotechnology (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 and apply plant tissue culture techniques and related approaches for biomass and secondary metabolite production.
2. Introduce biomanufacturing concepts in herbal drug technology, including plant-based production systems and edible vaccines.
3. Develop skills in the preparation and optimization of standardized herbal extracts using metabolite analysis and TLC fingerprinting.
4. Study the formulation of herbal products using standardized extracts in conventional and novel dosage forms.
5. Understand quality control, standardization, regulatory guidelines, and interaction studies for safe herbal drug development.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the role of biotechnology in pharmaceutical sciences, including monoclonal antibodies and enzyme immobilization.
2	Apply genetic engineering and recombinant DNA technology for the production of biopharmaceuticals such as insulin, interferons, and vaccines.
3	Describe microbial biotransformation and analyze fermentation processes used in pharmaceutical industries.
4	Assess the role of bioinformatics and artificial intelligence in the Human Genome Project and personalized medicine.
5	Describe vaccine and sera development, including preparation, evaluation, standardization, and regulatory requirements, and critically evaluate challenges and emerging approaches in vaccine and sera development and commercialization

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Introduction to Pharmaceutical Biotechnology** Introduction to biotechnology in pharmaceutical sciences; protein therapeutics; analytical characterization of proteins; monoclonal antibodies; antigens; enzyme immobilization; cell culture and immobilization techniques; pharmaceutical applications.	9 Hours
II	**Genetic Engineering and Recombinant DNA Technology** Principles of genetic engineering; recombinant DNA technology; production of interferons, hepatitis-B vaccine, and insulin; polymerase chain reaction (PCR) and its applications; mutations and types of mutants.	9 Hours
III	**Microbial Biotransformation and Fermentation Technology** Microbial biotransformation; fermentation principles and process control; industrial production of alcohol, penicillins, citric acid, and vitamin B_{12}; blood products—collection, processing, and storage.	9 Hours
IV	**Gene Therapy, Genomics and Personalized Medicine** Gene therapy—types and methodologies; delivery systems; ethical concerns and challenges; Human Genome Project; role of bioinformatics and artificial intelligence in personalized medicine.	9 Hours
V	**Immunology, Vaccines and Sera** Basics of immunology; types and generations of vaccines; immunization strategies; vaccine preparation, evaluation, and standardization; regulatory aspects; sera therapy; marketed products; challenges and newer approaches.	9 Hours

Recommended References (Preferably latest editions):

1. Crommelin, D. J. A., Sindelar, R. D. and Meibohm, B. *Pharmaceutical Biotechnology: Fundamentals and Applications.* Springer.
2. Walsh, G. *Biopharmaceuticals: Biochemistry and Biotechnology.* Wiley-Blackwell.
3. Brown, T. A. *Gene Cloning and DNA Analysis: An Introduction.* Wiley-Blackwell.
4. Glick, B. R., Pasternak, J. J. and Patten, C. L. *Molecular Biotechnology: Principles and Applications of Recombinant DNA.* ASM Press.
5. Doran, P. M. *Bioprocess Engineering Principles.* Academic Press.
6. Vogel, H. C. and Todaro, C. L. *Fermentation and Biochemical Engineering Handbook.* William Andrew.
7. Primrose, S. B., Twyman, R. M. and Old, R. W. *Principles of Gene Manipulation and Genomics.* Wiley-Blackwell.
8. Strachan, T. and Read, A. *Human Molecular Genetics.* Garland Science.
9. Plotkin, S. A., Orenstein, W. A., Offit, P. A. and Edwards, K. M. *Plotkin's Vaccines.* Elsevier.
10. Kindt, T. J., Goldsby, R. A., Osborne, B. A. and Kuby, J. *Kuby Immunology.* W. H. Freeman.
11. Janeway, C. A., Travers, P., Walport, M. and Shlomchik, M. *Janeway's Immunobiology.* Garland Science.

Semester-IV

Course Code	Course Title			Course Type
BP404T	**Social Pharmacy and Public Health (Theory)**			Core
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
2	2	--	--	30
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand the concepts of social pharmacy, public health, and their interrelation.
2. Identify the social determinants of health and their impact on health outcomes and medication use.
3. Recognize the role of pharmacists in public health initiatives, health promotion, and disease prevention.
4. To gain knowledge about the Indian healthcare system, national health policies, and important health programs.
5. To understand basic epidemiological principles and their application in public health.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Describe the scope of social pharmacy and the pharmacist's role in the public health system.
2	Explain the influence of socio-cultural and behavioral factors on health, illness, and medication adherence.
3	Discuss various national health programs and the pharmacist's contribution to their success.
4	Apply basic principles of epidemiology to understand disease distribution and control.
5	Develop health education materials and counsel patients on preventive healthcare measures and rational drug use.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Introduction to Social Pharmacy and Public Health** a) Social Pharmacy: Definition, scope, historical development, and importance. Social pharmacy as a multidisciplinary field. b) Public Health: Definition, concepts, history, core functions, and ethical	6 Hours

	considerations. c) Interplay between Social Pharmacy and Public Health: The evolving role of the pharmacist in the public health arena. d) Concept of Health and Disease: WHO definition of health; dimensions of health – physical, mental, social, spiritual, and environmental. e) Determinants of Health: Social, economic, environmental, lifestyle, and healthcare service determinants and their impact on population health. f) Health Indicators: Indicators used to measure health status and health outcomes in a population.	
II	**Health Systems, Policy, and Pharmacoepidemiology** a) Healthcare Delivery Systems: Overview of global healthcare systems. b) Indian Healthcare System: Structure, public and private sectors, primary, secondary, and tertiary levels of care. c) Health Policy: Introduction to health policy formulation and analysis; objectives of India's National Health Policy. d) National Health Mission (NHM): NRHM and NUHM – goals, strategies, and impact on public health indicators. e) Pharmacoepidemiology: Definition, aims, scope, and applications. f) Measures of Disease Frequency and Distribution: Incidence, prevalence, endemic, epidemic, pandemic; morbidity and mortality rates, Odds ratio and relative risk. g) Introduction to Biostatistics: Role in public health; types of data; basic data presentation methods.	6 Hours
III	**Preventive Healthcare, Health Promotion, and Communicable Diseases** a) Levels of Prevention: Primordial, primary, secondary, and tertiary prevention with examples. b) Role of Pharmacists in Disease Prevention and Health Promotion: Immunization services, screening programs, lifestyle counselling. c) Health Education: Definition, principles, methods, and importance; development of effective health education materials. d) Mother and Child Health (MCH): Antenatal care, postnatal care, breastfeeding, immunization schedules. e) Communicable Diseases: Modes of transmission, prevention, and control of tuberculosis, HIV/AIDS, malaria, dengue, typhoid, influenza; pharmacist's role.	6 Hours
IV	**Non-Communicable Diseases, Nutrition, Mental Health, and National Programs** a) Non-Communicable Diseases (NCDs): Diabetes, hypertension, cardiovascular diseases, chronic respiratory diseases, cancer; prevention and management. b) Nutrition and Health: Balanced diet, macro- and micronutrients, malnutrition, nutritional deficiency disorders, food safety, and adulteration. c) Mental Health: Common mental disorders, stigma, promotion of mental well-being; pharmacist's role. d) National Health Programs in India: Programs related to MCH, NCDs, communicable diseases, tobacco control, and deafness prevention.	6 Hours

V	**Pharmacoeconomics, Rational Use of Medicines, Professional Roles, and Future Trends** a) Pharmacoeconomics: Introduction, significance; Cost-Benefit Analysis (CBA), Cost-Effectiveness Analysis (CEA), Cost-Utility Analysis (CUA). b) Rational Use of Medicines (RUM): Definition, importance, problems of irrational drug use; pharmacist's role. c) Medication Adherence: Factors affecting adherence, consequences of non-adherence, improvement strategies. d) Drug Misuse and Abuse: Alcohol, tobacco, opioids, prescription drug abuse; pharmacist's role. e) Professionalism and Ethics in Social Pharmacy: Ethical dilemmas in public health pharmacy. f) Disaster Management: Role of pharmacists. g) Emerging Trends: Telepharmacy, digital health, personalized medicine, expanding public health responsibilities of pharmacists.	6 Hours

Recommended References (Preferably latest editions)

1. Anderson, S., Dedrick, R. and Tiffany, B. *Community Pharmacy Practice for Public Health.* McGraw-Hill Education.
2. Desselle, S. *Public Health and Pharmacy Practice.* McGraw-Hill Education.
3. Donyai, P. *Social and Cognitive Pharmacy: Theory and Case Studies.* Pharmaceutical Press.
4. Gillam, S., Yates, J. and Badrinath, P. *Essential Public Health: Theory and Practice.* Cambridge University Press.
5. Levin, B. L. and Hanson, A. *Essentials of Public Health Pharmacy.* Jones & Bartlett Learning.
6. Park, K. *Park's Textbook of Preventive and Social Medicine.* Banarsidas Bhanot Publishers.
7. Schneider, M. J. *Introduction to Public Health.* Jones & Bartlett Learning.
8. Taylor, K. and Harding, G. *Pharmacy Practice.* CRC Press.
9. Wertheimer, A., Ibrahim, M. I. M. and Babar, Z. U. D. *Social and Administrative Aspects of Pharmacy in Low- and Middle-Income Countries.* Elsevier.

Course Code	Course Title			Course Type
BP405T	**Systemic Pharmacology I (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. Develop a comprehensive understanding of neurohumoral transmission, neurotransmitters, and the organization and function of the autonomic nervous system.
2. Provide knowledge of the classification, mechanisms of action, and pharmacological effects of various classes of drugs.
3. Explain the pharmacology of drugs acting on the peripheral nervous system, cardiovascular system, and urinary system.
4. Describe the physiological roles of autacoids and the pharmacology of drugs used in the management of pulmonary diseases and related disorders.
5. Familiarize students with the pharmacology of drugs acting on the immune system, hematopoietic system, and blood, and relate pharmacological principles to clinical conditions through case-based learning.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Explain the classification of neurotransmitters and describe neurohumoral transmission, including the organization, function, and pharmacological modulation of the autonomic nervous system.
2	Classify and explain the mechanisms of action, pharmacological effects, and therapeutic uses of drugs used in cardiovascular disorders such as heart failure, arrhythmias, hypertension, angina, and lipid disorders.
3	Describe the pharmacology and therapeutic uses of drugs acting on blood and kidney, including anticoagulants, antiplatelet agents, hematinics, and diuretics.
4	Explain the physiological roles of autacoids and analyze the pharmacology of drugs that modulate autacoid pathways, including antihistamines, antimigraine agents, NSAIDs, and antirheumatic drugs.
5	Evaluate the mechanisms of action, therapeutic uses, and adverse effects of drugs acting on the respiratory and immune systems.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Pharmacology of drugs acting on the peripheral nervous system** a) Organization and functions of PNS. b) Neurohumoral transmission, co-transmission. Neurotransmitters and their receptors, including non-adrenergic and non-cholinergic (NANC) neurotransmitters. c) Parasympathomimetic and Parasympatholytic drugs. d) Sympathomimetic and sympatholytic drugs. e) Skeletal muscle relaxants (peripheral and central). f) Drugs used in the treatment of myasthenia gravis and glaucoma	10 Hours
II	**Pharmacology of drugs acting on the cardiovascular system** a) Introduction to cardiovascular hemodynamic and cardiac electrophysiology. b) Drugs used in congestive cardiac failure. c) Anti-arrhythmic drugs. d) Anti-anginal and newer anti-ischemic drugs. e) Anti-hypertensive drugs. f) Shock, types of shocks and drugs used in their management. g) Stroke, types of strokes and drugs used in their management	10 Hours
III	**Pharmacology of drugs acting on blood and kidney** 1. Pharmacology of drugs acting on blood a) Anti-platelet agents b) Coagulants and anticoagulants. c) Fibrinolytics and Plasma expanders. d) Haematinics. e) Anti-hyperlipidaemic drugs. 2. Pharmacology of drugs acting on kidney a) Diuretics. b) Anti-diuretics.	10 Hours
IV	**Pharmacology of autacoids and related drugs** a) Introduction to autacoids and their classification. Therapeutic significance of important agonists and antagonists of prostaglandins, thromboxane, leukotrienes, angiotensin, bradykinin and substance P. b) Histamine and antihistamines. c) 5-HT, its agonists and antagonists, drugs used in migraine. d) Non-steroidal anti-inflammatory drugs, antipyretics and analgesics. e) Anti-gout and Antirheumatic drugs including Disease Modifying Antirheumatic Drugs (DMARDs).	9 Hours
V	**i) Pharmacology of Drugs acting on respiratory system** a) Drugs used in the treatment of bronchial asthma and COPD. b) Definitions, classification and therapeutic uses of nasal decongestants,	6 Hours

	mucolytics, expectorants and antitussives. c) Respiratory stimulants. **ii) Pharmacology of Drugs acting on immune system** Mechanism of action, adverse effects and therapeutic uses of important classes of immune stimulants and immunosuppressants.	

Recommended References (Preferably latest editions):

1. Brunton, L., Hilal-Dandan, R. and Knollmann, B. *Goodman and Gilman's The Pharmacological Basis of Therapeutics.* McGraw-Hill Education.
2. Craig, C. R. and Stitzel, R. E. *Modern Pharmacology with Clinical Applications.* Lippincott Williams & Wilkins.
3. DiPiro, J. T., Talbert, R. L., Yee, G. C. and Matzke, G. R. *Pharmacotherapy: A Pathophysiologic Approach.* McGraw-Hill Education.
4. Katzung, B. G. and Trevor, A. J. *Basic and Clinical Pharmacology.* McGraw-Hill Education.
5. Rang, H. P., Dale, M. M., Ritter, J. M., Flower, R. J. and Henderson, G. *Rang and Dale's Pharmacology.* Elsevier.
6. Tripathi, K. D. *Essentials of Medical Pharmacology.* Jaypee Brothers Medical Publishers.

Course Code	Course Title			Course Type
BP406P	**Herbal Drug Technology (Practical)**			Core
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	--	--	3	45
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are:

1. To apply seed germination and plant tissue culture techniques for medicinal plants.
2. To prepare and standardize herbal extracts and phytoconstituent-enriched fractions as per Pharmacopoeial procedures.
3. To evaluate natural excipients and standardized herbal extracts for formulation development.
4. To develop and evaluate herbal cosmetic, pharmaceutical, and novel delivery systems using standardized extracts.
5. To assess the quality of marketed herbal formulations and extracts through experiential learning and surveys.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Perform seed germination and plant tissue culture of medicinal plants.
2	Prepare and standardize herbal extracts and enriched phytoconstituent fractions following official guidelines.
3	Evaluate excipients of natural origin and select suitable ingredients for herbal formulations.
4	Formulate and assess herbal cosmetics, dosage forms, and novel delivery systems as per Pharmacopoeial standards.
5	Analyze and compare marketed herbal medicines and cosmetics for quality, compliance, and performance

Detailed Syllabus:

List of practical
(Minimum 12 experiments must be performed) 1. To establish seed germination and plant tissue culture of a medicinal plant. 2. Preparation and standardization of extracts of Phenol-rich fraction of Green Tea. 3. Preparation and standardisation of Aqueous and hydro-alcoholic extracts of Ashwagandha or Haritaki (as per IP procedure) 4. Preparation and standardization of Flavonoid-enriched fraction of Sweet lime peel

5. Preparation and standardization of Terpenoid-rich fraction of Bacopa.
6. Preparation and standardization of Steroid-rich fraction of Tribulus
7. Preparation and standardization of Alkaloid-rich fraction of Vasaka
8. Evaluation of excipients of natural origin.
9. To develop and evaluate herbal cosmetics in form of gel, cream, lotion using standardized herbal extract.
10. To develop and evaluate herbal shampoo using standardized herbal extract.
11. To develop herbal formulations in form of syrups and mixtures using standardized herbal extract and their evaluation as per Pharmacopoeial guidelines.
12. To develop herbal tablets using standardized herbal extract and their evaluation as per Pharmacopoeial guidelines.
13. Preparation of botanicals-based new herbal medicinal product delivery systems (phytosomes).
14. Experiential learning-based experiments involving collection of herbal formulations/ extracts from the market and their quality evaluation as per Pharmacopoeial guidelines.
15. Survey on different commercialized marketed herbal cosmetics.
16. Survey on different commercialized marketed herbal medicine.

Recommended References (Preferably latest editions):

1. Evans, W. C. *Trease and Evans' Pharmacognosy.* Elsevier.
2. Harborne, J. B. *Phytochemical Methods: A Guide to Modern Techniques of Plant Analysis.* Springer.
3. Houghton, P. J. and Raman, A. *Laboratory Handbook for the Fractionation of Natural Extracts.* Chapman & Hall.
4. Indian Pharmacopoeia Commission. *Indian Pharmacopoeia.* Indian Pharmacopoeia Commission.
5. Mukherjee, P. K. *Quality Control and Evaluation of Herbal Drugs.* Elsevier.
6. Sarker, S. D., Latif, Z. and Gray, A. I. *Natural Products Isolation.* Humana Press.
7. World Health Organization. *WHO Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants.*
8. World Health Organization. *WHO Quality Control Methods for Herbal Materials.*

Course Code	Course Title			Course Type
BP407P	**Medicinal Chemistry (Practical)**			Core
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	--	--	3	45
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Comprehend the fundamental principles of drug synthesis, assay, and monograph analysis.
2. Acquire practical skills in the synthesis of selected drug molecules and intermediates.
3. Develop proficiency in performing qualitative and quantitative assays of drugs.
4. Understand the requirements and procedures involved in drug monograph analysis.
5. Apply appropriate techniques and methodologies for the preparation, assay, and monograph analysis of various drugs.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Demonstrate the ability to synthesize various drug molecules and intermediates using standard laboratory procedures.
2	Perform qualitative and quantitative assays of drugs with accuracy and precision.
3	Analyze and interpret drug monographs according to pharmacopeial standards.
4	Utilize appropriate instrumentation and techniques for drug preparation, assay, and monograph analysis.
5	Document and report experimental procedures and results in a clear and concise manner.

Detailed Syllabus:

List of practical

(Minimum 12 experiments must be performed)

1. **Preparation of Drugs / Intermediates**
   a. Aspirin
   b. Benzotriazole
   c. Benzocaine
   d. Phenytoin
   e. Dibenzalacetone
   f. Paracetamol
2. **Assay of Drugs** ***(Any 3)***
   a. Aspirin
   b. Ibuprofen
   c. Furosemide
   d. Paracetamol
3. **Monograph Analysis** ***(Any 3)***
   a. Paracetamol
   b. Aspirin
   c. Phenobarbital
   d. Diclofenac
   e. Phenytoin

Recommended References (Preferably latest editions):

1. Abraham, D. J. and Rotella, D. P. *Burger's Medicinal Chemistry, Drug Discovery and Development.* John Wiley & Sons.
2. Beckett, A. H. and Stenlake, J. B. *Practical Pharmaceutical Chemistry.* CBS Publishers & Distributors.
3. Furniss, B. S., Hannaford, A. J., Smith, P. W. G. and Tatchell, A. R. *Vogel's Textbook of Practical Organic Chemistry.* Pearson Education.
4. Indian Pharmacopoeia Commission. *Indian Pharmacopoeia.* Indian Pharmacopoeia Commission.
5. Kar, A. *Advanced Practical Medicinal Chemistry.* New Age International Publishers.
6. Lednicer, D. *The Organic Chemistry of Drug Synthesis.* John Wiley & Sons.
7. Moffat, A. C., Osselton, M. D. and Widdop, B. *Clarke's Analysis of Drugs and Poisons.* Pharmaceutical Press.
8. United States Pharmacopeial Convention. *United States Pharmacopeia National Formulary (USP–NF).* United States Pharmacopeial Convention.
9. Vogel, A. I. *Vogel's Textbook of Quantitative Chemical Analysis.* Longman Scientific & Technical.

Course Code	Course Title			Course Type
BP408P	**Pharmaceutical Biotechnology (Practical)**			Core
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	--	--	3	45
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Provide fundamental knowledge of biotechnology concepts, including protein therapeutics, monoclonal antibodies, enzyme immobilization, and their pharmaceutical applications.
2. Explain the principles and applications of genetic engineering and recombinant DNA technology in pharmaceutical sciences.
3. Develop understanding of microbial biotransformation, fermentation processes, and large-scale production of pharmaceutical products such as alcohol, antibiotics, vaccines, and blood products.
4. Describe the principles, methodologies, delivery systems, and ethical considerations associated with gene therapy and modern vaccine technologies.
5. Introduce the regulatory requirements and standardization procedures for vaccines, sera, and other biopharmaceutical products.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the fundamental principles of biotechnology and apply genetic engineering and recombinant DNA technology concepts in pharmaceutical sciences.
2	Describe the production and applications of biopharmaceutical products such as protein therapeutics and monoclonal antibodies.
3	Explain the principles, delivery systems, and ethical considerations associated with gene therapy.
4	Describe fermentation processes and microbial biotransformation involved in the large-scale production of pharmaceutical products such as vaccines, hormones, and blood products.
5	Explain the principles of immunization, types of vaccines and sera, and the regulatory and ethical considerations involved in the development of biopharmaceutical products.

Detailed Syllabus:

List of practical
(Minimum 12 experiments must be performed) 1. Understanding Good microbiological laboratory practices while working in Microbiology laboratory aseptic handling in microbiology lab: growth and isolation of microbes using streaking, spreading and subculturing techniques: study of various equipments such as loop, straight wire, spreader, forceps, pipette, test tube, petridish, burner etc and apparatus used in microbiology lab- BOD incubator, laminar flow, aseptic hood, autoclave, hot air sterilizer, deep freezer and microscopes. 2. Handling of biological spill, decontamination procedures and hygiene while handling microorganisms and disposal 3. Sterilization and evaluation of glassware and apparatus using hot air oven 4. Preparation and sterilization of solid and liquid culture medium using different techniques 5. Determination of microbiological efficacy of disinfectant/ preservative efficacy test 6. Tests for sterility of ophthalmic or parenteral marketed formulation according to IP. 7. Analysis of Biotechnological product (Protein, nucleic acid materials) by UV Vis and FTIR spectrophotometer 8. Production of alcohol using Fermentation process 9. Practice Whole cell immobilization technique (any one) 10. Practice Enzyme immobilization technique and its kinetics 11. Isolation and estimation of DNA and RNA 12. Isolation of plasmids and expression of protein 13. Agarose gel electrophoresis of DNA/ RNA 14. SDS – polyacrylamide gel electrophoresis for proteins. 15. Microbiological assay of antibiotics.
Recommended References (Preferably latest editions): 1. Baltz, R. H., Davies, J. E. and Demain, A. L. *Manual of Industrial Microbiology and Biotechnology.* ASM Press. 2. Carter, S. J. *Cooper and Gunn's Tutorial Pharmacy.* CBS Publishers & Distributors. 3. Chou, S. L. M. *Practical Biotechnology: A Guide to Biochemical Engineering.* Springer. 4. Denyer, S. P., Hodges, N. A. and Gorman, S. P. *Hugo and Russell's Pharmaceutical Microbiology.* Wiley-Blackwell. 5. Glick, B. R., Pasternak, J. J. and Patten, C. L. *Molecular Biotechnology: Principles and Applications of Recombinant DNA.* ASM Press. 6. Lachman, L., Lieberman, H. A., Kanig, J. L. and Khar, R. K. *The Theory and Practice of Industrial Pharmacy.* CBS Publishers & Distributors. 7. Pelczar, M. J., Chan, E. C. S. and Krieg, N. R. *Microbiology.* McGraw-Hill.

Course Code	Course Title			Course Type
BP409P	**Social Pharmacy and Public Health (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. Understand and apply basic health assessment techniques (blood pressure, BMI, and blood glucose levels), and perform essential first aid skills.
2. Gain skills in the development of health education tools and communication strategies to promote prevention and control of communicable diseases and encourage healthy lifestyle modifications.
3. Familiarize with mental health assessment tools and improve clinical communication skills through simulated role-play exercises focused on patient screening.
4. Acquire practical knowledge of immunization practices and demonstrate correct vaccine administration techniques using simulation models.
5. Understand the principles of epidemiology and designing preventive strategies for common communicable diseases. Develop foundational knowledge of Pharmacoeconomics and its applications. Evaluate health interventions, while identifying irrational drug use practices.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Perform basic health screening and first aid procedures using appropriate techniques.
2	Develop and disseminate health promotion and disease prevention materials
3	Apply mental health screening tools and demonstrate patient assessment skills using role plays and relevant psychological scales.
4	Demonstrate vaccination techniques using appropriate models and standard protocols for immunization practices.
5	Interpret epidemiological data and apply to create preventive measures Evaluate healthcare interventions using pharmacoeconomic principles and recognize irrational drug use in real-world scenarios.

Detailed Syllabus:

List of practical
(Minimum 12 Experiments must be performed; * Mandatory experiments) 1. Training on health screening services (Blood pressure, body mass index (BMI), blood glucose levels, heart rate (pulse rate), respiratory rate, body temperature, oxygen saturation (SpO_2), hemoglobin levels (basic anemia screening)). 2. Develop health promotion material for the prevention of communicable diseases. 3. Role play- usage of different mental scales in patient screening. 4. Case study on calculation of prevalence; incidence, odds ratio and relative risk. 5. Design and demonstrate preventive strategies for major communicable diseases (group activity) 6. Present a case study highlighting cost-benefit analysis in healthcare. 7. Perform cost-effectiveness analysis for selected health interventions. 8. Conduct cost-utility analysis to assess health program efficiency. 9. Perform basic first aid techniques. 10. Design informational leaflet on lifestyle modifications for disease prevention. 11. Identify and illustrate irrational drug use with a real-world example. 12. Prepare an immunization chart, interpret the vaccination schedule and perform patient counselling for vaccination*. 13. Hand wash and hand sanitizing techniques*. 14. Demonstration and practice of wound dressing in first aid and basic suturing techniques*. 15. Practical training on routes of drug administration-oral, and other non-parenteral routes*. 16. Practical training on routes of drug administration- parenteral routes*. 17. Training on basic life support (BLS)*.
Recommended References (Preferably latest editions): 1. Drummond, M. F., Sculpher, M. J., Claxton, K., Stoddart, G. L. and Torrance, G. W. *Methods for the Economic Evaluation of Health Care Programmes.* Oxford University Press. 2. Harding, G. and Taylor, K. *Social Pharmacy.* Pharmaceutical Press. 3. Jain, S. and Parle, M. *Community Pharmacy Practice.* CBS Publishers & Distributors. 4. Park, K. *Park's Textbook of Preventive and Social Medicine.* Banarsidas Bhanot Publishers.

Course Code	Course Title			Course Type
BP410P	**Systemic Pharmacology I (Practical)**			Core
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	--	--	3	45
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Provide understanding of the theoretical and practical aspects of different pharmacological experiments using virtual simulations and video demonstrations.
2. Develop skills to assess drug effects on various systems such as cardiovascular, respiratory, skeletal muscle, and gastrointestinal tract using simulation models.
3. preparation, spasmogen and spasmolytic effects, and PA2 value determination using Schild plot.
4. Provide knowledge of modern techniques for drug evaluation.
5. Explore clinical pharmacology aspects through case studies on drug interactions, management of cardiovascular and respiratory diseases, and plasma volume expanders.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Describe the drug effects on blood pressure, heart rate, and understand their relevance to cardiovascular pharmacotherapy through virtual simulations.
2	Evaluate the pharmacological management of asthma, analyse drug actions on the respiratory system, and correlate them with clinical data.
3	Interpret experimental data, calculate and analyse PA2 values, plot standard curves, and estimate drug effects using hypothetical data from computer simulations.
4	Present case studies and explore drug interactions and rational drug management in cardiovascular situations and asthma, applying pharmacological knowledge to patient care.
5	Demonstrate competence in various pharmacological measurements, such as intraocular pressure estimation, nitric oxide estimation in plasma, and spirometry.

Detailed Syllabus:

List of practical
(Minimum 12 Experiments must be performed) 1. To demonstrate Langendorff's heart assembly and its application in pharmacology (only video demonstration/or charts and illustrations). 2. Recording of the effects of different electrolytes, agonists and antagonists on the isolated and perfused frog heart preparation using interactive computer simulation experiment. 3. To study the effect of various drugs on blood pressure and heart rate anaesthetized dog using interactive computer simulation experiment. 4. Demonstration of the estimation of intraocular pressure on rabbit eye and human eye by using conventional Schiotz tonometer and non-contact tonometer. 5. To evaluate the muscle relaxant activity of drugs on Rota-rod apparatus using interactive computer simulation experiment. 6. Demonstration of the effect of spasmogens and spasmolytic using rabbit jejunum using interactive computer simulation experiment. 7. Determination of PA2 value of Atropine using a suitable isolated tissue preparation by Schild plot plot method with the help of hypothetical data using interactive computer simulation experiment. 8. Determination of PA2 value of Prazosin using a suitable isolated tissue preparation by Schild method with the help of hypothetical data using interactive computer simulation experiment. 9. To study the antiallergic effects of drugs using mast cell degranulation assay using interactive computer simulated experiment 10. Evaluation of diuretic activity of drugs in rats using metabolic cages (simulation) and estimation of electrolytes in the urine samples/serum using flame photometer/commercially available kits. 11. Evaluation of effects of antihistaminic drugs on the histamine-induced bronchospasm in guinea pigs using interactive simulated experiment. 12. To study and analyse drug-drug interaction/ rational drug management of asthma with the help of Case Study/ hypothetical data/ any clinical report. 13. To study clinical pharmacology of the plasma volume expanders and their importance (using charts/open sources videos). 14. Demonstration of evaluation of anti-inflammatory activity in paw oedema model using plethysmometer using simulations. 15. Concept of Biobanking and its significance in drug screening. 16. Isolation of Polymorphonuclear cells from blood and evaluation of endotoxin-induced oxidative stress in them using Nitrobluetetrazolium dye method by colourimetry. 17. Determination of viability of cells (using isolated polymorphonuclear cells) by Trypan blue dye exclusion assay to determine cell viability using microscopy method. 18. Determination of anti-inflammatory activity of durgs in vitro using RBC membrane stabilization assay 19. Determination of protein concentrations using Bradford reagent and plotting of standard curve of bovine serum albumin. 20. Estimation of anticholinesterase inhibitory activity of drugs using Ellman's reagent (DTNB) 21. Determination and and plotting of standard curve for LPO, Nitric oxide and GSH.
Recommended References (Preferably latest editions): 1. Ghosh, M. N. Fundamentals of Experimental Pharmacology. Hilton & Company. 2. Goyal, R. K. Practical Pharmacology. B. S. Shah Prakashan. 3. Kulkarni, S. K. Handbook of Experimental Pharmacology. Vallabh Prakashan. **4.** Computer Assisted Learning (CAL) software packages for experimental pharmacology simulations.

Course Code	Course Title		Course Type
BP411I	**Internship**		**Internship**
Credit	Hours Per Week (L-T-P)		
	L	T	P
4	--	--	8
Maximum Marks	SE		ESE
100	--		100

Semester V

Course Code	Name of the Course	No. of hours per week (L/P)	Continuous Mode (Marks)	Sessional Exam (Marks)	Sessional Duration	Internal Total	End Semester Marks	Exam Duration	Total Marks	Credit Points
BP501T	Biomedicinal Chemistry (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP502T	Industrial Pharmacognosy (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP503T	Innovation and Startup Ecosystem (Theory)	2	10	10	1 Hr	20	30	1.5 Hr	50	2
BP504T	Pharmaceutical Dosage Forms II (Theory)	2	10	10	1 Hr	20	30	1.5 Hr	50	2
BP505T	Pharmaceutical Quality Assurance (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP506T	Systemic Pharmacology II (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP507P	Biomedicinal Chemistry (Practical)	4	10	10	4 Hr	20	30	4 Hr	50	2
BP508P	Industrial Pharmacognosy (Practical)	3	10	10	3 Hr	20	30	3 Hr	50	1
BP509P	Pharmaceutical Dosage Forms II (Practical)	3	10	10	3 Hr	20	30	3 Hr	50	1
BP510P	Systemic Pharmacology II (Practical)	4	10	10	4 Hr	20	30	4 Hr	50	2
Total		**30**	**120**	**120**	**20 Hr**	**240**	**360**	**25 Hr**	**600**	**22**

Course Code	Course Title		Course Type	
BP501T	**Biomedicinal Chemistry (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. Provide comprehensive knowledge of drugs acting on the central nervous system, including anesthetics, sedatives, antipsychotics, and anticonvulsants, with emphasis on their chemical classification and structure activity relationships (SAR).
2. Familiarize students with anti-infective chemotherapeutic agents used against tuberculosis, malaria, protozoal, viral, fungal, helminthic, and urinary tract infections, including their chemical structures and SAR.
3. Impart understanding of antibiotics and sulfa drugs, focusing on their chemical classes, mechanisms, therapeutic relevance, and structure activity relationships.
4. Introduce antineoplastic agents and endocrine drugs, highlighting their chemical nature, classification, therapeutic applications, and structure activity correlations.
5. Develop knowledge of antidiabetic agents and narcotic analgesics, including opioid antagonists, with emphasis on medicinal chemistry principles and SAR of key drug classes.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Classify and explain the chemistry, therapeutic use, and structure ~~a~~ctivity relationships of drugs acting on the central nervous system, including anesthetics, sedatives, antipsychotics, and anticonvulsants.
2	Describe the chemical classification, mechanism of action, and SAR of major anti-infective agents such as antituberculars, antimalarials, antivirals, antifungals, anthelmintics, and urinary tract anti-infectives.
3	Analyze the chemistry and SAR of antibiotics and sulfonamides and correlate structural features with antimicrobial activity and spectrum of action.
4	Explain the chemical basis, therapeutic significance, and SAR of antineoplastic agents and endocrine drugs used in cancer and hormonal disorders.
5	Interpret the chemistry, pharmacological relevance, and SAR of antidiabetic agents and narcotic analgesics, including opioid agonists and antagonists, for rational drug use and development.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
	*Study of the development of the following classes of drugs includes chemical classification, structure, uses, SAR of selective drug classes, and synthesis of selected drugs as superscripted**	
I	**Drugs Acting on the Central Nervous System** **General Anesthetics** Halothane, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane, Methohexital, Thiamylal, Thiopental, Ketamine*, Ramelteon, Remimazolam, Fospropofol, Dexmedetomidine **Sedatives and Hypnotics** Barbital, Phenobarbital*, Mephobarbital, Amobarbital, Butabarbital, Pentobarbital, Secobarbital, Chlordiazepoxide, Diazepam*, Oxazepam, Chlorazepate, Lorazepam, Alprazolam, Zolpidem, Glutethimide, Meprobamate, Ethchlorvynol, Triclofos, Paraldehyde SAR of Barbiturates and Benzodiazepines **Antipsychotics** Promazine, Chlorpromazine*, Triflupromazine, Thioridazine, Piperacetazine, Prochlorperazine, Trifluoperazine, Chlorprothixene, Thiothixene, Loxapine, Clozapine, Haloperidol, Droperidol, Risperidone, Molindone, Sulpiride, Brexpiprazole, Lumateperone, Pimavanserin, Samidorphan SAR of Phenothiazines **Anticonvulsants** Phenobarbitone, Methabarbital, Phenytoin*, Mephenytoin, Ethotoin, Oxazolidinediones: Trimethadione, Paramethadione Succinimides: Phensuximide, Methsuximide, Ethosuximide Phenacemide, Carbamazepine*, Clonazepam, Primidone, Valproic acid, Gabapentin, Felbamate, Perampanel, Lacosamide, Retigabine SAR of Anticonvulsants	10 Hours
II	**Anti-Infective Chemotherapeutic Agents** **Antitubercular Agents** Isoniazid*, Ethionamide, Ethambutol, Pyrazinamide, Para-amino salicylic acid*, Rifampicin, Rifabutin, Cycloserine, Streptomycin, Capreomycin, Pretomanid, Clofazimine, Levofloxacin, Bedaquiline, Linezolid, Delamanid **Antimalarials** Quinine, Chloroquine*, Amodiaquine, Primaquine, Pamaquine, Quinacrine, Mefloquine, Cycloguanil pamoate, Proguanil, Pyrimethamine, Artesunate, Artemether, Atovaquone SAR of Quinoline derivatives	12 Hours

	Antiprotozoals Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine isethionate, Atovaquone,Eflornithine, Paromomycin, Nitazoxanide **Antivirals** Amantadine, Rimantadine, Idoxuridine, Acyclovir*, Ganciclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine,Loviride, Delavirdine, Ribavirin, Saquinavir, Indinavir, Ritonavir, Valganciclovir, Peramivir, Lenacapavir **Antifungals** Amphotericin-B, Nystatin, Natamycin, Griseofulvin, Clotrimazole, Econazole, Butoconazole, Oxiconazole, Tioconazole, Miconazole, Ketoconazole*, Terconazole, Itraconazole, Fluconazole, Naftifine, Tolnaftate, Posaconazole, Isavuconazole **Anthelmintics** Diethylcarbamazine, Thiabendazole, Mebendazole, Albendazole*, Niclosamide, Oxamniquine, Praziquantel, Ivermectin **Urinary Tract Anti-infective Agents** Nalidixic acid, Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Furazolidone, Nitrofurantoin, Methenamine, Moxifloxacin SAR of Quinolones	
III	**Antibiotics and Sulfa Drugs** **Antibiotics** Penicillins, Cephalosporins, β-Lactamase inhibitors, Monobactams Aminoglycosides: Streptomycin, Neomycin, Kanamycin, Tetracyclines: Tetracycline, Oxytetracycline, Minocycline, Doxycycline, Macrolides: Erythromycin, Clarithromycin, Azithromycin Chloramphenicol*, Clindamycin, Clavulanic acid SAR of Penicillins, Tetracyclines, and Cephalosporins **Sulfa Drugs** Sulphamethizole, Sulfisoxazole, Sulphapyridine, Sulphathiazole, Sulfacetamide, Sulphamethoxazole,Sulphadiazine, Mefenide, Sulfasalazine, Trimethoprim, Cotrimoxazole, Dapsone* SAR of Sulfonamides	8 Hours
IV	**Antineoplastic Agents** Mechlorethamine, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa, Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine, Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin, Etoposide, Vinblastine, Vincristine, Paclitaxel, Camptothecin, Cisplatin, Mitotane, Carboplatin	6 Hours

V	**Endocrine Drugs, Antidiabetic Agents and Narcotic Analgesics** **Endocrine Drugs** Sex hormones: Testosterone, Nandrolone, Progesterone, Oestriol, Oestradiol, Oestrone, Diethylstilbestrol Drugs for erectile dysfunction: Sildenafil, Tadalafil Oral contraceptives: Mifepristone, Norgestrel, Levonorgestrel Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone Thyroid and antithyroid drugs: L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole **Antidiabetic Agents** Insulin and preparations, Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride Biguanides: Metformin Thiazolidinediones: Pioglitazone, Rosiglitazone Repaglinide, Nateglinide, Acarbose, Voglibose **Narcotic Analgesics** Morphine, Codeine, Meperidine, Anilerdine, Diphenoxylate, Loperamide, Fentanyl*, Methadone, Propoxyphene, Pentazocine, Levorphanol Nalorphine, Levallorphan, Naloxone SAR of Morphine analogues	9 Hours

Recommended References (Preferably latest editions):

1. Abraham, D. J. and Griffin, J. L. *Burger's Medicinal Chemistry and Drug Discovery.* Wiley.
2. Brunton, L., Hilal-Dandan, R. and Knollmann, B. *Goodman and Gilman's The Pharmacological Basis of Therapeutics.* McGraw-Hill Education.
3. Kar, Ashuthosh. *Medicinal Chemistry.* New Age International.
4. Lednicer, D. *The Organic Chemistry of Drug Synthesis.* Wiley.
5. Li, J. J. *Modern Drug Synthesis.* Wiley.
6. Patrick, G. L. *An Introduction to Medicinal Chemistry.* Oxford University Press.
7. Vogel, A. I. *Vogel's Textbook of Practical Organic Chemistry.* Pearson Education.
8. Williams, D. A., Lemke, T. L. and Roche, V. F. *Foye's Principles of Medicinal Chemistry.* Lippincott Williams & Wilkins.
9. Wilson, C. O., Beale, J. M. and Block, J. H. *Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry.* Lippincott Williams & Wilkins.

Course Code	Course Title		Course Type	
BP502T	**Industrial Pharmacognosy (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 students to the industrial, commercial, and economic aspects of herbal drugs in national and global markets.
2. Knowledge of commercial production, quality assurance, and standardization of herbal extracts, volatile oils, and traditional AYUSH formulations
3. Train students in modern analytical techniques for the identification, characterization, and quality evaluation of plant-based drugs and herbal products
4. Develop skills in isolation, characterization, commercial production, and analysis of bioactive phytoconstituents.
5. Familiarize students with national and international regulatory frameworks, pharmacopoeial standards, and safety, efficacy, and pharmacovigilance requirements governing herbal medicinal products.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Describe the economic significance, trade potential, emerging therapeutic categories, and institutional support for medicinal and aromatic plant ~~b~~ased industries at national and international levels.
2	Explain the principles of commercial production, standardization, and quality control of herbal extracts, volatile oils, cosmeceuticals, and traditional formulations in compliance with AYUSH, WHO-GMP, and global regulatory norms.
3	Demonstrate analytical competence in evaluating herbal drugs and botanicals using modern spectroscopic and chromatographic techniques such as UV, IR, NMR, MS, HPTLC, HPLC, UPLC, and GC.
4	Describe the process to isolate, characterize, identify, and analyze important phytoconstituents used in pharmaceutical, nutraceutical industries.
5	Interpret and apply international regulatory guidelines, pharmacopoeial monographs, and safety, efficacy, and pharmacovigilance requirements for herbal and traditional medicinal products

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**General Introduction to Herbal Industries, institutions and trade status of herbals** (a) Role of medicinal and aromatic plants trade in national economy of a country and introduction of Current trade status and potential of some commercially important medicinal plants/natural products like Ashwagandha, Turmeric, Ginseng, Amla and essential oils. (b) A brief account of bioeconomy, biodiversity hot spots and plant-based industries and institutions involved in research work on medicinal and aromatic plants in India. (c) Emerging therapeutic categories of Herbal Medicinal Products available in market, their composition with rationale for Aphrodisiac, Antistress, anti-diabetics, antihyperlipidemic, immunomodulator, hepatoprotective and kidney disorders (d) Emerging Herbal cosmeceuticals: Anti-Aging, Depigmenting, anti-acne, sunscreen, detoxifying, anti-irritant, nutricosmetics.	8 Hours
II	**Commercial Production and Standardization of botanicals** Significance of AYUSH/ WHO-GMP, GLP and USFDA compliant facility in production of quality herbal products. Commercial production of standardized herbal extracts with clinical relevance: Coleus, Amla, Turmeric, Ashwagandha and Senna. Commercial production and standardization of volatile oils: Eucalyptus oils, Lavender oil and Peppermint oil, Rosemary oil Preparation and standardization of Ayush formulations viz Aristas and Asawas, Ghutika/Habb, Churna/ Shafoof Arq, Sharbat, Tincture and Bhasma.	10 Hours
III	**Modern methods of analysis of Plants and Plant-based products** Basic principles and applications in analysis of botanicals: Spectroscopic methods: UV-Visible spectroscopy, IR Spectroscopy, NMR spectroscopy and Mass spectroscopy, Atomic Absorption Scpectroscopy Chromatographic methods: HPTLC, HPLC, UPLC, GC,	12 Hours
IV	**Isolation, Characterization, Commercial Production and analysis of bioactive phytoconstituents** Isolation, characterization with commercial production, identification and analysis of bioactive phytoconstituents: Artemisinin, Sennosides, Withanolids, Boswellic acid, Atropine, and Lycopene.	08 Hours
V	**International Regulatory Perspectives** (a) Overview of global regulations for herbal products (e.g., World	07 Hours

	Health Organization, United States Food and Drug Administration – Dietary Supplement Health and Education Act, European Medicines Agency, TGA-ARG Therapeutic Goods Administration – Australian Regulatory Guidelines for Complementary Medicines, Natural Health Products (Canada) (b) Harmonization challenges and mutual recognition of traditional medicine (c) Importance of safety, efficacy and pharmacovigilance in herbal product regulation (d) Study of Monographs on herbal drugs and botanicals related to Indian Pharmacopoeia, United States Pharmacopoeia Herbal Medicine and Dietary Supplement, Ayurvedic Pharmacopoeia of India and Unani Pharmacopoeia of India.	

Recommended References (Preferably latest editions)

1. Ayurvedic Pharmacopoeia Committee. *Ayurvedic Pharmacopoeia of India.* Government of India, Ministry of AYUSH.
2. European Medicines Agency. *Herbal Monographs and Regulatory Guidelines.*
3. Indian Drug Manufacturers' Association. *Indian Herbal Pharmacopoeia.*
4. Indian Pharmacopoeia Commission. *Indian Pharmacopoeia.* Government of India.
5. International Council for Harmonisation. *ICH Guidelines on Quality, Safety, Efficacy and Multidisciplinary Topics.*
6. Natural Health Products Directorate. *Regulatory Framework for Natural Health Products.*
7. Unani Pharmacopoeia Committee. *Unani Pharmacopoeia of India.* Government of India, Ministry of AYUSH.
8. United States Pharmacopeial Convention. *United States Pharmacopeia.*
9. World Health Organization. *Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants.*
10. *Drugs and Cosmetics Act and Rules (India).* Government of India.

Course Code	Course Title		Course Type	
BP503T	**Innovation and Startup Ecosystem (Theory)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
2	2	--	--	30
Maximum Marks	SE	ESE		
50	20	30		

COURSE OBJECTIVES:

The objectives of this course are to:

1. Introduce students to the fundamental concepts, principles, and significance of innovation and entrepreneurship in contemporary economic and social contexts.
2. Familiarize students with the structure, components, and key stakeholders of the startup and innovation ecosystem.
3. Provide students with an understanding of the startup lifecycle, including ideation, opportunity analysis, product development, validation, and scaling.
4. Equip students with practical tools and techniques for problem identification, opportunity recognition, business model development, and idea validation.
5. Foster an entrepreneurial mindset by encouraging active participation in innovation-related events, stakeholder interactions, and experiential learning activities.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the fundamental concepts of innovation, entrepreneurship, and the structure and role of the startup ecosystem in economic and social development.
2	Identify and analyze problems, market gaps, and opportunities using ideation tools, market research techniques, and feasibility analysis.
3	Design and validate an innovative solution by developing a minimum viable product (MVP) using lean startup principles and customer feedback.
4	Develop an appropriate business model using the Business Model Canvas, and evaluate legal, intellectual property, team, and funding considerations for startups.
5	Demonstrate effective ecosystem engagement skills by participating in innovation events and presenting a concise startup pitch, incorporating future trends and scaling strategies.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures

I	**Unit I: Introduction to Innovation and Entrepreneurship**
	
	Defining Innovation and Entrepreneurship
	• What is Innovation?
	• Types of Innovation: Product, Process, Business Model, Social
	• What is Entrepreneurship?
	• Characteristics of an Entrepreneur
	
	Invention vs Innovation
	• Distinction between Invention and Innovation
	• Importance of Innovation in the 21st Century
	  ○ Economic growth and job creation
	  ○ Solving societal problems
	• Disruptive technologies and their impact
	
	Case Studies
	• Innovative companies (e.g., Apple, Google, Tesla)
	
	Introduction to the Startup Ecosystem
	• Key components:
	  ○ Entrepreneurs
	  ○ Incubators/Accelerators
	  ○ Mentors
	  ○ Investors
	  ○ Government
	  ○ Academia
	  ○ Support Services
	• Role of each component in fostering innovation
	
	Practical Aspect:
	Participation in **National Innovation Day** and **National Startup Day**
		06 Hours

II	**Unit II: Ideation and Opportunity Identification**
	
	Identifying Problems and Market Gaps
	• Problem-solving approach to entrepreneurship
	• Techniques for problem identification:
	  ○ Observation
	  ○ Empathy mapping
	  ○ User interviews
		06 Hours

	• Market research basics:
	  ○ Understanding customer needs and pain points
	Generating Innovative Ideas
	• Brainstorming techniques:
	  ○ SCAMPER
	  ○ Mind Mapping
	  ○ Design Thinking principles for ideation
	• Lateral thinking and divergent thinking
	• From problem to solution: developing initial concepts
	Opportunity Analysis and Feasibility
	• Market sizing and potential
	• Competitive analysis
	• SWOT analysis for new ventures
	Practical Aspect:
	Participation in **Ideation Challenges or Hackathons** (e.g., *Smart India Hackathon* or IIC internal ideation competitions)	

III	**Unit III: Building a Minimum Viable Product (MVP) and Validation**
	Lean Startup Methodology
	• Introduction to Lean Startup principles
	• Build–Measure–Learn feedback loop
	• Concept of MVP:
	  ○ Importance
	  ○ Scope and objectives
	Designing and Developing an MVP
	• Different types of MVPs
	• Tools and resources for rapid prototyping
	• User experience basics for MVPs
	Validation
	• Customer interviews and feedback collection
	• A/B testing and split testing
	• Pivoting vs Persevering
	Practical Aspect:
	Participation in sessions/workshops on **Prototype, MVP, and Product Development**
		06 Hours

IV	**Unit IV: Business Models and Startup Operations** **Business Model Canvas (BMC)** • Introduction to the 9 building blocks of BMC • Developing a BMC for a new venture • Value Proposition Design **Legal and Financial Aspects for Startups** • Legal structures: ○ Sole Proprietorship	06 Hours

	○ Partnership ○ Private Limited Company • Intellectual Property Rights (IPR): ○ Patents ○ Trademarks ○ Copyrights • Startup funding: ○ Bootstrapping ○ Angel investors ○ Venture capital **Team Building and Mentorship** • Importance of a strong founding team • Roles and responsibilities in a startup • Value of mentors and advisors **Practical Aspect:** Participation in **IPR awareness programs** or **startup funding sessions**	
V	**Unit V: Scaling, Ecosystem Engagement, and Future Trends** **Growth Strategies and Scaling Up** • Marketing and sales for startups • User acquisition and retention • Challenges of scaling and solutions • Exit strategies: ○ Acquisition ○ IPO **Engaging with the Startup Ecosystem** • Networking with investors, mentors, and entrepreneurs • Participation in startup competitions and pitch events • Leveraging incubators and accelerators **Future Trends in Innovation and Entrepreneurship** • Emerging technologies: ○ Artificial Intelligence ○ Blockchain ○ Internet of Things (IoT) ○ Sustainable Technologies • Social entrepreneurship and impact investing • Global startup trends **Practical Aspect:** Participation in **National Innovation Day** and student engagement activities to prepare and deliver a concise pitch for their developed idea, simulating a startup pitch event.	06 Hours

Recommended References (Preferably latest editions)

1. Eric Ries. The Lean Startup: How Today's Entrepreneurs Use Continuous Innovation to Create Radically Successful Businesses. Crown Business.
2. Thiel, P. and Masters, B. Zero to One: Notes on Startups, or How to Build the Future. Crown Business.
3. Bansal, R. *Stay Hungry Stay Foolish.* Westland.
4. Dalal, M. *Big Billion Startup: The Untold Flipkart Story.* Pan Macmillan India.
5. Ivaturi, V. K. *The Manual for Indian Start-Ups: Tools to Start and Scale-Up Your New Venture.* Notion Press.
6. Mishra, S., Patjoshi, P. K. and Patnaik, S. K. *Innovation and Entrepreneurship.* Pearson India.
7. Sardar, R. and Waghmare, G. *Startup Ecosystem in India: Text and Cases.* Himalaya Publishing House.

Course Code	Course Title		Course Type	
BP504T	**Pharmaceutical Dosage Forms II (Theory)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
2	2	--	--	30
Maximum Marks	SE		ESE	
50	20		30	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand the principles of formulation and development of monophasic liquid dosage forms, including solvent selection and solubility enhancement techniques.
2. Acquire knowledge of biphasic liquid dosage forms, including physicochemical principles, formulation strategies, manufacturing processes, and stability considerations.
3. Develop competence in pressurised dosage forms such as aerosols, metered-dose inhalers, and dry powder inhalers, with emphasis on formulation design, device components, manufacturing, and quality evaluation.
4. Understand the formulation, manufacturing, and evaluation of semisolid dosage forms, with emphasis on drug permeation through the skin and factors affecting topical drug delivery.
5. Gain exposure to advanced drug delivery systems such as nanosuspensions, nanoemulsions, SMEDDS/SNEDDS, xerogels, and emulgels for improved therapeutic performance.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the fundamental principles, classification, formulation requirements, and quality aspects of monophasic and biphasic liquid dosage forms.
2	Formulate, manufacture, and evaluate monophasic and biphasic liquid preparations, including solutions, syrups, elixirs, suspensions, and emulsions, using appropriate excipients and processing techniques.
3	Apply physicochemical principles such as solubility enhancement, Stokes' law, DLVO theory, and emulsification theories to design stable liquid dosage forms and assess their stability and performance.
4	Design and evaluate pressurized and inhalation dosage forms, including aerosols, metered dose inhalers, and dry powder inhalers, by selecting suitable formulation components, devices, and quality control parameters.
5	Formulate, evaluate, and justify the use of semisolid and advanced drug delivery systems—including ointments, creams, gels, suppositories, nanosuspensions, nano-emulsions, SMEDDS/SNEDDS, xerogels, and emulgels —for enhanced drug delivery, stability, and patient compliance.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Monophasic Liquids & Pressurized Dosage Forms** **Foundations:** Need, advantages/limitations; monophasic vs biphasic; solubility-enhancement techniques. **Vehicles & solvents:** Pharmaceutical waters (types; manufacturing & Quality Control of Purified/Distilled); classes of solvents as per toxicity. **Formulation & manufacturing:** Raw-material considerations and additives; processing; Quality Control of solutions/syrups/elixirs; powders for reconstitution as **solutions**. **Measuring, filling & packaging:** Techniques; container–closure integrity; **automation** in liquid manufacturing.	06 Hours
II	**Biphasic Liquids - Suspensions** **Formulation & manufacturing:** Additives; classification of suspending agents; IPQC & Quality Control; instabilities and packaging. **Advances: Nanosuspensions**; dry powder for reconstitution as **suspensions**; **raft- forming** systems.	06 Hours
III	**Biphasic Liquids - Emulsions** **Formulation & manufacturing:** Additives; classification of emulsifying agents; IPQC & Quality Control; instabilities and packaging. **Advances: Nano-emulsions, micro-emulsions, SMEDDS/SNEDDS** (overview, applications).	06 Hours
IV	**Pressurized dosage forms (Aerosols/MDIs)** Concepts; propellant classification/selection; valves & containers; formulation, manufacturing, and Quality Control (leak, spray pattern, delivered dose, particle- size/aerodynamic performance). **Dry Powder Inhalers:** valves & containers; formulation, manufacturing, and Quality Control	06 Hours
V	**Semisolid Dosage Form** **Theory of Semisolid Dosage Forms:** Definition & Purpose, Drug Permeation Pathways through skin, Factors affecting Permeation, Permeation enhancers: Physical and Chemical. **Types of semisolid dosage form:** • **Ointments:** Base Selection, Formulation, Manufacturing and Evaluation	06 Hours

	• **Creams:** Formulation, Manufacturing and Evaluation • **Gels/Jellies:** Formulation, Manufacturing and Evaluation. • **Pastes:** Formulation, Manufacturing and Evaluation • **Suppositories and Pessaries:** Formulation, Manufacturing and Evaluation **Advances: Xerogels, emulgels** (overview, applications).	

Recommended References (Preferably latest editions)

1. Aulton, M. E. *Aulton's Pharmaceutics: The Science of Dosage Form Design.* Elsevier.
2. Gibson, M. *Pharmaceutical Preformulation and Formulation.* CRC Press.
3. Lachman, L., Lieberman, H. A. and Kanig, J. L. *The Theory and Practice of Industrial Pharmacy.* CBS Publishers & Distributors.
4. Robinson, J. R. and Lee, V. H. L. *Controlled Drug Delivery: Fundamentals and Applications.* CRC Press.
5. Troy, D. B. and Beringer, P. *Remington: The Science and Practice of Pharmacy.* Pharmaceutical Press.
6. *Indian Pharmacopoeia.* Indian Pharmacopoeia Commission.

Course Code	Course Title		Course Type	
BP505T	**Pharmaceutical Quality Assurance (Theory)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
3	3	--	--	45
Maximum Marks	SE		ESE	
75	30		45	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Introduce the concepts and systems of pharmaceutical quality management
2. Provide an overview of regulatory frameworks governing pharmaceutical quality.
3. Familiarize students with organizational, infrastructural, and operational requirements of pharmaceutical manufacturing and quality control.
4. Explain quality control testing of pharmaceutical products
5. Understand the documentation, validation, calibration, and data integrity essential for regulatory compliance.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the concepts of QA, QC, GMP, GLP and modern Quality Management Systems.
2	Apply TQM, QbD, and ICH guidelines to ensure consistent pharmaceutical quality.
3	Understand requirements related to personnel, premises, equipment, materials, and documentation.
4	Describe quality control testing of pharmaceutical products.
5	Explain calibration, qualification, and analytical method validation as per regulatory guidelines.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Quality Assurance and Quality Management Systems** 1. Quality Assurance and Quality Management concepts: Definition and concepts of Quality Control, Quality Assurance, and GMP 2. Total Quality Management (TQM): Definition, elements, and philosophies 3. ICH Guidelines: Purpose, process of harmonization, overview of QSEM with special emphasis on Q-series guidelines	10 hours

	4. Quality by Design (QbD): Definition, overview, elements of QbD program, and tools 5. ISO 9000 and ISO 14000: Overview, benefits, elements, and steps for registration 6. NABL Accreditation: Principles and procedures	
II	**Organization, Personnel, Premises, and Materials Management** 1. Organization and Personnel: Responsibilities, training, hygiene, and personal records 2. Premises: Design, construction, plant layout, maintenance, sanitation, environmental control, utilities, and control of contamination 3. Equipment and Raw Materials: Equipment selection, User Requirement Specifications (URS), handling and maintenance of raw materials 4. Warehousing: Good warehousing practices and materials management	10 hours
III	**Quality Control and Good Laboratory Practices** 1. Quality Control Tests for Formulations: In-process and finished product quality control tests for tablets, capsules, ointments, creams, ophthalmic and parenteral preparations 2. Quality Control of Raw Materials and Packaging Materials: Tests for raw materials, containers, rubber closures, and secondary packing materials 3. Good Laboratory Practices (GLP): General provisions, organization and personnel, facilities and equipment, ALCOA principles, reference standards, testing facility operations, records and reports, and disqualification of testing facilities	10 hours
IV	**Documentation, Complaints, and Product Recall** 1. Documentation in the Pharmaceutical Industry: Batch Formula Record, Master Formula Record, Drug Master File, SOPs, quality audits, preparation, handling, archival, and distribution of records 2. Complaints and Product Recall: Handling of complaints, evaluation of complaints, returned goods, recalls, and waste disposal	08 hours
V	**Calibration and Validation** 1. Calibration and Validation: Introduction, definitions, importance, and general principles Calibration of weights and measures, pH meter Qualification of UV-Visible spectrophotometer, electronic balance, IR spectrophotometer, and HPLC 2. Analytical Method Validation: General principles of analytical method validation as per ICH Q2 guidelines	07 hours

Recommended References ***(Preferably latest editions)***

1. Godfrey, A. B. and Juran, J. M. Juran's Quality Handbook. McGraw-Hill Education.
2. Organisation of Pharmaceutical Producers of India. Quality Assurance Guide. OPPI.
3. Weinberg, S. Good Laboratory Practice Regulations. Marcel Dekker.
4. World Health Organization. Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials. World Health Organization.

Course Code	Course Title		Course Type	
BP506T	**Systemic Pharmacology II (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 neurohumoral transmission in the central nervous system and the role of neurotransmitters and their modulators in CNS disorders.
2. Learn the pharmacology of drugs used in pathological conditions of CNS, GIT, and endocrine system.
3. Familiarize learners with concepts of drug abuse, addiction, dependence, tolerance, and their management.
4. Impart comprehensive knowledge of chemotherapeutic agents including anticancer drugs.
5. Introduce the principles of rational use of chemotherapeutic agents.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Identify the role of neurotransmitters in CNS diseases and explain pharmacology of drugs acting on central neurotransmission.
2	Apply principles of chemotherapy to explain mechanisms and uses of chemotherapeutic agents.
3	Recall pharmacology of hormones and drugs used in endocrine disorders.
4	Describe mechanisms and therapeutic uses of drugs acting on the gastrointestinal tract.
5	Recognize issues related to drug abuse, addiction, and dependence and their management.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Pharmacology of Drugs Acting on Central Nervous System** Neurohumoral transmission in the CNS; physiological roles of GABA, glutamate, glycine, serotonin, and dopamine. a. General anesthetics, pre-anaesthetic medications, and local anaesthetic agents b. Sedative–hypnotics c. Alcohol and disulfiram d. Opioids, opiate analgesics, and antagonists e. Drugs used in epilepsy f. Drugs used in Parkinson's and Alzheimer's diseases	10 hours
II	**Pharmacology of Drugs Used in Psychiatry** a. Antipsychotics, antidepressants, anti-anxiety drugs, mood stabilizers, CNS stimulants, and hallucinogens b. Substance abuse, drug addiction, and general principles of de-addiction	07 hours
III	**Chemotherapy** **i) Introduction** a. Definitions of chemotherapy, chemotherapeutic index, antibiotics, and antimicrobial agents b. Concept of selective targeting in chemotherapy c. Classification of antimicrobial agents based on mechanism of action d. Concept of superinfection, chemoprophylaxis, and combined use of antibiotics e. Antimicrobial resistance: causes, mechanisms, and preventive measures **ii) Antimicrobial Agents** Classification, mechanism of action, adverse drug reactions, and therapeutic uses of: • Sulphonamides and cotrimoxazole • Fluoroquinolones • Penicillins and cephalosporins • Macrolides and tetracyclines • Linezolid • Carbapenems and monobactams • Chloramphenicol and aminoglycosides **iii) Chemotherapy of Diseases** Drugs used in the treatment of: • Fungal infections • Viral infections	14 hours

	• Helminthiasis • Urinary tract infections • Tuberculosis • Leprosy • Malaria • Amoebiasis • Neoplastic diseases	
IV	**Pharmacology of Drugs Acting on Endocrine System** a. Introduction to basic concepts of endocrinology b. Thyroid and antithyroid agents c. Parathormone, calcitonin, and vitamin D d. Insulin and oral hypoglycaemic agents e. ACTH and corticosteroids f. Oral contraceptives g. Drugs acting on the uterus h. PCOD	10 hours
V	**Drugs Acting on Gastrointestinal Tract** a. Drugs used in peptic ulcer b. Drugs used for constipation and diarrhoea c. Emetics and anti-emetics d. Digestants, carminatives, appetizers, and anorectics – definitions and examples	04 hours

Recommended References *(Preferably latest editions):*

1. Brunton, L., Hilal-Dandan, R. and Knollmann, B. *Goodman and Gilman's The Pharmacological Basis of Therapeutics.* McGraw-Hill Education.
2. Craig, C. R. and Stitzel, R. E. *Modern Pharmacology with Clinical Applications.* Lippincott Williams & Wilkins.
3. DiPiro, J. T., Talbert, R. L., Yee, G. C. and Matzke, G. R. *Pharmacotherapy: A Pathophysiologic Approach.* McGraw-Hill Education.
4. Katzung, B. G. and Trevor, A. J. *Basic and Clinical Pharmacology.* McGraw-Hill Education.
5. Rang, H. P., Dale, M. M., Ritter, J. M., Flower, R. J. and Henderson, G. *Rang and Dale's Pharmacology.* Elsevier.
6. Tripathi, K. D. *Essentials of Medical Pharmacology.* Jaypee Brothers Medical Publishers.

Course Code	Course Title		Course Type	
BP507P	**Biomedicinal Chemistry (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. Comprehend the fundamental principles of drug synthesis and apply them to the preparation of selected drug molecules and intermediates.
2. Develop practical skills in performing laboratory techniques for the synthesis of organic compounds, including the use of microwave irradiation.
3. Understand and apply the principles of drug assay to quantitatively analyze the purity and concentration of given drug samples.
4. Learn and utilize computational tools to predict physicochemical and ADME properties of drug molecules.
5. Apply molecular docking techniques to predict drug-target interactions.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Successfully synthesize specified drug molecules and intermediates in the laboratory.
2	Demonstrate competence in using microwave irradiation for efficient chemical synthesis.
3	Accurately perform drug assays to determine the concentration and purity of drug samples.
4	Analyze physicochemical and ADME properties of drug candidates using computational tools.
5	Conduct and interpret molecular docking studies to understand drug-receptor binding.

Detailed Syllabus:

List of practical
1. Preparation of Drugs / Intermediates **(Any 4)** • 7-Hydroxy-4-methyl coumarin • Thiobarbituric acid • 2,3-Diphenylquinoxaline • Sulphanilamide • Triphenyl imidazole • Perform synthesis of intermediate/drug using microwave irradiation or green chemistry techniques. **2.** Assay of Drugs **(Any 4)** • Sulpha drugs • Metronidazole • Isoniazid • Phenobarbitone • Benzyl penicillin • Chloroquine **3.** Drug Design & Computational Tools **(Any 4)** • Calculate physicochemical and ADME properties using Swiss ADME (e.g. logP, molecular weight, H-bond donors/acceptors) • Perform basic molecular docking studies using any of open-source academic tools.
Recommended References *(Preferably latest editions):* 1. Abraham, D. J. and Griffin, J. L. *Burger's Medicinal Chemistry and Drug Discovery.* Wiley. 2. Finar, I. L. *Organic Chemistry.* Pearson Education. 3. Furniss, B. S., Hannaford, A. J., Smith, P. W. G. and Tatchell, A. R. *Vogel's Textbook of Practical Organic Chemistry.* Pearson Education. 4. Lednicer, D. *The Organic Chemistry of Drug Synthesis.* Wiley. 5. Patrick, G. L. *An Introduction to Medicinal Chemistry.* Oxford University Press. 6. Remington. *The Science and Practice of Pharmacy.* Pharmaceutical Press. 7. Williams, D. A., Lemke, T. L. and Roche, V. F. *Foye's Principles of Medicinal Chemistry.* Lippincott Williams & Wilkins. 8. Wilson, C. O., Beale, J. M. and Block, J. H. *Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry.* Lippincott Williams & Wilkins. 9. *Indian Pharmacopoeia.* Indian Pharmacopoeia Commission. 10. Brown, N. Artificial Intelligence in Drug Discovery. Cambridge: Royal Society of Chemistry.

Course Code	Course Title		Course Type	
BP508P	**Industrial Pharmacognosy (Practical)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
1	--	--	3	45
Maximum Marks	SE		ESE	
50	20		30	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Apply knowledge of chromatographic and spectroscopic techniques for the separation, isolation, and analysis of phytoconstituents.
2. Learn isolation and characterization of major secondary metabolites and volatile oil constituents using standard laboratory methods.
3. Perform chemoprofiling, purification, and quantitative estimation of herbal and Ayurvedic formulations.
4. Prepare and document herbal drug monographs and traditional formulations as per IP, API, and IHP guidelines.
5. Integrate experiential learning and community-based studies for understanding the use, quality, and awareness of traditional medicines.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Apply chromatographic techniques for isolation and analysis of phytoconstituents
2	Isolate and identify key compounds from medicinal plants phytoconstituents
3	Standardize Ayurvedic formulations and determine alcohol content.
4	Prepare herbal drug monograph and assess traditional formulations.
5	Evaluate and analyze marketed and community-used traditional formulations through case studies and experiential learning.

Detailed Syllabus:

List of practical ***(Minimum 12 experiments must be performed)***
1. To perform column chromatography for isolation of flavonoids/ colouring matter. 2. Preparative TLC of curcuminoids. 3. Isolation and identification of Piperine. 4. Isolation and identification of Sennoside. 5. Isolation and identification of Withanolide. 6. Isolation and identification of Lycopene. 7. Acid – base purification process for the separation of alkaloids. 8. Chemoprofiling of purified alkaloidal fraction. 9. Separation of amino acid by paper chromatography. 10. TLC/HPTLC/HPLC of herbal extracts/ botanicals. 11. Isolation and determination of total aldehyde content in volatile oil. 12. Preparation of monographs on herbal drugs wrt IP, API, IHP. 13. Determination of the alcohol content of Asava and Arista. 14. Standardization of any two Ayurvedic formulations using UV-spectroscopy. 15. Preparation of Ayurvedic churna. 16. Experiential learning-based experiments focused on the preparation and practical applications of folkloric or region-specific traditional formulations within the community. 17. Case studies analyzing community awareness and usage patterns of various traditional formulations.
Recommended References *(Preferably latest editions):* 1. Mukherjee, P. K. *Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals.* Business Horizons. 2. Sinha, D., Mukherjee, S. and Chowdhury, S. *Methods of Extraction of Phytochemicals.* IGI Global. 3. Zhang, J., Wen, C., Zhang, H., Duan, Y. and Ma, H. *Extraction of Bioactive Compounds with Subcritical Water.* Elsevier.

Course Code	Course Title			Course Type
BP509P	**Pharmaceutical Dosage Forms II (Practical)**			Core
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
1	--	--	3	45
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand various solubility enhancement techniques.
2. Provide hands-on experience in manufacturing processes and evaluation of monophasic and biphasic liquid dosage forms.
3. Provide hands-on experience in manufacturing processes and evaluation of semisolid dosage forms.
4. Learn manufacturing processes and evaluation of pressurised dosage forms.
5. Understand the effects of formulation parameters on the performance of biphasic and semisolid dosage forms.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Apply the fundamentals of solubility enhancement during dosage form development.
2	Explain manufacturing processes of monophasic and biphasic liquid dosage forms.
3	Demonstrate manufacturing processes of semisolid dosage forms.
4	Provide insights into evaluation of dosage forms.
5	Compare the effects of formulation parameters on the performance of biphasic and semisolid dosage forms.

Detailed Syllabus:

List of practicals ***(Minimum 12 experiments must be performed)***
1. To enhance the solubility of a BCS Class II drug by solid dispersion technique. 2. To enhance the solubility of a BCS Class II drug by cyclodextrin complexation. 3. Preparation and evaluation of medicated syrups using simple and artificial syrup bases. 4. Preparation and evaluation of different types of pharmaceutical emulsions. 5. Preparation and evaluation of an emulsion with a small-dose oily active (e.g., calciferol). 6. Preparation and evaluation of an oral suspension. 7. To study the effect of different suspending agents/concentrations on sedimentation volume. 8. Preparation and evaluation of a dry powder for reconstitution as a suspension. 9. Preparation and evaluation of pharmaceutical creams. 10. Preparation and evaluation of pharmaceutical gels. 11. To study the effect of different gelling agents/concentrations on viscosity of gels. 12. Preparation and evaluation of medicated suppositories. 13. Preparation and evaluation of medicated pessaries. 14. Preparation and evaluation of in-situ gels. 15. Preparation and evaluation of emulgels.
Recommended References *(Preferably latest editions):* 1. Aulton, M. E. *Aulton's Pharmaceutics: The Science of Dosage Form Design.* Elsevier. 2. Gibson, M. *Pharmaceutical Preformulation and Formulation.* CRC Press. 3. Lachman, L., Lieberman, H. A. and Kanig, J. L. *The Theory and Practice of Industrial Pharmacy.* CBS Publishers & Distributors. 4. Robinson, J. R. and Lee, V. H. L. *Controlled Drug Delivery: Fundamentals and Applications.* CRC Press. 5. Troy, D. B. and Beringer, P. *Remington: The Science and Practice of Pharmacy.* Pharmaceutical Press. 6. *Indian Pharmacopoeia.* Indian Pharmacopoeia Commission.

Course Code	Course Title			Course Type
BP510P	**SYSTEMIC PHARMACOLOGY II (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 understanding of the theoretical and practical aspects of different pharmacological experiments using virtual simulations and video demonstrations.
2. Develop skills to assess drug effects on various systems such as cardiovascular, respiratory, skeletal muscle, and gastrointestinal using simulation models.
3. preparation, spasmogenic and spasmolytic effects, and PA2 value determination using Schild plot.
4. Provide knowledge of the modern techniques for drug evaluation, such as intraocular pressure measurement, nitric oxide estimation, neutrophil function tests and spirometry.
5. Explore clinical pharmacology aspects through case studies on drug interactions, management of cardiovascular and respiratory diseases, and plasma volume expanders.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the pharmacological principles and mechanisms of drug action involved in analgesic, antiepileptic, antidepressant, antipsychotic, antianxiety, and antiulcer drugs using interactive computer-based experimental models.
2	Apply experimental and simulation-based methods to evaluate drug activity using models such as Eddie's hot plate, MES-induced seizures, tail suspension test, elevated plus maze, actophotometer, Morris water maze, and ulcer models.
3	Analyse and interpret experimental pharmacological data, including bioassay results, dose-response relationships, and estimation of agonist/antagonist concentrations using 3-point/4-point bioassay, matching/bracketing methods, and hypothetical simulation datasets.
4	Demonstrate advanced biomedical and laboratory techniques, including cell culture methods, PCR for mRNA estimation, electrophoresis of DNA/proteins, and antibacterial sensitivity testing, relevant to pharmaceutical and biomedical research.
5	Utilize bioinformatics tools, open-source pharmacological databases, and network pharmacology software to predict drug targets, analyse ADME/toxicity profiles, and construct pharmacological networks.

Detailed Syllabus:

List of practical
(Minimum 12 experiments must be performed)

1. Evaluation of analgesic activity of centrally and peripherally acting analgesics using Eddie's hot plate, tail-flick, tail immersion, and acetic acid-induced writhing methods through interactive computer simulation.
2. Evaluation of antiepileptic activity using maximal electroconvulsive shock (MES)-induced seizures through interactive computer simulation.
3. Demonstration of the antiepileptic activity using pentylenetetrazol-induced seizures through interactive computer simulation.
4. Evaluation of antidepressant activity of drugs using the tail suspension test through interactive computer simulation.
5. Demonstration and study of locomotor activity using actophotometer through interactive computer simulation.
6. Evaluation of antianxiety activity using the elevated plus maze or zero maze model through interactive computer simulation.
7. Evaluation of antipsychotic activity of drugs using inhibition of conditioned response on Cook's pole climbing apparatus through interactive computer simulation.
8. Study of the effect of drugs on learning and memory using the Morris water maze test through interactive computer simulation.
9. Study of antiulcer activity using indomethacin-induced or pylorus ligation-induced ulcer models.
10. Estimation of the concentration of oxytocin on isolated rat uterus preparation using a suitable method through interactive computer-based simulation.
11. Estimation of drug concentration by 3-point or 4-point bioassay through interactive computer simulation.
12. Bioassay of histamine using matching, bracketing, or interpolation methods on suitable isolated tissue preparation with the help of interactive computer simulation.
13. Study of cell culture techniques, including types of cell culture, laboratory instruments/equipment, culture media, and growth of cell cultures in laboratory facilities.
14. Study of antibacterial sensitivity testing of urine culture using techniques such as the disc diffusion method (theoretical details/case studies).
15. Demonstration using databases and software packages for predicting drug activity, ADME properties, and toxicity.
16. Study of electrophoresis of protein and DNA samples and gel visualization techniques.
17. Construction of pharmacological networks using predicted drug targets and disease genes with activity prediction databases, disease gene databases, and suitable software.

Recommended References *(Preferably latest editions):*

1. Ghosh, M. N. *Fundamentals of Experimental Pharmacology.* Hilton & Company.
2. Goyal, R. K. *Practical Pharmacology.* B. S. Shah Prakashan.
3. Kulkarni, S. K. *Handbook of Experimental Pharmacology.* Vallabh Prakashan.

Semester VI

Course Code	Name of the Course	No. of hours per week (L/P)	Continuous Mode (Marks)	Sessional Exam (Marks)	Sessional Duration	Internal Total	End Semester Marks	Exam Duration	Total Marks	Credit Points
BP601T	Advanced Pharmacognosy (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP602T	Biopharmaceutics and Pharmacokinetics (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP603T	Intellectual Property Rights (Theory)	2	10	10	1 Hr	20	30	1.5 Hr	50	2
BP604T	AI Applications in Pharmaceutical Sciences (Theory)	2	10	10	1 Hr	20	30	1.5 Hr	50	2
BP605T	Pharmaceutical Analysis (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP606T	Pharmaceutical Jurisprudence (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP607T	AEC* – Elective 3 (Theory)	1	10	10	1 Hr	20	30	1.5 Hr	50	1
BP608P	Biopharmaceutics and Pharmacokinetics (Practical)	3	10	0	3 Hr	20	30	3 Hr	50	1
BP609P	Pharmaceutical Analysis (Practical)	4	10	10	4 Hr	20	30	4 Hr	50	2
BP610P	SEC* – Elective 4 (Practical)	2	10	10	3 Hr	20	30	3 Hr	50	1
BP611P	VAC* – Elective 5 (Practical)	2	10	10	3 Hr	20	30	3 Hr	50	1
BP612I	Internship (Mandatory)	8	Refer Section 22 of the ordinance	–	–	–	100	4 Hr	100	4
Total		**28**	**130**	**130**	**20 Hr**	**260**	**490**	**29.5 Hr**	**750**	**26**

* Only 1 course shall be selected from each elective

Course Code	Course Title		Course Type	
BP601T	**Advanced Pharmacognosy (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 reverse pharmacology and integrative approaches in natural drug discovery.
2. Apply metabolomics and systems biology tools for quality control and bioactivity evaluation of herbal medicines.
3. Explore modern AI-driven, in-silico, and high-throughput techniques for identification and optimization of natural product leads.
4. Study validation, safety, and development pathways of herbal leads including preclinical and clinical evaluation.
5. Understand legal, ethical, and patenting frameworks related to bioprospecting, traditional knowledge protection, and natural product innovation.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain reverse pharmacology, traditional knowledge databases, and bioprospecting strategies.
2	To analyze herbal drugs using metabolomics, spectral libraries, and chemoinformatics tools.
3	Employ modern in-silico and AI techniques in lead identification and optimization from natural products.
4	Evaluate preclinical safety, pharmacokinetics, and efficacy of bioactive leads.
5	Interpret global IP frameworks and develop strategies for patenting herbal products and protecting traditional knowledge.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Reverse Pharmacology and Integrative Approaches** Reverse pharmacology and integrative approaches from the AYUSH perspective. Ethnopharmacological approach to bioprospecting. Traditional medicine databases: AYUSH Research Portal, ICMR Standards on Indian Medicinal Plants, TKDL, NAPRALERT, Super Natural, etc. Molecular docking and ADMET screening of bioactives. Concept of adjuvant therapy with herbals in metabolic and non-communicable diseases.	6 hours
II	**Metabolomics and Systems Biology** Introduction to metabolomics and its tools: applications of NMR and HRMS in metabolomics, Metabolomics profiling and dereplication studies, Role of metabolomics in quality control, scientific, validation of traditional claims and pharmacological evaluation, Network pharmacology and systems biology approaches to herbal medicine, Significance of spectral libraries and chemoinformatics databases in drug discovery	11 hours
III	**Modern Techniques in Natural Product Discovery** Role of artificial intelligence (AI), Machine learning and big data in Drug discovery from natural Products. Molecular docking, Virtual Screening and Pharmacophore modelling, Use of Genomic and transcriptomic tools in medicinal plant research, High-throughput screening (HTS) and bioautography.	10 hours
IV	**Validation and Development of Herbal Leads** Bioactivity Guided Fractionation, characterization /Structure Elucidation, Optimization of lead compounds for better efficacy, safety, and stability through SAR and QSAR modelling for semi-synthetic compounds of Salicin, Artemisinin, Piperine, Papaverine and Andrographolides. Preclinical, Clinical Evaluation and New Drug approvals: Testing for toxicity as per OECD guidelines, pharmacokinetics, and bioavailability of herbal products, extracts and lead compounds, assessment of safety and efficacy, clinical trials with or without placebo for clinical endpoints based on assessment of quality of life reporting adverse events if any, filing IND application, NDA submission, Regulatory review and post marketing surveillance.	12 hours
V	**Patenting of Natural Products** Key Terminologies and Concepts: Definitions and distinctions: Patent, Intellectual Property Rights (IPR) Farmers' Rights and Breeders' Rights, Bioprospecting and Biopiracy Patenting Aspects of Natural Products and Traditional Knowledge: Legal frameworks and challenges in patenting natural substances, Traditional Knowledge Digital Library (TKDL) and its role in protecting indigenous knowledge. Role of National Biodiversity Authority in patenting natural products and NAGOYA protocol. Case Studies: Turmeric – U.S. patent on wound healing and its revocation, Neem Biopiracy issue and patent cancellation.	6 hours

Recommended References (Preferably latest editions)

1. Bhat, S. V., Nagasampagi, B. A. and Sivakumar, M. *Chemistry of Natural Products.* Springer.
2. Gräbley, S. and Thiericke, R. *Drug Discovery from Nature.* Springer.
3. Hanessian, S. *Natural Products in Medicinal Chemistry.* Wiley-VCH.
4. Ikan, R. *Natural Products: A Laboratory Guide.* Academic Press.
5. Kemp, W. *Spectroscopic Methods in Organic Chemistry.* Macmillan.
6. Narayanan, P. *Intellectual Property Law.* Eastern Law House.
7. Sarker, S. D., Latif, Z. and Gray, A. I. *Natural Products: Isolation, Structure Elucidation and History.* Elsevier.

Course Code	Course Title		Course Type	
BP602T	**Biopharmaceutics and Pharmacokinetics (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. Describe fundamental biopharmaceutics and pharmacokinetic principles governing drug absorption, distribution, metabolism, and excretion.
2. Analyze the physicochemical and biological factors that determine drug bioavailability, protein binding, and elimination pathways.
3. Illustrate compartmental pharmacokinetic models, and their evaluations through application of mathematical equations to calculate key parameters.
4. Design, conduct, and interpret bioavailability, bioequivalence, and in vitro in vivo correlation studies.
5. Apply pharmacokinetic principles to optimize dosing regimens including loading and maintenance doses and steady-state kinetics and utilize software tools to analyze both linear and non-linear drug kinetics.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Interpret fundamental pharmacokinetic and pharmacodynamic principles and apply them to patient-centered clinical scenarios.
2	Evaluate the impact of physicochemical and biological variables on drug absorption, distribution, and protein binding in clinical practice.
3	Differentiate among bioavailability classifications and develop bioequivalence study protocols that comply with international regulatory standards.
4	Solve pharmacokinetic problems using compartment models by employing numerical techniques
5	Design optimal dosing regimens, interpret non-linear pharmacokinetic behaviors, and utilize simulation software for PK/PD analysis.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Introduction to Biopharmaceutics and pharmacokinetics:** Introduction to various Pharmacokinetic parameters (using Plasma drug Concentration vs Time curve) and Pharmacodynamic parameters and drug delivery index. **Absorption**; Mechanisms of drug absorption through GIT, Physicochemical, Biological and Dosage form related factors influencing drug absorption though GIT, methods of Assessment of GIT absorption, **Distribution** Tissue permeability of drugs, binding of drugs, apparent volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs.	10 hours
II	**Elimination (Metabolism and Elimination):** Drug metabolism and basic understanding of metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, non renal routes of drug excretion of drugs **Bioavailability and Bioequivalence:** Definition and Objectives of bioavailability, absolute and relative bioavailability, Introduction to BCS and biopharmaceutical drug disposition classification system, methods of measurement of bioavailability (Plasma data, Urinary excretion data), Protocol for assessment of bioavailability and bioequivalence studies. *in-vitro* drug dissolution methods (test apparatus I-VII), biorelevant dissolution mediums, *in-vitro in-vivo* correlations: Concept and Applications, Biowaivers, Methods of enhancement of bioavailability.	10 hours
III	**Pharmacokinetic Models: Compartment Models:** Definition, Basis of classification, Properties of compartment, Advantages and disadvantages of compartment modelling. Kinetic considerations of One compartment open model. (a). Intravenous Injection (Bolus/rapid) (b). Intravenous infusion and (c) Extra-vascular administration. (with emphasis on Curve Fitting, Wagner Nelson, Loo Riegelman) **Introduction to non - compartment model: Principles, estimation of PK parameters (AUC, AUMC, MRT, MAT statistical moment theory).**	10 hours
IV	**Multicompartment models:** Multiple dosage regimen: dosing interval, drug accumulation, loading dose, maintenance dose, PK Parameters Kinetic consideration of two compartment open model (a) Intravenous Injection (Bolus/rapid) and (b) Extra vascular administrations (oral administration). Kinetics of multiple dosing, steady state drug levels, calculation of loading and maintenance doses and their clinical significance. Multiple dosage regimen. Introduction to pharmacokinetic consideration of Modified release drug products.	9 hours
V	**Nonlinear Pharmacokinetics:** Introduction, Reasons for Non-linearity, Michaelis-menton method of estimating parameters, Explanation with example of drugs. **Application of PK software:** Introduction of various in -silico methods for calculating various PK parameters.	6 hours

Recommended References (Preferably latest editions)

1. Shargel, L. and Yu, A. B. C. *Applied Biopharmaceutics and Pharmacokinetics.* McGraw-Hill Education.
2. Gibaldi, M. *Biopharmaceutics and Clinical Pharmacokinetics.* Lea & Febiger.
3. Rowland, M. and Tozer, T. N. *Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications.* Wolters Kluwer.
4. Bonate, P. L. *Pharmacokinetic-Pharmacodynamic Modeling and Simulation.* Springer.
5. Brahmankar, D. M. and Jaiswal, S. B. *Biopharmaceutics and Pharmacokinetics: A Treatise.* Vallabh Prakashan.
6. Eddy, D. M. *Modeling and Simulation in the Medical and Health Sciences.* Springer.

Course Code	Course Title		Course Type	
BP603T	**Intellectual Property Rights (Theory)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
2	2	--	--	30
Maximum Marks	SE		ESE	
50	20		30	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Introduce the fundamental concepts and types of intellectual property (IP) and highlight their importance in the pharmaceutical and healthcare sectors.
2. Understand the procedures and legal frameworks related to patent filing, granting, and protection of intellectual property.
3. Develop awareness of international and national IP laws and treaties, including the TRIPS agreement and Indian Patent Act, and their implications for the pharmaceutical industry.
4. Provide insights into the management and commercialization of IP, including licensing, technology transfer, and joint ventures.
5. Familiarize with common IP infringement issues and remedies, using real-world case studies from the pharmaceutical industry to illustrate key principles.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Understand the basic concepts and significance of intellectual property rights with respect to pharmaceutical industries.
2	Learn the types of intellectual property rights such as patents, copyrights, trademarks, trade secrets.
3	Understand the procedure for patent filing in India and abroad.
4	Understand the key provisions of the Indian Patent Act.
5	Evaluate and understand the strategies for IP management and product commercialization.

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Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	Introduction to Intellectual Property Definition and scope of Intellectual Property (IP), Importance and types of IP: Patents, Trademarks, Copyrights and Trade Secrets, Overview of the origin and progression of intellectual property rights in India and internationally, Role of IP in the pharmaceutical industry	6 hours
II	**Patents – Fundamentals and Process** Definition and objectives of patents, Criteria for patentability such as Novelty/innovations, Non-obviousness, Utility, Types of patents and non-patentable inventions in India, Procedure for filing a patent in India, Rights of a patent holder and term of patent protection	6 hours
III	**Patent Laws and Acts** Overview of Indian Patent Act, 1970 (latest amendments and key provisions under the act), TRIPS Agreement and its implications on the Indian pharmaceutical sector, Compulsory licensing, patent opposition, and revocation, Indian pharmaceutical patents: Case studies.	6 hours
IV	**Other Forms of Intellectual Property** Trademarks, Copyrights, Industrial designs: Definition, importance, registration process**,** Basics and protection in scientific work**,** Importance and legal framework**,** Trade secrets and geographical indications in pharma industry	6 hours
V	**IPR Management and Commercialization** Valuation and strategies for commercialization of intellectual property; processes of technology transfer, licensing agreements, and collaborative ventures; issues related to IP infringement and available legal remedies; management practices of IPR in the pharmaceutical industry supported by relevant case studies.	6 hours

Recommended References (Preferably latest editions):

1. World Intellectual Property Organization. *Introduction to Intellectual Property.* WIPO.
2. Indian IPR. https://ipindia.gov.in/
3. Ahuja, V. K. *Law Relating to Intellectual Property Rights.* LexisNexis.
4. Bouchoux, D. *Intellectual Property.* Cengage Learning.
5. Ganguli, P. *Intellectual Property Rights: Unleashing the Knowledge Economy.* Tata McGraw-Hill.
6. Narayanan, P. *Intellectual Property Law.* Eastern Law House.
7. Ramakrishna, T. *Basic Principles and Acquisition of Intellectual Property Rights.* CIPRA.
8. Sreenivasulu, N. S. *Law Relating to Intellectual Property.* Partridge Publishing.
9. Vaidhyanathan, S. *Intellectual Property: A Very Short Introduction.* Oxford University Press.
10. Wadehra, B. L. *Law Relating to Intellectual Property.* Universal Law Publishing.

Course Code	Course Title		Course Type	
BP604T	AI applications in Pharmaceutical Sciences (Theory)		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
2	2	--	--	30
Maximum Marks	SE		ESE	
50	20		30	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Introduce applications of artificial intelligence and machine learning across major pharmaceutical disciplines.
2. Understand the structured data in natural products, medicinal chemistry, formulation science, and manufacturing
3. Interpret regression and classification models in drug discovery, product performance, and quality monitoring.
4. Build awareness of predictive modeling for pharmaceutical decision-making.
5. Understand multivariate analysis in pharmaceutical analytical techniques.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain how pharmaceutical data from various domains can be structured for machine learning applications.
2	Interpret regression and classification models used in natural products and medicinal chemistry.
3	Analyze predictive modeling approaches in formulation, release, and stability studies.
4	Evaluate AI applications in manufacturing process monitoring and quality prediction.
5	Assess analytical modeling and chemometric applications in pharmaceutical quality control.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**AI in Natural Products & Pharmacognostic Data Modeling** Overview of ML applications in natural products: • Representation of crude drug data (morphological, microscopic, phytochemical, chromatographic features) • Structuring herbal datasets for predictive modeling	6 Hours

	• Classification models for authentication of crude drugs (authentic vs adulterated) • Regression models for prediction of secondary metabolite yield • Application of AI in phytochemical screening and prioritization • Herb-drug interaction prediction using database-driven approaches • Limitations of predictive modeling in natural products.	
II	**AI in Medicinal & Pharmaceutical Chemistry** Overview of the role of AI applications in pharmaceutical chemistry with focus on drug discovery concepts: • Conversion of molecular structures into numerical descriptors (MW, logP, HBD/HBA, TPSA) • Structured chemical datasets and QSAR modeling • Regression and classification models for predicting biological activity (IC_{50}, solubility, ADMET properties), toxicities. • Virtual screening and lead optimization concepts • Limitations of ML models and importance of chemical reasoning	6 Hours
III	**AI in Drug Product Design & Performance Prediction** Overview of AI models across formulation development stages, with emphasis on the applications and limitations: • Overview of dosage form development and formulation variables • Machine learning in formulation optimization and excipient selection • Regression modeling for solubility and bioavailability enhancement • Time-concentration modeling for drug release interpretation • Stability study design and modeling degradation trends • Shelf-life estimation using regression-based approaches • Practical limitations of extrapolation in formulation science	(6 Hours)
IV	**AI in Process Monitoring & Production Systems** Overview of introduces multivariate analysis in pharmaceutical analytical techniques with focus on the different models and their applications: • Digital data acquisition in pharmaceutical production • Critical Quality Attributes (CQAs) and Critical Process Parameters (CPPs)	6 hours

	• Correlation analysis for identifying process variability • Logistic regression models for batch pass/fail prediction • Feature importance in process monitoring, predictive maintenance concepts. Ethical and regulatory considerations in automated decision-making, and limitations of predictive models in manufacturing environments.	
V	**AI in Pharmaceutical Analysis & Chemometrics** Overview of multivariate analysis in pharmaceutical analytical techniques with focus on the different models and their applications: • Introduction to chemometrics and multivariate analytical data • Spectroscopic data modeling (UV/IR interpretation) • Regression analysis in quantitative pharmaceutical analysis • Chromatographic peak modeling and interpretation • Classification models for genuine vs counterfeit detection • Handling noise and variability in analytical datasets • Limitations of AI models in analytical decision-making •	6 Hours

Recommended References *(Preferably latest editions)*:

1. Bakeev, K. A. Process Analytical Technology: Spectroscopic Tools and Implementation Strategies for the Chemical and Pharmaceutical Industries. Wiley.
2. Brown, N. Artificial Intelligence in Drug Discovery. Royal Society of Chemistry.
3. Chavda, V., et al. Bioinformatics Tools for Pharmaceutical Drug Product Development.
4. Gibson, M. Pharmaceutical Preformulation and Formulation. CRC Press.
5. Hanessian, S. Natural Products in Medicinal Chemistry. Wiley.
6. Pais, A., et al. Artificial Intelligence for Drug Product Lifecycle Applications.
7. Schlindwein, W. S. and Gibson, M. Pharmaceutical Quality by Design: A Practical Approach. Wiley.
8. World Health Organization. Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials. WHO Press

Course Code	Course Title		Course Type	
BP605T	**Pharmaceutical Analysis (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 interaction of matter with electromagnetic radiation and its application in spectroscopic methods for pharmaceutical drug analysis.
2. Study the principles, instrumentation, and pharmaceutical applications of electroanalytical techniques such as potentiometry, conductometry, polarography, and amperometry.
3. Understand and apply various chromatographic and electrophoretic separation techniques used for qualitative and quantitative analysis of drugs.
4. Impart knowledge of instrumental methods used for accurate qualitative and quantitative analysis of pharmaceutical substances.
5. Develop the ability to select, optimize, and validate suitable analytical techniques, interpret analytical data.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the theoretical basis of electrochemical methods (potentiometry, conductometry, polarography, amperometry) and spectroscopic techniques (UV-Visible, IR, fluorometry, atomic absorption).
2	Explain the instruments involved in electroanalytical and spectroscopic methods.
3	Describe the principles, instrumentation, and applications of various chromatographic and electrophoretic techniques.
4	Select suitable analytical techniques for specific pharmaceutical analysis requirements.
5	Analyze, interpret, and report analytical data accurately and draw meaningful conclusions.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Electrochemical Methods of analysis** 1. **Potentiometry:** Electrode potential, electrochemical cell, construction and working of reference and indicator electrodes including membrane electrodes, measurement of potential and	10 hours

	pH, potentiometric titrations, methods of detecting end point and Karl Fischer titration. 2. **Conductometry**: Introduction, conductivity cell, conductometric titrations and applications. 3. **Polarography:** Introduction, residual current, migration current, diffusion current and limiting current, DME, polarographic wave, Ilkovic's equation (Statement Only), and applications.	
II	**Spectroscopy** 1. **Fundamentals of Spectroscopy:** Properties of electromagnetic radiation, electromagnetic spectrum. 2. **UV Visible spectroscopy:** Beer and Lambert's law, Derivation and deviations. Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors (Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode). Applications - single and multi-component analysis of pharmaceuticals. 3. **IR spectroscopy:** Introduction, fundamental modes of vibrations in poly atomic molecules, factors affecting vibrations, Instrumentation of dispersive Infrared spectrophotometer (including sample handling Techniques) and FTIR. Pharmaceutical applications.	10 hours
III	**Fluorometric Analysis** 1. Theory, luminescence, factors affecting fluorescence, quenching, Instrumentation and pharmaceutical applications. 2. **Flame Photometry and Atomic Absorption Spectrometry:** Theory, nebulisation, flame and flame temperature, interferences, instrumentation and pharmaceutical applications. 3. **Nepheloturbidometry**: Principle, instrumentation and applications.	7 hours
IV	**Introduction to Chromatographic Techniques** 1. Principle, various stationary and mobile phases, diverse development and detection techniques and applications of column, paper and thin layer chromatography. 2. **Ion-exchange chromatography**: Introduction, principles, types of ions exchange resins, factors affecting ion exchange, methodology and applications. 3. **Gel filtration and affinity chromatography**: Principles and applications. 4. **Electrophoresis**: Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications.	8 hours
V	1. **Gas chromatography:** Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications 2. **High performance liquid chromatography:** Introduction, theory, instrumentation, advantages and applications. 3. **HPTLC:** Principle, instrumentation and applications.	10 hours

Recommended References *(Preferably latest editions)*:

1. Braun, R. D. *Analytical Chemistry: A Modern Approach to Analytical Science.* McGraw-Hill.
2. Dyer, J. R. *Applications of Absorption Spectroscopy of Organic Molecules.* Prentice Hall.
3. Harvey, D. *Modern Analytical Chemistry.* McGraw-Hill.
4. Sharma, Y. R. *Organic Spectroscopy.* S. Chand.
5. Skoog, D. A., Holler, F. J. and Crouch, S. R. *Principles of Instrumental Analysis.* Cengage Learning.
6. Watson, D. G. *Pharmaceutical Analysis.* Elsevier.

Course Code	Course Title		Course Type	
BP606T	**Pharmaceutical Jurisprudence (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 fundamental principles and scope of pharmaceutical legislations governing drug development, manufacture, distribution, and marketing.
2. Gain comprehensive knowledge of Indian pharmaceutical Acts and Rules, including Drugs and Cosmetics Act, Pharmacy Act, NDPS Act, and related regulations.
3. Learn the roles, responsibilities, and functions of regulatory authorities involved in regulation and control of pharmaceuticals in India.
4. Learn the code of pharmaceutical ethics and legal responsibilities in professional pharmacy practice.
5. Develop the ability to analyse regulatory frameworks, pricing controls, and emerging regulations, and assess their impact on public health, industry compliance, and patient safety.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Demonstrate understanding of major pharmaceutical legislations and explain their relevance in pharmaceutical product development and marketing.
2	Interpret and apply the provisions of various Indian pharmaceutical Acts and laws in real-world scenarios.
3	Identify regulatory bodies such as CDSCO, IPC, and state regulatory authorities, and explain their roles in drug approval, manufacturing, and distribution.
4	Exhibit ethical awareness by applying the code of ethics in professional pharmaceutical practices.
5	Critically analyze regulatory frameworks and assess their impact on public health, industry operations, and compliance requirements.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Drugs and Cosmetics Act, 1940 and its rules 1945:** Objectives, Definitions, Legal definitions of schedules to the Act and Rules, CDSCO guidelines for Import & export of Pharmaceuticals Manufacture of drugs Prohibition of manufacture and sale of certain drugs, Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.	10 hours
II	**Drugs and Cosmetics Act, 1940 and its rules 1945.** • Detailed study of Schedule G, H, H1, M, N, P, T, U, V, X, Y, Sch F, Part XII B. • Sale of Drugs –Wholesale, Retail sale and Restricted license. Offences and penalties • Labeling & packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties. • Administration of the Act and Rules –Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors	10 hours
III	• **Pharmacy Act -1948:** Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations including ER20, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and Penalties • **Medicinal and Toilet Preparation Act -1955**: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Offences and Penalties. • **Narcotic Drugs and Psychotropic substances Act-1985 and Rules**: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic &Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties	8 hours
IV	• **Study of Salient Features of Drugs and Magic Remedies Act and its rules:** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties • **Prevention of Cruelty to animals Act-1960**: Objectives, Definitions, Institutional Animal Ethics Committee, *CCSEA* guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties	8 hours

	• **National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO)- 2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM).	
V	• **Pharmaceutical Legislations** –A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee • **Code of Pharmaceutical ethics:** Definition, Pharmacist in relation to his job, trade, medical profession and his profession, • Medical Termination of Pregnancy Act • Brief Introduction to Right to Information Act • Introduction New Drugs and Clinical Trials Rules, 2019 and amendments. • Cosmetic rules 2020 • Regulatory guidelines on similar biologics. • Overview of Medical Device Regulations, Guidelines on Probiotics, Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016	9 hours

Recommended References (Preferably latest editions)

1. Government of India. Drugs and Cosmetics Act and Rules. Government of India.
2. Government of India. Drugs and Magic Remedies (Objectionable Advertisements) Act. Government of India.
3. Government of India. Medicinal and Toilet Preparations (Excise Duties) Act. Government of India.
4. Government of India. Narcotic Drugs and Psychotropic Substances Act. Government of India.
5. Government of India. New Drugs and Clinical Trials Rules, 2019. Government of India.
6. Central Drugs Standard Control Organization and Department of Biotechnology. *Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India*. Government of India.

<table>
<tr><th>Course Code*</th><th colspan="4">Course Title*</th><th>Course Type</th></tr>
<tr><td>BP607T AEC1</td><td colspan="4">Green Chemistry</td><td rowspan="6">Elective</td></tr>
<tr><td>BP607T AEC2</td><td colspan="4">Materiovigilance and Hemovigilance</td></tr>
<tr><td>BP607T AEC3</td><td colspan="4">Scientific Writing</td></tr>
<tr><td>BP607T AEC4</td><td colspan="4">Drug Store and Business Management</td></tr>
<tr><td>BP607T AEC5</td><td colspan="4">Career Building in Cultivation of Medicinal Plants</td></tr>
<tr><td>BP607T AEC6</td><td colspan="4">Active Pharmaceutical Ingredients and Excipient Sciences</td></tr>
<tr><td rowspan="2">Credit</td><td colspan="3">Hours Per Week (L-T-P)</td><td rowspan="2">Max. Hours.</td></tr>
<tr><td>L</td><td colspan="2">T</td><td>P</td></tr>
<tr><td>1</td><td>1</td><td colspan="2">--</td><td>--</td><td>15</td></tr>
<tr><td>Maximum Marks</td><td colspan="3">SE</td><td colspan="2">ESE</td></tr>
<tr><td>50</td><td colspan="3">20</td><td colspan="2">30</td></tr>
</table>

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

Course Code	Course Title		Course Type	
BP608P	**Biopharmaceutics and Pharmacokinetics (Practical)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
1	--	--	3	45
Maximum Marks	SE		ESE	
50	20		30	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand the dissolution profiles of pharmaceutical formulations using various media and conditions.
2. Apply *in vitro* and *ex vivo* techniques to assess drug absorption, dissolution, and bioavailability.
3. Interpret pharmacokinetic parameters using plasma and urinary excretion data.
4. Establish *in vitro in vivo correlation* (IVIVC) for drug products based on experimental datasets.
5. Utilize software tools to simulate and analyze pharmacokinetic and pharmacodynamic data.

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 such as orodispersible tablets, bilayer tablets, osmotic systems, microspheres, microcapsules, buccal/sublingual dosage forms, transdermal patches, gastroretentive systems, and lipid-based carriers.
3	Select appropriate excipients and techniques for the development of NDDS considering drug properties, patient needs, and target site requirements.
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
1. To calculate MRT from the given data. 2. To assess the effect of protein binding of a drug 3. To report relative bioavailability of given drug product using urinary excretion data 4. To report relative bioavailability of given drug product using plasma data 5. Establish IVIVC from the given *in vitro* and *in vivo* data. 6. To calculate pharmacokinetic parameters of a drug using given plasma level data. 7. To report bioequivalence of drug products using given urinary excretion data administered 8. To calculate absorption rate constant, elimination rate constant and elimination half-life of given excretion data by sigma minus method. 9. To calculate absorption rate constant, elimination rate constant and elimination half-life of the given drug data administered by IV bolus injection represented by one compartment model. 10. To calculate the absorption rate constant by using curve fitting method. 11. To calculate various pharmacokinetic parameters using *in silico* methods.
Recommended References (Preferably latest editions): 1. Bonate, P. L. *Pharmacokinetic-Pharmacodynamic Modeling and Simulation.* Springer. 2. Brahmankar, D. M. and Jaiswal, S. B. *Biopharmaceutics and Pharmacokinetics: A Treatise.* Vallabh Prakashan. 3. Eddy, D. M. *Modeling and Simulation in the Medical and Health Sciences.* Springer. 4. Gibaldi, M. *Biopharmaceutics and Clinical Pharmacokinetics.* Lea & Febiger. 5. Rowland, M. and Tozer, T. N. *Clinical Pharmacokinetics and Pharmacodynamics.* Wolters Kluwer. 6. Shargel, L. and Yu, A. B. C. *Applied Biopharmaceutics and Pharmacokinetics.* McGraw-Hill Education.

Course Code	Course Title		Course Type	
BP609P	**Pharmaceutical Analysis (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. Understand the fundamental principles behind various analytical techniques including titrations, spectrophotometry, fluorimetry, flame photometry, and chromatography.
2. Develop proficiency in performing quantitative and qualitative analyses of pharmaceutical compounds using classical and instrumental methods.
3. Learn to operate and maintain laboratory instruments such as potentiometers, conductometers, spectrophotometers, fluorimeters, flame photometers, and chromatographic systems.
4. Apply appropriate analytical techniques for specific analytical challenges and interpretation, including single and multi-component assays, identification of functional groups, and separation of mixtures.
5. Learn good laboratory practices and safety protocols in handling chemicals and operating instruments.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Perform accurate titrations (potentiometric and conductometric) to determine the endpoint of acid-base reactions.
2	Determine absorption maxima, perform assays, and analyze multi-component formulations using spectrophotometric and colorimetric techniques.
3	Identify functional groups in compounds using FTIR spectroscopy and conduct quantitative analysis using fluorimetry and flame photometry.
4	Separate and analyze mixtures of compounds using paper chromatography, thin-layer chromatography (TLC), gas-liquid chromatography (GLC), high-performance liquid chromatography (HPLC), and high-performance thin-layer chromatography (HPTLC).
5	Interpret spectral and chromatographic data to identify compounds and quantify analytes.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	Cosmetics and cosmeceuticals, Classification of Cosmetics (Cosmetics and Cosmeceuticals for Skin Care, Hair Care, Oral Care, foot care, body cavities, Decorative Cosmetics, Cleansing cosmetics, Perfumes and Fragrances.) Types of various dosage forms for Cosmetics, Common excipients for cosmetic.	6 hours
II	Common skin problems (Dry Skin, Oily skin, Pimples and acne, Pigmentation, Prickly heat and Sun burn) and general composition, method for preparation, packing and evaluation of the skin Cosmetics and cosmeceuticals. Herbal cosmetics for skin. Types of soaps, syndet bars, general composition, method for preparation, packing and evaluation of soaps. Introduction to Perfumes and toiletries.	6 hours
III	Common Hair problems, Hair Cosmetics and cosmeceuticals: Types of shampoos, general composition, method for preparation, packing and evaluation of shampoos. Introduction to hair oils, hair serums, conditioners, hair colors, Depilatory and shaving products. Herbal hair care products.	6 hours
IV	Various problems of oral cavity, Oral Cosmetics, and cosmeceuticals: general composition, method for preparation, packing and evaluation of mouth wash and toothpaste. Herbal oral care cosmetics. Types of Cosmetics for nails, eyes, body odor, lip care and cleansing. Intimate hygiene products for males and females.	6 hours
V	Role of Regulatory authorities for Cosmetics and cosmeceuticals (CDSCO and FDA). Cosmetics regulations 2020 and role of BIS. Role of certifying bodies like ECCERT and COSMOS in herbal cosmetics. Labeling requirement of cosmetics and Packaging of cosmetics. Testing as per BIS specification and analytical methods (including sensory test, sensitivity test).	6 hours

Recommended References (Preferably latest editions)

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

Course Code*	Course Title*		Course Type	
BP610P SEC1	Computer-Aided Drug Design		**Elective**	
BP610P SEC2	Analytical Method Development and Validation			
BP610P SEC3	Principles of Preclinical Studies			
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 in each elective

Course Code*	Course Title*		Course Type	
BP611P VAC1	Professional Skills		**Elective**	
BP611P VAC2	Process Analytical Technology (PAT) and QbD in Formulation Science			
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

Course Code	Course Title		Course Type
BP612I	**Internship**		**CORE**
Credit	Hours Per Week (L-T-P)*		
	L	T	P
4	--	--	--
Maximum Marks	SE		ESE
100	00		100

* Refer section 22 of Regulation

Semester VII

Course Code	Name of the Course	No. of hours per week (L/P)	Continuous Mode (Marks)	Sessional Exam (Marks)	Sessional Duration	Internal Total	End Semester Marks	Exam Duration	Total Marks	Credit Points
BP701T	Biostatistics and Research Methodology (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP702T	Cosmetics and Cosmeceuticals (Theory)	2	10	10	1 Hr	20	30	1.5 Hr	50	2
BP703T	AI in Clinical Applications (Theory)	2	10	10	1 Hr	20	30	1.5 Hr	50	2
BP704T	Modern Analytical Techniques (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP705T	Pharmacovigilance (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP706T	Pharmacy Practice (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP707T	Regulatory Affairs (Theory)	2	10	10	1 Hr	20	30	1.5 Hr	50	2
BP708T	AEC* – Elective 6 (Theory)	1	10	10	1 Hr	20	30	1.5 Hr	50	1
BP709P	Modern Analytical Techniques (Practical)	3	10	10	3 Hr	20	30	3 Hr	50	1
BP710RP	Research Project	–	Refer Section 21 of the Ordinance	–	–	–	150	4 Hr	150	6
Total		**22**	**110**	**110**	**11 Hr**	**220**	**480**	**21 Hr**	**700**	**26**

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

Course Code	Course Title		Course Type	
BP701T	**Biostatistics and Research Methodology (Theory)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
3	3	--	--	45
Maximum Marks	SE		ESE	
75	30		45	

COURSE OBJECTIVES

The objectives of this course are to:

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

Course Outcomes (CO):

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

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Basic concepts of biostatistics** 1. Definition, meaning and type of variables Data – Meaning and methods of data collection, data preprocessing and cleaning Population and sample, Importance of sampling, Sampling methods Probability and non-probability sampling o Probability sampling - Random, systematic, stratified, cluster sampling o Non-probability sampling - Convenience sampling, purposive sampling, snowball sampling Types of statistics - Descriptive statistics and inferential statistics Descriptive statistics – Meaning and types of descriptive statistics • Frequency distribution, measures of central tendency • Measures of dispersion – Range, variance and standard deviation. Concept of degrees of freedom, quartiles, skewness and kurtosis Diagrammatic representation of frequency distribution	**9 hours**
II	**Probability and probability distributions** 1. Probability and probability distributions- Classical probability and statistical probability Probability of union, intersection and complement of events, conditional probability, marginal probability 2. Probability distributions- Meaning of a probability distribution Discrete probability distribution- Meaning and examples of discrete probability distribution, meaning of PMF Continuous probability distribution – Meaning and examples of normally distributed data, meaning of PDF • Normal distribution – Meaning and characteristics of a normal distribution, parameters of a normal distribution, equation for PDF of a normal distribution. Pharmaceutical examples of data which can be modelled with Poisson Normal distribution. • Standard normal distribution, Z transformation, reading the table of Z values Problems based on standard normal distribution, binomial and Poisson distributions 3. Sampling distributions – Meaning of sampling distributions • t distribution ~~the~~ t statistic, equation for calculating t statistic, meaning of t distribution, meaning of degrees of freedom and their relevance to t distribution, reading and interpreting table of t values, applications of t distribution • F distribution – the F statistic, equation for calculating F statistic, meaning of F distribution, reading and interpreting table of F values • Chi square distribution ~~the~~ Chi square statistic, meaning of chi square distribution, reading and interpreting the table of chi square values, applications of chi square distribution.	**9 hours**

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

	Decision tree approach for selection of statistical tests on the basis of research question and type of data Descriptive research design – Examples of application Observational research design – Examples of application Experimental research design – Examples of application Scientific report writing, plagiarism, referencing styles, selection of research journals, abstracting services and databases Screening and Optimization – Concept and experimental designs used for screening and optimization including Plackett Burman design, factorial designs, D optimal design, sequential simplex design, central composite design and response surface methodology, blocking and confounding in experimental designs.	

Recommended References (Preferably latest editions)

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

Course Code	Course Title		Course Type	
BP702T	**Cosmetics and Cosmeceuticals (Theory)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
2	2	--	--	30
Maximum Marks	SE		ESE	
50	20		30	

COURSE OBJECTIVES

The objectives of this course are to:

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

Course Outcomes (CO):

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

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	Cosmetics and cosmeceuticals, Classification of Cosmetics (Cosmetics and Cosmeceuticals for Skin Care, Hair Care, Oral Care, foot care, body cavities, Decorative Cosmetics, Cleansing cosmetics, Perfumes and Fragrances.) Types of various dosage forms for Cosmetics, Common excipients for cosmetic.	6 hours
II	Common skin problems (Dry Skin, Oily skin, Pimples and acne, Pigmentation, Prickly heat and Sun burn) and general composition, method for preparation, packing and evaluation of the skin Cosmetics and cosmeceuticals. Herbal cosmetics for skin. Types of soaps, syndet bars, general composition, method for preparation, packing and evaluation of soaps. Introduction to Perfumes and toiletries.	6 hours
III	Common Hair problems, Hair Cosmetics and cosmeceuticals: Types of shampoos, general composition, method for preparation, packing and evaluation of shampoos. Introduction to hair oils, hair serums, conditioners, hair colors, Depilatory and shaving products. Herbal hair care products.	6 hours
IV	Various problems of oral cavity, Oral Cosmetics, and cosmeceuticals: general composition, method for preparation, packing and evaluation of mouth wash and toothpaste. Herbal oral care cosmetics. Types of Cosmetics for nails, eyes, body odor, lip care and cleansing. Intimate hygiene products for males and females.	6 hours
V	Role of Regulatory authorities for Cosmetics and cosmeceuticals (CDSCO and FDA). Cosmetics regulations 2020 and role of BIS. Role of certifying bodies like ECCERT and COSMOS in herbal cosmetics. Labeling requirement of cosmetics and Packaging of cosmetics. Testing as per BIS specification and analytical methods (including sensory test, sensitivity test).	6 hours

Recommended References (Preferably latest editions)

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

Course Code	Course Title			Course Type
BP703T	**AI in Clinical applications (Theory)**			Core
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
2	2	--	--	30
Maximum Marks	SE		ESE	
50	20		30	

COURSE OBJECTIVES:

The objectives of this course are to:

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

COURSE OUTCOMES (CO):

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

Unit No.	Topics	No. of Lectures
I	**AI in Pharmacokinetics & Dose Optimization** • Review of pharmacokinetic parameters (Cmax, Tmax, AUC, clearance) • Modeling concentration-time relationships: Linear regression in PK data modeling, multiple regression for dose adjustment based on patient variables (age, weight, renal function) • Interpretation of regression coefficients in clinical context • Error metrics (RMSE, R^2) in PK modeling • Limitations of linear modeling in nonlinear pharmacokinetics	6 Hours
II	**AI in Drug Safety & Pharmacovigilance** • Overview of pharmacovigilance systems • Structure and data formats from real systems (e.g. FAERS, EudraVigilance) • Conceptual overview of frequency analysis and signal detection • Logistic regression for ADR risk prediction • Confusion matrix and clinical performance metrics • Sensitivity, specificity, precision, recall • Bias and confounding in observational datasets	6 Hours
III	**AI in Personalized Medicine & Risk Stratification** • Concept of precision medicine • Patient covariates and therapeutic response • Logistic regression for disease risk prediction • Classification of responders vs non-responders • Evaluation metrics in healthcare prediction • Ethical implications of predictive modeling	6 Hours
IV	**AI in Clinical Decision Support & Real-World Data** • Structure of Electronic Health Records (EHR) • AI in Clinical Decision Support Systems (CDSS) • Regression models for outcome prediction • Classification models for risk scoring • Real-world data analytics	6 hours

	• Limitations of AI in clinical environments • Accountability and interpretability	
V	**Guided Supervised Learning Project – Pharmaceutical and Clinical Applications** Students will undertake a guided supervised learning project (individually or in groups) applying regression or classification models to pharmaceutical or clinical datasets. The project should include the following steps: • Identification and definition of a relevant pharmaceutical or clinical problem • Selection of an appropriate publicly available dataset • Identification of predictor variables and outcome variables • Data preprocessing and preparation for analysis • Application of suitable supervised learning methods (e.g., linear regression or logistic regression) • Evaluation of model performance using appropriate metrics • Interpretation of results in the context of pharmaceutical or clinical relevance • Discussion of limitations, potential biases, and ethical considerations • Presentation of findings to faculty mentors or peers. Suggested project topics (not limited to): Dissolution rate prediction, tablet hardness prediction, stability degradation modelling, quality control batch failure prediction, assay variability modelling, impurity prediction, moisture impact on formulation stability, coating thickness prediction, solubility enhancement modelling, tablet defect classification, adverse drug reaction (ADR) prediction, therapeutic response prediction using patient datasets, hospital readmission risk prediction, dose requirement prediction using pharmacokinetic data, diabetes risk prediction from health markers, antibiotic treatment success prediction, ICU stay duration prediction, medication adherence analysis, and disease severity classification.	6 Hours

Recommended References (Preferably latest editions)

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

Course Code	Course Title		Course Type	
BP704T	**Modern Analytical Techniques (Theory)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
3	3	--	--	45
Maximum Marks	SE		ESE	
75	30		45	

COURSE OBJECTIVES:

The objectives of this course are to:

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

COURSE OUTCOMES (CO):

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

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	1. **Nuclear Magnetic Resonance Spectroscopy:** Principles of ^{1}H-NMR and ^{13}C-NMR, various solvents used, chemical shift, factors affecting chemical shift, coupling constant, spin–spin coupling, relaxation, instrumentation of FT-NMR and its applications. 2. **Mass Spectrometry:** Principles, fragmentation and its rules, ionization techniques –	10 hour

	Electron impact, chemical ionization, MALDI, FAB, API, analyzers – Time of flight and quadrupole, ion trap, detectors and applications.	
II	1. **X-Ray Diffraction Methods:** Origin of X-Rays, basic aspects of crystals, X-Ray crystallography, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications. 2. **Thermal Analysis:** Introduction, instrumentation, factors affecting measurements, applications of TGA, DSC (types) and DTA.	08 hour
III	1. UPLC and Nano LC: Principle, advantages over LC and applications. 2. Principle and applications of hyphenated techniques: GC-MS, LC-MS/MS, ICP-MS. 3. Supercritical chromatography and flash chromatography: principles and applications.	10 hour
IV	1. **Green Analytical Chemistry:** Types of green solvents, various computational tools used to assess the greenness and its applications in sample preparation and analytical method development. 2. **Bio-analytical Methods:** Introduction to bioanalytical method development, extraction of drugs and metabolites from biological fluids – SPE, LLE, PPE, BCS classification, PK-PD interaction, microsomal assays, MTT assay, BA & BE study protocol, biosimilars. 3. **Radio Immune Assays and ELISA:** Importance, various components, principle, different methods, limitations and applications of radio immunoassay and ELISA.	12 hour
V	1. **Microscopy-Based Analytical Techniques:** Principle, instrumentation, and applications of optical microscopy, scanning electron microscopy and transmission electron microscopy.	5 hour

Recommended References (Preferably latest editions)

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

Course Code	Course Title		Course Type	
BP705T	**Pharmacovigilance (Theory)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
3	3	--	--	45
Maximum Marks	SE		ESE	
75	30		45	

COURSE OBJECTIVES:

The objectives of this course are to:

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

COURSE OUTCOMES (CO):

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

Detailed Syllabus:

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

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

Recommended References (Preferably latest editions)

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

Course Code	Course Title		Course Type	
BP706T	**Pharmacy Practice (Theory)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
3	3	--	--	45
Maximum Marks	SE		ESE	
75	30		45	

COURSE OBJECTIVES:

The objectives of this course are to:

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

COURSE OUTCOMES (CO):

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

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Introduction to Pharmacy Practice** Definition, scope and evolution of: • Hospital and clinical pharmacy • Pharmacist's role from dispenser to healthcare provider • WHO and FIP guidelines on pharmacy practice • Pharmacy practice regulations in India • Role of pharmacy in public health and policymaking • Promoting rational use of medicines • Concepts of Good Pharmacy Practice • Pharmacy practice settings: inpatient, outpatient • Concept of healthcare delivery system and interprofessional collaboration • Primary (PHC), Secondary (CHC), Tertiary (District Hospitals, Medical Colleges) – role of pharmacists at various levels of care.	8 hour
II	**Hospital and Community Pharmacy** **Hospital and its Organization** Classification of hospitals, organizational structure of a hospital, healthcare staff involved in hospital services and their functions **Hospital Pharmacy and its Organization** Definition, organization structure, location, layout, and staff requirements, responsibilities and functions of hospital pharmacists **Pharmacy and Therapeutic Committee** Organization, functions, and policies, drug inclusion into formulary, inpatient and outpatient prescriptions, automatic stop order, emergency drug list preparation **Hospital Formulary** Definition of hospital formulary, contents of hospital formulary, differentiation between hospital formulary and drug list, preparation and revision of hospital formulary **Drug Distribution System in a Hospital** Drug procurement and inventory control, dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labeling, dispensing of drugs to ambulatory patients, dispensing of controlled drugs, outpatient medication dispensing, NABH standards for medication management in hospital settings **Community Pharmacy** Organization and structure of retail and wholesale drug stores, types and design of a drug store, legal requirements for establishment and maintenance of a drug store, dispensing of proprietary products, maintenance of records of retail and wholesale drug stores, prescription handling, labelling, and patient counselling, introduction, definition, sale, and OTC medication list, vaccination services	10 hour

III	**Clinical Pharmacy Services** • Introduction to clinical pharmacy and its concept • Drug therapy monitoring o Medication chart review o Clinical review o Pharmacist intervention o Ward round participation o Medication history o Pharmaceutical care • Drug information services • Drug/Medication related problems • Drug and poison information services • Therapeutic drug monitoring (TDM)	9 hour
IV	**Patient-Oriented Services** **Medication Adherence and Non-Adherence** Definition Factors influencing non-adherence Pharmacist's role in medication adherence Monitoring of patient medication adherence Tools used to assess medication adherence Strategies to overcome non-adherence **Patient Counselling Techniques and Communication Skills** Definition of patient counselling Steps involved in patient counselling Communication skills – communication with prescribers and patients Types of educational materials used in patient counselling Barriers to effective counselling – types and strategies to overcome barriers **Health Screening Services** Definition and importance Methods for screening: Blood pressure, Blood sugar, Body Mass Index, Lung function test Role of pharmacist in health screening services Telemedicine	9 hour
V	**Prescribing Guidelines, Essential Drug Concept and Rational Drug Therapy** **Prescribing Guidelines** Pediatrics, geriatrics, pregnant and lactating women ISMP guidelines for high risk medicines **Essential Drug Concept** WHO definition Core principles and key features Procedure involved in adding a drug into the essential drug list **Rational Use of Medications** • Antibiotics • Antibiotic stewardship program Injections OTC drugs Consequences of irrational drug use. • Dose calculations in chemotherapy, renal and hepatic failure patients.	9 hour

Recommended References (Preferably latest editions)

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

Course Code	Course Title		Course Type	
BP707T	Regulatory Affairs (Theory)		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
2	2	--	--	30
Maximum Marks	SE		ESE	
50	20		30	

COURSE OBJECTIVES:

The objectives of this course are to:

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

COURSE OUTCOMES (CO):

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

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Fundamentals of Regulatory Affairs** Introduction to Drug Regulatory Affairs, Overview of regulatory authorities in India and major international markets (US FDA, EMA, PMDA), Role and responsibilities of Regulatory Affairs Professionals, Organizational structure of regulatory bodies. • Basic regulatory terminologies: Guidance, Guidelines, Regulations, Laws, Acts. • Regulatory reference resources: Orange Book, Purple Book, Federal Register, Code of Federal Regulations (CFR).	6 hour
II	**Regulatory Requirements in Drug Development** • Drug discovery and development process, Drug development teams and their functions. • Non-clinical drug development: Pharmacology, Drug metabolism, Toxicology. • Regulatory documentation: Investigational New Drug (IND) application, Investigator's Brochure (IB), Clinical research protocols, Biostatistics in pharmaceutical product development, Bioequivalence (BE) studies, Data presentation for regulatory submissions.	6 hour
III	**Indian Regulatory Framework and Approval Process** • Central Drugs Standard Control Organization (CDSCO) and State Licensing Authorities: Organization and responsibilities, Regulatory requirements for import, manufacture, and sale of pharmaceuticals in India, Certificate of Pharmaceutical Product (COPP), Regulatory approval procedure for new drugs in India, Clinical trial regulatory requirements in India, phytopharmaceutical regulations, Good Clinical Practice (GCP) guidelines and Schedule Y, Innovator and generic drugs, Generic drug product development • Phytopharmaceutical regulation by AYUSH and CDSCO.	6 hour
IV	**International Regulatory Systems & Global Drug Registration:** • Types of regulatory applications: Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA) • Drug Master Files (DMF), Common Technical Document (CTD), electronic CTD (eCTD), ASEAN CTD (ACTD), • Registration procedure for Indian drug products in overseas markets, Post-approval changes to NDA and ANDA.	6 hour

V	**Clinical Trials, Ethics, and Post-Marketing Surveillance:** • Clinical research phases (I-IV), Clinical trial documents, Institutional Review Board (IRB) and Independent Ethics Committee (IEC): Formation and functions • Informed consent process and documentation, Good Clinical Practice (GCP) obligations of investigators, sponsors, and monitors, Management and monitoring of clinical trials, Pharmacovigilance: Safety monitoring during clinical trials and post- marketing,	6 hour

Recommended References (Preferably latest editions)

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

Course Code*	Course Title*			Course Type	
BP708T AEC1	Current Good Manufacturing Practices (cGMP)			**Elective**	
BP708T AEC2	Pharmaceutical Automation				
BP708T AEC3	Modern Techniques in Cellular Biology				
BP708T AEC4	Medical Devices				
BP708T AEC5	Transformation of Food Waste into Medicinal Products				
BP708T AEC6	Biosimilars, Vaccines & Macromolecules				
BP708T AEC7	Precision Medicine				
Credit	Hours Per Week (L-T-P)				Max. Hours.
	L	T	P		
1	1	--	--		15
Maximum Marks	SE		ESE		
50	20		30		

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

Course Code	Course Title		Course Type	
BP709P	**Modern Analytical Techniques (Practical)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
1	--	--	3	45
Maximum Marks	SE		ESE	
50	20		30	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Provide practical training in interpretation of advanced instrumental data used for structural and physicochemical characterization.
2. Introduce quantitative analytical techniques using modern separation methods, such as UHPLC and HPLC, for the estimation of pharmaceutical substances.
3. Familiarize students with the principles and practice of green analytical chemistry, including preparation of green solvents and development of environmentally sustainable analytical methods.
4. Develop understanding of bioanalytical sample preparation techniques for pharmaceutical analysis in biological matrices, including solid phase extraction, liquid liquid extraction, and protein precipitation.
5. Learn applied pharmaceutical analysis and methods including cell viability assays, residual solvent analysis, and estimation of drugs from biological fluids.

COURSE OUTCOMES (CO):

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

Detailed Syllabus:

List of Practicals **(Minimum 12 experiments must be performed)**

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

Recommended References (Preferably latest editions)

1. Beckett, A. H. and Stenlake, J. B. *Practical Pharmaceutical Chemistry.* CBS Publishers & Distributors.
2. Brittain, H. G. *Analytical Profiles of Drug Substances and Excipients.* Elsevier.
3. Kemp, W. *Organic Spectroscopy.* Palgrave Macmillan.
4. Munson, J. W. *Pharmaceutical Analysis: Modern Methods.* Marcel Dekker.
5. Sethi, P. D. *Quantitative Analysis of Drugs in Pharmaceutical Formulations.* CBS Publishers & Distributors.
6. Sharma, B. K. *Instrumental Methods of Chemical Analysis.* Goel Publishing House.
7. Sharma, Y. R. *Organic Spectroscopy.* S. Chand.
8. Silverstein, R. M., Webster, F. X., Kiemle, D. J. and Bryce, D. L. *Spectrometric Identification of Organic Compounds.* Wiley.
9. Willard, H. H., Merritt, L. L., Dean, J. A. and Settle, F. A. *Instrumental Methods of Analysis.* Brooks/Cole.
10. *Indian Pharmacopoeia.* Indian Pharmacopoeia Commission.

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

* Refer section 21 of regulation.

Semester VIII

Course Code	Name of the Course	No. of hours per week (L/P	Continuous Mode (Marks)	Sessional Exam (Marks)	Sessional Duration	Internal Total	End Semester Marks	Exam Duration	Total Marks	Credit Points
BP801T	Ethical Considerations and Translational Applications of AI in Pharmacy (Theory)	2	10	10	1 Hr	20	30	1.5 Hr	50	2
BP802T	Clinical Pharmacotherapeutics (Theory)	2	10	10	1 Hr	20	30	1.5 Hr	50	2
BP803T	Industrial Pharmacy and Facility Design (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP804T	Pharmaceutical Management (Theory)	2	10	10	1 Hr	20	30	1.5 Hr	50	2
BP805T	Sterile Dosage Forms and Novel Drug Delivery System (Theory)	3	15	15	1 Hr	30	45	2 Hr	75	3
BP806T	AEC* – Elective 7 (Theory)	2	10	10	1 Hr	20	30	1.5 Hr	50	2
BP807P	Pharmaceutical Marketing Skills (Practical)	2	10	10	3 Hr	20	30	3 Hr	50	1
BP808P	Sterile Dosage Forms and Novel Drug Delivery System (Practical)	4	10	10	4 Hr	20	30	4 Hr	50	2
BP809P	VAC* – Elective 8 (Practical)	2	10	10	3 Hr	20	30	3 Hr	50	1
BP810RP	Research Project	–	Refer Section 21 of the Ordinance	–	–	–	150	4 Hr	150	6
Total		**22**	**100**	**100**	**16 Hr**	**200**	**450**	**24 Hr**	**650**	**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

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, isolators, Modular cleanrooms Automation and robotics in pharmaceutical manufacturing operations.	6 hours

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 sterilization; filtration **lyophilization** 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**/endotoxin particulate matter, clarity, extractable volume; labelling & documentation overview of **cGMP/cleanrooms** and environmenta 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.

<table>
<tr><th>Course Code*</th><th colspan="3">Course Title*</th><th colspan="2">Course Type</th></tr>
<tr><td>BP806T AEC1</td><td colspan="3">Pharmaceutical Packaging</td><td colspan="2" rowspan="6">Elective</td></tr>
<tr><td>BP806T AEC2</td><td colspan="3">Supply Chain Management</td></tr>
<tr><td>BP806T AEC3</td><td colspan="3">Industrial Safety and Waste Management</td></tr>
<tr><td>BP806T AEC4</td><td colspan="3">Traditional Healing Practices of India</td></tr>
<tr><td>BP806T AEC5</td><td colspan="3">Futuristic Pharma through AR/VR: Pharma 4.0</td></tr>
<tr><td>BP806T AEC6</td><td colspan="3">Herbal Cosmetics for Industry Perspective</td></tr>
<tr><td rowspan="2">Credit</td><td colspan="3">Hours Per Week (L-T-P)</td><td colspan="2" rowspan="2">Max. Hours.</td></tr>
<tr><td>L</td><td>T</td><td>P</td></tr>
<tr><td>2</td><td>2</td><td>--</td><td>--</td><td colspan="2">30</td></tr>
<tr><td>Maximum Marks</td><td colspan="3">SE</td><td colspan="2">ESE</td></tr>
<tr><td>50</td><td colspan="3">20</td><td colspan="2">30</td></tr>
</table>

* 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. 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

APPENDIX

List of Recommended Electives (AEC/SEC/VAC courses to be prescribed by HEI)

Semester	Elective	Course Code	Course Title	Type	Category
II	Elective 1	BP212P SEC1	Communication Skills	Practical	SEC
		BP212P SEC2	Mental Well-Being, Stress & Conflict Management	Practical	SEC
		BP212P SEC3	Fundamentals of Computer Operations	Practical	SEC
III	Elective 2	BP312P AEC1	Nutraceuticals and Functional Foods	Practical	AEC
		BP312P AEC2	Food Analysis	Practical	AEC
		BP312P AEC3	Yoga and Life Sciences	Practical	AEC
VI	Elective 3	BP607T AEC1	Green Chemistry	Theory	AEC
		BP607T AEC2	Materiovigilance and Hemovigilance	Theory	AEC
		BP607T AEC3	Scientific Writing	Theory	AEC
		BP607T AEC4	Drug Store and Business Management	Theory	AEC
		BP607T AEC5	Career Building in Cultivation of Medicinal Plants	Theory	AEC
		BP607T AEC6	Active Pharmaceutical Ingredients and Excipient Sciences	Theory	AEC
	Elective 4	BP610P SEC1	Computer Aided Drug Design	Practical	SEC
		BP610P SEC2	Analytical Method Development and Validation	Practical	SEC
		BP610P SEC3	Principles of Preclinical Studies	Practical	SEC
	Elective 5	BP611P VAC1	Professional Skills	Practical	VAC
		BP611P VAC2	Process Analytical Technology (PAT) and QbD in Formulation Science	Practical	VAC
		BP708T	Current Good Manufacturing	Theory	AEC

VII	Elective 6	AEC1	Practices (cGMP)		
		BP708T AEC2	Pharmaceutical Automation	Theory	AEC
		BP708T AEC3	Modern Techniques in Cellular Biology	Theory	AEC
		BP708T AEC4	Medical Devices	Theory	AEC
		BP708T AEC5	Transformation of Food Waste into Medicinal Products	Theory	AEC
		BP708T AEC6	Biosimilars, Vaccines & Macromolecules	Theory	AEC
		BP708T AEC7	Precision Medicine	Theory	AEC
VIII	Elective 7	BP806T AEC1	Pharmaceutical Packaging	Theory	AEC
		BP806T AEC2	Supply Chain Management	Theory	AEC
		BP806T AEC3	Industrial Safety and Waste Management	Theory	AEC
		BP806T AEC4	Traditional Healing Practices of India	Theory	AEC
		BP806T AEC5	Futuristic Pharma through AR/VR: Pharma 4.0	Theory	AEC
		BP806T AEC6	Herbal Cosmetics for Industry Perspective	Theory	AEC
	Elective 8	BP809P VAC1	Cleaning Validation	Practical	VAC
		BP809P VAC2	Basic Training in Aseptic Handling Techniques	Practical	VAC
		BP809P VAC3	Impurity Profiling	Practical	VAC

SEC – Skill Enhancement Course
AEC –Ability Enhancement Course
VAC –Value Added Course

SEMESTER II

Course Code	Course Title			Course Type
BP212P SEC1	**Communication Skills (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 to:

1. Enhance verbal and non-verbal communication skills in academic, clinical, and professional pharmacy settings.
2. Develop competence in patient counselling, prescription communication, and interprofessional dialogue.
3. Promote empathetic and ethical communication in diverse cultural and patient contexts.
4. Use digital tools and professional formats (e.g., email, reports, posters) for effective communication.
5. Foster confidence, active listening, and clarity in pharmacy-related presentations and conversations.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Demonstrate effective verbal and non-verbal communication in clinical, retail, and academic pharmacy contexts.
2	Perform patient counselling and handle real-world pharmacy interactions using role-play and case scenarios.
3	Draft professional emails, prepare patient information leaflets, and create drug labels with clarity and accuracy.
4	Deliver confident oral presentations and communicate complex medical information in a simplified, patient-friendly manner.
5	Apply principles of ethical and culturally sensitive communication in handling patients and professional peers.

Detailed Syllabus

List of practical
(Perform any 12 Experiments) 1. Introduction to Communication in Pharmacy • Types of communication: verbal, non-verbal, written

- Importance in clinical, academic, and retail pharmacy

2. Listening and Observation Skills Workshop
   - Active listening techniques, barriers to listening
   - Observation of cues: patient posture, tone, compliance
3. Role-play: Communicating with a Patient for Dispensing a Prescription
   - Explanation of dosage, frequency, side effects, and precautions
4. Role-play: Handling Difficult Conversations (e.g., Angry Patient or Confused Elderly)
   - Empathy, patience, tone modulation, de-escalation techniques
5. Written Communication I: Professional Email Writing & Documentation
   - Writing emails to doctors, suppliers, institutions
   - Structure, etiquette, and clarity in pharmacy communications
6. Written Communication II: Preparing Patient Information Leaflets and Drug Labels
   - Use of simple language, drug facts, precautions, icons
   - Creating flyers for common conditions (e.g., diabetes, asthma)
7. Non-verbal Communication Skills
   - Body language, eye contact, gestures, tone of voice
   - Cross-cultural sensitivity in pharmacy communication
8. Presentation Skills I – Basic Techniques
   - Voice projection, clarity, use of visuals
   - Individual practice with simple pharmacy topics
9. Presentation Skills II – Group Presentations
   - Topics: health awareness campaigns, drug education, OTC safety
   - Peer and faculty feedback
10. Patient Counseling Practice (Case-Based)
    - Counseling for chronic illness (e.g., hypertension, diabetes)
    - Role-playing real-life counseling situations
11. Communicating with Healthcare Professionals
    - Case handoff, drug information request, referral writing
    - Using SBAR (Situation, Background, Assessment, Recommendation) format
12. Mock Interview / Group Discussion Practice
    - Industry/clinical job interview scenarios
    - GD on topics like "Generic vs Branded Medicines"
13. Digital Communication Skills for Pharmacists
    - Creating a simple health blog, social media awareness post
    - Basics of teleconsultation and ePharmacy chat support
14. Ethics and Professionalism in Communication
    - Confidentiality, patient rights, informed consent
    - Role-play ethical dilemmas in pharmacy
15. Assessment & Reflection
    - Final presentation or counseling demo
    - Feedback, self-evaluation, and faculty observation

Recommended References *(Preferably latest edition)*:

1. Communication Skills in Pharmacy Practice E. M. Kelly & S. L. Svarstad, Lippincott Williams & Wilkins
2. Developing Communication Skills for Pharmacy – Catherine Langford, Pharmaceutical Press
3. Patient Counselling Guidelines for Pharmacists – WHO India, World Health Organization

Course Code	Course Title			Course Type
BP212P SEC2	**Mental Well-Being, Stress and Conflict Management (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 to:

1. Introduce students to the concepts of mental well-being and stress.
2. Equip students with techniques to manage stress, anxiety, and emotional well-being.
3. Develop conflict resolution skills for personal and professional life.
4. Encourage emotional intelligence and interpersonal communication.
5. Promote resilience and positive mindset development.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Identify sources and effects of stress in personal and professional life.
2	Apply stress management techniques such as mindfulness, journaling, and relaxation exercises.
3	Utilize conflict management strategies to resolve interpersonal and workplace conflicts.
4	Demonstrate improved emotional intelligence and resilience.
5	Develop effective communication skills for personal and professional growth.

Detailed Syllabus

List of practical
(Perform any 12 Experiments) 1. Self-assessment of stress levels using Perceived Stress Scale (PSS) 2. Journaling activity: Maintain a 7-day emotional diary 3. Mindfulness breathing exercise and reflection 4. Guided meditation session and feedback form 5. Time management activity using Eisenhower Matrix 6. Role-play exercise on workplace conflict resolution 7. SWOT analysis of personal behavior and coping mechanisms 8. Cognitive restructuring worksheet for negative thoughts 9. Group discussion: "How do you respond to stress?" 10. Conflict styles self-test (Thomas-Kilmann Conflict Mode Instrument) 11. Visualization technique to reduce anxiety 12. Progressive muscle relaxation practice 13. Team activity: Building trust through icebreakers and communication 14. Reflection report after practicing gratitude for 5 days 15. Case study analysis: Conflict scenario in a healthcare/pharma setup
Recommended References *(Preferably latest edition)*: 1. The Relaxation and Stress Reduction Workbook – Martha Davis, Elizabeth Robbins Eshelman & Matthew McKay, New Harbinger Publications 2. Managing Stress: Principles and Strategies for Health and Well-Being – Brian Luke Seaward, Jones & Bartlett Learning 3. Emotional Intelligence – Daniel Goleman, Bantam Books 4. The 7 Habits of Highly Effective People – Stephen R. Covey, Simon & Schuster 5. Conflict Management: A Practical Guide to Developing Negotiation Strategies – Barbara A. Budjac Corvette, Pearson Education 6. Mindfulness: An Eight-Week Plan for Finding Peace in a Frantic World – Mark Williams & Danny Penman, Rodale Books 7. Stress Management for Life: A Research-Based Experiential Approach – Michael Olpin & Margie Hesson, Cengage Learning 8. Crucial Conversations: Tools for Talking When Stakes Are High – Kerry Patterson, Joseph Grenny, Ron McMillan & Al Switzler, McGraw-Hill Education

Course Code	Course Title			Course Type
BP212P SEC3	**Fundamentals of Computer Operations (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 to:

1. Provide foundational knowledge of computer systems, operating environments, and digital tools used in academic and professional settings.
2. Develop practical skills in digital documentation, data handling, and presentation using commonly available office productivity tools.
3. Familiarize students with file management practices and digital communication methods used in professional environments.
4. Enhance the ability to access, search, and retrieve scientific and academic information from online resources.
5. Prepare students to utilize computer-based tools for managing pharmaceutical data, documentation, and basic professional tasks.

COURSE OUTCOMES (CO):

Upon successful completion of this course, the students will be able to:

CO No.	Upon successful completion of this course, the students will be able to
1	Demonstrate the ability to operate computer systems and perform basic system and file management functions.
2	Prepare and format digital documents and spreadsheets for academic and pharmaceutical applications.
3	Develop presentations and use digital communication tools for effective professional communication.
4	Access and retrieve scientific information using online databases and academic search platforms.
5	Apply basic computer skills for organizing, analyzing, and managing pharmaceutical data and documentation.

Detailed Syllabus

List of practical

(Perform any 12 Experiments)

General Instruction on Digital Tools

Open-source digital tools are ***preferred for teaching and learning purposes****. However, institutions may* ***choose appropriate software platforms, applications, or online services depending on availability, institutional policy, and infrastructure****. The selected tools should enable students to perform the required digital and documentation tasks effectively. The* ***specific software may vary****, but the* ***skills and competencies listed below must be achieved using suitable tools.***

Practical Components

1. Basic operation and navigation of a computer operating system, including system settings and file explorer functions.
2. Creating, renaming, organizing, moving, and deleting files and folders within a computer system.
3. Preparing a structured academic or pharmacy-related report using a word-processing application with appropriate formatting, tables, headers, and page layout.
4. Inserting equations, images, and formatted elements while preparing documents such as reports, notices, or certificates using document editing tools.
5. Creating spreadsheets for pharmacy-related calculations such as dose calculations, inventory records, or sales data using spreadsheet applications.
6. Applying basic spreadsheet formulas and functions such as summation, averaging, conditional calculations, and counting operations.
7. Generating graphs, charts, and data visualizations from experimental or pharmaceutical data using spreadsheet tools.
8. Preparing a short academic presentation (approximately five slides) using presentation software with text, images, and basic design elements.
9. Performing effective internet browsing and academic search techniques using online scientific literature databases and search platforms.
10. Writing and sending professional emails including file attachments, proper subject lines, and appropriate use of CC and BCC with correct communication etiquette.
11. Introduction to digital systems used in pharmacy practice such as billing, inventory management, or prescription management through demonstration or simulation.
12. Using cloud-based storage platforms for saving, organizing, and sharing academic or pharmacy-related files and data.
13. Exploring digital health technologies such as pharmacy-related mobile applications or electronic health tools used in healthcare practice.
14. Accessing and utilizing online learning platforms for professional education and course materials.
15. Preparing and submitting digital assignments using word-processing, spreadsheet, or presentation tools.

Recommended References *(Preferably latest edition)*:

1. Introduction to Computers – Peter Norton, McGraw-Hill Education
2. Computer Basics: Absolute Beginner's Guide – Michael Miller, Que Publishing

SEMESTER III

Course Code	Course Title			Course Type
BP312P AEC1	**Nutraceuticals and Functional Foods (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 to:

1. Introduce the concept and classification of nutraceuticals and functional foods.
2. Explore the role of bioactive components in health promotion and disease prevention.
3. Familiarize students with the formulation, labelling, and quality control of nutraceuticals.
4. Understand the regulatory aspects governing nutraceuticals and dietary supplements.
5. Develop practical skills in extraction, analysis, and preparation of functional foods.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Classify and explain the functions of various nutraceuticals and functional foods.
2	Identify sources of important phytochemicals and dietary bioactives.
3	Perform basic laboratory techniques for nutraceutical product development.
4	Analyze labels and evaluate quality and efficacy of marketed supplements.
5	Understand regulatory frameworks (FSSAI, FDA, EFSA) and apply them in practice.

Detailed Syllabus

List of practical
(Perform any 12 Experiments) 1. Identification and classification of nutraceuticals and functional foods from marketed products 2. Preparation of a probiotic drink or yogurt using lactic acid bacteria 3. Extraction of phytochemicals (flavonoids, alkaloids) from plant material 4. Estimation of antioxidant activity using DPPH method 5. Formulation of a herbal supplement capsule or powder 6. Demonstration of dietary fiber content from cereals or vegetables 7. Assessment of total polyphenol content using Folin–Ciocalteu reagent 8. Label analysis of functional foods and dietary supplements (FSSAI standards)

9. Case study presentation: Role of omega-3 fatty acids in cardiovascular health
10. Demonstration of stability testing of a nutraceutical formulation
11. Preparation of fortified food product (e.g., iron-fortified juice)
12. Visit to a food testing laboratory or nutraceutical industry (or virtual tour)
13. Evaluation of glycemic index of selected carbohydrate-rich foods (conceptual)
14. Regulatory comparison of nutraceutical guidelines (FSSAI vs. FDA vs. EFSA)
15. Preparation of a functional food label with nutrition facts and claims

Recommended References *(Preferably latest edition)*:

1. Functional Foods: Concept to Product by **M. Guo**, **Woodhead Publishing (Elsevier)**
2. Handbook of Nutraceuticals and Functional *Foods* by **Robert E.C. Wildman**, **CRC Press (Taylor & Francis Group)**
3. Nutraceuticals and Functional Foods in Human Health and Disease Prevention by **Debasis Bagchi**, **CRC Press (Taylor & Francis Group)**
4. Functional Foods and Nutraceuticals: Sources and their Development Techniques by **Rotimi E. Aluko**, **Springer Nature**
5. Dietary Supplements and Nutraceuticals: Market, Regulations and Health Impacts by **Yashwant Pathak**, **Academic Press (Elsevier)**

Course Code	Course Title			Course Type
BP312P AEC2	**Food Analysis (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 primary objectives of this course are:

1. Understand to perform proximate analysis.
2. Know to operate, maintain, interpret and evaluate the data of instruments.
3. Understand and apply quality control principles.
4. Know to detect and analyze Food adulteration.
5. Knew to nutritional and quality aspects of food products

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Gain knowledge on nutritional and quality aspects of food products.
2	Understand troubleshoot common issues of instruments.
3	Execute and apply theoretical knowledge of food chemistry.
4	Understand the various analytical techniques for qualitative and quantitative analysis.
5	Understand the significance and application of food analysis in ensuring safety and quality.

Detailed Syllabus

List of practical
(Perform any 12 Experiments) 1. Determination of the acid value for the given oil/fat 2. Determination of the ester value of the given oil/fat 3. Determination of the saponification value of the given oil/fat 4. Determination of total and free acidity in honey as per FSSAI method. 5. Quantification of caffeine content in soft drinks. 6. Determination of fat content in milk by gravimetric method 7. Detection of starch and urea in milk as per FSSAI method. 8. Assessment of fluoride content in drinking water 9. Assessment of total hardness in drinking water 10. Determination of the rancidity of the oil by UV Visible spectrophotometer 11. Quantification of benzoic acid as preservative in beverages/jam/ jellies by titrimetric/spectrophotometric method. 12. Isolation and identification of synthetic food colours by paper chromatography/Thin layer chromatography. 13. Determination of total curcuminoid content in turmeric by UV visible spectrophotometer. 14. Assessment of the total ash content for spices and condiments. 15. Determination of gluten content in whole wheat/wheat flour. 16. Determination of alcoholic acidity in bread and bread products. 17. Determination of Caloric value of food and nutritional supplements.
Recommended References (Preferably latest edition): 1. Food Analysis – Suzanne Nielsen, Springer 2. Introduction to Food Analysis – S. Suzanne Nielsen, Springer 3. Food Analysis: Theory and Practice – Y. Pomeranz & Clifton E. Meloan, Springer 4. Manual of Methods of Analysis of Foods – Food Safety and Standards Authority of India (FSSAI), Government of India 5. Food Chemistry – H.-D. Belitz, Werner Grosch & Peter Schieberle, Springer

Course Code	Course Title			Course Type
BP312P AEC3	**Yoga and Life Sciences (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 introduce students to the principles of yoga and its scientific basis.
2. To teach the practical aspects of yoga, including asanas (postures), pranayama (breathing exercises), and meditation.
3. To enhance students' understanding of the health benefits of yoga on physical and mental well-being.
4. To explore the role of yoga in the prevention and management of diseases.
5. To encourage a holistic lifestyle by incorporating yoga into daily routines.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Perform basic yoga postures (asanas) and breathing exercises (pranayama).
2	Understand the physiological and psychological benefits of yoga.
3	Apply yoga techniques for stress relief, flexibility, and mental clarity.
4	Recognize the therapeutic potential of yoga in managing chronic health conditions.
5	Integrate yoga into daily life for improved well-being and productivity.

Detailed Syllabus

List of practical
(Perform any 12 Experiments) 1. Demonstration and practice of Surya Namaskar (Sun Salutation) 2. Practice of basic asanas: Tadasana, Vrikshasana, Bhujangasana 3. Practice of Pranayama techniques: Nadi Shodhana, Bhramari 4. Meditation session: Focused awareness and breath control 5. Yoga-based stretching and warm-up routine 6. Recording physiological parameters (heart rate, BP) before and after yoga 7. Yoga journal: Track weekly yoga practice and mood changes 8. Poster presentation on "Scientific benefits of yoga on immunity" 9. Yoga for specific health conditions: Back pain, asthma, stress 10. Group chanting of Mantra – observation of mental state 11. Learning the role of yoga in circadian rhythm regulation 12. Visit to a yoga wellness center or attending a virtual session 13. Assessment of flexibility using sit-and-reach test before/after practice 14. Demonstration of Yog Nidra (guided relaxation technique) 15. Case presentation: Impact of yoga on a chronic disease condition
Recommended References (Preferably latest edition): 1. Light on Yoga by B. K. S. Iyengar – A comprehensive guide to yoga postures and philosophy. 2. The Heart of Yoga by T. K. V. Desikachar – Explains principles and therapeutic applications of yoga. 3. Asana Pranayama Mudra Bandha by Swami Satyananda Saraswati – A classical reference on yogic practices and breathing techniques. 4. Ministry of AYUSH. Yoga Education and Practice Guidelines. Government of India. 5. World Health Organization. Traditional Medicine Strategy and integrative health resources.

SEMESTER VI

Course Code	Course Title			Course Type
BP607T AEC1	**Green Chemistry (Theory)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	1	--	--	15
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Comprehend the foundational principles and overarching scope of green chemistry within pharmaceutical sciences.
2. Analyze and evaluate the environmental impact of traditional pharmaceutical manufacturing processes and the significance of green chemistry metrics.
3. Acquire knowledge of diverse green chemical techniques, including alternative solvents and various catalytic approaches, for sustainable drug synthesis.
4. Recognize the industrial application of green chemistry principles in pharmaceutical manufacturing processes, focusing on waste minimization and pollution control.
5. To articulate the principles of green chemistry.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Articulate the principles of green chemistry and provide relevant pharmaceutical examples for each.
2	Identify and propose suitable green solvents and catalysts,
3	Understand the advanced synthetic methods using Green synthesis using microwave, Ultrasonic for the production of active pharmaceutical ingredients (APIs).
4	Develop strategies for waste minimization and continuous flow reactor in pharmaceutical manufacturing in industries.
5	Articulate the principles of green chemistry and provide relevant pharmaceutical examples for each.

Detailed Syllabus

Unit No.	Topics	No. of Lectures
I	**Introduction to Green Chemistry in Pharmacy** 1. Definition and scope of green chemistry in pharmaceutical sciences 2. Principles of Green Chemistry with pharmaceutical examples	3 hours
II	**Environmental Aspects and Metrics in Green Pharmacy** • Comparison of traditional vs. green chemical approaches in drug synthesis • Environmental impact of pharmaceutical manufacturing • Overview of pharmaceutical pollutants and their life cycle • Metrics: Atom economy, E-factor, Process Mass Intensity (PMI)	3 hours
III	**Green Techniques in Pharmaceutical Synthesis –I** 1. Green Solvents and use of green solvents (e.g. water, supercritical fluids, ionic liquids) in drug synthesis 2. Solvent-free reactions in pharmaceutical synthesis 3. Green Catalysis and Reaction Enhancement in pharmaceutical green chemistry Overview of catalysis in pharmaceutical green chemistry, Photochemical Transformations, Phase Transfer Catalysis	3 hours
IV	**Green Techniques in Pharmaceutical Synthesis – II** 1. Microwave assisted reactions: Merit and demerits of its use 2. Mechanism, superheating effects of microwave 3. Effects of solvents in microwave assisted synthesis 4. Microwave technology in process optimization 5. Applications in various organic reactions and heterocycles synthesis	3 hours
V	**Green Chemistry in Industrial and Regulatory Aspects** 1. Green chemistry in pharmaceutical manufacturing processes 2. Ultrasound assisted reactions: Types of sonochemical reactions, synthetic applications 3. Continuous flow reactors: Working principle, advantages and synthetic applications 4. Waste minimization and pollution control in formulation industries 5. Role of green chemistry in Good Manufacturing Practices (GMP)	3 hours

Recommended References *(Preferably latest edition)*:

1. Anastas, P.T. and Warner, J.C., 2000. Green chemistry: theory and practice. Oxford university press.
2. Lancaster, M. (2016). Green Chemistry: An Introductory Text (3rd ed.). Royal Society of Chemistry.
3. Green Chemistry in the Pharmaceutical Industry, Edited by Peter J. Dunn, Andrew Wells, and Michael T. Williams, 2010.
4. Green Chemistry and Sustainable Technology: Biological, Pharmaceutical, and Macromolecular Systems, Edited by Satish A. Dake, Ravindra S. Shinde, Suresh C. Ameta, A. K. Haghi, 2022.
5. Scalable Green Chemistry: Case Studies from the Pharmaceutical Industry, Edited by Stefan Koenig, 2013.

Course Code	Course Title			Course Type
BP607T AEC2	**Materiovigilance and Hemovigilance (Theory)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	1	--	--	15
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand the concepts, scope, and importance of materiovigilance and hemovigilance systems in ensuring patient safety in healthcare.
2. Familiarize students with national and international regulatory frameworks, reporting systems, and global initiatives related to vigilance programs.
3. Identify and evaluate adverse events associated with medical devices and blood transfusion practices.
4. Develop competencies in detection, reporting, investigation, and documentation of vigilance-related incidents.
5. Promote awareness of safety culture, quality assurance, and ethical responsibilities in clinical and healthcare practices.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Explain the principles, scope, and significance of materiovigilance and hemovigilance in ensuring patient and public health safety.
2	Describe the structure and functioning of the Materiovigilance Programme of India (MvPI) and the procedures for reporting medical device-related adverse events.
3	Outline the framework of the Hemovigilance Programme of India (HvPI) and classify different types of transfusion-related adverse reactions.
4	Compare national and international vigilance systems and apply basic methods of risk assessment, signal detection, and root cause analysis.
5	Demonstrate appropriate documentation and reporting practices and recognize the role of healthcare professionals in promoting vigilance and patient safety.

Detailed Syllabus

Unit No.	Topics	No. of Lectures
I	**Introduction to Vigilance Systems** • Overview of Materiovigilance, Hemovigilance and other vigilance system in Healthcare • Importance of post-marketing surveillance in patient safety • Scope and objectives of materiovigilance and hemovigilance programs • Basic concepts of adverse event reporting and safety monitoring • Historical evolution and global relevance of Materiovigilance, Hemovigilance practices	3 hours
II	**Materiovigilance – Principles and Practices** • Introduction to Materiovigilance Programme of India (MvPI) • Roles of NCC-MvPI and technical collaborators (e.g., Sree Chitra Tirunal Institute) • Classification of medical devices (Class A to D) based on risk • Identification and documentation of Medical Device Adverse Events (MDAEs) • Medical device reporting forms, process flow, and responsibilities • Causality assessment of Medical Device Adverse Events	3 hours
III	**Hemovigilance – Principles and Practices** • Overview of Hemovigilance Programme of India (HvPI) • Organizational structure: NIB, NBTC, hospital-based hemovigilance • Adverse Transfusion Reactions (ATRs): Types and clinical manifestations • Use of TRRF (Transfusion Reaction Reporting Form) and Haemo-Vigil software • Responsibilities of blood banks, transfusion officers, and healthcare providers • Case examples along with Causality assessment of Hemolytic reactions, TRALI, TACO, allergic responses.	3 hours
IV	**Global Regulations, Risk Assessment & Root Cause Analysis** • International frameworks: US FDA (MAUDE), EU MDR, SHOT (UK), French Hemovigilance • Comparison of Indian and global materiovigilance/hemovigilance practices • Signal detection and evaluation of adverse events • Root cause analysis (RCA) and implementation of corrective & preventive actions (CAPA) • Risk communication and role of healthcare teams in mitigation	3 hours

V	**Reporting Systems, Quality Assurance, and Professional Role** Demonstration: Reporting of MDAEs and ATRs using mock forms • Practical exercises in form-filling and event documentation • Integration of vigilance into hospital quality systems (e.g., NABH, ISO) • Strategies to enhance adverse event reporting culture • Ethical considerations and communication with patients/families • Role of pharmacists, nurses, clinicians, biomedical engineers in vigilance programs	3 hours

Recommended References *(Preferably latest edition)*:

1. Bertil Jacobson - Medical Device Safety: The Regulation of Medical Devices for Public Health and Safety, CRC Press
2. Jack Wong - Handbook of Medical Device Regulatory Affairs in Asia, Pan Stanford Publishing
3. Denise M. Harmening - Modern Blood Banking and Transfusion Practices, F.A. Davis Company
4. World Health Organization (WHO)- Blood Safety: Basic Elements

Course Code	Course Title			Course Type
BP607T AEC3	**Scientific Writing (Theory)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	1	--	--	15
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Develop the ability to write clearly, concisely, and effectively for scientific audiences.
2. Understand the structure and components of scientific documents such as research papers, proposals, and literature reviews.
3. Learn the principles of scientific style, tone, and formatting in academic writing.
4. Apply correct citation practices and reference management techniques.
5. Recognize and address ethical issues in scientific communication, including plagiarism and data integrity.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Understand the principles of scientific writing
2	Develop clear and concise scientific writing skills
3	Use effective scientific citation techniques
4	Understand and apply the ethical principles of scientific writing
5	Develop the ability to critically evaluate scientific literature

Detailed Syllabus

Unit No.	Topics	No. of Lectures
I	**Introduction to Scientific Writing** • Overview of the course • Principles of scientific writing • Overview of scientific research • Introduction to Microsoft tools and its application	2
II	**Writing Literature Reviews and Scientific Papers** • Structure and format of literature reviews • Conducting a literature review • Analyzing literature and developing themes	5

	• Writing a compelling introduction • Developing a clear methodology • Results and analysis	
III	**Communicating Results and Data** • Understanding data presentation • Developing tables and figures • Using effective graphic design	3
IV	**Scientific Citation and Referencing** • Understanding citation styles • Citation and plagiarism • Referencing in scientific writing	3
V	**Ethical Issues in Scientific Writing and Peer Review and Revision** • Ethical principles in scientific writing • Misconduct and fraud in scientific writing • Peer review and publication ethics • Providing Constructive feedback • Responding to feedback	2

Recommended References *(Preferably latest edition)*:

1. Day, R. A., Gastel, B. How to Write and Publish a Scientific Paper. Bloomsbury Publishing, USA.
2. Hofmann, A. H. Scientific Writing and Communication: Papers, Proposals, and Presentations. Oxford University Press, USA.
3. Schimel, J. Writing Science: How to Write Papers That Get Cited and Proposals That Get Funded. Oxford University Press, USA.
4. Alley, M. The Craft of Scientific Writing. Springer, New York, USA.
5. Machi, L. A., McEvoy, B. T. The Literature Review: Six Steps to Success. SAGE Publications, Thousand Oaks, USA.
6. Jesson, J., Matheson, L., Lacey, F. M. Doing a Literature Review in Health and Social Care. SAGE Publications, London, UK.
7. Tufte, E. R. The Visual Display of Quantitative Information. Graphics Press, Cheshire, USA.
8. American Medical Association. AMA Manual of Style. Oxford University Press, New York, USA.
9. American Psychological Association. Publication Manual of the American Psychological Association. American Psychological Association, Washington, DC, USA.
10. National Academies of Sciences, Engineering, and Medicine. On Being a Scientist: A Guide to Responsible Conduct in Research. National Academies Press, Washington, DC, USA.

Course Code	Course Title			Course Type
BP607T AEC4	**Drug Store and Business Management (Theory)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	1	--	--	15
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand the principles of trade, commerce, and different types of business organizations.
2. Gain knowledge on effective drug store layout, procurement, and inventory control.
3. Apply basic accounting and financial principles for pharmacy business operations.
4. Explore marketing and sales strategies applicable to pharmaceutical products.
5. Develop entrepreneurial skills and understand legal aspects of drug store management.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Describe different business models and their relevance to pharmaceutical trade.
2	Manage drug store operations, including procurement, storage, and customer service.
3	Maintain basic accounting records and interpret financial statements.
4	Implement inventory control techniques and pricing policies.
5	Apply marketing principles and legal guidelines for establishing a retail pharmacy.

Detailed Syllabus

Unit No.	Topics	No. of Lectures
I	**Introduction to Trade and Industry** • Objectives and scope of business • Classification of business activities – industry, commerce, trade • Forms of business organization: sole proprietorship, partnership, cooperatives, corporations • Features and merits/demerits of each form Pharmacy business and its legal considerations	3 hours
II	**Drug Store Management** • Selection of site, space, and layout of a drug store	3 hours

	• Types of drug stores – hospital pharmacy, community pharmacy, chain pharmacy • Procurement of drugs and inventory control • Storage conditions and stock maintenance (cold storage, poisonous drugs, etc.) • Records and registers to be maintained	
III	**Inventory Control and Sales Promotion** • Introduction to inventory control: need and methods • Economic Order Quantity (EOQ), Reorder Level (ROL), Lead time • FIFO and LIFO methods • Sales promotion techniques: advertising, displays, discounts • Customer relationship management (CRM) in pharmacy	3 hours
IV	**Financial Management and Bookkeeping** • Basics of accounting: journal, ledger, trial balance • Introduction to financial statements: profit and loss account, balance sheet • Pricing policies: markup, markdown, break-even analysis • Bank transactions: types of accounts, cheques, drafts • Taxation basics: GST, income tax (as applicable to pharmacies)	3 hours
V	**Pharmaceutical Marketing and Entrepreneurships** • Definition and scope of pharmaceutical marketing • Elements of marketing mix (4Ps) for pharmacy • Drug distribution channels: wholesale and retail • Entrepreneurship development in pharmacy • Regulatory aspects of retail drug licensing (Drug and Cosmetics Act overview)	3 hours

Recommended References *(Preferably latest edition)*:

1. Elements of Business Management by T.R. Jain & Mukesh Trehan, VK Publications
2. Retail Pharmacy Management by R.C. Goyal, CBS Publishers & Distributors
3. Principles and Practice of Management by L.M. Prasad, Sultan Chand & Sons
4. Business Organization and Management by C.B. Gupta, Sultan Chand & Sons
5. Drug Store and Business Management by R.M. Mehta, Pharma Med Press
6. A Textbook of Drug Store and Business Management by T.K. Ghosh, S. Chand Publishers
7. Pharmaceutical Marketing in India by Subba Rao Chaganti, Excel Books

Course Code	Course Title			Course Type
BP607T AEC5	**Career Building in Cultivation of Medicinal Plants (Theory)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	1	--	--	15
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Explain the significance, historical background, and therapeutic importance of medicinal plants.
2. Examine the structure, scope, and economic potential of the medicinal plant industry.
3. Identify and describe important medicinal plants of India and their applications.
4. Develop knowledge of sustainable, organic, and scientific cultivation practices for medicinal plants.
5. Explore entrepreneurship opportunities and value chain development in the medicinal plant sector.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Explain the importance and historical development of medicinal plants in traditional and modern healthcare systems.
2	Describe the structure and functioning of the medicinal plant industry and its economic significance.
3	Identify major medicinal plants of India and explain their uses and sources.
4	Apply principles of sustainable and organic cultivation practices for medicinal plants.
5	Analyze entrepreneurship opportunities and value chain development in the medicinal plant sector.

Detailed Syllabus

Unit No.	Topics	No. of Lectures
I	**Introduction and Industry Overview** • Definition, importance, and cultural background (Ayurveda & ethnobotany) • Global and Indian demand, healthcare and pharma role • Key stakeholders: farmers, traders, processors, exporters • Value chain, supply-demand, government/private initiatives (NMPB, AYUSH, NABARD)	3 hours

II	**Key Medicinal Plants and Cultivation Basics** • Botanical characteristics and uses of major plants: Ashwagandha, Tulsi, Aloe vera, Shatavari, Brahmi, etc. • Regional suitability and agro-climatic zones • Factors affecting Cultivation: Soil, propagation, irrigation, pest control, organic inputs • Harvesting, post-harvest management and storage	3 hours
III	**Organic Farming and Market Linkages** • Organic certification and sustainable farming practices • Biodiversity conservation and agroforestry integration • Processing, drying, packaging, branding • Market linkages: pharma, cooperatives, online platforms, export guidelines	3 hours
IV	**Policy, Entrepreneurship and Digital Tools** • Government schemes and legal frameworks (NMPB, AYUSH, forest laws, GACP) • Entrepreneurship: starting herbal farms, franchises, consulting, contract farming • Digital tools: farm management software, GIS, mobile apps, e-commerce marketing	3 hours
V	**Practical Exposure and Project Presentation** • Virtual/shortened farm/nursery visit or guest lecture (can be online) • Group/individual project: business plan or herbal enterprise pitch presentation	3 hours

Recommended References *(Preferably latest edition)*:

1. Kumar, N., Misra, J. B. M., et al. Cultivation of Medicinal and Aromatic Crops. ICAR Publications, New Delhi, India.
2. Shah, B., Seth, A. Textbook of Pharmacognosy and Phytochemistry. Elsevier / Reed Elsevier India, New Delhi, India.
3. Planning Commission / National Medicinal Plants Board. Medicinal Plants Sector in India: Challenges and Opportunities. Government of India, New Delhi, India.
4. Planning Commission (NITI Aayog). Herbal Industry in India. Government of India, New Delhi, India.
5. National Medicinal Plants Board (NMPB). Annual Reports. Ministry of AYUSH, Government of India, New Delhi, India.
6. World Health Organization. Good Agricultural and Collection Practices (GACP) for Medicinal Plants. WHO Press, Geneva, Switzerland.

Course Code	Course Title			Course Type
BP607T AEC6	**Active Pharmaceutical Ingredients and Excipient Sciences (Theory)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	1	--	--	15
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand the fundamental concepts of Active Pharmaceutical Ingredients (APIs) and excipients in dosage form development.
2. Analyse the physicochemical properties influencing API excipient compatibility and formulation performance.
3. Develop knowledge of industrial methodologies for characterization and quality control.
4. Understand GMP protocols and regulatory frameworks governing API and excipient manufacturing.
5. Explore emerging industrial trends including green chemistry and bio-based excipients.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	To explain the classification, properties and functional roles of APIs and excipients.
2	To apply analytical and preformulation methodologies for compatibility and stability evaluation.
3	To understand manufacturing, scale-up and quality control procedures used in industry.
4	To evaluate regulatory documentation and compliance requirements for API and excipient approval.
5	To develop awareness of current industrial practices and innovation trends.

Detailed Syllabus

Unit No.	Topics	No. of Lectures
I	**Introduction to APIs and Excipients** • Definitions, classifications, and sources (synthetic, natural, biotech APIs; functional excipients). • Physicochemical properties: Solubility, polymorphism, hygroscopicity, particle characteristics. • Roles in formulations: Bioavailability enhancement, stability, manufacturability.	3 hours

	• Industry overview: Global market trends, common examples (e.g., paracetamol API, HPMC excipient).	
II	**Methodologies for Selection and Pre-formulation** • Excipient selection criteria: Functionality-related characteristics (FRC). • Compatibility studies: Binary mixtures via DSC, FTIR, XRD. • Analytical methodologies: HPLC/GC for purity, Karl Fischer titration, laser diffraction for PSD. • QbD approach: Risk assessment for API-excipient interactions.	3 hours
III	**Manufacturing Protocols** • API processes: Synthesis routes, crystallization, drying, milling; lab-to-pilot scale-up. • Excipient handling: Sieving, blending, lubrication protocols. • GMP essentials: Equipment qualification, process validation. • Unit operations: Wet/dry granulation, direct compression.	3 hours
IV	**Quality Control and Stability Protocols** • QC tests: Assay, dissolution, content uniformity (IP/USP methods). • Stability studies: ICH Q1A zones, accelerated/forced degradation. • Impurity profiling: Genotoxic impurities (ICH M7), residual solvents. • In-process controls: Blend uniformity, weight variation.	3 hours
V	**Regulatory Compliance and Industry Practices** • ICH Q7 guidelines for APIs • USP-NF excipient monographs and Schedule M requirements • Drug Master File (DMF) for APIs • Certificate of Suitability (COS) for excipients • Process and cleaning validation protocols • Regulatory inspections (USFDA 483, EMA expectations) • Emerging trends: green chemistry and bio-based excipients	3 hours

Recommended References *(Preferably latest edition)*:

1. Gibson, M. Pharmaceutical Preformulation and Formulation. Informa Healthcare, London.
2. Rowe, R. C., Sheskey, P. J., Quinn, M. E. Handbook of Pharmaceutical Excipients. Pharmaceutical Press, London.
3. Aulton, M. E. Aulton's Pharmaceutics: The Design and Manufacture of Medicines. Elsevier, London.
4. ICH Guidelines (Q7, Q8, Q1A). International Council for Harmonisation, Geneva.
5. Indian Pharmacopoeia (Latest Edition). Indian Pharmacopoeia Commission, Ghaziabad, India.
6. United States Pharmacopeia–National Formulary (USP-NF). USP Convention, USA.
7. Banker, G. S., Rhodes, C. T. Modern Pharmaceutics. CRC Press, USA.
8. Allen, L. V., Popovich, N. G., Ansel, H. C. Pharmaceutical Dosage Forms and Drug Delivery Systems. Lippincott Williams & Wilkins, USA.

SEMESTER VI

Course Code	Course Title			Course Type
BP610P SEC1	**Computer Aided Drug Design (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 to:

1. Familiarize students with target identification and protein preparation using biological databases and molecular visualization tools.
2. Develop skills in ligand design, optimization, and 3D conformer generation using computational chemistry software.
3. Provide practical understanding of molecular docking and interaction analysis for structure-based drug design.
4. Introduce pharmacophore modelling and QSAR techniques for virtual screening and predictive modelling.
5. Train students in ADMET prediction and molecular dynamics simulations for evaluating drug-likeness and stability of drug target complexes.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1.	Retrieve and prepare biological targets from protein databases and analyze active sites using molecular modelling tools.
2.	Design and optimize ligand structures and generate energetically stable conformers for computational drug design studies.
3.	Perform molecular docking and analyze drug–target interactions to evaluate ligand binding affinity and stability.
4.	Apply pharmacophore modelling and QSAR methods for virtual screening and prediction of biological activity.
5.	Evaluate drug candidates using ADMET prediction tools and molecular dynamics simulations to assess drug-likeness and complex stability.

Detailed Syllabus

List of Practical

General Instruction on Computational Tools

Open-source computational tools are preferred for teaching and learning purposes. However, institutions may select appropriate software platforms or online resources based on availability, institutional policy, and technical feasibility. The choice of software should enable students to perform the required computational tasks effectively. The specific software used may vary, but the learning outcomes and computational procedures described below must be achieved using suitable tools.

1. Target Identification and Preparation

- Retrieve protein sequence or structural information from publicly available biological databases.
- Prepare the target protein by removing unwanted molecules, correcting structural issues, and adding necessary atoms or charges using appropriate molecular visualization or preparation tools.
- Identify potential binding or active sites using computational methods that analyze structural pockets and cavities.

2. Ligand Design and Optimization

- Design or sketch candidate molecules using suitable molecular drawing tools.
- Convert structures into three-dimensional form and optimize their geometry using computational chemistry methods.
- Generate multiple conformations of the molecule and perform energy minimization to obtain stable structures.

3. Molecular Docking

- Perform docking simulations using computational docking platforms to predict the interaction between ligands and the target protein.
- Examine binding orientations and molecular interactions using visualization tools.
- Rank compounds based on predicted binding affinity and interaction quality.

4. Pharmacophore Modeling

- Identify essential molecular features responsible for biological activity such as hydrogen bond donors/acceptors, hydrophobic regions, and aromatic centers.
- Construct pharmacophore models representing these key features.
- Use these models to screen compound libraries for molecules that match the required feature pattern.

5. QSAR Modeling

- Calculate molecular descriptors that represent structural and physicochemical properties of compounds.
- Develop predictive statistical or machine learning models that relate these descriptors to biological activity.
- Validate models using appropriate validation techniques such as cross-validation and external datasets.

6. ADMET Prediction

- Evaluate pharmacokinetic and toxicity properties computationally, including:
  - Absorption
  - Distribution
  - Metabolism
  - Excretion
  - Toxicity
- Use predictive computational models and online resources to assess drug-likeness and safety profiles.

7. Molecular Dynamics Simulations

- Conduct simulations to study the dynamic behavior of the protein ligand complex over time.
- Analyze parameters such as structural stability, atomic fluctuations, hydrogen bonding, and interaction persistence.
- Visualize simulation trajectories to understand conformational changes and binding stability.

Recommended References *(Preferably latest edition)*:

1. Leach, A.R., *Molecular Modelling: Principles and Applications*. Harlow: Prentice Hall.
2. Todeschini, R. and Consonni, V., *Molecular Descriptors for Chemoinformatics*. Weinheim: Wiley-VCH.
3. Gupta, S.P., *QSAR and Molecular Modeling*. Berlin: Springer.
4. Jorgensen, W.L., *Efficient Drug Discovery and Development*. Hoboken, NJ: Wiley.
5. Bultinck, P., De Winter, H., Langenaeker, W. and Tollenaere, J.P., *Computational Medicinal Chemistry for Drug Discovery*. New York: Marcel Dekker.
6. Andrew, L.H. and Brown, F.K., *Rational Drug Design: Novel Methodology and Practical Applications*. Washington, DC: American Chemical Society.
7. Ward, S.E. and Davis, A., *The Handbook of Medicinal Chemistry: Principles and Practice*.

Course Code	Course Title			Course Type
BP610P SEC2	**Analytical Method Development and 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 to:

1. Provide practical exposure to analytical method development using spectrophotometric, chromatographic, and titrimetric techniques for pharmaceutical analysis.
2. Introduce principles of optimization of analytical parameters such as wavelength, mobile phase composition, column selection, flow rate, temperature, and pH for reliable analysis.
3. Familiarize students with validation requirements of analytical methods as per regulatory guidelines, including assessment of sensitivity, linearity, and specificity.
4. Expose students to advanced chromatographic applications such as dissolution testing, impurity profiling, forced degradation studies, and residual solvent analysis.
5. Bridge analytical theory with industrial and regulatory practices relevant to quality control and quality assurance of pharmaceutical products.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Develop and optimize analytical methods using UV –Visible spectrophotometry, HPLC, GC, and titrimetric techniques for pharmaceutical substances.
2	Construct calibration curves and perform quantitative estimation of APIs and formulations with appropriate analytical validation.
3	Select and optimize chromatographic conditions including column type, mobile phase composition, flow rate, temperature, and detection wavelength.
4	Apply analytical method validation parameters such as LOD, LOQ, and robustness to ensure reliability and regulatory compliance.
5	Conduct stability-indicating and impurity-related studies, including forced degradation, dissolution testing, and residual solvent analysis.

Detailed Syllabus

List of Practical
(Perform any 12 Experiments) 1. Development of a UV-Visible spectrophotometric method for the assay of paracetamol API. Construction of calibration curve for a model API using UV-Visible spectrophotometry. 2. Determination of solid dosage form by using dissolution method. 3. Analytical method development and validation of Atenolol/metformin by using HPLC. 4. Investigation of different columns for HPLC separation of a Multi-component Drug Mixture. 5. Optimization of mobile Phase composition for HPLC analysis of a selected drug. 6. Optimization of Flow rate and temperature in HPLC for paracetamol/ caffeine. 7. Selection of wavelength for spectrophotometric analysis by HPLC of Marketed drugs. 8. Determination of λmax and calibration curve for qualitative analysis of paracetamol. 9. Determination of effect of pH on Retention time in RP-HPLC. 10. Validation of HPLC method: Determination of LOD and LOQ for paracetamol by HPLC 11. Preliminary Investigation of forced Degradation studies on Ibuprofen by HPLC. 12. Method development for related substances of a drug substance using HPLC. 13. Determination of residual solvent analysis for ethanol/acetone in API by using Gas Chromatography. 14. Development of titrimetric method for the assay of marketed drugs (Ascorbic acid/sodium bicarbonate).
Recommended References *(Preferably latest edition)*: 1. Ahuja S, Dong MW, editors. Handbook of pharmaceutical analysis by HPLC. Amsterdam: Elsevier; 2005. 2. Moldoveanu SC. Method development in analytical HPLC. Amsterdam: Elsevier; 2014. 3. Swartz ME, Krull I. Analytical method development and validation. Boca Raton (FL): CRC Press; 2018. 4. Gorog S. Ultraviolet–visible spectrophotometry in pharmaceutical analysis. Boca Raton (FL): CRC Press; 2018. 5. Rehman K, Akash MSH. Essentials of pharmaceutical analysis. Singapore: Springer; 2020. 6. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Q2(R2): Validation of analytical procedures. Geneva: ICH; 2023.

Course Code	Course Title			Course Type
BP610P SEC3	**Principles of Preclinical Studies (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 to:

1. Introduce the role and importance of preclinical studies in the drug discovery and development process.
2. Familiarize students with laboratory animal handling, ethical considerations, and experimental protocols used in preclinical research.
3. Explain the principles of pharmacokinetics and toxicology as applied to animal models.
4. Describe the regulatory guidelines and standards governing preclinical research and animal experimentation.
5. Develop skills in analyzing and interpreting preclinical data to support decision-making for clinical trials.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Explain the role and significance of preclinical studies in drug discovery and development.
2	Demonstrate appropriate laboratory animal handling practices in accordance with ethical and regulatory guidelines.
3	Analyze pharmacokinetic parameters obtained from preclinical animal studies.
4	Design and interpret basic toxicological studies to evaluate drug safety.
5	Apply preclinical data in assessing drug candidates for progression to clinical trials.

Detailed Syllabus

List of Practical
(Perform any 12 Experiments) 1. Handling, restraining, and sex differentiation of laboratory animals (demo/video) 2. Calculation of dose for animals based on body surface area 3. Routes of administration: oral, intraperitoneal, subcutaneous (simulation) 4. Observation of behavioral effects using actophotometer/rotarod (if available) 5. Determination of acute toxicity (LD50 concept) – case-based calculation 6. Planning a 28-day sub-acute toxicity study protocol 7. Pharmacokinetic study: Cmax, Tmax, AUC calculation (sample dataset) 8. Observation of histopathological slides from toxicity studies 9. Demonstration of sampling methods – blood, urine (case or video) 10. Writing an animal study protocol using CPCSEA format 11. Identification of organs for toxicity evaluation – liver, kidney, brain 12. Visit to CPCSEA-approved animal house/laboratory 13. Observation of animal behavior – grooming, nesting (case-based) 14. Simulated ethics committee approval process (IAEC) 15. Group activity: Design of a preclinical study for a hypothetical drug
Recommended References *(Preferably latest edition)*: 1. Preclinical and Clinical Research – A Handbook – S. K. Gupta, Jaypee Brothers Medical Publishers 2. Drug Discovery and Clinical Research – B. T. James & M. M. Gupta, CBS Publishers & Distributors 3. Textbook of Preclinical Toxicology – R. K. Goyal, B. S. Shah Prakashan 4. Fundamentals of Experimental Pharmacology – M. N. Ghosh, Hilton & Company 5. Textbook of Pharmacology – S. D. Seth, Elsevier India

SEMESTER VI

Course Code	Course Title			Course Type
BP611P VAC1	**Professional Skills (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 to:

1. Develop effective verbal and interpersonal communication skills required for professional environments.
2. Train students in workplace etiquette, interview preparation, and team collaboration.
3. Enhance problem-solving, time management, and critical thinking abilities relevant to professional settings.
4. Promote personal grooming, digital professionalism, and responsible social media etiquette.
5. Prepare students to face professional challenges through experiential learning, role play, and interactive activities.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Demonstrate professional communication skills in interviews, emails, presentations, and workplace meetings.
2	Prepare and present an industry-standard résumé and professional online profile.
3	Exhibit confidence and clarity during group discussions, presentations, and interviews.
4	Apply time management, decision-making, and conflict resolution strategies in professional situations.
5	Maintain workplace ethics, etiquette, and a professional demeanor in both physical and digital environments.

Detailed Syllabus

List of Practical
(Perform any 12 Experiments) 1. Self-introduction exercise – verbal and written presentation 2. Resume/CV writing – using current industry formats 3. Mock job interview – panel-based or peer-reviewed 4. Group discussion (GD) – on current healthcare or industry topics 5. Public speaking practice – impromptu and prepared speeches 6. Email etiquette and writing professional emails 7. Time management matrix creation (Eisenhower box) 8. Body language analysis – observe and present feedback 9. Conflict resolution role play – team-based activity 10. Creating a LinkedIn profile and optimizing it professionally 11. Debate session – critical thinking and communication 12. Listening skills test – audio-based task with Q&A 13. Workplace scenario simulation – ethics, teamwork, communication 14. Presentation skills – create and deliver PowerPoint presentations 15. Goal-setting and career mapping – using SMART goals
Recommended References *(Preferably latest edition)*: 1. Soft Skills: Enhancing Employability by Meenakshi Raman & Sangeeta Sharma, Oxford University Press 2. The 7 Habits of Highly Effective People by Stephen R. Covey, Simon & Schuster 3. Personality Development and Soft Skills by Barun K. Mitra, Oxford University Press 4. Effective Technical Communication by M. Ashraf Rizvi, Tata McGraw-Hill Education 5. The Art of Public Speaking by Stephen E. Lucas, McGraw-Hill Education

Course Code	Course Title			Course Type
BP611P VAC2	**Process Analytical Technology (PAT) and QbD in Formulation Science (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 to:

1. Introduce PAT concepts so students grasp how in-line sensors monitor critical quality attributes (CQAs).
2. Explain QbD thinking for defining design space, critical process parameters (CPPs), and risk-based control strategies.
3. Teach basic PAT tools near-infrared (NIR) probes, focused-beam reflectance (FBRM), and multivariate models.
4. Demonstrate mini-DoE methods that link process variables to CQAs and support real-time release testing (RTRT).
5. Instil risk-analysis skills using Ishikawa diagrams and FMEA to prioritise and mitigate formulation hazards.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Describe the role of PAT and QbD in ensuring consistent product quality throughout a formulation process.
2	Identify and justify key CQAs, CPPs, and potential failure modes for a solid-dosage product.
3	Collect and interpret real-time data from an NIR or FBRM sensor and decide when a blend or granulation meets targets.
4	Design and analyse a small factorial experiment that optimises at least one CQA within a defined design space.
5	Prepare a brief risk-control plan showing ranked RPN values and proposed PAT-based monitoring to enable RTRT**.**

Detailed Syllabus

List of Practical
1. Identify Critical Quality Attributes (CQAs) – Brainstorm and list five tablet CQAs (hardness, dissolution, etc.) and link each to patient safety or efficacy. 2. Ishikawa (Fish-Bone) Diagram – Draw a cause-and-effect diagram for poor tablet dissolution, categorising factors into Materials, Methods, Machines and Manpower. 3. Blend-Uniformity by NIR Probe – Collect in-line near-infrared spectra during 10 min of blender operation and plot real-time API concentration trends. 4. Moisture Tracking with NIR – Use a portable NIR gun to measure LOD in wet granules every 2 min, stopping when the plot hits the 3 % target. 5. Mini DoE for Granulation – Run a 2^2 design varying impeller speed and granulation time; measure granule mean size and create main-effects plots. 6. Real-Time Release Test (RTRT) – Set up an at-line NIR hardness prediction model, test 20 tablets, and compare predicted vs. actual hardness. 7. Control Chart of Particle Size (FBRM) – Stream Focused Beam Reflectance data during milling; plot $\bar{X}$ and R for d_{50} and decide if the process is in control. 8. Multivariate Calibration Model – Build a partial-least-squares (PLS) model correlating NIR spectra to drug content; report R^2 and RMSEP. 9. FMEA Risk-Priority Number – Score severity, occurrence and detectability for three high-risk process variables; rank them by RPN and suggest mitigation. 10. PAT Model Verification Batch – Run the optimised process, capture PAT data, and confirm that all CQAs meet specification without end-product testing.

Recommended References *(Preferably latest edition)*:

1. Bakeev KA, editor. Process Analytical Technology: Spectroscopic Tools and Implementation Strategies for the Chemical and Pharmaceutical Industries. 2nd ed. Chichester: Wiley; 2010.
2. Rathore AS, Winkle H. Quality by Design for Biopharmaceuticals. 2nd ed. Hoboken: Wiley; 2019.
3. Kourti T, Bakeev K. Process Analytical Technology: Theory and Applications. 1st ed. Oxford: Butterworth-Heinemann; 2022.
4. Patil AS, Rane VP. Practical Implementation of Quality by Design (QbD) for Pharmaceutical Product Development. 1st ed. Amsterdam: Elsevier; 2019.

SEMESTER VII

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

COURSE OBJECTIVES:

The objectives of this course are to:

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

COURSE OUTCOMES (CO):

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

Detailed Syllabus

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

Recommended References *(Preferably latest edition)*:

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

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

COURSE OBJECTIVES:

The objectives of this course are to:

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

COURSE OUTCOMES (CO):

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

Detailed Syllabus

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

Recommended References *(Preferably latest edition)*:

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

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

COURSE OBJECTIVES:

The objectives of this course are to:

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

COURSE OUTCOMES (CO):

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

Detailed Syllabus

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

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

Recommended References *(Preferably latest edition)*:

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

Course Code	Course Title			Course Type
BP708T AEC4	**Medical Devices (Theory)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	1	--	--	15
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

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

COURSE OUTCOMES (CO):

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

Detailed Syllabus

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

V	**Biomedical Engineering; Instrumentation: Emerging Technologies** 1. Principles of biomedical sensors and transducers 2. Medical imaging techniques (X-ray, CT, MRI, ultrasound) 3. Telemedicine and remote monitoring 4. Integration of Electronics and Software in Medical Devices 5. Wearable Devices and Remote Monitoring 6. Ethical issues in device development and use	3 hours

Recommended References *(Preferably latest edition)*:

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

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

COURSE OBJECTIVES:

The objectives of this course are to:

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

COURSE OUTCOMES (CO):

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

Detailed Syllabus

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

Recommended References *(Preferably latest edition)*:

1. Ranjna Sirohi et al., 2025. Sustainable Technologies for Food Waste Management. Taylor and Francis Group.
2. Monika Thakur et al., 2020. Sustainable Food Waste Mangement: Concepts and Innovations. Ist ed., Springer.
3. Arvanitoyannis, 2013. Waste management for food industries. Food Science and Technology International series.
4. Prabhjot Kaur Sabharwal and Savitri Gupta, 2025. Handbook of Food waste and byproduct utilization. New Delhi Publishers.

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

COURSE OBJECTIVES:

The objectives of this course are to:

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

COURSE OUTCOMES (CO):

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

Detailed Syllabus

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

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

Recommended References *(Preferably latest edition)*:

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

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

COURSE OBJECTIVES:

The objectives of this course are to:

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

COURSE OUTCOMES (CO):

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

Detailed Syllabus

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

Recommended References *(Preferably latest edition)*:

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

SEMESTER VIII

Course Code	Course Title			Course Type
BP806T AEC1	**Pharmaceutical Packaging (Theory)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
2	2	--	--	30
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are:

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

COURSE OUTCOMES (CO):

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

Detailed Syllabus

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

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

Recommended References *(Preferably latest edition)*:

1. Brody, A. L., Marsh, K. S. The Wiley Encyclopedia of Packaging Technology. John Wiley & Sons, New York, USA.
2. Lachman, L., Lieberman, H. A., Kanig, J. L. The Theory and Practice of Industrial Pharmacy. Lea & Febiger, Philadelphia, USA.
3. KacChesney, T. C. Packaging of Cosmetics and Toiletries. Newness-Butterworth, London, UK.
4. Allen, L. V. Jr. Remington: The Science and Practice of Pharmacy. Mack Publishing Company, Easton, USA.
5. Bauer, E. J. Pharmaceutical Packaging Handbook. CRC Press / Informa Healthcare Ltd, USA.
6. Dean, D. A., Evans, E. R., Hall, I. H. (Eds.) Pharmaceutical Packaging Technology. CRC Press, USA.
7. Lockhart, H., Paine, F. A. Packaging of Pharmaceuticals & Healthcare Products. Chapman & Hall, UK.
8. Harburn, K. Quality Control of Packaging Materials in the Pharmaceutical Industry. CRC Press, USA.

Course Code	Course Title			Course Type
BP806T AEC2	**Supply Chain Management (Theory)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
2	2	--	--	30
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand and apply key SCM concepts and frameworks.
2. Analyze and optimize supply chain processes using industry-standard models.
3. Evaluate the impact of digital technologies and sustainability on supply chains.
4. Develop strategies for risk management and resilience in supply chains.
5. Implement best practices for procurement, logistics, and inventory management.

COURSE OUTCOMES (CO):

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

Detailed Syllabus

Unit No.	Topics	No. of Lectures
I	**Introduction to Supply Chain Management** o 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. o Supply Chain Models: SCOR Model (Plan, Source, Make, Deliver, Return) CSCMP Supply Chain Process Standards. o Supply Chain Network Design, Facility location and layout, Transportation planning. o Supply Chain Performance Metrics, Key Performance Indicators (KPIs) o Performance measurement tools o 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 for factory location, premises, plant layout and infrastructure and materials.	6 hours

II	**Fundamentals of Entrepreneurship** Characteristics and skills of successful entrepreneurs. Types of entrepreneurship: product, process, and quality testing entrepreneurship. Developing Entrepreneurial mind-set. Case studies Success Stories of some successful herbal cosmetic brands (e.g., Forest Essentials, Biotique, Khadi Naturals) **Steps involved in setting up a start-up:** • Identifying gaps in the herbal cosmetics market • Business plan development for a herbal cosmetic product • SWOT analysis for herbal cosmetics start-ups • Technical, financial, and market feasibility study • Planning for scalability and sustainability	6 hours
III	**Financial Management and Marketing Strategies** Budgeting and cost estimation. Sources of finance: loans, grants, angel investors, venture capital. Government schemes (STARTUP INDIA) and support for MSMEs and herbal industries. Overview on branding essentials positioning and brand identity. Distribution channels: retail, e-commerce, exports. Digital marketing: social media, Search Engine Optimization (SEO) influencer marketing	6 hours
IV	**Legal and Regulatory Framework** Licensing and registration for herbal cosmetics as per the Drugs and Cosmetics Act (1940) and rules (1945) of India. The role of CDSCO, AYUSH ministry, FSSAI, ISO, GMP in the herbal cosmetics industry Labelling and packaging norms (Schedule S and role of Bureau of Indian Standards –BIS) Advertising regulation for herbal cosmetics IP rights: patents, trademarks, and protection of herbal knowledge	8 hours
V	**Quality and safety evaluation of herbal cosmetics** Importance of quality assurance in herbal cosmetics. Key safety concerns (contamination, allergens, microbial growth). Quality evaluation of herbal raw material. **Product-Specific Quality Parameters -** Quality standards for creams, lotions, shampoos, oils, face packs, etc. Specific marker compounds and their quantification in herbal products. **Toxicological and Safety Evaluation:** *In vitro* and *in vivo* safety testing (skin irritation, sensitization, eye irritation). Patch testing, Draize test, and OECD 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.