भारतीय भेषजी परिषद्
(स्वास्थ्य एवं परिवार कल्याण मंत्रालय के अंतर्गत सांविधिक निकाय)
भारत सरकार
आई-300, तीसरी मंजिल, टावर-1, वर्ल्ड ट्रेड सेंटर,
नौरोजी नगर, नई दिल्ली-110029
टेलीफोन नंबर 011-65218900-01
E-mail: registrar@pci.nic.in

कामये दुःखतप्तानाम् प्राणिनामार्तिनाशनम्

PHARMACY COUNCIL OF INDIA
(Statutory body under Ministry of Health & Family Welfare)
Government of India
I-300, 3rd floor, Tower-I, World Trade Centre,
Nauroji Nagar, New Delhi-110029
Telephone No. 011-65218900-01
E-mail: registrar@pci.nic.in

Public Notice

Ref. No. 14-154/2025-PCI Date – 20.8.2025

Sub: Invite Comments on the proposed draft B.Pharm Syllabus.

Sir/Madam,

This has a reference to the subject cited above.

The PCI has framed the syllabus for B.Pharm Course, a copy of proposed draft B.Pharm syllabus is enclosed herewith as **Appendix-1**.

Kindly forward your comments on the said draft proposed Syllabus on the email ID as given below within one month i.e upto 20.9.2025.

bpharmsyllabus2025@gmail.com

The format in which comments is to be filled is attached herewith as **Appendix-2**.

It is further informed that no comments will be entertained after 20.9.2025.

Yours faithfully

(PRATIMA TIWARI)
Deputy Secretary

Appendix-1

कामये दुःखतप्तानाम् प्राणिनामार्तिनाशनम्

Pharmacy Council of India

New Delhi

Proposed Syllabus for the Bachelor of Pharmacy

[As per NEP 2020]

July 2025

PREFACE

The Bachelor of Pharmacy (General) curriculum has been designed in alignment with the vision and framework of the **National Education Policy (NEP) 2020**, integrating the core principles of pharmaceutical sciences with the evolving demands of healthcare, industry, research, and technology. Rooted in NEP's foundational pillars of access, equity, quality, affordability, and accountability, the program aims to develop graduates who are not only proficient in their chosen profession but also adaptable, ethical, and future-ready contributors to India's role as the "Pharmacy of the World."

This curriculum offers a balanced progression from foundational to advanced learning. The first four semesters focus on establishing a strong base in pharmaceutics, pharmaceutical chemistry, pharmacology, pharmacognosy, and analytical techniques, complemented by essential courses in anatomy, physiology, and healthcare psychology. The structure blends theoretical understanding with extensive practical exposure, ensuring that students can translate classroom knowledge into professional competence.

One of the distinctive strengths of this curriculum is its forward-looking inclusion of **Artificial Intelligence (AI) and Python Programming**, taught progressively from foundational concepts to advanced applications across preformulation, drug design, pharmacology, pharmacognosy, quality assurance, manufacturing, and patient care. This equips graduates with the skills to work in data-driven and technology-enabled pharmaceutical environments, positioning them for leadership in areas such as computational drug discovery, precision medicine, and intelligent manufacturing systems. The syllabus also incorporates emerging domains such as **Novel Drug Delivery Systems (NDDS), Modern Analytical Techniques, Precision Medicine, and Pharmacovigilance**, ensuring alignment with the latest advancements in research and practice.

Reflecting NEP's emphasis on **multidisciplinary learning**, the curriculum draws on diverse domains such as biotechnology, forensic sciences, law, management, engineering, statistics, nutrition, sports sciences, and nanotechnology, fostering cross-sectoral competencies. This integration enables pharmacy graduates to work effectively not only within traditional pharmaceutical roles but also in areas like pharmaco-economics, pharmaco-legal affairs, medical device development, nutraceutical formulation, and AI-enabled healthcare analytics.

Experiential learning forms the backbone of this program. Students engage in **two mandatory internships**—one in a clinical or community setting and another in an industrial or manufacturing environment—providing exposure to real-world professional challenges. A **two-semester undergraduate research project** further develops analytical thinking, innovation capacity, and problem-solving skills, encouraging contributions to industry, academia, or entrepreneurial ventures. The curriculum also integrates training in pharmaceutical management, jurisprudence, innovation, and startup ecosystems, nurturing entrepreneurial abilities and leadership qualities.

Throughout the course, equal emphasis is placed on theory and practical training. Laboratory-based learning in areas such as pharmaceutics, pharmacognosy, pharmaceutical chemistry, and analytical sciences is reinforced with case studies, simulations, and role-play exercises in healthcare communication, ethics, and patient counseling. This holistic approach ensures that graduates not only acquire technical expertise but also the interpersonal and ethical competencies essential for patient-centered care.

By blending rigorous scientific training, interdisciplinary integration, hands-on experience, and emerging technology adoption, the Bachelor of Pharmacy (General) curriculum seeks to produce **competent, compassionate, and innovative professionals** who can excel in healthcare delivery, industrial excellence, research innovation, and regulatory engagement. In doing so, it contributes to India's aspiration to emerge as a **global hub of skilled pharmaceutical manpower** during the **Amrit Kaal**, supporting the vision of **Viksit Bharat 2047** through transformative leadership and meaningful contributions to healthcare.

Index

SALIENT FEATURES

1. **Number of credits would be 191.**
2. **Flexibility to students to choose electives.**
3. **Emphasis on Experiential Learning given.**
4. **Majors and Minors, Value added courses, Skill Enhancement and Ability Enhancement courses are also included apart from other practical courses.**
5. **Two mandatory internships included.**
6. **Emphasis on Research project at UG level in two semesters.**
7. **Artificial Intelligence and similar New age Technologies are also embedded in the curriculum**

Curricular Structure

Course	Level1(Mode & Credits)		L-2 (Mode & Credits)		L-3 (Mode & Credits)		L-4 (Mode & Credits)		Total
Sem	**I**	**II**	**III**	**IV**	**V**	**VI**	**VII**	**VIII**	
MJ-1	L 3	L 3	L4	L 3	L3	L 3	L 3	L3	
	General Pharmacy	Physical Pharmaceutics	Pharmaceutical Dosage Forms	Herbal Drug Technology	Biomedical Chemistry	Pharmaceutical Quality Assurance	Biostatistics Research methodology	NDDS and Precision Medicine	
MJ-2	P 1	P 1	P2	P1	P2	P 1		P1	
	General Pharmacy	Physical Pharmaceutics	Pharmaceutical Dosage Forms	Herbal Drug Technology	Biomedical Chemistry		—-	NDDS and Precision Medicine	
MJ-3	L 3	L 3	L 3	L 3	L 3		L3		
	Pharmaceutical Inorganic and Analytical Chemistry	Biochemistry	Heterocyclic Compounds and Stereochemistry	Medicinal Chemistry	Pharmaceutical Analysis	—-	Modern analytical techniques		
MJ-4	P1	P 1	P2	P1	P 2		P1		

	Pharmaceutical Inorganic and Analytical Chemistry	Biochemistry	Heterocyclic Compounds and Stereochemistry	Medicinal Chemistry	Pharmaceutical Analysis	—-	Modern analytical techniques	—-	
	L 4	L 4	L 3	L3	L3		L3	--	
MJ-5	Human Anatomy, Physiology and Pathophysiology I	Human Anatomy, Physiology and Pathophysiology 2	General Pharmacology	Systemic Pharmacology and Autacoids	Systemic Pharmacology and Chemotherapy	—-	Pharmacovigilance	—-	
	P 1	P 1	P2	P1	P2		L3	--	
MJ-6	Human Anatomy, Physiology and Pathophysiology	Human Anatomy, Physiology and Pathophysiology 2	General Pharmacology	Systemic Pharmacology and Autacoids	Systemic Pharmacology and Chemotherapy	—-	Pharmacy Practice	—-	
	L 3	L 3			L 3	L3			

MJ-7	Introduction To Pharmacognosy	Pharmacognosy And Phytochemistry	—--	—--	Industrial Pharmacognosy	Advanced Pharmacognosy	—-	—-	
	P1	P1			P2	L3			
MJ-8	Introduction To Pharmacognosy	Pharmacognosy And Phytochemistry	—-	—-	Industrial Pharmacognosy	Biopharmaceutics and Pharmaco-kinetics	—-	—-	
						P1		L3	
MJ-9						Biopharmaceutics and Pharmaco-kinetics		Industrial Pharmacy & Facility Design	
		L2	L2	L2		L2	L2		
MN-1	—--	Pharmaceutical Organic Chemistry	Pharmaceutical Microbiology	Pharmaceutical Biotechnology	—-	Intellectual Property Rights	Regulatory Affairs		
MN-2		P1	L1	P 1				L2	

	—-	Pharmaceutical Organic Chemistry	Environmental Science	Pharmaceutical Biotechnology	—-	—-	—-	Clinical Pharmacotherapeutics	
	L2	L2	L2	L2	L2	L2	L2	L2	
MN-3	AI & Python Programming for Pharmacy I	AI & Python Programming for Pharmacy II	AI in preformulation & formulation	AI in Drug Design, Discovery & Bioinformatics	AI in Pharmacology & Drug Safety	ML in Pharmacognosy & Biotechnology	Intelligent Manufacturing & Smart QA in Pharmacy	AI in Pharmacy Practice & Patient Care	
			L2						
MN-4			Pharmaceutical Engineering						
MD - 1	L1		L1	L2	L2	L3	L2	L 2	
	Healthcare Psychology and Communication Skills		Ethics and Universal Human Values	Social Pharmacy & Public Health	Innovation And Startup Ecosystem	Pharmaceutical Jurisprudence	Cosmetics and Cosmeceuticals	Pharmaceutical Management	
	P1	—-	—-	P1	—-	—-	—-	P1	

MD2	Healthcare Psychology and Communication Skills	—-	—-	Social Pharmacy & Public Health	—-	—-	—-	Pharmaceutical marketing Skills	
AEC	—-	—-	P1	—-		L 1	L 1	L 2	
	—-		Elective 2	—-		Elective 3	Elective 6	Elective 7	
SEC	—-	P1		—-		P 1	—-	—-	
	—-	Elective 1	—-	—-	—-	Elective 4	—-	—-	
VAC	—-	—-	—-	—-	—-	P 1	—-	P1	
		—-	—-	—-	—-	Elective 5	—-	Elective 8	
Internship	----	----	----	**Internship (Mandatory) 4**	----	**Internship (Mandatory) 4**	----	----	
Research	—-	—-	—-	—-	—-	—-	Research Project 6	Research Project 6	
Total Credits	**21**	**23**	**23**	**24**	**24**	**24**	**26**	**24**	**191**

SEMESTER I

GENERAL PHARMACY

Total Credits 3 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES:

The objective of this course is to lay a foundation for the understanding and learning of Advanced Pharmaceutical technology courses in the successive years of the B.Pharmacy program. During this course, the students should be able to understand the fundamentals and concepts of:

1. Evolution and development of Pharmacy profession in Ind ia and the growth of the Pharmaceutical Industries over the years.
2. Role of Pharmacopoeias and other official books in maintaining the standards of medicines.
3. Responsibilities of Pharmacist in various domains of pharmacy
4. The role as hospital pharmacist in communicating with healthcare professionals and patients effectively.
5. The basic pharmaceutical calculations used in dispensing and compounding.
6. Role of active pharmaceutical ingredients and pharmaceutical excipients in drug formulations
7. Basics knowledge about formulation and preparation of various solid, liquid and semisolid dosage forms

COURSE OUTCOMES:

Upon completion of this course, the students will 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.

COURSE CONTENTS

UNIT – 1

Introduction to Profession of Pharmacy **09 Hours**

- **History of the Profession of Pharmacy in India, in relation to Pharmacy Education, Pharmaceutical Industries and Organizations:** **02 Hours**

  Evolution, Development and Milestones

- **Scope of Pharmacy Profession:** **02 Hours**

  Role and Responsibilities of Pharmacist in –Retail/ Community Pharmacy, Hospital and Clinical Pharmacy, and Industrial Pharmacy including research and development

- **Pharmacopoeias:** **03 Hours**

  Introduction to IP, BP, USP, BPC, International Pharmacopoeia, Other pharmacopeia Pharmacopoeia and National Formulary of India, Structure and Content of IP, Study of one model IP monograph

- **Prescription** **02 Hours**

  Structure and Format/ Parts of Prescription, Handling of Prescription,

  Latin Terminology related to prescription

UNIT – II

Pharmaceutical Calculations and Dosage Forms **09 Hours**

- **Pharmaceutical Calculations:** **03 Hours**

  Metric System of Weights and Measures, Understanding of Calculations based on Alligation, Proof Spirit, Isotonic Solutions, Dilute Solutions (percentage and ratio), and Geometric Dilution. Scientific notations of units and measures.

- **Posology:** **02 Hours**

  Definition and Dose Calculation based on Age, Body Weight, and Body Surface Area.

- **Introduction to Dosage Forms** **04 Hours**

  Introduction to Routes of administration**,** Classification of Dosage Forms.

  Introduction to Active Pharmaceutical Ingredient and Excipients: Definition, Ideal Characteristics and Importance.

UNIT – III

Solid Dosage Forms **09 Hours**

- **Powders:** **02 Hours**

  Classification, Advantages & Disadvantages, Study of Official Preparations – Dusting Powders, Effervescent Powders, Efflorescent Powders, Hygroscopic Powders, and Eutectic Mixtures

- **Tablets:** **04 Hours**

  Definition, Types of Tablets including moulded Tablets and pills with Examples, Advantages and Disadvantages. Brief introduction to methods of preparation.

- **Capsules** **03 Hours**

  Definition, Types of Capsules, Advantages and Disadvantages, Capsule sizes.
  Brief introduction to methods of preparation.

UNIT – IV

Liquid Dosage Forms **09 Hours**

- **Monophasic Liquids:** **05 Hours**

  For internal use: Definition and Preparation of Aromatic Waters, Syrups, Elixirs, Linctus
  For external Use and body cavities: Liniments, Lotions, Throat Paints, applications, Gargles, Mouthwashes, Enemas, eye drops, ear drops, Nasal drops, tinctures with Examples

- **Biphasic Liquids**

a) Suspensions: **02 Hours**

Definition and Types (Flocculated & deflocculated), Advantages and Disadvantages, Formulation Excipients, General Method of Preparation

b) Emulsions: **02 Hours**

Definition and Types, Emulsifying Agents, Test for identification of types of Emulsion, General Methods of Preparation.

UNIT – V

Semisolid Dosage Forms and Suppositories **09 Hours**

- **Semisolid Dosage Forms:** **05 Hours**

  Definitions, Classification, Advantages & disadvantages, Ointment Bases and other excipients used in Semi-Solid Dosage Forms, General Methods of Preparation of Ointments, Pastes, Creams, and Gels

- **Suppositories/Pessaries** **04 Hours**

  Definition, Types of Suppositories, Advantages and Disadvantages, Formulation Excipients used in Suppositories, Properties of Ideal Suppository Bases, Types of Suppository Bases, Displacement value, General Method of Preparation

RECOMMENDED BOOKS:

1. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and Walkins, New Delhi, 9th edition, Wolters Kluwer (India) Pvt. Ltd. New Delhi
2. Carter S.J., Cooper and Gunn's-Dispensing for Pharmaceutical Students, CBS publishers, 12th edition
3. M.E. Aulton, Pharmaceutics, The Science& Dosage Form Design, Churchill Livingstone, Edinburgh, 2nd edition
4. Khar,R.K.,et al., Lachman/ lieberman's The Theory and Practice of Industrial Pharmacy, CBS publishers, 4thedition
5. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, CBS Publishers, 6th edition
6. E.A. Rawlins, Bentley's Textbook of Pharmaceutics, English Language Book Society, Elsevier Health Sciences, USA., 8th edition
7. Goel H, KalraV,Tiwary AK, Fundamentals of Pharmaceutics and dispensing Pharmacy Theory with Practical Applications, Pharma Med Press, 1st edition
8. Introduction to Pharmaceutics, Gupta, A.K., CBS Publishers and distributors, 2nd edition
9. Modern Dispensing Pharmacy, Jain, N.K., Gupta G.D., Pharma Book Syndicate, 1st edition

PHARMACEUTICAL INORGANIC AND ANALYTICAL CHEMISTRY-THEORY

Total Credits 3 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

1. Understand the pharmaceutical importance of inorganic compounds
2. Comprehend the principles of volumetric analysis
3. Develop practical skills in performing and interpreting limit tests and analytical tests.
4. Emphasize the importance of radiopharmaceuticals in Pharmacy
5. Analyze inorganic compounds products by different volumetric methods

COURSE OUTCOMES

Upon completion of the course the students shall be able to:

1. Identify sources and types of errors in pharmaceutical analysis, and impurities products
2. Describe and differentiate various analytical techniques used in pharmaceutical analysis, including titrimetric methods, and their specific applications in quality assessment.
3. Apply concepts of acid-base chemistry, buffer systems with importance of electrolytes
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.

COURSE CONTENTS

For compounds marked with an asterisk (*), study the general methods of preparation, properties, assay procedures, and medicinal uses. For compounds without an asterisk, study their formula and medicinal uses.

UNIT-I **07 hours**

1. **Introduction to pharmaceutical analysis:** Different techniques of analysis, Methods of expressing strength of solutions, Primary and secondary standards with examples.
2. **Errors:** Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures.
3. **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.

UNIT-II **08 hours**

1. **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.
2. **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.

UNIT-III **14 hours**

Principles and applications of the following titrimetric methods of analysis:

1. **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.
2. **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.
3. **Precipitation titrations and gravimetry**: Mohr's method, Volhard's, Modified Volhard's, Fajans method. Estimation of barium sulphate by gravimetry.
4. **Complexometric titrations**: Classification, metal ion indicators, masking and demasking reagents, preparation and standardization of disodium EDTA. Estimation of Magnesium sulphate and Calcium gluconate*.
5. **Redox titrations:** Concepts of oxidation and reduction, Types of redox titrations *viz*. Permanganometry, Cerimetry, Iodimetry, Iodometry and titrations with potassium iodate.

UNIT-IV **10 hours**

1. **Gastro intestinal agents**
   a. **Acidifiers:** Sodium acid phosphate and Dilute Hydrochloric acid
   b. **Antacids:** Ideal properties of antacids, combinations of antacids, Sodium bicarbonate*, Aluminium hydroxide gel*
   c. **Agents promote bowl movements:** Magnesium hydroxide, Sodium orthophosphate, Sodium Potassium tartrate
   d. **Antimicrobials:** Mechanism, classification, Potassium permanganate, Boric acid, Hydrogen peroxide*, Chlorinated lime*, Iodine and its preparations
2. **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.

UNIT-V **06 hours**

Miscellaneous Compounds

1. **Expectorants:** Potassium iodide, Ammonium chloride*.
2. **Emetics:** Copper sulphate*, Sodium potassium tartrate
3. **Haematinics:** Ferrous sulphate*, Ferrous gluconate
4. **Poison and Antidote:** Definition, classification of antidotes, Sodium thiosulphate, Activated charcoal, Sodium nitrite
5. **Astringents:** Zinc Sulphate, Aluminium sulphate

RECOMMENDED BOOKS:

1. Vogel's Text Book of Quantitative Chemical Analysis. Pearson Education Limited, Essex, England
2. Block JH. Inorganic, Medicinal and Pharmaceutical Chemistry. Philadelphia: Lea & Febige.
3. Beckett AH, Stenlake JB. Practical Pharmaceutical Chemistry. Part I & II London: Stahlone Press, University of London.
4. Indian Pharmacopoeia. Indian Pharmacopoeia Commission, Ghaziabad.

HUMAN ANATOMY, PHYSIOLOGY AND PATHOPHYSIOLOGY I - THEORY

Total Credits 4 **Hours / Week: 4** **60 HR**

Scope: This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also imparts a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic pathophysiological mechanisms.

COURSE OBJECTIVES

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

Upon completion of this course the student should be able to:

- Explain the gross morphology, structure and functions of various organs of the human body.
- Understand the etiology and pathogenesis of diseases/disorders associated with integumentary system, peripheral nervous system and cardiovascular system
- Understand the basic mechanism behind inflammation
- Identify and differentiate the various tissues and organs of different systems of human body.

COURSE CONTENTS

Unit I **12 hours**

a) 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, 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

b) 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.

Unit II **12 hours**

a) Integumentary system and wound healing

Structure and functions of skin. Skin disorders and pathophysiology of Leprosy. Basic principles of wound healing.

b) 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.

c) Diseases of bones and joints

Pathophysiology of rheumatoid arthritis, osteoporosis and gout.

Unit III **12 hours**

a) 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 circulation and functions of lymphatic system.

b) Basic mechanism of inflammation and repair

Introduction, classification and symptoms of inflammation, mechanisms of inflammation, mediators of inflammation and pathophysiology of inflammation.

c) Haematological diseases

Pathophysiology of iron deficiency, megaloblastic anaemia (Vit B12 and folic acid), sickle cell anaemia, Thalassemia, hereditary acquired anaemia and haemophilia. Nutritional defficiency, defective fabrication, hemolysis and blood loss, heredity

Unit IV **12 hours**

a) 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.

b) Special senses

Structure and functions of eye, ear, nose and tongue. Pathophysiology of special sense disorders- Glaucoma, cataract, myopia, otitis externa, otitis media , vertigo and anosmia

Unit V **12 hours**

a) 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.

b) Pathophysiology of hypertension, congestive heart failure, ischemic heart disease (angina, myocardial infarction, atherosclerosis and arteriosclerosis).

RECOMMENDED BOOKS:

a) For Anatomy and Physiology (Latest Editions):

1. Ross and Wilson Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
2. Principles of Anatomy and Physiology by Tortora, Grabowski. Palmetto, GA, U.S.A.
3. Textbook of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
4. Human Physiology (vol 1 and 2) by Dr. C. C. Chatterjee, Academic Publishers Kolkata

b) For Pathophysiology (Latest Editions Only):

1. Textbook of pathology by Harsh Mohan Pathophysiology of Disease – Jaypee publisher.
2. Pathophysiology - Concepts of Altered HealthScience By Carol Matson Porth (Lippincott Williams &Wilkins)
3. Pathophysiology – Principles of disease by Marhta J. Miller

FURTHER READINGS:

1. Anatomy and Physiology in Health and Illness by Kathleen J.W. Silson
2. Introduction to Human Disease by Thomos H.Kent, Michael N. Hart
3. Cotran RS, Kumar V, Collins T., Robbins. Pathologic basis of disease, WB Saunders.
4. Green RJ, Harris ND, Pathology andTherapeutics for Pharmacist: A basis for clinical Pharmacy Practices, Chapman and Hall Publication.
5. Roger Walker and Cate Whittlesea, Clinical Pharmacy and Therapeutics, Churchill Churchill Livingstone (Elsevier) Publication.
6. Joseph T. Dipiro, Pharmacotherapy: A Patho-Physiological Approach, Appleton Lange.
7. Harrison's Principles of Internal Medicine, McGraw Hill Publication, 21st Edition, Joseph Loscalzo, Anthony S. Fauci, Dennis L. Kasper, Stephen L. Hauser, Dan L. Longo, J. Larry Jameson.
8. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co Riverview, MI, USA.
9. Anatomy and Physiology in Health and Illness byKathleen J.W. Wilson.

INTRODUCTION TO PHARMACOGNOSY - THEORY

Total Credits 3 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

1. To explain the origin, history, and classification of natural drugs.

2. To understand cultivation and conservation methods for medicinal plants.

3. To study quality control and evaluation of crude drugs.

4. To introduce traditional systems of medicine and phytotherapeutic agents.

COURSE OUTCOMES

After completion of the 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.

COURSE CONTENTS

UNIT-I **10 Hours**

Fundamentals of Pharmacognosy:

(a) Definition, history, present status, scope and development of Pharmacognosy

(b) Sources of Drugs–Plants, Animals, Microbial, Marine, Mineral, Plant tissue culture

(c) Historical milestone in drug discovery: Morphine, quinine, aspirin, warfarin, penicillin, cephalosporin, taxol, artemisinin

(d) Introduction to different herbal/ traditional Pharmacopoeias: Indian Pharmacopoeia, British Herbal Pharmacopoeia, United States Pharmacopoeia Herbal Medicine and Dietary Supplement, Ayurvedic Pharmacopoeia of India, Unani Pharmacopoeia of India, American herbal Pharmacopoeia

(e) Official/ non-official; codified / non-codified drugs Classification of Crude Drugs: Alphabetical, morphological, taxonomical, chemical, pharmacological and chemotaxonomic classification of crude drugs along with their merits and limitations

Classification of Crude Drugs:

Alphabetical, morphological, taxonomical, chemical, pharmacological and chemotaxonomic classification of crude drugs along with their merits and limitations

UNIT-II **8 Hours**

Cultivation, Collection, Processing and Storage of drugs of natural origin:

Methods of plant cultivation and Good agricultural/ 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 chiraita.

UNIT-III

Quality control of Drugs of Natural Origin: **10 Hours**

Adulteration of drugs of natural origin. Evaluation of drugs using organoleptic, microscopic, physical, chemical and biological methods.

Physicochemical: Extractive value(s), moisture content, foreign organic matter, ash value(s), bitterness value, foaming index, heamolytic potential, swelling index, viscosity, optical rotation, refractive index, acid value, saponification value etc. DNA barcoding and WHO guidelines for quality control of crude drugs and medicinal plants.

UNIT-IV **12 Hours**

Introduction to metabolites of plant origin:

Definition, classification, properties and test for identification of primary and secondary metabolites such as carbohydrates, proteins, lipids, alkaloids, glycosides, flavonoids, tannins, terpenoids, volatile oil and resins. Traditional systems of medicine Basic Principles of treatment of diseases in different systems of medicine of Ayush and TCM, Types of dosage forms in Ayush medicines, Role of Pharmacognosy in allopathy and traditional systems of medicine viz, Ayush and TCM.

UNIT-V **05 Hours**

Phyto-therapeutic agents:

Biological source, major constituents and uses of following class of drugs: Adaptogens & Immunomodulators: Ashwagandha, Tulsi, Giloe; Hepatoprotectives: Milk thistle, Kutki, Bhui Amla; Cardiovascular drugs: Digitalis, Garlic and Arjuna; Antidiabetics: Gymnema, Pterocarpus, Curry leaves and Fenugreek; Anti-inflammatory & analgesics: Turmeric, Boswellia, and Ginger; CNS drugs: Brahmi, Gotu kola, and Ashwagandha; Antimicrobial & Antivirals: Neem, Andrographis; Gastrointestinal drugs: Psyllium, Licorice, umbelliferous fruits, Mint, Mangosteen, ; Dermatological agents Aloe, Calendula, and Tea tree oil; Drugs used in Women's health: Chasteberry, Shatavari, and Ashoka; Respiratory drugs: Vasaka, Tylophora, and Banafsha; Urogenital and nephroprotective drugs: Gokharu, Punarnava, and seeds of Cucumis, chicory; Drugs for Metabolic disorders: Fenugreek, Gymnema, Ginseng, Omega 3 and 6 acids.

Recommended Books:(Latest Editions)

1. Evans, W.C. Trease and Evans Pharmacognosy, 16th Edition, W.B. Saunders & ; Co., 30 London, 2009.
2. Tyler, V.E., Brady, L.R., and Robbers, J.E. Pharmacognosy, 9th Edition, Lea & Febiger, Philadelphia, 1988.
3. Wallis, T.E. Textbook of Pharmacognosy.
4. Ali, Mohammad. Pharmacognosy and Phytochemistry, CBS Publishers & Distributors, New Delhi.
5. Ahmad S, Introduction to Pharmacognosy, Dreamtech Press, New Delhi, 2 nd Edition, 20019
6. Kalia, A.N. Pharmacognosy and Phytochemistry – I, CBS Publishers & Distributors, New Delhi.
7. Kokate, C.K., Purohit, A.P., and Gokhale, S.B. Textbook of Pharmacognosy, 37th Edition (2007), Nirali Prakashan, Pune.
8. Jalalpure, Sunil S. and Patil, Akshay K. Textbook of Pharmacognosy and Phytochemistry – I, Nirali Prakashan, Pune, 2024.
10. Ansari, S.H. Essentials of Pharmacognosy, 2nd Edition, Birla Publications, New Delhi,2007.
11. Iyengar, M.A. Anatomy of Crude Drugs.

HEALTHCARE PSYCHOLOGY AND COMMUNICATION SKILLS - THEORY

Total Credits 1 **Hours / Week: 1** **15 HR**

COURSE OBJECTIVES

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

COURSE OUTCOMES

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.

COURSE CONTENTS

Unit I: Introduction to Psychology in Healthcare **3 Hours**

- Definition, scope, and relevance of psychology in health sciences
- Branches of psychology with healthcare relevance: clinical, health, behavioural, developmental
- Sensation, perception, and attention in clinical assessment
- Learning and memory: reinforcement in health behaviour change
- Emotion and motivation: theories and implications in health contexts

Unit II: Developmental and Behavioural Psychology **3 Hours**

- Human development stages and healthcare needs
- Personality theories and patient interaction styles
- Psychological factors affecting illness perception and recovery
- Common psychological disorders in healthcare: anxiety, depression, somatization
- Coping strategies, resilience, and stress management techniques

Unit III: Foundations of Health Communication **3 Hours**

- Elements and models of communication in healthcare
- Types: interpersonal, group, mass, telehealth
- Barriers to effective communication in clinical settings
- Active listening, questioning techniques, and empathy
- Culturally appropriate and inclusive communication

Unit IV: Professional Communication in Healthcare Settings **3 Hours**

- Communicating with patients, caregivers, and interdisciplinary teams
- Delivering difficult news, 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 health services

Unit V: Health Psychology and Behavioural Interventions **3 Hours**

- Health belief models and illness behaviour
- Psychosomatic illnesses and 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

AI & PYTHON PROGRAMMING FOR PHARMACY – I - THEORY

Total Credits 2 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

1. Introduce foundational concepts of Artificial Intelligence and Machine Learning so students grasp the historical context, core approaches, and common problem-solving paradigms.
2. Explain key learning paradigms (supervised, unsupervised, reinforcement) and representative algorithms-Naive Bayes, KNN, regression models, clustering techniques, and basic neural networks-to build analytical intuition.
3. Demonstrate real-world applications of AI/ML across the pharmaceutical value chain, highlighting contemporary research avenues in drug discovery, formulation, quality assurance, and personalized medicine.
4. Develop practical Python programming skills-from installation and scripting fundamentals to control structures, data types, collections, functions, and basic file/exception handling-enabling students to implement AI/ML workflows.
5. Cultivate problem-solving and critical-thinking abilities by integrating AI/ML algorithms with Python to tackle pharmacy-relevant case studies, fostering readiness for advanced study or industry projects.

COURSE OUTCOMES

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

1. Describe the evolution, key approaches, and knowledge-representation methods of AI.
2. Differentiate and choose appropriate ML paradigms (supervised, unsupervised, reinforcement) and implement basic algorithms
3. Analyze pharmaceutical case studies and justify AI/ML techniques that improve efficiency in drug development, manufacturing, or pharmacovigilance
4. Write well-structured Python programs employing variables, control flow, collections, functions, and file/exception handling to solve defined tasks.
5. Integrate AI/ML algorithms with Python to design and execute a mini-project addressing a real pharmacy challenge, and interpret the results critically

COURSE CONTENTS

Unit 1 – Foundations of Artificial Intelligence **4 Hours**

- History of AI

- Major approaches to AI (symbolic, statistical, connectionist, evolutionary, hybrid, etc.)
- AI problem-solving paradigms
- Knowledge representation techniques
- Reasoning under uncertainty
- Decision-making strategies

Unit 2 – Machine-Learning Essentials **7 Hours**

- Learning paradigms:
  - Supervised learning
  - Unsupervised learning
  - Reinforcement learning
- Core algorithms and where they fit:
  - Naïve Bayes
  - k-Nearest Neighbours (KNN)
  - Linear & logistic regression
  - Clustering algorithms (e.g., k-means, hierarchical)
  - Neural networks (basic feed-forward concepts)

Unit 3 – AI/ML in Pharmaceutical Sciences **4 Hours**

- Industrial applications of AI/ML in the pharmaceutical sector (formulation, process optimisation, quality control, supply-chain analytics, pharmacovigilance, etc.)
- Research avenues of AI/ML in pharmacy (drug discovery, QSAR/QSPR, clinical trial design, personalised medicine, regulatory science, real-world evidence, etc.)

Unit 4 – Python Setup and Language Basics **8 Hours**

- Why Python for AI/ML and scientific computing
- Installing Python and choosing an IDE (IDLE, VS Code, PyCharm, Jupyter, etc.)
- Writing and running your first Python script
- Core syntax rules: indentation, comments
- Declaring and using variables
- Built-in data types (int, float, str, bool)
- Type casting and the type() function

Unit 5 – Python Programming Constructs & Data Handling **7 Hours**

- Operators and expressions
    - Arithmetic and assignment operators
    - Comparison and logical operators
- Conditional statements
    - if, elif, else
    - Nested conditions and typical use cases
- Looping constructs
    - for loops with range()
    - while loops
    - Loop controls: break, continue, pass
    - Iterating through strings and lists
- Core collections
    - Creating, accessing, and modifying lists
    - List methods and slicing
    - Tuples and immutability
    - Iterating over collections
- Functions: defining, calling, returning values
- File handling basics (open, read, write, close)
- Exception handling (try–except–finally)

RECOMMENDED BOOKS

1. For depth on core concepts, start with Artificial Intelligence: A Modern Approach by Russell & Norvig (4th ed., 2021).
2. Ethem Alpaydin's Introduction to Machine Learning (4th ed., 2020) adds a concise, mathematically grounded view of supervised, unsupervised, and reinforcement methods.
3. To get hands-on, Aurélien Géron's Hands-On Machine Learning with Scikit-Learn, Keras & TensorFlow (3rd ed., 2022) walks you through coding every major algorithm in Python.
4. Pair that with Eric Matthes' Python Crash Course (3rd ed., 2023) for a brisk but thorough introduction to the language itself.
5. Finally, Nathan Brown's Artificial Intelligence in Drug Discovery (2020) shows how AI/ML directly accelerates target identification, lead optimization, and formulation within the pharmaceutical arena.

GENERAL PHARMACY - PRACTICALS

Total Credits 1 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES:

Upon completion of this course, the students will able:

1. To familiarize students with simple pharmaceutical calculations like dilution, concentration, and allegation techniques.
2. To impart practical training on the preparation of various dosage forms like monophasic, biphasic, solid, semisolid, and paediatric preparations.
3. To make students understand pharmacopeial requirements and implement them in preparation of pharmaceutical products.
4. To cultivate the skill to analyze formulation ingredients and achieve stability, safety, and therapeutic efficacy.
5. To encourage awareness of principles of formulation design, patient compliance, and product assessment.

COURSE OUTCOMES:

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

1. Perform accurate pharmaceutical calculations using the principles of dilution and allegation.
2. Prepare monophasic dosage forms - including solutions, syrups, linctuses, and elixirs - according to official pharmacopeial techniques.
3. Formulate and evaluate biphasic preparations (suspensions and emulsions), considering methods of preparation, stability factors, and clinical applications.
4. Develop, test, and optimize solid dosage forms such as powders, granules, and suppositories for their intended therapeutic use.
5. Design and produce semisolid systems (ointments, liniments, paints) and specialized patient-friendly liquids (mouthwashes, gargles, paediatric elixirs), selecting appropriate excipients and ensuring accurate dosing and patient compliance.

COURSE CONTENTS

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 & USP**
b) Compound syrup of Ferrous Phosphate – **BPC**

4. LINCTUS

a) Terpin Hydrate Linctus – **IP**

5. ELIXIRS

a) Piperazine citrate elixir – **BPC**
b) Paracetamol paediatric elixir – **IP**

6. THROAT PAINT

a) Iodine Throat Paint (Mandl's Paint) – **BPC**

7. SUSPENSIONS

a) Calamine lotion – **IP**
b) Magnesium Hydroxide mixture – **IP**
c) Aluminium Hydroxide gel – **IP**

8. EMULSIONS

a) Castor oil emulsion – **IP**
b) Liquid paraffin emulsion – **IP**
c) Turpentine liniment – **IP**

9. POWDERS & GRANULES

a) ORS powder – **WHO**
b) Effervescent granules – **IP**
c) Dusting powder – **IP**

d) Divided powders – **IP**

10. SUPPOSITORIES

a) Glycerogelatin suppository – **BPC**
b) Cocoa butter suppository – **IP**
c) Zinc Oxide suppository – **IP**

11. SEMISOLIDS

a) Sulphur ointment – **IP**
b) Non-staining iodine ointment with methyl salicylate – **BPC**

12. 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 from different Units must be performed

RECOMMENDED BOOKS

1. Practical pharmaceutics, Gaud, R.S., Gupta G.D., CBS Publishers and Distributors, 2nd edition
2. Subrahmanyam CVS, J. Thimma Setty, G.L. PrabhuShankar, Laboratory Manual of Pharmaceutics, Vallabh Prakashan, Delhi, 1st edition
3. Goel H, KalraV, Tiwary AK, Fundamentals of Pharmaceutics and dispensing Pharmacy Theory with Practical Applications, Pharma Med Press, 1st edition
4. **Cooper and Gunn's Dispensing for Pharmaceutical Students** – S.J. Carter, *CBS Publishers, 12th edition*
5. Indian Pharmacopoeia (IP), Volume I
6. United States Pharmacopoeia – National Formulary (USP–NF)
7. British Pharmacopoeia Codex (BPC)
8. World Health Organization (WHO) ORS Formulary / Guidelines

PHARMACEUTICAL INORGANIC AND ANALYTICAL CHEMISTRY - PRACTICALS

Total Credits 1 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

1. Gain practical knowledge on various volumetric titrations 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

Upon completion of the course the student shall 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..

CONTENTS OF COURSE

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 aluminium 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 BOOKS (LATEST EDITIONS)

1. Bentley and Driver's Textbook of Pharmaceutical Chemistry. Oxford University Press, Oxford, UK
2. Vogel's Text Book of Quantitative Chemical Analysis. Pearson Education Limited, Essex, England
3. Block JH. Inorganic, Medicinal and Pharmaceutical Chemistry. Philadelphia: Lea & Febige.
4. Beckett AH, Stenlake JB. Practical Pharmaceutical Chemistry. Part I & II London: Stahlone Press, University of London.
5. Kennedy JH. Analytical Chemistry: Principles. Saunders College Publishing. NewYork.
6. Schroff ML. Inorganic Pharmaceutical Chemistry: Oxford Book Company. Delhi
7. Indian Pharmacopoeia. Indian Pharmacopoeia Commission, Ghaziabad.
8. Anand & Chatwal, Inorganic Pharmaceutical Chemistry
9. P. Gundu Rao, Inorganic Pharmaceutical Chemistry,

HUMAN ANATOMY, PHYSIOLOGY AND PATHOPHYSIOLOGY – I - PRACTICALS

Total Credits 1 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES:

1. To provide fundamental knowledge of the structure and functions of various organ systems of the human body.
2. To help students understand the mechanisms of homeostasis and their role in maintaining normal physiological functions.
3. To introduce the basic concepts of pathophysiology and the causes of diseases affecting different organ systems.
4. To explain the body's physiological responses to disease-producing agents.
5. To lay the foundation for understanding clinical conditions through the study of functional alterations in organs and systems.

COURSE OUTCOMES:

Upon completion of this course the student should be able to:

1. Describe the principles and applications of various microscopy techniques.
2. Explain the gross morphology, structure, and functions of major organs and organ systems of the human body.
3. Estimate key hematological parameters and explain the mechanisms of homeostasis and related disorders.
4. Discuss the etiology and pathogenesis of selected disease states.
5. Identify the signs, symptoms, risk factors, diagnostic methods, preventive measures, treatment strategies, and complications of common diseases.
6. Explain the coordinated functioning of different organs within each physiological system.
7. Perform experiments related to the nervous system and special senses.

COURSE CONTENTS:

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 microscope.

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. Enumeration of white blood cell (WBC) count, differential count.

8. Enumeration of total red blood corpuscles (RBC) count

9. Determination of bleeding time and clotting time

10. Estimation of hemoglobin content

11. Determination of blood group.

12. Determination of erythrocyte sedimentation rate (ESR).

13. Determination of pulse rate, heart rate and blood pressure.

14. To study the cardiovascular system and integumentary system.

15. Case studies/files of patients with anaemia, thalassemia, haemophilia, leprosy, gout, hypertension, angina, and ischemic heart disease.

Recommended Books (Latest Editions)

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,Riverview,MI USA
4. Text book of Medical Physiology- Arthur C,Guyton andJohn.E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
6. Textbook of Human Histology by Inderbir Singh, Jaypee brother's medical publishers, New Delhi.
7. Laurence B, Bruce C, Bjorn K. ; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12th edition; New York; McGraw-Hill; 2011.
8. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston;Davidson's Principles and Practice of Medicine; 21st edition; London; ELBS/Churchill Livingstone; 2010.
9. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia; WB Saunders Company; 1997

10. Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins &Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier; 2014
11. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother's medical publishers,New Delhi.
12. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

Reference Books (Latest Editions)

1. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje ,Academic Publishers Kolkata

INTRODUCTION TO PHARMACOGNOSY - PRACTICALS

Total Credits 1 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

1. To develop skills in identifying crude drugs using microscopy.
2. To train students to perform chemical tests for phytoconstituents.
3. To enable analysis of physicochemical parameters of crude drugs.
4. To provide experience in collection and identification of medicinal plants.
5. To introduce standardization and quality control of herbal materials.

COURSE OUTCOMES

After completion of the course, the students will be able to:

1. Identify crude drugs using transverse section microscopy.
2. Perform chemical tests to detect key phytoconstituents.
3. Analyze physicochemical parameters of crude drugs.
4. Collect and identify medicinal plants and prepare voucher specimens.
5. Apply pharmacognostic knowledge for herbal drug standardization.

COURSE CONTENTS:

1. Transverse section for microscopic studies of Clove, Fennel, Cinnamon, Ginger, Giloe, and Senna.
2. Chemical tests for identification of carbohydrates, proteins, lipids, alkaloids, anthraquinones, cardiac glycosides, flavonoids, and tannins. Terpenoids
3. Determination of loss on drying, ash values, extractive value(s), moisture content, foreign organic matter, bitterness value, foaming index, swelling index, viscosity, optical rotation, refractive index, acid value, and saponification value.
4. Experiential learning-based experiments involving collection, identification of medicinal plant material, preparation of voucher specimens and excursion visits to medicinal plant garden.

RECOMMENDED BOOKS :(LATEST EDITIONS)

1. Evans, W.C. Trease and Evans Pharmacognosy, 16th Edition, W.B. Saunders & Co., London, 2009.

2. Tyler, V.E., Brady, L.R., and Robbers, J.E. Pharmacognosy, 9th Edition, Lea & Febiger, Philadelphia, 1988.

3. Wallis, T.E. Textbook of Pharmacognosy.

4. Ali, Mohammad. Pharmacognosy and Phytochemistry, CBS Publishers & Distributors, New Delhi.

5. Ahmad S, Introduction to Pharmacognosy, Dreamtech Press, New Delhi, 2nd Edition, 20019

6. Kalia, A.N. Pharmacognosy and Phytochemistry – I, CBS Publishers & Distributors, New Delhi.

7. Kokate, C.K., Purohit, A.P., and Gokhale, S.B. Textbook of Pharmacognosy, 37th Edition (2007), Nirali Prakashan, Pune.

8. Jalalpure, Sunil S. and Patil, Akshay K. Textbook of Pharmacognosy and Phytochemistry – I, Nirali Prakashan, Pune, 2024.

9. Ansari, S.H. Essentials of Pharmacognosy, 2nd Edition, Birla Publications, New Delhi, 2007.

10. Iyengar, M.A. Anatomy of Crude Drugs.

11. Khandelwal, K.R. and Sethi, Vrinda. Practical Pharmacognosy.

12. Kokate, C.K., Purohit, A.P., and Gokhale, S.B. Practical Pharmacognosy, Nirali Prakashan, Pune.

HEALTHCARE PSYCHOLOGY AND COMMUNICATION SKILLS

Total Credits 1 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

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

After successful completion of the course, 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.

COURSE CONTENTS

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 BOOKS

1. Morgan & King – Introduction to Psychology
2. Health Psychology – Taylor, S.E.
3. Skilled Interpersonal Communication – Owen Hargie
4. Communication in Nursing & Healthcare – Balzer-Riley, Julia
5. The Psychology of Health and Illness – Weinman, J., Petrie, K., Moss-Morris, R.

SEMESTER II

PHYSICAL PHARMACEUTICS - THEORY

Total Credits 3 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

This course of Physical Pharmaceutics with Pharmaceutical Engineering is mainly designed to:

1. Understand the theory and principles behind various processes and operations in pharmaceutical manufacturing.
2. Theory, principles and pharmaceutical applications of various pharmaceutical processes and phenomenon like Solubility, dissolution, flow properties and Interfacial phenomenon in designing and evaluation of dosage forms.
3. Analyse and correlate the factors affecting formulation and stability of dosage forms.
4. Develop the practical skills of determining various parameters and physicochemical properties for optimizing pharmaceutical processes.
5. Understand important pharmaceutical unit operations like mixing, clarification, filtration, size reduction and centrifugation.
6. Create a foundation for understanding of formulation and development concepts.

COURSE OUTCOMES

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

1. Understand the principles and theory behind various processes and operations in pharmaceutical manufacturing.
2. Analyse the physicochemical properties of various materials and its relation with formulation, quality and stability of dosage form.
3. Know the principle and working of various equipment used in pharmaceuticals operations and processes.
4. Develop ability of practically determining and establishing various parameters behind pharmaceutical processes.
5. Optimize pharmaceutical processes with respect to various parameters for desired outcome.

COURSE CONTENTS

Unit I **9 Hours**

Solubility distribution phenomenon & buffers

Solubility expression, Solute solvent interactions, Solubility of liquid and liquids, Solubility of solids and liquids, Rault's Law. Factors affecting solubility, Measurement of saturation Solubility, Effect of pH on solubility, Partition Coefficient-Measurement and significance.

Introduction to buffers, Buffers in pharmaceutical and biological system, Buffer equation / Factor influencing the pH of buffer solutions, Factor influencing Buffer capacity, General procedure for preparing buffers.

Unit II **7 Hours**

Interfacial phenomenon

Liquid interface: - Surface and interfacial tension, surface free energy, Measurement of surface and interfacial tension, Spreading coefficient. Adsorption at liquid interface: surface active agent, HLB, 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.

Unit III **14 Hours**

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, 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 stabilizaition (DLVO Theory Monomolecular adsorption, Multimolecular adsorption, Film formation, Solid particle adsorption.) Physical instabilities of emulsions (creaming, coalescence and breaking, and phase inversion.)

Unit IV **7 Hours**

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 pharmacy.

Unit V **8 Hours**

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)

RECOMMENDED BOOKS:

1. Sinko PJ Martin's Physical Pharmacy and Pharmaceutical Sciences 8th Edition, 2023
2. Allen, Loyd V., Jr. , McPherson, Timothy B. , Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, 12th Edition, 2021
3. Adejare, A., Remington: The science and practice of pharmacy, 23rd edition, 2021,
4. Aulton M. E and Taylor, KMG, Aulton Pharmacceutics: the design and manufacture of medicines 3rd edition, Elsevier.
5. Al-Achi, A., Gupta, MR Stagner, WC Integrated Pharmaceutics: Applied Preformulation, Product Design, and Regulatory Science, 1st Edition, 2022
6. Lachman, L , and Libbermann, HA., The Theory And Practice Of Industrial Pharmacy, 3rd Edition 2009
7. Carter, SJ, Cooper and Gunn's Tutorial pharmacy, 12th Edition
8. Vogel's Textbook of Quantitative Chemical Analysis, 6th Edition – Mendham et al.
9. Myers, D. – Surfaces, Interfaces, and Colloids: Principles and Applications, 3rd Edition
10. Ladisch, M.R. – Rheology of Fluid and Semisolid Foods, Springer

PHARMACEUTICAL ORGANIC CHEMISTRY - THEORY

Total Credits 2 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

1. To enable students to demonstrate a clear understanding of foundational organic chemistry concepts.
2. To help students accurately classify various types of organic compounds based on structural features and functional groups.
3. To develop students' abilities in synthesizing simple organic compounds using established laboratory methods.
4. To provide a solid understanding of organic reaction mechanisms, enhancing analytical and problem-solving skills in chemical transformations.

COURSE OUTCOMES

1 To describe the fundamental chemical reactions and reaction mechanisms of aliphatic hydrocarbons.

2 To understand the fundamental chemical reactions and reaction mechanisms of alkyl halides.

3 To explain the fundamental chemical reactions and reaction mechanisms of aromatic hydrocarbons

4 To evaluate the mechanisms of electrophilic aromatic substitution reactions of benzene and its derivatives, considering the influence of substituents on reactivity and orientation.

COURSE CONTENTS:

UNIT-I: Chemistry of aliphatic hydrocarbons (alkanes, cycloalkanes, alkenes, and conjugated dienes) **10 hours**

1. **Alkanes**
   a. Methods of preparation of alkanes by Wurtz reaction, Kolbe's Reaction, Clemmensen reduction and Wolf-Kishner reduction
   b. Study of chemical reactions of alkanes: Mechanism of Free radical substitution of alkanes exemplified with halogenation. Pharmaceutical applications of alkanes (Liquid paraffin, soft paraffin, hard paraffin)
2. **Cycloalkanes**

Study of Baeyer's strain theory and its limitations, Coulson-Moffitt's modification and Sachse - Mohr's theory.

3. Alkenes

a. Methods of preparation of alkenes by dehydration of alcohols, dehydrohalogenation of alkyl halides, dehalogenation of vicinal dihalides and Wittig reaction

b. Chemical reactions of alkenes: Study of mechanism of electrophilic addition reaction exemplified with addition of hydrogen halides and water to alkenes (Markovnikoff's rule and anti-Markovnikoff's rule) and ozonolysis

4. Electrophilic addition of Conjugated dienes

Study of stability of conjugated dienes. Study of mechanism of Diel-Alder reaction, electrophilic addition and free radical addition reactions of 1,3-butadiene with bromine and hydrogen bromide (1,2 and 1,4 addition reactions).

UNIT-II: Chemistry of alkyl halides **7 hours**

1. Study of mechanism of nucleophilic substitution reactions of alkyl halides (S_N1 and S_N2 reactions with evidences including-kinetics, substrate structure, solvent effect and stereochemistry). Difference between S_N1 and S_N2 reactions
2. Mechanism of dehydrohalogenation of alkyl halides (E1 and E2 reactions with evidences including kinetics, solvent effect, substrate structure and stereochemistry. Differences between E1 and E2 reactions
3. Zaitsev's Rule (Saytzeff's) with examples. Difference between E_1 and E_2 reactions. Substitution Vs Elimination reactions

UNIT-III: Chemistry of benzene and its derivatives **8 hours**

1. IUPAC system of nomenclature for mono and di substituted benzene derivatives
2. Structure of benzene, molecular orbital picture, resonance in benzene and aromaticity including Huckel's rule
3. Electrophilic aromatic substitution reactions of benzene which includes nitration, halogenation, Friedel-Crafts alkylation and its limitations, Friedel-Crafts acylation, sulphonation and desulfonation reactions
4. Effect of substituents on reactivity and orientation of mono substituted benzene derivatives towards electrophilic aromatic substitution reaction

UNIT-IV: Chemistry of carbonyl compounds (Aldehydes and Ketones) 05 hours

1. Preparation of properties of carbonyl compounds
2. Study of mechanism of nucleophilic addition reaction which includes Aldol condensation, Crossed-aldol condensation, Cannizzaro reaction, Crossed-Cannizzaro reaction, Benzoin condensation and Perkin condensation, oxidation and reduction reactions of carbonyl compounds. Pharmaceutical applications of carbonyl compounds (Chloral, Paraldehyde, Ketoprofen)

RECOMMENDED BOOKS

(Latest Editions)

1. Organic Chemistry, by Robert Thornton Morrison, Robert Neilson Boyd and Saibal Kanti Bhattacharjee, Pearson Education India,
2. Organic Chemistry, Vol. 1, by IL Finar, Pearson Books,
3. A Text Book of Organic Chemistry, by B S Bahl and Arun Bahl,S Chand and Company,
4. Principles of Pharmaceutical Organic Chemisty, by Rama Rao Nadendla, PharmMed Press.
5. Text Book of Organic Chemistry, by Sony PL and Chawla HM, Sultan Chand and Sons,
6. Reaction and reaction mechanism by Ahluwaliah/Chatwal.
7. Vogel's text book of Practical Organic Chemistry

HUMAN ANATOMY, PHYSIOLOGY AND PATHOPHYSIOLOGY – II - THEORY

Total Credits 4 **Hours / Week: 4** **60 HR**

COURSE OBJECTIVES

The course aims 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

Upon completion of this course the student should be able to:

1. Explain the gross morphology, structure and functions of nervous system, respiratory system, Gastrointestinal system, endocrine system, reproductive system and urinary system.
2. Understand the etiology and pathogenesis of the various disorders/diseases of nervous system, respiratory system, Gastrointestinal system, endocrine system, reproductive system and urinary system.
3. Understand the pathophysiology of cancer
4. Perform the various experiments related to special senses and nervous system.
5. Understand the pathophysiology of various diseases through case files of patients

COURSE CONTENTS

Unit I **14 hours**

a) Nervous system

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, depression, schizophrenia and Alzheimer's disease and meningitis.

Unit II **12 hours**

a) Gastrointestinal system

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. The role of pepsin in protein digestion). 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 liver disease.

Unit III **12 hours**

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 base balance. Role of RAS in kidney.

d) **Pathophysiology** of Acute and chronic renal failure and Urinary tract infections.

Unit IV **10 hours**

a)Endocrine system

Classification of hormones, mechanism of hormone action. Structure and functions of pituitary gland, thyroid gland, parathyroid gland, adrenal gland, pancreas, pineal gland, thymus.

b) **Pathophysiology** of Diabetes, Hypothyroidism, hyperthyroidism, goiter and polycystic ovary syndrome.

Unit V **12 hours**

a) Reproductive system

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

RECOMMENDED BOOKS (LATEST EDITIONS):

a) For Anatomy and Physiology (Latest Editions):

1. Ross and Wilson Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
2. Principles of Anatomy and Physiology by Tortora, Grabowski. Palmetto, GA, U.S.A.
3. Textbook of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
4. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterjee, Academic Publishers Kolkata
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.

b) For Pathophysiology (Latest Editions):

1. Textbook of pathology by Harsh Mohan Pathophysiology of Disease – Jaypee publisher.
2. Pathophysiology - Concepts of Altered HealthScience By Carol Matson Porth (Lippincot Williams &Wilkins)
3. Pathophysiology – Principles of disease byMarhta J. Miller

Further readings:

1. Anatomy and Physiology in health and Illness byKathleen J.W. Silson
2. Introduction to Human Disease by Thomos H.Kent, Michael N. Hart
3. Cotran RS, Kumar V, Collins T., Robbins. Pathologic basis of disease, WB Saunders.
4. Green RJ, Harris ND, Pathology andTherapeutics for Pharmacist: A basis for clinical Pharmacy Practices, Chapman and Hall Publication.
5. Roger Walker and Cate Whittlesea, Clinical Pharmacy and Therapeutics, Churchill Churchill Livingstone (Elsevier) Publication.
6. Joseph T. Dipiro, Pharmacotherapy: A Patho-physiological Approach, Appleton Lange.
7. Harrison's Principles of Internal Medicine, McGraw Hill Publication, 21st Edition, Joseph Loscalzo, Anthony S. Fauci, Dennis L. Kasper, Stephen L. Hauser, Dan L. Longo, J. Larry Jameson.
8. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co Riverview, MI, USA
7. Textbook of Human Histology by Inderbir Singh, Jaypee brother's medical publishers, New Delhi.
8. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother's medical publishers, New Delhi.
9. Practical workbook of Human Physiology by K. Sri Nageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.
10. Anatomy and Physiology in Health and Illness byKathleen J.W. Wilson.

PHARMACOGNOSY AND PHYTOCHEMISTRY - THEORY

Total Credits 3 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

1. To understand metabolic pathways and biogenetic origin of phytoconstituents.
2. To study pharmacognostic features of crude drugs of primary and secondary metabolites.
3. To gain knowledge of modern and traditional extraction and isolation methods.
4. To develop practical competency in identification, microscopy, phytochemical analysis, and
2. quality evaluation of herbal materials.

COURSE OUTCOMES

After successful completion of this course, the student will be able to:

1. Describe biosynthetic pathways and genetic tools in phytoconstituent production.
2. Classify and explain primary and secondary metabolite-containing drugs.
3. Apply traditional and modern methods of extraction and isolation.
4. Perform qualitative and quantitative analysis of plant metabolites.
5. Evaluate identity, purity, and quality of herbal raw materials

COURSE CONTENTS

UNIT-I **6 Hours**

Metabolic Pathways and Biogenetic Studies

Brief study of basic metabolic pathways and biosynthesis of different secondary metabolites, including the Shikimic acid pathway, Acetate pathways, Mevalonate, Malonate, Amino acid, and Mixed pathways. Study of the utilization of radioactive isotopes in the investigation of biogenetic studies, Pathway prediction tools, CRISPR/Cas9, Genome Editing

UNIT-II **8 Hours**

Pharmacognosy of drugs: Primary Metabolites

Pharmacognosy (Biological sources, distribution, cultivation, identifying characters,

phytochemistry & chemical tests, therapeutic uses and commercial applications) of following drugs: 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

UNIT-III **13 Hours**

Pharmacognosy of drugs: Secondary Metabolites

Pharmacognosy (Biological sources, distribution, cultivation, identifying characters, phytochemistry & chemical tests, therapeutic uses and commercial applications) of following drugs: Alkaloids: Vinca, Rauwolfia, Opium, Colchicum, Nux-Vomica Volatile oils: Lemongrass, Clove, Cinnamon, Fennel Tannins: Myrobalans, Catechu, Pomegranate Resins: Guggul, Asafoetida, Boswellia Glycosides: Senna, Aloes, Bitter Almond, Liquorice, Digitalis Phenylpropanoids and Flavonoids: Lignans (Flax, Sesame), Green Tea, Tulsi, Ginkgo Iridoids, Other terpenoids & Naphthaquinones: Gentian, Artemisia, kalmegh, carrot & Henna Miscellaneous: Ashwagandha, Shatavari, Shankpushpi, Giloy, Bhringaraj

UNIT-IV **08 Hours**

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: Counter Current Extraction, Turbo extraction, Supercritical Fluid Extraction, Microwave-Assisted Extraction, Ultrasonic-Assisted Extraction, Enzyme-Assisted Extraction, Pressurized Liquid Extraction, Sub-Critical Water Extraction**.**

UNIT-V **10 Hours**

Isolation, Identification and characterization of Drugs and Botanicals

Microscopy: Role of microscopy of Roots, stem, heart wood, leaf, fruit, seed and bark in identification of crude drug samples. Quantitative microscopy of crude drugs including lycopodium spore method, leaf constants, camera lucida, micrometers, measurement of dimension of starch grains, aleurone grains, phloem fibres and calcium oxalate crystals. Details of mountants, clearing agents, chemo microscopic reagents.

Separation/ Isolation techniques: Planar chromatography, Column chromatography, Preparatory TLC, Flash chromatography. Identification techniques: Phytochemical, Chromatographic and Spectroscopic techniques: A brief Overview:Fingerprinting of medicinal plants using TLC/HPTLC.

Types and significance of Markers (Phytochemical Reference Standards) in quality control of medicinal plants and their products. Methods and role of screening and analysis of major metabolites:

alkaloids, glycosides, saponins, tannin, resins, flavonoids, phenolics, steroids in quality control of medicinal plants and their products.

RECOMMENDED BOOKS

1. Dewick, P.M. Medicinal Natural Products: A Biosynthetic Approach, 2nd Edition, John Wiley & Sons, 2002.
2. Evans, W.C. Trease and Evans' Pharmacognosy, 16th Edition, W.B. Saunders & Co., London, 2009.
3. Ali, Mohammad. Pharmacognosy and Phytochemistry, CBS Publishers & Distributors, New Delhi.
4. Ansari, S.H. Essentials of Pharmacognosy, 2nd Edition, Birla Publications, New Delhi, 2007.
5. Ahmad S, Introduction to Pharmacognosy, Dreamtech Press, New Delhi, 2nd Edition, 2019
6. Jalalpure, S.S., Patil, A.K. Textbook of Pharmacognosy and Phytochemistry I, Nirali Prakashan, Pune.
7. Kalia, A.N., Pharmacognosy and Phytochemistry–I, CBS Publishers & Distributors, New Delhi.

BIOCHEMISTRY - THEORY

Total Credits 3 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

1. To understand the biochemical pathways and clinical relevance of carbohydrate, lipid, and protein metabolism, and relate metabolic alterations to associated diseases.
2. To explain the principles of fluid and electrolyte balance and the mechanisms of acid-base homeostasis, highlighting their physiological and pathological importance.
3. To describe the structure and function of nucleic acids and the molecular mechanisms of DNA replication, transcription, translation, and associated genetic disorders.
4. To demonstrate knowledge of enzyme kinetics and regulation, and evaluate their diagnostic and therapeutic roles in clinical biochemistry.
5. To understand the processes of digestion, absorption, and assimilation of nutrients, and assess the biochemical consequences of nutrient deficiencies and malnutrition.

COURSE OUTCOMES

Upon completion of this course, the student should be able to:

1. Recall the classification, structure, and functions of major biomolecules such as carbohydrates, lipids, proteins, nucleic acids, enzymes, and vitamins.
2. Explain the principles of bioenergetics, biological oxidation, and the overview of metabolic pathways of biomolecules, along with their clinical significance.
3. Apply the concepts of digestion, absorption, and assimilation of nutrients to interpret the biochemical basis of malnutrition and nutritional disorders.
4. Analyze the molecular mechanisms of DNA replication, transcription, and translation, and correlate them with genetic regulation and disease conditions.
5. Evaluate biochemical parameters used in the diagnosis and monitoring of metabolic and organ-specific disorders.
6. Design a case-based diagnostic approach by integrating biochemical and molecular information for selected metabolic or genetic disorders.

COURSE CONTENTS

UNIT-I **10 hours**

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. Therapeutic and diagnostic application of enzymes and isoenzymes. Digestion, absorption function of dietary Macro and Micronutrients, including Vitamins and Minerals

b. **pH and Buffer Systems:** Concept of pH, Physiological buffer systems: Role in acid-base homeostasis

c. Clinical Chemistry: Liver function tests (routinely performed tests based on liver function). Renal function tests (routinely performed tests based on kidney function, ELISA test)

UNIT-II **10 hours**

a. **Introduction about biomolecules**- Introduction, classification, chemical nature and biological role 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:** 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.

UNIT-III **07 hours**

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

Unit-IV **10 Hours**

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

- **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).
- **Catabolism of Specific Amino Acids and Related Disorders**: Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenylketonuria, Albinism, Alkaptonuria, Tyrosinemia) and Inborn errors of branched chain and aromatic amino acids

a. **Biochemical significance of neurotransmitters and hormones derived from amino acids**: 5-HT (serotonin), melatonin, dopamine, noradrenaline, adrenaline: 5-HT, melatonin, dopamine, noradrenaline, adrenaline.

b. Catabolism of heme and related disorders (jaundice).

UNIT-V **08 hours**

Nucleic acid metabolism and genetic information transfer

a. **Nucleotide Metabolism:** 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. 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. Clinical disorders associated with faulty DNA repair.

Recommended Books (Latest Edition):

1. Lehninger's Principles of Biochemistry by David Nelson, Michael Cox, and Aaron Hoskins. Macmillan Publishing Company. Eight edition, 2021,
2. Harper's Illustrated Biochemistry, by Kennelly PJ, Botham KM, mcguinness OP, Rodwell VW, Weil P.Peter J. Kennelly, Kathleen M. Botham, Owen mcguinness, Victor W. Rodwell, P. Anthony Weil. McGraw-Hill Education. Thirty-Second Edition, 2023,
3. Harper"s Biochemistry, Ed. R.K. Murray, D.K. Granner, P.A. Mayes and V.W. Rodwell. Appleton and Lange, Stamford, Connecticut.
4. Biochemistry. Ed. Donald Voet and Judith G. Voet. John Wiley & Sons, Inc.
5. Textbook of Biochemistry with Clinical Correlations. Ed. Thomas M. Devlin, Wiley-Liss Publishers
6. Biochemistry by U.Satyanarayana, U.Chakrapani, Elsevier Health Sciences, 5th edition, 2020.

7. Biochemistry Ed. Lubert Stryer. W.H. Freeman and Company, New York.
8. A Textbook of Biochemistry, A.V.S.S.Rama Rao UBS Publishers' Distributors Pvt. Limited, 10th Edition, 2006,
9. Fundamentals of Biochemistry by Deb, A. C. New Central Book Agency (P) Limited, Edition 7th, .2014.
10. Biochemistry by Berg, Jeremy M.Tymoczko, John L.., Gatto, Gregory J, Stryer, Lubert. United Kingdom: Macmillan Learning, 7th International ed, 2015.
11. Outlines of Biochemistry by Erice Conn, Paul Stumpf. John Wiley & Sons Publishers, 5TH EDITION 2009
12. Practical Biochemistry by RC Gupta and S Bhargava. New Delhi : CBS Publishers & Distributors Pvt Ltd, 2023. 6TH EDITION
13. An Introduction to Practical Biochemistry BY David T. Plummer. Mcgraw hill; 2016 3RD EDITION
14. Practical Biochemistry for Medical Students. by Rajagopal, G., Ramakrishnan, S., Orient Longman, 1983,
15. Practical Clinical Biochemistry . By Harold Varley. CBS Publishers & Distributors Ltd , 2005, 4th edition.

AI & PYTHON PROGRAMMING FOR PHARMACY – II - THEORY

Total Credits 2 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

1. To introduce the fundamentals of matrices, determinants, eigenvalues/eigenvectors, and calculus essential for applications in AI and pharmacokinetic modeling.
2. To explain the role of matrix operations in the forward and backward propagation of neural networks.
3. To apply linear algebra and differential equations in building and interpreting basic pharmacokinetic models.
4. To provide an overview of AI tools used in pharmacy practice for automated dispensing, inventory control, and medication error detection.
5. To explore AI-based clinical decision support systems and adherence-monitoring tools that enhance patient care and outcomes.

COURSE OUTCOMES

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

1. Calculate determinants, eigenvalues, and perform key matrix operations to prepare data for AI tasks.
2. Solve basic differentiation, integration, and differential-equation problems applied to drug-level prediction.
3. Implement a small neural network and clearly describe how matrix multiplication enables training.
4. Evaluate a pharmacy workflow and recommend AI solutions for dispensing, inventory control, and error prevention.
5. Interpret results from a clinical decision support or adherence-monitoring tool and suggest optimized medication therapy.

COURSE CONTENTS

Unit 1 **6 Hours**

Matrices and Determinants, Eigenvalues and Eigenvectors

- Introduction to matrices: types, operations, and properties
- Determinants: calculation, properties, and applications
- Eigenvalues and eigenvectors: concepts, computation, and relevance
- Application of linear algebra in AI: representing and transforming data
- Use of matrices in modeling pharmacokinetic systems

Unit 2 **6 Hours**

Calculus: Differentiation and Integration, Differential Equation

- Fundamentals of differentiation and integration
- Application of derivatives and integrals in pharmacokinetics (e.g., drug absorption and elimination)
- Introduction to ordinary differential equations (ODEs)
- Solving first-order and second-order ODEs
- Application of differential equations in drug-level prediction and modeling of biological processes

Unit 3 **6 Hours**

Matrix Multiplication and Neural Networks

- Concept of matrix multiplication and its properties
- Role of matrices in neural networks
- Forward and backward propagation in AI models
- Building a simple neural network using matrix operations
- Hands-on demonstration or simulation of basic model training

Unit 4 **6 Hours**

AI Applications in Pharmacy Operations

- Automated Dispensing Systems: Electronic prescriptions, barcoding, and robotic packaging
- AI in Inventory Management: Predictive analytics for stock optimization and expiry tracking
- Medication Error Detection: AI tools for identifying drug interactions, dosage anomalies, and patient safety risks
- Medication Adherence Monitoring: AI-enabled reminder systems, personalized notifications, and real-time adherence tracking

Unit 5 **6 Hours**

Clinical Decision Support Systems (CDSS)

- Overview of CDSS and their role in pharmacy and healthcare

- AI-based decision support tools for medication therapy optimization
- Case-based examples: How CDSS improve clinical decision-making and patient outcomes
- Ethical and practical considerations in deploying AI for clinical use

RECOMMENDED BOOKS

1. Linear Algebra and Its Applications – David C. Lay
2. Advanced Engineering Mathematics – Erwin Kreyszig
3. Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications – Malcolm Rowland & Thomas N. Tozer
4. Introduction to Machine Learning for Healthcare – James C. Chen, Gabriel J. Escobar & Katherine P. A. Chua
5. Artificial Intelligence in Drug Discovery – Nathan Brown

PHYSICAL PHARMACEUTICS - PRACTICALS

Total Credits 1 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

1. To present basic concepts and techniques adopted for the estimation of physicochemical properties like surface tension, viscosity, and density in pharmaceutical systems.
2. To form a conceptual understanding of micellar systems, HLB value, and isotonicity for drug formulation and stability.
3. To train students in conducting laboratory techniques for the estimation of sedimentation, flow properties, solubility, and partition coefficients with different pharmaceutical instruments.
4. To allow students to examine the effect of variables of formulation like suspending agents and glidants on performance and physical stability.
5. To improve students' capacity to critically evaluate and interpret experimental results concerning drug solubility, and powder properties.

COURSE OUTCOMES

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

1. Remember basic principles and definitions of surface tension, viscosity, density, and flow characteristics in pharmaceutical systems.
2. Describe mechanisms and implications of micellar formation, HLB system, and isotonicity in formulation development.
3. Show competence in performing experiments on viscosity, sedimentation, isotonicity, and solubility utilizing standard apparatus and methodology.
4. Explain the influence of formulation factors such as various suspending agents and glidants on sedimentation and powder flow.
5. Assess experimental findings for partition coefficient, solubility, and powder properties to decide on formulation appropriateness.

COURSE CONTENTS

1. Determination of surface tension of given liquids by drop count and drop weight method
2. Determination of critical micellar concentration of surfactants
3. Determination of viscosity of liquid using Ostwald’s viscometer and Brookfield viscometer

4. Determination sedimentation volume with effect of different suspending agent
5. Determination sedimentation volume with effect of different concentration of single suspending agent
6. To determine the HLB of surfactant
7. To calculate the isotonicity by different method (Sodium Chloride Equivalent Method)
8. Determination of particle size, particle size distribution using sieving method
9. Determination of particle size, particle size distribution using microscopic method
10. Determination of densities and derived properties of powders (Bulk density, tapped density, hausners ration, carr's compressibility index) true density and porosity
11. Determine the angle of repose and influence of glidants on angle of repose.
12. Determining the solubility of drug at different buffer/pH at room temperature
13. Determination of Partition coefficient of drug in n-octanol and water system
14. Determination of Partition coefficient of drug in benzene and water system

Note: Compare the values of various physicochemical properties with marketed formulation wherever possible. Minimum 12 experiments must be performed

RECOMMENDED BOOKS

1. Sinko PJ Martin's Physical Pharmacy and Pharmaceutical Sciences 8th Edition, 2023
2. Allen, Loyd V., Jr. , McPherson, Timothy B. , Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, 12th Edition, 2021
3. Adejare, A., Remington: The science and practice of pharmacy, 23rd edition, 2021,
4. Aulton M. E and Taylor, KMG, Aulton Pharmacceutics: the design and manufacture of medicines 3rd edition, Elsevier.
5. Al-Achi,A., Gupta, MR Stagner, WC Integrated Pharmaceutics: Applied Preformulation, Product Design, and Regulatory Science, 1st Edition, 2022
6. Lachman, L , and Libbermann, HA., The Theory And Practice Of Industrial Pharmacy, 3rd Edition 2009
7. Carter, SJ, Cooper and Gunn's Tutorial pharmacy, 12th Edition

PHARMACEUTICAL ORGANIC CHEMISTRY - PRACTICALS

Total Credits 1 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

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

By the end of this course, 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.

COURSE CONTENTS

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, test for aromaticity, test for saturation/unsaturation etc.
   b. Solubility tests

c. Detection of elements such as nitrogen, sulphur and halogens by Lassaigne's test

d. Functional group tests such as phenols, amides, amines, carboxylic acids, aldehydes and ketones, alcohols, esters, aromatic and halogenated hydrocarbons and nitro compounds.

e. 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 BOOKS (Latest Editions)

1. Vogel's Text Book of Practical organic Chemistry, by B S Furniss, Pearson India,.
2. Textbook of Organic Chemistry, by Sony PL and Chawla HM, Sultan Chand and Sons,
3. Practical Organic Chemistry, by Mann and Saunders, Pearson Education India,
4. Advanced Practical Organic Chemistry, by N.K. Vishnoi, Vikas Publishing,
5. Introduction to Organic Laboratory Techniues: A Small Scale Approach, by Donald L. Pavia, Gary M. Lampman, George S. Kriz, Brooks/Cole
6. Reaction and reaction mechanism by Ahluwaliah/Chatwal.

HUMAN ANATOMY, PHYSIOLOGY AND PATHOPHYSIOLOGY- II - PRACTICALS

Total Credits 1 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

1. To provide foundational knowledge of the structure and functions of major organ systems of the human body.
2. To develop understanding of the physiological mechanisms that maintain homeostasis.
3. To explain the pathophysiology of diseases affecting different organ systems.
4. To explore the causes of diseases and the body's responses to pathological conditions.
5. To build a strong base for clinical learning through the study of functional and structural changes in disease states

COURSE OUTCOMES

Upon completion of this course the student should be able to

1. Explain the gross morphology, structures and functions of various organs and organ systems
2. of the human body.
3. Describe the various homeostatic mechanisms and their imbalances.
4. Describe the etiology and pathogenesis of the selected disease states.
5. Know the signs and symptoms, risk factors, diagnosis, prevention, treatment strategies and
6. complications of the diseases.
7. Understand coordinated working patterns of different organs of each system.
8. Perform the various experiments related to special senses and nervous system

COURSE CONTENTS:

Practical HAPP allows the verification of physiological processes discussed in theory classes through experiments on living tissues, simulated videos models and charts.

1. To study the nervous system using specimen, models, etc.,

2. To study the respiratory system using models.

3. To study gastrointestinal system using models.

4. To study the reproductive system using models.

5. To demonstrate the general neurological examination.

6. To demonstrate the function of olfactory nerve.

7. To examine the different types of taste.

8. To demonstrate the visual acuity.

9. To demonstrate the reflex activity.

10. Recording of body temperature.

11. Determination of tidal volume and vital capacity.

12. Recording of basal mass index .

13. Study of family planning devices and pregnancy diagnosis test.

14. Demonstration of total blood count by cell analyser

15. To understand the pathophysiology of IBD, peptic ulcer, jaundice, hepatitis, typhoid, asthma, tuberculosis, diabetes and thyroid through case files/case reports

RECOMMENDED BOOKS (LATEST EDITIONS)

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
4. Text book of Medical Physiology- Arthur C,Guyton and John.E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
6. Textbook of Human Histology by Inderbir Singh, Jaypee brother's medical publishers, New Delhi.
7. Laurence B, Bruce C, Bjorn K. ; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12th edition; New York; McGraw-Hill; 2011.
8. Best, Charles Herbert 1899-1978; Taylor, Norman Burke 1885-1972; West, John B (John Burnard); Best and Taylor's Physiological basis of medical practice; 12th ed; united states;
9. William and Wilkins, Baltimore;1991 [1990 printing].
10. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston; Davidson's Principles and Practice of Medicine; 21st edition; London; ELBS/Churchill Livingstone; 2010.
11. Guyton A, John .E Hall; Textbook of Medical Physiology; 12th edition; WB Saunders Company; 2010.

12. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; 9th edition; London; McGraw-Hill Medical; 2014.
13. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia; WB Saunders Company; 1997
14. Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins & Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier; 2014
15. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother's medical publishers, New Delhi.
16. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

REFERENCE BOOKS (LATEST EDITIONS)

1. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterjee ,Academic Publishers Kolkata

PHARMACOGNOSY AND PHYTOCHEMISTRY - PRACTICALS

Total Credits 1 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

1. To provide knowledge of chemical tests for identifying selected crude drugs.
2. To train students in quantitative microscopy for measuring diagnostic plant features.
3. To develop skills in the identification of medicinal plants through various evaluation methods.
4. To impart techniques for gravimetric estimation of major phytoconstituents.
6. To enable evaluation of herbal materials using spectrophotometric methods and standard comparisons.

COURSE OUTCOMES

After completion of the course, the students will be able to:

1. Identify crude drugs through specific chemical tests. CO2: Perform quantitative microscopy to measure diagnostic plant features.
2. Conduct sensory, morphological, chemical, and powder microscopic evaluation of medicinal
3. plants.
4. Estimate phytoconstituent content using gravimetric analysis techniques.
5. Evaluate and compare herbal raw materials using spectrophotometry and pharmacopoeial
6. standards.

COURSE CONTENTS

1. Chemical tests for identification of :(i) Asafoetida (ii)Boswellia (iii) Aloes (iv) Guggulu (v) Catechu

2. Quantitative microscopy for determination of size of starch grains, calcium oxalate crystals, fiber length and width using eyepiece micrometre

3. Quantitative microscopy for determination of stomatal number and index, vein islet number and vein termination number, palisade ratio using camera lucida

4. Sensory, Morphological, Chemical and Microscopical (Powder Microscopic) identification of Ashwagandha, Cinnamon, Fennel, Senna, Tulsi, Kalmegh and Nux-vomica

5. Gravimetric determination of content of alkaloid, glycoside, saponin and resin

6. Spectrophotometric determination of phenols and flavonoids

7. Experiential learning-based experiments involving evaluation and comparison of field / market collected herbal raw materials with pharmacopeial standards.

RECOMMENDED BOOKS

1. Khandelwal, K.R., Iyengar, M.A. Practical Pharmacognosy Manual, Pune.

2. Kokate, C.K., Purohit, A.P., Gokhale, S.B. Textbook of Pharmacognosy, 37th Edition, Nirali Prakashan, Pune, 2007.

3. Moffat, A.C. (Ed.) Clarke's Isolation and Identification of Drugs, The Pharmaceutical Press, London.

4. Sarwa, K.K., et al. (2021). Standardization and Quality Evaluation of Botanicals with Special Reference to Marker Components. In: Mandal, S.C., Chakraborty, R., Sen, S. (Eds.) Evidence-Based Validation of Traditional Medicines, Springer, Singapore.

5. WHO Guidelines on Good Agricultural and Collection Practices (GACP), Quality Control of Herbal Medicines, and DNA Barcoding Applications

BIOCHEMISTRY - PRACTICALS

Total Credits 1 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

1. Develop skills to identify and differentiate carbohydrates and proteins through classical qualitative tests.
2. Apply biochemical techniques to analyze pathological conditions using urine and blood
3. samples.
4. Perform estimations of clinically important biomolecules such as glucose, cholesterol, urea, creatinine, and proteins in biological fluids.
5. Demonstrate enzymatic activity and analyze factors affecting enzyme function, including substrate concentration and temperature.
6. Interpret biochemical results and relate them to clinical conditions, such as diabetes, renal dysfunction, or lipid disorders.

COURSE OUTCOMES

After completion of the course, the students will be able to:

1. Identify proteins and carbohydrates using qualitative biochemical tests and explain their physiological relevance.
2. Detect abnormal constituents in urine and interpret their diagnostic significance.
3. Estimate and interpret the levels of glucose, cholesterol, urea, creatinine, uric acid, and serum proteins, and correlate them with clinical conditions.
4. Demonstrate the principle of enzyme-substrate reactions and evaluate how temperature and substrate concentration affect enzymatic activity.
5. Analyze and report biochemical results with accuracy and relate practical findings to theoretical knowledge and clinical application.

COURSE CONTENTS (Any 13 Experiments)

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/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 the enzymatic hydrolysis of starch
9. Study the effect of Temperature on Salivary amylase activity.
10. Study the effect of substrate concentration on salivary amylase activity.

Elective 1 – SEC - I (Practical)

Total Credits 1 **Hours / Week: 2** **30 HR**

The syllabi for elective subjects are given in the appendices

SEMESTER III

Pharmaceutical Dosage Forms (Theory)

Credits: 4 **Hours/Week:** 4 **Hours/Sem:** 60

Course Objectives: Fundamentals and processes in the development of **pharmaceutical solids** (powders, granules, tablets; coatings; advances).

1. Development and manufacturing of **filled solids** (**hard/soft capsules**).
2. Formulation considerations, manufacturing, and evaluation of **monophasic liquids** (with pressurised dosage forms).
3. Formulation considerations, manufacturing, and evaluation of **biphasic liquids** and their advances.
4. Principles, cGMP, and evaluation of **sterile dosage forms** (parenterals and ophthalmics).

Course Outcomes

Upon successful completion, students will be able to:

1. **Describe** pre-formulation principles and evaluate key physicochemical parameters critical to solid dosage-form development.
2. **Explain** tablet types, excipients, manufacturing processes, coating methods, and troubleshoot common defects.
3. **Demonstrate** production and quality control of **hard/soft capsules**, including shell design, filling, and testing.
4. **Design and justify** the composition, manufacturing, packaging, and evaluation of **monophasic and biphasic liquids**, including **pressurised aerosols**.
5. **Apply** cGMP and pharmacopeial requirements to **sterile dosage forms** (parenteral & ophthalmic): WFI, aseptic processing/terminal sterilisation, lyophilisation, container–closure systems, and QC (sterility, LAL, particulates, isotonicity).

Course Content

UNIT I — Fundamentals and Compressed Solids [14 Hrs]

Pre-formulation studies: Concept, need; solubility, pKa, polymorphism, particle size/flow; drug–excipient compatibility (thermal/FTIR/DSC).

Medicated powders & granules: Formulation considerations, manufacturing (mixing, granulation), quality control, packaging.

Tablets: Excipients (roles & examples); tooling (types/specifications); manufacturing methods & equipment; defects & remedies; IPQC; finished-product tests; packaging.

Tablet coating: Types (sugar, film, compression, enteric); need, advantages/limitations; polymers & process specs; coating defects; QC of coated tablets.

UNIT II — Filled Solids (Capsules) [8 Hrs]

Gelatin & non-gelatin shells: Composition; empty shell manufacturing & QC; capsule sizes.

Hard capsules: Formulation design; filling (manual, semiauto, automatic); IPQC/finished-product tests; packaging.

Softgel capsules: Shell composition & plasticisers; fill types; manufacturing (rotary die/other); defects; quality control & stability.

UNIT III — Monophasic Liquids & Pressurised Dosage Forms [10 Hrs]

Foundations: Need, advantages/limitations; monophasic vs biphasic; solubility-enhancement techniques.

Vehicles & solvents: Pharmaceutical waters (types; manufacturing & QC of Purified/Distilled); classes of solvents as per toxicity.

Formulation & manufacturing: Raw-material considerations and additives; processing; QC of solutions/syrups/elixirs; powders for reconstitution as **solutions**.

Measuring, filling & packaging: Techniques; container–closure integrity; **automation** in liquid manufacturing.

Pressurised dosage forms (Aerosols/MDIs): Concepts; propellant classification/selection; valves & containers; formulation, manufacturing, and QC (leak, spray pattern, delivered dose, particle-size/aerodynamic performance).

UNIT IV — Biphasic Liquids (Suspensions & Emulsions) [14 Hrs]

Suspensions: Stokes' law; DLVO theory; flocculated vs deflocculated systems; Brownian movement; sedimentation parameters; flocculation & controlled-structure flocculation.

Formulation & manufacturing: Additives; classification of suspending agents; IPQC & QC; instabilities and packaging.

Advances: Nanosuspensions; dry powders for reconstitution as **suspensions**; **raft-forming** systems.

Emulsions: Instabilities (creaming, coalescence, breaking, phase inversion); theories of emulsification/stabilisation; types (o/w, w/o, multiple).

Formulation & manufacturing: Additives; classification of emulsifying agents; QC and packaging.

Advances: Nano-emulsions, micro-emulsions, SMEDDS/SNEDDS (overview, applications).

UNIT V — Sterile Dosage Forms (Parenteral & Ophthalmic) [14 Hrs]

Introduction & classification: SVP vs LVP; routes; advantages/limitations.

Water for Injection (WFI): Types, preparation, storage/distribution; pharmacopoeial requirements.

Formulation components: Vehicles, buffers, co-solvents, surfactants, antioxidants, preservatives, chelators; isotonicity & osmolality.

Manufacturing: Aseptic vs terminal sterilisation; filtration; **lyophilisation** principles; environmental controls.

Containers & closures: Glass/Plastic systems; elastomers; selection factors; evaluation & container–closure integrity.

Ophthalmics: Solutions/suspensions/ointments/gels/inserts; physiological factors (pH, tonicity, viscosity); residence-time enhancers; preservative-free systems (e.g., BFS).

Quality control & compliance: Sterility tests, **LAL**/endotoxins, particulate matter, clarity, extractable volume; labelling & documentation; overview of **cGMP/cleanrooms** and environmental monitoring.

Recommended Books:

1. Aulton's Pharmaceutics: The Science of Dosage Form Design – Michael J. Aulton
2. The Theory and Practice of Industrial Pharmacy – Lachman, Lieberman & Kanig
3. Remington: The Science and Practice of Pharmacy – Troy & Beringer
4. Pharmaceutical Preformulation and Formulation – Mark Gibson
5. Controlled Drug Delivery: Fundamentals and Applications – Joseph R. Robinson & Vincent H.L. Lee
6. Indian Pharmacopoeia / USP / BP

HETEROCYCLIC COMPOUNDS AND STEREO CHEMISTRY - THEORY

Total Credits 3 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

This course focuses on the fundamental principles and synthetic strategies involved in the preparation and chemical reactions of various classes of organic compounds. The main objectives are to:

1. Enable students to apply IUPAC rules for naming organic and heterocyclic compounds accurately.
2. Develop students' ability to synthesize aromatic, polynuclear aromatic, and heterocyclic compounds using general methods of preparation.
3. Introduce and explain the concepts of stereoisomerism and their pharmaceutical significance.
4. Equip students with knowledge of organic reaction mechanisms and their applications in drug synthesis.

COURSE OUTCOMES

Upon completion of the course the student will be able to:

1. To recall and outline methods for the preparation and chemical reactions of various organic compounds.
2. To explain the acidity and basicity of organic compounds and recognize the medicinal relevance of polynuclear hydrocarbons and heterocyclic compounds.
3. To illustrate the concepts of stereoisomerism with appropriate examples.
4. To classify, name, and interpret the structures of heterocyclic compounds.
5. To describe and analyze the synthesis, chemical behavior, and applications of heterocyclic and polynuclear hydrocarbon compounds.

COURSE CONTENTS

UNIT-I: Chemistry of Carboxylic acids, Phenols, Amines and Polynuclear Aromatic hydrocarbons **15 hours**

1. **Aliphatic and aromatic carboxylic acids:**

a. Methods to prepare carboxylic acids (Oxidation of alcohols, carbonation of Grignard reagent, Kolbe-Schmidt reaction)

b. Study of acidity of carboxylic acids and effect of substituents on acidity

c. 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

a. Methods to prepare amines (Reduction of nitro compound, reduction of nitriles and Hofmann degradation of amides)

b. Study of basicity of amines and effect of substituents on basicity

c. Study of mechanism and synthetic applications of diazonium salts including Sandmeyer's and azo-dye coupling reaction

3. Alcohols and Phenols:

a. Classification of alcohols, methods to prepare alcohols (oxymercuration - demercuration, reduction of carbonyl compounds)

b. Acidity of alcohols

c. Definition of phenols, method to prepare phenols by cumene process. Comparison of the acidity of phenol vs alcohol

d. Study of mechanism of chemical reactions of phenols (Reimer-Tiemann reaction, halogenation and nitration of phenols). Pharmaceutical applications of alcohols and phenols (Glycerine, 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).

UNIT II Optical isomerism **07 hours**

1. Definition of stereoisomerism and types of stereoisomerism with examples
2. Definition with examples for optical activity, origin of chirality, elements of symmetry, chiral and achiral molecules, enantiomerism, diastereoisomerism and meso compounds
3. Study of configuration including D & L system, sequence rules, R & S system. Medicinal importance of optical isomers with examples
4. Racemic mixture and resolution of racemic mixtures

UNIT III Geometrical isomerism: **06 hours**

1. Nomenclature of geometrical isomers (Cis & Trans, E & Z, Syn & Anti system)
2. Conformational isomerism and its analysis in ethane, butane and cyclohexane **(3 hrs)**
3. Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity in biphenyl compounds

UNIT IV Chemistry of five membered heterocycles **10 hours**

1. IUPAC nomenclature and classification of heterocyclic compounds as per the Hansch-Widman system
2. Relative aromaticity and reactivity of pyrrole, furan and thiophene
3. 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 **(4 hrs)**
4. Medicinal uses of drugs containing pyrrole (Ethosuximide, procyclidine), furan (Furosemide, Nitrofurazone) and thiophene (Cephaloridine, Clopidogrel)

UNIT V Chemistry of other heterocycles: **7 hours**

1. Study of nomenclature of fused heterocyclic compounds, synthesis for pyrazole (Knorr synthesis), imidazoe (Debus-Radziszewski reaction), pyridine (The Hantzsch synthesis), quinoline (The Skraup synthesis) and Electrophilic aromatic substitution reactions of pyrazole and imidazole
2. Chemical structures of Indole, pyrimidine, benzimidazole, purine, azepine, pyrazole, oxazole, Phenothiazine, benztriazole, quinoxaline
3. Basicity of imidazole, pyridine and quinolone
4. 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

RECOMMENDED BOOKS (Latest Editions)

1. Organic Chemistry, by Robert Thornton Morrison, Robert Neilson Boyd and Saibal Kanti Bhattacharjee, Pearson Education India,
2. Organic Chemistry, Vol. 1, by IL FINAR, Pearson Books,
3. Organic Chemistry, Stereochemistry and Natural Products, Vol. 2, by IL FINAR, Pearson Books
4. March's Advanced Organic Chemistry: Reactions, Mechanisms, and Structure" **Author**: Michael B. Smith and Jerry March
5. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.

6. Pharmaceutical Organic Chemistry (Part-1 Heterocyclic and Natural Products), by Rama Rao Nadendla, Vallabh Publications,
7. "Mechanisms of Organic Reactions" **Author**: Raj K. Bansal
8. "Advanced Organic Chemistry: Part A: Structure and Mechanisms"**Author**: Francis A. Carey and Richard J. Sundberg
9. Heterocyclic Chemistry, By Thomas L Gilchrist, Prentice Hall Publication,
10. Principles of Pharmaceutical Organic Chemisty, by Rama Rao Nadendla, PharmMed Press,

GENERAL PHARMACOLOGY - THEORY

Total Credits 3 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

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

Upon completion of this course, 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.

COURSE CONTENTS

UNIT-I **08 Hours**

Introduction to Pharmacology

a) Definition, historical perspectives, branches of pharmacology and their scope, drug, nature and sources of 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.

UNIT-II **07 Hours**

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

c) protein binding and its therapeutic importance. 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.

UNIT-III **10 Hours**

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 etc.

e) Adverse drug reactions (ADR) and types of ADRs.

f) Drug interaction, types, pharmacokinetic and pharmacodynamic drug-drug interactions.

UNIT-IV **12 Hours**

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 Peptide Reactivity Assay.

c) Advantages and disadvantages of *in vitro* and *in silico* Pharmacological screening and evaluation

Recent trends in pharmacology

d) 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.

e) Introduction, general principles, applications and scope of Pharmacogenomics, Gene therapy, Biosimilars and Precision medicine.

UNIT-V **08 Hours**

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 chronic 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 guidelines.

RECOMMENDED BOOKS (LATEST EDITIONS):

Updated versions of the following books are recommended

1. Rang & Dale's Pharmacology, H.P. Rang, M.M. Dale, J.M. Ritter, R.J. Flower, G. Henderson,Publisher: Elsevier
2. Katzung & Trevor's Pharmacology Examination and Board Review, Bertram G. Katzung, Marieke Kruidering-Hall, Rupa Lalchandani Tuan, Todd W. Vanderah, Anthony J. Trevor Publisher: McGrow Hills Lange.
3. Goodman & Gilman's: The Pharmacological Basis of Therapeutics, Laurence L. Brunton, Randa Hilal-Dandan, Bjorn Knollmann. Publisher: McGraw-Hill Education, Edition: 13th Edition (2017)
4. Basic and Clinical Pharmacology, Bertram Katzung, Anthony Trevor. Publisher: McGraw-Hill Education.
5. Richard Finkel, Lippincott's Illustrated Reviews: Pharmacology, Karen Whalen, Publisher: Wolters Kluwer.
6. Pharmacology and Pharmacotherapeutics, R.S. Satoskar, Nirmala N. Rege, S.D. Bhandarkar. Publisher: Elsevier India
7. Modern Pharmacology with Clinical Applications, U.D. Tripathi, U. K. Seth. Publisher: CBS Publishers & Distributors Pvt Ltd
8. Essentials of Medical Pharmacology, K.D. Tripathi., Publishers: Jaypee Brothers Medical
9. Pharmacotherapy: A Pathophysiologic Approach. Joseph T. DiPiro, Robert L. Talbert, Gary C.Yee, Gary R. Matzke. Publisher: McGraw-Hill Education

10. Modern Pharmacology with Clinical Applications, Charles R. Craig, Robert E. Stitzel. Publisher: Lippincott Williams and Wilkins publisher. 7812.
11. Integrated Pharmacology, Clive P. Page, Brian Hoffman, Michael Curtis, Michael Walker; Publisher: Mosby Elsevier.
12. Introduction to Pharmacology, S.K Kulkarni, Vallabh Prakashan.

PHARMACEUTICAL MICROBIOLOGY - THEORY

Total Credits 2 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

The Course aims to

1. Introduce students to 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. Educate on Good Manufacturing Practices (GMP) related to microbial contamination control.
4. Train students 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

By the end of the course, 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.
6. Perform microbial limit and sterility tests in compliance with pharmacopeial guidelines.

COURSE CONTENTS

UNIT I **6 Hours**

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.
- Identification of bacteria using staining techniques (simple, Gram‘s &Acid-fast staining) and biochemical tests (IMViC).
- Antibiotics produced by microbiology (Production and uses of Penicillin,

streptomycin, cephalosporin)

UNIT II **6 Hours**

Evaluation of microbiological contamination

- Sources and types of microbial contaminant
- Control of microbial contamination during manufacture of Non sterile 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.

UNIT III **6 Hours**

Microbial control and evaluation

- Designing of aseptic area. Laminar flow equipments, Clean area classification, Biological Safety Level categories. Methods of prevention. Disinfectants, antiseptics, and preservatives, and their evaluation, Factors affecting the antimicrobial activity of disinfectants

UNIT IV **6 Hours**

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

UNIT V **6 Hours**

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

RECOMMENDED BOOKS:

1. Pelczar, M.J., Chan, E.C.S., & Krieg, N.R. Microbiology: Concepts and Applications
2. Prescott, L.M., Harley, J.P., & Klein, D.A. Microbiology, 9th Edition
3. *Hugo, W.B. & Russell, A.D.* Pharmaceutical Microbiology, 8th Edition
4. Waites, M.J., Morgan, N.L. et al. – Industrial Microbiology: An Introduction
5. Denyer, S.P., Hodges, N.A. & Gorman, S.P. – Hugo and Russell's Pharmaceutical Microbiology
6. Atlas, R.M. – Handbook of Microbiological Media
7. Sandle ,T., Pharmaceutical Microbiology: Essentials for Quality Assurance and Quality Control, Publisher: Elsevier
8. Richard, P., Microbiology in Pharmaceutical Manufacturing, Publisher: PDA/DHI Edition: 2nd Edition (2008)

ENVIRONMENTAL SCIENCES - THEORY

Total Credits 1 **Hours / Week: 1** **15 HR**

COURSE OBJECTIVES:

1. Understand 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. Advocate for sustainable practices and energy-efficient operations within pharmaceutical industries.
6. Interpret environmental policies and engage in field-based learning through visits to treatment or purification facilities.

COURSE OUTCOMES

After completing this course, 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.
6. Familiarize with environmental laws, regulatory bodies, and major government initiatives promoting environmental protection and public health

COURSE CONTENTS:

Unit 1: Environmental Pollution **3 Hours**

- Definition, scope, and importance of environmental studies
- Types, causes, effects, and control measures:

    - 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

UNIT II: Pharmaceutical Waste and Effluent Management 3 Hours

- 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)

UNIT III: Environmental Impact of the Pharmaceutical Industry 3 Hours

- 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

UNIT IV: Sustainability in the Pharmaceutical Sector 3 Hours

- Principles of sustainable development in pharma
- Principles and Practices of Green pharmacy
- Energy conservation and resource optimization.

UNIT V: Government Policies, Compliance, and Practical Exposure 3 Hours

- Environmental laws:
    - Environmental Protection Act, 1986
    - Water (Prevention and Control of Pollution) Act
- National Green Tribunal (NGT) and regulatory bodies (CPCB, SPCB)
- Government initiatives:
    - Swachh Bharat Abhiyan
    - Namami Gange Programme
    - Jal Jeevan Mission

RECOMMENDED BOOKS (LATEST EDITION):

1. Dr. Erach Bharucha, *Environmental Studies*, Publisher: University Grants Commission (UGC), New Delhi
2. Anubha Kaushik & C.P. Kaushik, *Textbook of Environmental Studies*, Publisher: New Age International
3. Rajagopalan, R., *Environmental Studies*, Publisher: Oxford University Press
4. Benny Joseph, *Environmental Studies*, Publisher: Tata McGraw Hill
5. Purohit, Agrawal & Mathur, *A Textbook of Environmental Science*, Publisher: Agrobios (India)
6. R.K. Sharma, *Biomedical Waste Management: Handling and Practices*, Publisher: VK Global Publications

Pharmaceutical engineering (Theory)

Credits :2 **Hours / Week : 2** **Hours /Sem: 30**

Course Objectives :
This course is designed to give insights to students regarding Unit operations associated with pharmaceutical manufacturing . During this course, the students should be able to:

1. Understand the basic principles of pharmaceutical unit operations and equipments associated with pharmaceutical solid manufacturing.
2. Understand the basic principles of pharmaceutical unit operations and equipments associated with pharmaceutical liquid manufacturing.
3. Know various drying, evaporation, and distillation methods utilized in pharmaceutical production.
4. Gain insight into material handling systems, corrosion control, and waste management for pharmaceutical plants.
5. Utilize fluid dynamics and flow measurement concepts to pharmaceutical processes.

Course Outcomes:
On successful completion of the course, the students will be able to:

1. Describe the fundamentals and pharmaceutical applications of unit operations such as size reduction, mixing, and size separation.
2. Identify and describe the construction, working, and utility of various pharmaceutical engineering equipment.
3. Apply knowledge of fluid flow concepts, including Bernoulli's theorem and Reynolds number, to analyze pharmaceutical flow systems.
4. Compare and evaluate different thermal processes such as drying, evaporation, distillation, and heat transfer based on operational efficiency.
5. Demonstrate knowledge of safe and effective material handling systems and the influence of corrosion on drug plant design.
6. Examine the relevance of contemporary technological trends such as PAT, automation, and AI to improving pharmaceutical manufacturing processes.

Course Content

Unit I [6 Hrs]

Unit operations associated with solids

Fundamentals , theory and pharmaceutical applications of size reduction , size separation , Mixing, along with equipments (Principle, construction, working , advantages and disadvantages)

Unit II [7 Hrs]

Unit operations associated with liquids

Fundamentals , theory and pharmaceutical applications of Filtration , extraction , centrifugation along with equipments (Principle, construction, working , advantages and disadvantages)

Unit 3 [7 Hrs]

Unit operations associated with Heat transfer

Fundamentals , theory and pharmaceutical applications of Evaporation , drying , Distillation and Heat transfer along with equipments (Principle, construction, working , advantages and disadvantages), Energy losses

Unit 4 [7Hrs]

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.

Unit 5 [3 Hrs]

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.

Recommended Books

1. **"Pharmaceutical Engineering"** – Dr. G.S. Banker
2. **"Handbook of Pharmaceutical Manufacturing Formulations" (Vol. 1–6)** – Sarfaraz K. Niazi
3. **"Pharmaceutical Industry: An Introduction"** – Graham Dukes
4. **"Introduction to Pharmaceutical Engineering"** – K. Sambamurthy
5. **"Principles and Modern Applications of Mass Transfer Operations"** – Jamie Valenzuela and Jaime Benitez
6. **"Environmental Management in the Pharmaceutical Industry"** – Bernd Bilitewski
7. **"Pharmaceutical Manufacturing Handbook: Production and Processes"** – Shayne Cox Gad

8. Pharmaceutical Engineering", Author: Michael Levin Publisher: Informa Healthcare
9. Good Design Practices for GMP Pharmaceutical Facilities", Editor: T. F. Kennedy, Publisher: CRC Press
10. "Modern Pharmaceutics" (Volumes 1 & 2), Authors: Gilbert S. Banker & Christopher T. Rhodes, Publisher: CRC Press
11. "Pharmaceutical Process Engineering", Author: Anthony J. Hickey, Publisher: CRC Press
12. Pharmaceutical Facilities: Design, Layouts and Validation", Author: G. C. Cole, Publisher: CRC Press
13. Fundamentals of Modern Pharmaceutical Process Engineering", Author: F. John Bertch, Publisher: Academic Press.
14. Environmental Management in the Pharmaceutical Industry" Editor: Andrew G. Chase, Publisher: Springer
15. Pharmaceutical Production Facilities: Design and Applications", Author: Graham Bunn, Publisher: CRC Press

ETHICS AND UNIVERSAL HUMAN VALUES - THEORY

Total Credits 1 **Hours / Week: 1** **15 HR**

COURSE OBJECTIVES

1. To create an awareness on Pharmacy Ethics and Human Values.
2. To understand social responsibility as Pharmacist.
3. To appreciate ethical dilemma while discharging duties in professional life.

COURSE OUTCOMES

On completion of this course, the students will be able to

1. Understand the significance of value inputs in a classroom and start applying them in their life and profession
2. Distinguish between values and skills, happiness and accumulation of physical facilities, the Self and the Body, Intention and Competence of an individual, etc.
3. Understand the role of a human being in ensuring harmony in self, family, society & nature and apply in professional life.

COURSE CONTENTS

UNIT I: Introduction to Value Education **5 Hours**

1. Value Education, Definition, Concept and Need for Value Education.
2. The Content and Process of Value Education.
3. Apply Different values in the regular life
4. Self-exploration-Attitude, confidence.. as a means of Value Education.
5. Right understanding about Happiness and Prosperity.

UNIT II: Harmony in the Human Being **5 Hours**

1. Human Being is more than just the Body.
2. Harmony of the Self ('I') with the Body.
3. Understanding Myself as Co-existence of the Self and the Body.
4. Understanding Needs of the Self and the needs of the Body.
5. Understanding the activities in the Self and the activities in the Body.

UNIT III: Harmony in the Family and Society and Harmony in the Nature 5 Hours

1. Family as a basic unit of Human Interaction and Values in Relationships.
2. The Basics for Respect and today's Crisis: Affection, kindness, Guidance, Reverence, Glory, Gratitude and Love.
3. Comprehensive Human Goal: The Five Dimensions of Human Endeavour.

4. Harmony in Nature: The Four Orders in Nature.
5. The Holistic Perception of Harmony in Existence.

RECOMMENDED BOOKS

1. Human Values, A.N. Tripathi, New Age Intl. Publishers, New Delhi, 2004.
2. A Foundation Course in Human Values and Professional Ethics, R R Gaur, R Asthana, G P Bagaria, 2nd Revised Edition, Excel Books, New Delhi, 2019.
3. Teachers' Manual for A Foundation Course in Human Values and Professional Ethics, R R Gaur, R Asthana, G P Bagaria, 2nd Revised Edition, Excel Books, New Delhi, 2019.

AI IN PREFORMULATION & FORMULATION

Total Credits 2 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

1. Explain how AI supports decision-making in pre-formulation studies.
2. Teach AI methods to improve solubility and predict key physicochemical properties.
3. Train students to model fluid dynamics, particle behavior, and rheology with machine learning.
4. Show how AI optimizes processes, prevents equipment failures, and safeguards product quality.
5. Enable learners to build models that forecast degradation, shelf life, and drug-release kinetics.

COURSE OUTCOMES

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

1. Describe the role of AI across pre-formulation workflows.
2. Generate regression models to estimate solubility, melting point, and boiling point using molecular descriptors.
3. Apply machine learning tools to analyze fluid flow, particle separation, and predict viscosity behavior.
4. Implement AI-based control strategies for early detection of process faults.
5. Develop neural network models to predict drug stability and release profiles under various conditions.

COURSE CONTENTS

Unit 1: Introduction to AI in Preformulation Studies **6 Hours**

- Overview of artificial intelligence in pharmaceutical sciences
- Role of AI in decision-making during preformulation workflows
- Importance of predictive modeling in early-stage drug development

Unit 2: AI-Driven Physicochemical Property Prediction **6 Hours**

- Strategies to enhance solubility and bioavailability using AI
- Regression models for predicting melting and boiling points from molecular descriptors
- Data sources and feature selection in predictive property modelling

Unit 3: AI for Fluid Dynamics and Rheology **6 Hours**

- Machine learning in fluid dynamics analysis
- Prediction of particle behavior and separation techniques
- AI/ML algorithms for modeling viscosity and rheological profiles

Unit 4: AI-Based Process Optimization and Control **6 Hours**

- Role of AI in pharmaceutical process optimization
- Predictive maintenance and equipment failure prevention
- AI systems for ensuring consistent product quality and compliance

Unit 5: Stability, Shelf Life, and Drug Release Prediction **6 Hours**

- Neural network models for degradation pathway and shelf-life prediction under varying conditions
- Machine learning for modeling drug-release kinetics
- Case studies of AI applications in formulation design and lifecycle management

RECOMMENDED BOOKS

1. Pharmaceutical Preformulation and Formulation by Mark Gibson.
2. A Handbook of Artificial Intelligence in Drug Delivery edited by Abhay S. Shukla and Reinhold Kesharwani.
3. Artificial Intelligence for Drug Product Lifecycle Applications by Alexander Pais and José M. Martínez.
4. Machine Learning in Materials Science (ACS In Focus series) by the American Chemical Society
5. Artificial Intelligence in Manufacturing: Applications and Case Studies edited by O. Pierson and colleagues.

Pharmaceutical Dosage Forms: Solids and Liquids (Practicals)

Credits: 2 . **Hours/Week:** 4 **Hours/Sem:** 60

Course Objectives

1. Understand preformulation principles and evaluation of key parameters for drugs, excipients, and dosage forms.
2. Apply compatibility and solubility testing to inform successful formulation development.
3. Distinguish manufacturing processes for powders/solids, liquids, and selected sterile preparations.
4. Assess quality control and stability testing for solids and liquids, with extensions to sterile products.
5. Differentiate coated vs uncoated tablets and gelatin vs non-gelatin capsules by physicochemical tests.
6. Compare drug-release profiles and utilize sustained/controlled-release concepts in development.
7. Practice fundamentals of sterile product handling, water quality, packaging components, and basic sterility/endotoxin testing (demonstration/simulation as appropriate).

Course Outcomes

Upon completion, students will be able to:

1. Identify and execute preformulation studies for drug and excipient selection.
2. Perform drug–excipient compatibility and saturation-solubility experiments.
3. Develop and evaluate granulated, coated, and sustained-release tablets.
4. Conduct pharmacopeial QC tests for tablets and capsules.
5. Design, manufacture, and evaluate monophasic/biphasic liquids; compare dissolution/release profiles.
6. Evaluate stability under accelerated conditions using stability chambers.
7. Demonstrate foundational sterile practices: water quality specs, container–closure evaluation, basic sterility and endotoxin testing, and injectability/syringability assessment.

List of Practicals

1. Preformulation study of any drug/excipient as per pharmacopoeia.
2. Preparation & evaluation of tablets by direct compression.
3. Preparation & evaluation of tablets by dry granulation.
4. Preparation & evaluation of tablets by wet granulation.
5. Quality control of marketed tablets (IR, coated, enteric-coated).
6. Preparation & evaluation of coated tablets (include dissolution profile comparison).
7. Preparation & evaluation of hard-/non-gelatin capsules (fill weight, disintegration).
8. Virtual demonstration: hard-gelatin shell and soft-gel manufacturing (with overview of aseptic line/isolator).
9. Evaluation of pharmaceutical waters: Purified & Distilled Water as per IP; review of WFI specifications(conductivity/TOC limits—demo/simulation).
10. Preparation & evaluation of medicated syrups using simple and artificial syrup bases.
11. Preparation & evaluation of an emulsion with a small-dose oily active (e.g., calciferol).
12. Preparation & evaluation of an oral suspension, including sedimentation-volume study using different suspending agents/concentrations.
13. Preparation & evaluation of a dry powder for reconstitution as a suspension.

14. Evaluation of packaging components for sterile products: glass vials, plastic infusion bottles, rubber closures (basic extractables screening/closure integrity demonstration).
15. Preparation & evaluation of a sterile ophthalmic solution (e.g., timolol): pH, tonicity adjustment, drop size, clarity (sterility by simulation).
16. Sterility test (direct inoculation) – demonstration on a marketed parenteral product.
17. QC analysis of a marketed aerosol/MDI: spray pattern, dose per actuation, drug content.
18. Syringability and injectability assessment of a parenteral formulation (simulated setup).

Note: A minimum of **12** experiments must be performed.

HETEROCYCLIC COMPOUNDS AND STEREO CHEMISTRY - PRACTICALS

Total Credits 2 **Hours / Week: 4** **60 HR**

COURSE OBJECTIVES

This course focuses on the preparation, purification, and reactions of organic compounds, as well as the separation of binary organic mixtures. The key objectives are:

1. Students will understand basic laboratory safety rules and learn how to handle chemicals and glassware properly.
2. Students will gain hands-on experience in preparing, purifying, and identifying organic compounds.
3. Students will learn practical techniques to separate components of binary organic mixtures.
4. Students will be introduced to digital tools for drawing chemical structures and Chemical Reactions.

COURSE OUTCOMES

Upon completion of this course, the students will 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. Estimate molecular properties of aromatic organic and heterocyclic compounds.

COURSE CONTENTS (Any 13 experiments)

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 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 BOOKS

1) Practical Organic Chemistry, by Mann and Saunders, Pearson Education India

2) Introduction to Organic Laboratory Techniues: A Small Scale Approach, by Donald L. Pavia, Gary M. Lampman, George S. Kriz,Brooks/Cole,

3) Heterocyclic Chemistry, by Raj K Bansal, New Age International,

4) Vogel's text book of Practical Organic Chemistry

5) Advanced Practical organic chemistry by N.K.Vishnoi

GENERAL PHARMACOLOGY - PRACTICALS

Total Credits 2 **Hours / Week: 4** **60 HR**

COURSE OBJECTIVES

1. To understand the historical and foundational aspects of experimental pharmacology
2. To develop knowledge and practical awareness of ethical and regulatory standards in laboratory animal care and use, as outlined in CCSEA guidelines
3. To acquire skills in pharmacological data acquisition and analysis
4. To interpret and construct dose-response curves (DRCs) and calculate and interpret pharmacological indices such as LD50, threshold and ceiling dose, slope of DRC, and PD_2,
5. To calculate the pharmacokinetic parameters and analyse the roles of pharmacokinetic parameters in the drug effects, and dosing schedule.

COURSE OUTCOMES

Upon completion of this course, 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 analyse 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

COURSE CONTENTS

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.

- To study concept of 3Rs along with the maintenance and experimentation on laboratory animals as per the CCSEA guidelines.

4. To demonstrate collection/isolation of the following biological samples- blood, cerebrospinal fluid, DNA and RNA using computer simulations and audiovisual aids.
5. To study important anaesthetics and euthanasia procedures for experimental animals.
6. To demonstrate different routes drug administration using computer simulation and understand the significance of each route along with the maximum administrable dose.
7. 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.
8. To study the instrumentation used for isolated tissue experiments (students organ bath assembly) and recent development in recording of the responses of isolated tissues.
9. To record the dose response curve of any two agonists on suitable isolated tissue preparation using computer simulation experiment.
10. To study the potentiating effect of physostigmine on DRC of acetyl choline through interactive computer simulation.
11. To study antagonizing effect of d-tubocurarine on the DRCs of acetylcholine through interactive computer simulation.
12. To determine of PD2 of given agonists using isolated tissue preparation using computer simulation experiment.
13. To study and determine various pharmacokinetic parameters (Cmax, tmax, KE, t1/2, Vd, Clt, AUC, AUMC) from a given hypothetical data.
14. To estimate LD 50 by using the given of hypothetical data using computer simulation experimentation (as per OECD 425 guideline using opensource AOT software).
15. Zebra fish embryotoxicity testing with the help of simulations and charts (optional 1).

RECOMMENDED BOOKS (LATEST EDITIONS/VERSIONS)

1. CAL software package: a suitable interactive simulation on which examination can be conducted.

2. Fundamentals of Experimental Pharmacology. Ghosh MN. Publisher: Hilton & Company, Kolkata.

3. Handbook of experimental pharmacology. Kulkarni SK. Publisher: Vallabh Prakashan.

4. Practical Pharmacology, Goyal RK. Publisher: B. S. Shah Publisher805. OECD guidelines for toxicity and Safety Pharmacology

6. ICH guideline 7A and 7B.

Elective 2 – AEC (Practical)

Total Credits 1 **Hours / Week: 2** **30 HR**

The syllabi for elective subjects are given in the appendices

SEMESTER IV

HERBAL DRUG TECHNOLOGY - THEORY

Total Credits 3 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

1. Understand and apply plant tissue culture techniques for secondary metabolite production.
2. Learn the standardization and formulation of herbal products and cosmetics.
3. Evaluate herb-drug and herb-food interactions for clinical safety.
4. Interpret regulatory frameworks and quality standards for herbal medicines.

COURSE OUTCOMES

After successful completion, students will be able to:

1. Demonstrate tissue culture applications for herbal drug production and edible vaccines.
2. Develop standardized extracts and incorporate them in herbal formulations and cosmetics.
3. Apply analytical and spectroscopic 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.

COURSE CONTENTS

UNIT-I **11 Hours**

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 soma-clonal 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 example Shikonin and Paclitaxel, status and future scope of edible vaccines in health care.

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 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 Adulsa

UNIT-II **10 Hours**

Herbal formulations, excipients and cosmetics

Herbal formulations: Conventional herbal formulations like syrups, mixtures, powders, capsules, tablets, creams and ointments and Novel dosage forms like phytosomes, liposomes, nano formulations, their composition, preparation and characterization using standardized extracts and bio actives.

Excipients: Natural origin excipients colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes.

Herbal Cosmetics: Sources and description of raw materials of herbal origin like fixed oils, waxes, gums, colours, perfumes, protective agents, bleaching agents, antioxidants used 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.

UNIT-III **5 Hours**

Quality Control and Standardisation of Herbal Medicines

WHO, AYUSH, and ICH guidelines on quality control, stability, and shelf life studies of herbal medicines. Approaches for the standardisation and quality control of botanicals and formulations, including testing methods and regulatory considerations. Role of Molecular Markers such as DNA Fingerprinting rbcL, matK and SCAR marker in quality control of botanicals and formulations. Forensic pharmacognosy: Role of Forensic pharmacognosy in identification of illicit herbal drugs (Ex: Cannabis, Opium)

UNIT-IV **05 Hours**

Herb-Drug/Food/Herb Interactions: General introduction to interaction and role of ADME, Cytochrome p450 and P-gp in herb-Drug/Food/Herb interactions. Ex: Black pepper, Garlic

Herb-drug interactions: St. John's Wort with warfarin, Ginkgo biloba with aspirin.

Herb-food interactions: Licorice with salty foods, Turmeric with fats and Green tea with iron rich foods.

Herb-herb interactions: Ephedra with Ginseng, Chamomile with Valerian.

Adverse reactions related to plants and foods such as allergy, intolerance, toxicity etc.

UNIT-V **08 Hours**

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 Z: Guidelines for clinical evaluation of Ayurvedic, Siddha, and Unani drugs

(f) Schedule E1: Poisonous drugs listed under Ayush

(g) The Drugs and Cosmetics Act – Regulatory provisions relevant to herbal/ASU medicines, procedures for registration, trade, and export of herbal medicinal products in India.

(h) Concept of Phytopharmaceuticals and Ayush Aahara in bridging Indian traditional knowledge with modern science

RECOMMENDED BOOKS: (LATEST EDITIONS)

1. Waldesch, F.G. (2003). Herbal Medicinal Products. CRC Press, London.
2. Choudhary, R.D. (1996). Herbal Drug Products Industry. 1st Ed., Eastern Publishers, New Delhi.
3. Mukherjee, P.K. (2003). GMP for Botanicals: Regulatory and Quality Issues on Phytomedicine, 1st Ed., Business Horizons, New Delhi.
4. Pande, H. (2004). Herbal Cosmetics, Asia Pacific Business Press Inc., New Delhi.
5. Pande, H. (2008). The Complete Technology Book on Herbal Perfumes and Cosmetics, National Institute of Industrial Research, Delhi.
6. Kalia, A.N. (2005). Herbal Drug Technology. Vallabh Prakashan, New Delhi.
7. Mukherjee, P.K. (2002). Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals, 1st Ed., Business Horizons Pharmaceutical Publishers, New Delhi.
8. Jalalpure, S.S., Kurangi, B.K., & Nirmale, D.M. (2023). Intellectual Property Rights. Nirali Prakashan, Pune.
9. PDR for Herbal Medicines (2000). 2nd Ed., Medicinal Economic Company, Montvale, New Jersey.
10. Indian Herbal Pharmacopoeia (2002). Revised Edition, IDMA, Mumbai.

11. Sinha, D., Mukherjee, S., & Chowdhury, S. (2022). "Methods of Extraction of Phytochemicals." In: Recent Advances in Extraction Technologies, IGI Global. DOI: 10.4018/978-1-6684-7337-5.ch010
12. Jalalpure, S.S. & Kurangi, B.K. (2022). Textbook of Herbal Drug Products Technology, Vallabh Prakashan, Delhi.
13. World Health Organization (WHO). Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants, Geneva. Available at: WHO GACP PDF 14. Kalia, A.N. (2005).
14. Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi.
15. The Drugs and Cosmetics Act (India) – Relevant Schedules: • Schedule T: GMP requirements for ASU Drugs • Schedule Z: Clinical evaluation of ASU drugs • Schedule E1: List of poisonous substances under AYUSH

MEDICINAL CHEMISTRY - THEORY

Total Credits 3 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

The primary objectives of this course are to;

1. Acquire a thorough understanding of the core principles of medicinal chemistry, including physicochemical properties, drug metabolism, and prodrug concepts.
2. Classify and characterize 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 predict and explain the pharmacological activity of selected drug classes.
4. Describe the synthesis of selected drugs from different therapeutic categories, focusing on key reaction steps and chemical transformations.
5. Analyze the relationship between drug structure and its overall pharmacological effect and therapeutic utility.

COURSE OUTCOMES

Upon completion of the course, students shall 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.
6. Apply the knowledge of medicinal chemistry principles to understand and potentially contribute to the drug discovery and development process.

COURSE CONTENTS

Unit I: Fundamentals of Medicinal Chemistry **10 Hours**

- **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
- **Prodrug Concept:** Basic principles, Types and applications of the **Prodrug**

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 (*)

Unit II: Drugs Acting on the Autonomic Nervous System **12 Hours**

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, Methysergide. Propranolol*, Metibranolol, Atenolol, Betazolol, Bisoprolol, Esmolol, Metoprolol, Labetolol, 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 sulphate, Hyoscyamine sulphate, Scopolamine hydrobromide, Homatropine hydrobromide, Ipratropium bromide*, Tropicamide, Cyclopentolate hydrochloride, Clidinium Glycopyrrolate, Dicyclomine hydrochloride*, Methantheline bromide, Propantheline bromide, Benztropine mesylate, Orphenadrine citrate, Biperidine hydrochloride, Procyclidine hydrochloride, Tridihexethyl chloride, Isopropamide iodide, Ethopropazine hydrochloride, 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

Unit III: Drugs Acting on the Cardiovascular System 8 Hours

1. **Anti-anginals:** Amyl nitrite, Nitroglycerin, Pentaerythritol tetranitrate, Isosorbide dinitrite*, Dipyridamole, Verapamil, Bepridil hydrochloride, Diltiazem hydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine.
2. **Anti-hypertensives:** Timolol, Captopril, Lisinopril, Enalapril, Benazepril hydrochloride, Quinapril hydrochloride, Methyldopate hydrochloride,* Clonidine hydrochloride, Guanethidine monosulphate, Guanabenz acetate, Sodium nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.
3. **Drugs to treat Congestive Heart Failure (CHF):** Digoxin, Digitoxin, Nesiritide, Bosentan,Tezosentan.
4. **Anti-arrhythmics (Class I–IV):** Quinidine sulphate, Procainamide hydrochloride, Disopyramide phosphate*, Phenytoin sodium, Lidocaine hydrochloride, Tocainide hydrochloride, Mexiletine hydrochloride, Lorcainide hydrochloride, Amiodarone, Sotalol.

Unit IV: Drugs acting on blood and Renal System 7 Hours

1. **Antihyperlipidemic Agents:** Clofibrate*, 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.

Unit V: Autacoids and related drugs 8 Hours

1. **Antihistamines**
   a. **H1–antagonists:** Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines succinate, Clemastine fumarate, Diphenylphyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride, Phenindamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium
   b. **H2-antagonists:** Cimetidine*, Famotidine, Ranitidine.
2. **Gastric Proton pump inhibitors:** Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole
3. **Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), Antipyretics:** Sodium salicylate, Aspirin, *Diflunisal,* Mefenamic acid*, *Niflumic acid,* Meclofenamate, Indomethacin, Sulindac, Tolmetin, Zomepriac, Diclofenac, Ketorolac, Ibuprofen*, Naproxen, Piroxicam, Phenacetin, Acetaminophen, Antipyrine, Phenylbutazone, *Celecoxib*, *Etoricoxib,* SAR of representative agents by class.

RECOMMENDED BOOKS

1. Foye's Principles of Medicinal Chemistry – Authors: Thomas L. Lemke, David A. Williams, and Virginia F. Roche
2. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry –Editors: John M. Beale Jr., John T. Thomas, and Michael H. Duckett
3. Burger's Medicinal Chemistry and Drug Discovery, Editors: Donald J. Abraham and John L. Griffin
4. An Introduction to Medicinal Chemistry by Graham L.Patrick.
5. Medicinal Chemistry by Ashutosh Kar
6. Modern Drug Synthesis" by Jie Jack Li, William M. Welch, and others
7. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
8. Medicinal Chemistry by Sriram & Yogeeswari
9. Textbook of Medicinal Chemistry Vol. 1 & 2 by V. Alagarsamy
10. Text book of practical organic chemistry- A.I.Vogel
11. Goodman & Gilman's The Pharmacological Basis of Therapeutics – Laurence L. Brunton et al.

SYSTEMIC PHARMACOLOGY AND AUTACOIDS - THEORY

Total Credits 3 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

1. To provide detailed information on the mechanisms of neurohumoral transmission including classification of the neurotransmitters to enable the learners to understand structure, role, and function of the autonomic nervous system (ANS)
2. To impart the knowledge regarding the pharmacology of various classes of drugs
3. To provide understanding of the classification and pharmacology of drugs acting on Peripheral nervous system, cardiovascular system, and urinary system
4. To impart knowledge regarding the pharmacology of autacoids and pharmacology of drugs used in treatment of acute and chronic pulmonary diseases and disorders.
5. To familiarize the learners regarding the pharmacology of drugs acting on immune system, hematopoietic system, and blood

COURSE OUTCOMES

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

1. Write classification of neurotransmitters and describe the neurohumoral transmission along with the organization, function, and pharmacological modulation of the autonomic nervous system and its neurotransmitters.
2. Classify, differentiate, and appraise the mechanisms of action and pharmacology of drugs used in the treatment of cardiovascular diseases, including heart failure, arrhythmias, hypertension, angina, and lipid disorders.
3. Evaluate the therapeutic uses of stroke and shock drugs used in treating renal and fluid-related conditions and describe the sites of actions of diuretics.
4. Enlist the physiological and pathological roles of autacoids along the classification of their receptors and explain the pharmacology of drugs related to modulation of autacoids.
5. Critically evaluate the mechanisms of action, therapeutic uses, and potential side effects of various drugs acting on blood and immune system.

COURSE CONTENTS

UNIT–I **10 Hours**

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.

UNIT–II **10 Hours**

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.

UNIT–III **10 Hours**

i) 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.

ii) Pharmacology of drugs acting on kidney

a) Diuretics.

b) Anti-diuretics.

UNIT- IV **09 Hours**

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,99bradykinin 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).

UNIT–V **06 Hours**

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, 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 BOOKS (LATEST EDITIONS):

Updated versions of the following books are recommended

1. Rang & Dale's Pharmacology, H.P. Rang, M.M. Dale, J.M. Ritter, R.J. Flower, G. Henderson,Publisher: Elsevier
2. Katzung & Trevor's Pharmacology Examination and Board Review, Bertram G. Katzung, Marieke Kruidering-Hall, Rupa Lalchandani Tuan, Todd W. Vanderah, Anthony J. Trevor Publisher: McGrow Hills Lange.
3. Goodman & Gilman's: The Pharmacological Basis of Therapeutics, Laurence L. Brunton, Randa Hilal-Dandan, Bjorn Knollmann. Publisher: McGraw-Hill Education, Edition: 13th Edition (2017)
4. Basic and Clinical Pharmacology, Bertram Katzung, Anthony Trevor. Publisher: McGraw-Hill Education.
5. Richard Finkel, Lippincott's Illustrated Reviews: Pharmacology, Karen Whalen, Publisher:Wolters Kluwer.
6. Pharmacology and Pharmacotherapeutics, R.S. Satoskar, Nirmala N. Rege, S.D. Bhandarkar. Publisher: Elsevier India
7. Modern Pharmacology with Clinical Applications, U.D. Tripathi, U. K. Seth. Publisher: CBS Publishers & Distributors Pvt Ltd
8. Principles of Pharmacology, H.L. Sharma, K.K. Sharma, Publisher: Paras Medical Publisher.
9. Essentials of Medical Pharmacology, K.D. Tripathi., Publishers: Jaypee Brothers Medical
10. Pharmacotherapy: A Pathophysiologic Approach. Joseph T. DiPiro, Robert L. Talbert, Gary C. Yee, Gary R. Matzke. Publisher: McGraw-Hill Education
11. Modern Pharmacology with Clinical Applications, Charles R. Craig, Robert E. Stitzel.

Publisher: Lippincott Williams and Wilkins publisher.

12. Integrated Pharmacology, Clive P. Page, Brian Hoffman, Michael Curtis , Michael Walker; Publisher: Mosby Elsevier.
13. Introduction to Pharmacology, S.K Kulkarni, Vallabh Prakashan.

PHARMACEUTICAL BIOTECHNOLOGY - THEORY

Total Credits 2 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

1. **Understanding Biotechnology in Pharmaceuticals**: To provide foundational knowledge on biotechnology concepts, including protein therapeutics, monoclonal antibodies, enzyme immobilization, and their pharmaceutical applications, along with an understanding of genetic engineering and recombinant DNA technology in medical applications.
2. **Exploring Microbial Biotransformation and Production Techniques**: To equip students with knowledge of microbial biotransformation, fermentation methods, and large-scale production of various pharmaceutical products like alcohol, penicillin, vaccines, and blood products, alongside an introduction to the design and operation of production fermenters.
3. **Focusing on Gene Therapy and Vaccines**: To delve into gene therapy, its ethical concerns, methodologies, and delivery systems, while exploring vaccine types, preparation, and immunization strategies, as well as addressing the regulatory and standardization aspects of vaccines and sera in the pharmaceutical industry.

COURSE OUTCOMES

Upon completion of this course the student should be able to:

1. Describe the role of biotechnology in pharmaceuticals and explain monoclonal antibody production and enzyme immobilization.
2. Apply genetic engineering techniques for the production of biopharmaceuticals like insulin, interferons, and vaccines.
3. Describe microbial biotransformation and analyze industrial fermentation processes and their pharmaceutical applications.
4. Assess the role of bioinformatics and AI in the Human Genome Project and personalized medicine.
5. Describe vaccine and sera development processes, including standardization, evaluation, and regulatory considerations.
6. Critically assess new approaches and challenges in vaccine and sera development and commercialization.

COURSE CONTENTS

Unit I **6 Hours**

Brief introduction to Biotechnology with reference to Pharmaceutical Sciences. Pre-formulation study including the analytical characterization of protein therapeutics, Monoclonal antibodies and antigens. Methods of enzyme immobilization, Cell Culture and immobilization Techniques and its pharmaceutical applications.

Unit II **5 Hours**

Basic principles and applications of genetic engineering in pharmaceutical sciences. Application of r DNA technology and genetic engineering in the production of: i) Interferon ii) Vaccines- hepatitis- B iii) Hormones-Insulin. PCR and its application.

Mutations & Types of mutations/mutants.

Unit III **6 Hours**

Introduction to microbial biotransformation and applications. Basic principles and applications of fermentation technology and its various controls. Study of the production of- alcohol, penicillin's, citric acid, Vitamin B12. Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substitutes.

Unit IV **6 Hours**

Gene therapy and its types, basic methodologies for gene therapy. Current status and recent trends in gene therapy, Delivery systems in gene therapy, Ethical concerns of gene therapy, Challenges to gene therapy.

Overview of Human Genome Project, Role of AI in Personalized medicines using Bioinformatics tools

Unit V **7 Hours**

Immunology and Concept of Vaccines: types and generations of vaccines, Immunization, Immunology of vaccines Vaccine preparation Vaccines evaluation and standardization Regulatory consideration of vaccines Licensed vaccines Sera. Revolutions in serum therapy General method of preparation of sera Evaluation of sera, Standardization of sera, Regulatory consideration of sera, Marketed products of vaccines and sera, Challenges to vaccine and sera success, Introduction to New approaches for vaccines and sera.

RECOMMENDED BOOKS:

1. "Pharmaceutical Biotechnology: Fundamentals and Applications" by Daan J. A. Crommelin, Robert D. Sindelar, and Bernd Meibohm
2. "Biotechnology for Beginners" by Reinhard Renneberg
3. "Pharmaceutical Biotechnology: Drug Discovery and Clinical Applications" by J. G. McGinnity and R. M. B. L. Green
4. "Molecular Pharmaceutics and Nano Drug Delivery: Fundamentals and Challenges by Goyal A.K. and Gupta U.
5. "Fermentation and Biochemical Engineering Handbook" by Henry C. Vogel and Celeste L. C. Todaro
6. "Vaccines: Design, Delivery, and Development" by Gregory J. G. W. McDonald
7. "Recombinant DNA and Biotechnology: A Guide for the Educator" by James D. Watson
8. "Pharmaceutical Biotechnology by S. P. Vyas, V.K. Dixit
9. Biotechnology wiley -VCH, Volume 1-12

SOCIAL PHARMACY AND PUBLIC HEALTH - THEORY

Total Credits: 2 **2 Hours/Week** **30 Hours**

COURSE OBJECTIVES

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. Gain knowledge about the Indian healthcare system, national health policies, and important health programs.
5. Understand basic epidemiological principles and their application in public health.
6. Develop skills in health education, communication, and promoting rational drug use in the community.

COURSE OUTCOMES

Upon successful completion of this course, students should 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.
6. Analyze the impact of health policies and pharmacoeconomics on public health.

COURSE CONTENTS:

Unit 1: Introduction to Social Pharmacy and Public Health **6 Hours**

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 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, comprehensive dimensions of health (physical, mental, social, spiritual, and environmental).

e) **Determinants of Health:** In-depth look at social, economic, environmental, lifestyle, and healthcare service determinants and their impact on population health.

f) **Health Indicators:** Understanding various indicators used to measure health status and health outcomes in a population.

Unit 2: Health Systems, Policy and Pharmacoepidemiology 6 Hours

a) **Healthcare Delivery Systems:** Overview of global healthcare systems. Detailed study of the Indian Health System: structure, components (public and private sectors), and levels of care (primary, secondary, tertiary).

b) **Health Policy:** Introduction to health policy formulation and analysis. Key features and objectives of India's current National Health Policy.

c) **National Health Mission (NHM):** Goals, strategies, components (NRHM & NUHM), and its impact on public health indicators.

d) **Introduction to Pharmacoepidemiology:** Definition, aims, scope, and fundamental applications in identifying health problems and guiding interventions.

e) **Measures of Disease Frequency & Distribution:** Incidence, prevalence, endemic, epidemic, pandemic. Basic understanding of morbidity and mortality rates.

f) **Introduction to Biostatistics:** Role in public health, types of data, basic data presentation methods.

Unit 3: Preventive Healthcare, Health Promotion, and Communicable Diseases 6 Hours

a) **Principles of Prevention:** Levels of prevention (primordial, primary, secondary, tertiary) with examples.

b) **Role of Pharmacists in Disease Prevention and Health Promotion:** Immunization services, health screenings (e.g., blood pressure, blood glucose), counselling on lifestyle modifications (nutrition, physical activity, stress management, substance abuse cessation).

c) **Health Education:** Definition, principles, methods, and importance. Developing effective health education materials and communication strategies for diverse populations.

d) **Mother and Child Health (MCH):** Significance, components of MCH services, antenatal and postnatal care, importance of breastfeeding, immunization schedules.

e) **Communicable Diseases:** Pharmacoepidemiology, modes of transmission, prevention, and control strategies for major communicable diseases prevalent in India (e.g., Tuberculosis,

HIV/AIDS, Malaria, Dengue, Typhoid, Influenza). Pharmacist's role in management and awareness.

Unit 4: Non-Communicable Diseases, Nutrition, Mental Health, and National Programs

6 Hours

a) **Non-Communicable Diseases (NCDs):** Burden, major risk factors, prevention, screening, and management strategies for key NCDs (e.g., Diabetes Mellitus, Hypertension, Cardiovascular Diseases, Chronic Respiratory Diseases, Cancer). Pharmacist's role in NCD management and patient support.

b) **Nutrition and Health:** Concepts of balanced diet, macro and micronutrients, malnutrition (undernutrition and overnutrition), nutritional deficiency disorders, impact of junk food and processed foods. Food safety basics and adulteration.

c) **Mental Health and Well-being:** Introduction to mental health, common mental health disorders (anxiety, depression), stigma, promoting mental well-being, and the pharmacist's role in supporting individuals with mental health concerns.

d) **Overview of Key National Health Programs in India:** Focus on objectives, strategies, and the pharmacist's involvement in programs related to MCH, NCDs, communicable diseases, and others (e.g., National Tobacco Control Program, National Programme for Prevention and Control of Deafness).

Unit 5: Pharmacoeconomics, Appropriate use of medicines, Professional Roles, and Future Trends **6 Hours**

Introduction to Pharmacoeconomics: Basic concepts, significance in healthcare decision-making. Brief overview of methods like Cost-Benefit Analysis (CBA), Cost-Effectiveness Analysis (CEA), Cost-Utility Analysis (CUA).

a) **Appropriate Use of Medicines (RUM):** Definition, importance, problems of inappropriate drug use, and the pharmacist's crucial role in promoting RUM through patient counselling and collaboration with prescribers.

b) **Medication Adherence:** Factors influencing medication adherence, consequences of non-adherence, and pharmacist-led strategies to improve adherence.

c) **Drug Misuse and Abuse:** Social and health consequences of commonly abused substances (alcohol, tobacco, opioids, prescription drugs). Pharmacist’s role in prevention, identification of at-risk individuals, and referral.

d) **Professionalism and Ethics in Social Pharmacy:** Ethical dilemmas in public health pharmacy.

e) **Disaster Management:** Role of pharmacists in emergency preparedness and response.

f) **Emerging Trends in Social Pharmacy and Public Health:** Telepharmacy, digital health interventions, personalized medicine, and the expanding public health responsibilities of pharmacists.

RECOMMENDED BOOKS:

1. Park, K. (Year of latest edition). *Park's Textbook of Preventive and Social Medicine*. Banarsidas Bhanot Publishers.
2. Taylor, K., & Harding, G. (Year of latest edition). *Pharmacy Practice*. CRC Press, Taylor & Francis Group.
3. Essentials of Public Health Pharmacy – Bruce Lubotsky Levin, Ardis Hanson
4. Public Health and Pharmacy Practice – Shane Desselle
5. Social and Administrative Aspects of Pharmacy in Low- and Middle-Income Countries: Present Challenges and Future Solutions. Eds. Albert Wertheimer, Mohamed Izham Mohamed Ibrahim, Zaheer-Ud-Din Babar. Elsevier Science.
6. Introduction to Public Health – Mary-Jane Schneider
7. Anderson, S., Dedrick, R., & Tiffany, B. Community Pharmacy Practice for Public Health. Jones & Bartlett Learning.
8. Introduction To Public Health by by Mary-Jane Schneider. Jones and Bartlett Publishers, Inc.
9. Essential Public Health: Theory and Practice by Stephen Gillam, Jan Yates, Padmanabhan Badrinath. Cambridge University Press.
10. Social and Cognitive Pharmacy: Theory and Case Studies. Parastou Donyai. Pharmaceutical Press.

Online Learning Resources:

1. **World Health Organization (WHO):** https://www.who.int (Provides extensive information on global health issues, policies, and reports).
2. **Ministry of Health and Family Welfare, Government of India:** https://www.mohfw.gov.in (Source for national health policies, programs, and health statistics in India).
3. **National Health Portal (NHP) India:** https://www.nhp.gov.in (Information on diseases, health services, and wellness).
4. **Centre for Disease Control and Prevention (CDC):** https://www.cdc.gov (Comprehensive information on diseases, health promotion, and emergency preparedness).

5. **PubMed Central (PMC) and other Open Access Journals:** For research articles and reviews on social pharmacy and public health topics. (e.g., https://www.ncbi.nlm.nih.gov/pmc/)

AI IN DRUG DESIGN & DISCOVERY AND BIOINFORMATICS - THEORY

Total Credits 2 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

1. To introduce the fundamental principles of drug discovery and the evolution of scientific approaches across its stages.
2. To explain the role of biological targets, disease pathways, and screening strategies in early-stage drug development.
3. To familiarize students with computational methods used in structure prediction, virtual screening, pharmacokinetic, and toxicity profiling.
4. To develop an understanding of in silico modeling techniques and their integration into rational drug design.
5. To provide insights into regulatory frameworks and ethical considerations associated with modern drug development processes.

COURSE OUTCOMES

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

1. Know about various biological targets, Drug – receptor interactions, Molecular descriptors.
2. Interpret structural and biological data to assess target relevance
3. Describe the stages of drug discovery and the data-driven strategies used in target identification and druggability.
4. Analyze 2D and 3D-QSAR to optimize lead compounds.
5. Apply computational methodologies to simulate molecular interactions, evaluate compound properties, and predict pharmacokinetics

COURSE CONTENTS

Unit-I: Introduction to Drug Discovery and Development **10 Hours**

1. Historical evolution and milestones in drug discovery
2. Role of Artificial intelligence (AI) in accelerating drug discovery Disease linkage and types of biological targets
3. Introduction to Databases and Resources for major repository of biological data to carry out protein structure predictions.
4. 2D & 3D representations of chemical structure
5. Artificial Intelligence in ADMET prediction, Insilico prediction of activity, Drug design, QSAR studies, Drug Repurposing,
6. Computer Aided Drug Design (CADD) and Its applications

7. Various software and modules used in CADD and its applications (Both open source and commercial)
8. Chemical and Biological databases including natural, small molecule and protein databases like PubChem, ChEMBL, DrugBank, Zinc, Coconut, RCSB, NCBI etc.
9. Energy minimization and force fields
10. Drug – receptor interactions

Unit-II: Drug Design, Discovery and Lead Identification 10 Hours

1. Artificial Intelligence in Bioinformatics: Algorithms, Applications, and Advances, Deep learning-based methods to drug discovery
2. Target identification, Protein structure prediction, protein preparation using open source or commercial software
3. Ligand preparation using open source or commercial software
4. Principles of Molecular Docking studies using open source or commercial software
5. Virtual screening
6. Structure-based and Ligand-Based drug design
7. In-silico ADMET & Drug-Likeness Prediction using open source or commercial software

Unit-III: Lead Optimization & AI/ML Applications 10 Hours

1. 2D & 3D-QSAR
2. Pharmacophore modeling
3. Prediction of binding energy of ligand-receptor complex
4. Molecular similarity and similarity searching
5. Molecular dynamics
6. Drug repurposing
7. Reaction Prediction & Synthesis Planning
8. Artificial Intelligence in Interpretation of Advanced Spectroscopic and Chromatographic Data, Interpretation of NMR spectra for structural elucidation using AI
9. Demonstration of CADD modules using open-access or commercial software

Stage	Tool/Platform
Target Validation & Data Mining	KNIME, DrugBank, PubChem, STITCH, MolProphet
Structure Prediction	AlphaFold (AI-based), SWISS-MODEL
Molecular Docking	AutoDock, MZDock (open-source), iGemDock, GLIDE*, GOLD*
Pharmacophore Modeling	PharmaGist, PHASE*, MOE*

QSAR / Machine Learning	AutoQSAR*, KNIME, QSAR Toolbox, DTC QSAR, MolProphet
ADMET Prediction & Drug-likeness	SwissADME, pkCSM, Qikprop*, ProTox 3.0

*Commercial tools that may be demonstrated based on access and availability

REFERENCE BOOKS

1. Patrick, G. L. – An Introduction to Medicinal Chemistry
2. Silverman, R., Holladay, M. – The Organic Chemistry of Drug Design and Drug Action
3. Liu, X., Altman, R. – Drug Discovery and Development: Technology in Transition
4. Artificial Intelligence in Drug Discovery — Nathan Brown — Royal Society of Chemistry, 2020
5. Deep Learning for the Life Sciences — Bharath Ramsundar, Peter Eastman, Patrick Walters, Vijay Pande — O'Reilly Media, 2019
6. Machine Learning in Chemistry: The Impact of Artificial Intelligence — Hugh M. Cartwright (ed.) — Royal Society of Chemistry, 2020
7. Drug Design and Development: From Practice to Concept – Robin Ganellin

HERBAL DRUG TECHNOLOGY - PRACTICALS

Total Credits 1 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

1. To develop skills in seed germination and plant tissue culture of medicinal plants.
2. To learn preparation and standardization of herbal extracts and their phytochemical fractions.
3. To formulate and evaluate herbal cosmetics and dosage forms using natural excipients.
4. To introduce advanced herbal delivery systems like phytosomes.
5. To assess quality of marketed herbal formulations as per pharmacopoeial standards.

COURSE OUTCOMES

After successful completion, students will be able to:

1. Perform seed germination and plant tissue culture of medicinal plants.
2. Prepare and standardize various herbal extracts and phytochemical-rich fractions.
3. Formulate and evaluate herbal cosmetics and dosage forms.
4. Prepare and characterize phytosome-based herbal delivery systems.
5. Evaluate quality of marketed herbal formulations following pharmacopoeial guidelines.

COURSE CONTENTS

1. To establish seed germination and plant tissue culture of a medicinal plant.

2. Preparation and standardization of extracts of following drugs:

a) Aqueous and hydro-alcoholic extracts of Ashwagandha and Haritaki (as per IP procedure)

b) Flavonoid-enriched fraction of Sweet lime peel

c) Terpenoid-rich fraction of Bacopad) Phenol-rich fraction of Green Tea

e) Steroid-rich fraction of Tribulus

f) Alkaloid-rich fraction of Adulsa

3. Evaluation of excipients of natural origin.

4. Incorporation of prepared and standardized extracts in any of the cosmetic formulations such as gel, creams, lotions, shampoos, and their evaluation.

5. Incorporation of prepared and standardized extracts in any of the formulation like syrups, mixtures, and tablets, and their evaluation as per pharmacopoeial requirements.

6. Preparation of botanicals-based new herbal medicinal product delivery systems (phytosomes)

7. Experiential learning based experiments involving collection of herbal formulations/ extracts from the market and their quality evaluation as per Pharmacopoeial guidelines.

RECOMMENDED BOOKS: (LATEST EDITIONS)

1) Zhang, J., Wen, C., Zhang, H., Duan, Y., & Ma, H. (2020). "Recent Advances in the Extraction of Bioactive Compounds with Subcritical Water: A Review." Trends in Food Science & Technology, 95:183–195.

2) Asl, A.H., & Khajenoori, M. (2013). "Subcritical Water Extraction." In: Mass Transfer— Advances in Sustainable Energy and Environment Oriented Numerical Modeling, pp. 459-487.

3) Khandelwal, K.R. (2020). Practical Pharmacognosy: Techniques and Experiments. Nirali Prakashan, Pune.

4) Sarwa, K.K., et al. (2021). "Standardization and Quality Evaluation of Botanicals." In: Evidence-Based Validation of Traditional Medicines, Springer, Singapore.

5) WHO, AYUSH, and ICH Guidelines on quality control, safety, and efficacy of herbal products.

6) Indian Pharmacopoeia – Latest Edition, Government of India, Ministry of Health and Family Welfare.

MEDICINAL CHEMISTRY - PRACTICALS

Total Credits 1 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

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.
6. Ensure compliance with laboratory safety protocols and quality control measures during experiments.

COURSE OUTCOMES

At the end of the course, 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.
6. Apply principles of quality control and quality assurance in the preparation, assay, and monograph analysis of drugs.

COURSE CONTENTS

1. Preparation of Drugs / Intermediates (Any 6)

a. Aspirin

b. Benzimidazole

c. Benztriazole

d. Benzocaine

e. Phenytoin

f. Dibenzalacetone

g. 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 BOOKS (LATEST EDITIONS)

1. Vogel's textbook of practical organic chemistry – Brian S. Furniss Et Al.
2. Advanced practical medicinal chemistry by Ashutosh Kar
3. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5
4. Burger's Medicinal Chemistry, Vol I to IV.
5. Textbook of medicinal chemistry by Alagarsamy V
6. Indian pharmacopoeia

SYSTEMIC PHARMACOLOGY AND AUTACOIDS - PRACTICALS

Total Credits 1 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

1. To provide understanding of the theoretical and practical aspects of different pharmacological experiments using virtual simulations and video demonstrations.
2. To develop skills to assess drug effects on various systems such as cardiovascular, respiratory, skeletal muscle, and gastrointestinal using simulation models.
3. To familiarize the learners with experimental methodologies such as Langendorff's heart preparation, spasmogen and spasmolytic effects, and PA2 value determination using Schild plot.
4. To provide knowledge of the modern techniques for drug evaluation, such as intraocular pressure measurement, nitric oxide estimation, 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

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

1. To describe the drug effects on blood pressure, heart rate, and understand their relevance to cardiovascular pharmacotherapy through virtual simulations.
2. To evaluate the pharmacological management of asthma, analyse drug actions on the respiratory system, and correlate them with clinical data.
3. To interpret experimental data, calculate and analyse PA2 values, plot standard curves, and estimate drug effects using hypothetical data from computer simulations.
4. To present the case studies and explore drug interactions and rational drug management in cardiovascular situations and asthma, applying pharmacological knowledge to patient care.
5. To demonstrate competence in various pharmacological measurements, such as intraocular pressure estimation, nitric oxide estimation in plasma, and spirometry.
6. To Appreciate modern pharmacological techniques and gain insights into techniques used in experimental pharmacology, such as flame photometry, metabolic cage urine collection, and non-invasive drug testing methods.
7. To comprehend drug interactions: Study drug-drug interactions, rational drug use, and pharmacokinetic principles in real-life clinical scenarios

COURSE CONTENTS

1. To demonstrate Langendorff's heart assembly and its applications 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 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 plot 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. Evaluation of anti-inflammatory activity in paw oedema model using plethysmometer.
15. Concept of Biobanking and its significance in drug screening

RECOMMENDED BOOKS (LATEST EDITIONS/VERSIONS)

1. CAL software package: a suitable interactive simulation on which examination can be conducted.
2. Fundamentals of Experimental Pharmacology. Ghosh MN. Publisher: Hilton & Company, Kolkata.
3. Handbook of experimental pharmacology. Kulkarni SK. Publisher: Vallabh Prakashan.

Practical Pharmacology, Goyal R K. Publisher: B. S. Shah Publisher

PHARMACEUTICAL BIOTECHNNOLOGY - PRACTICALS

Total Credits 1 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES:

The objectives of the course are;

1. To provide fundamental knowledge on biotechnology concepts, including protein therapeutics, monoclonal antibodies, enzyme immobilization, and their pharmaceutical applications.
2. Knowledge of genetic engineering and recombinant DNA technology for pharmaceutical applications.
3. Exploring Microbial Biotransformation and Production Techniques: To equip students with knowledge of microbial biotransformation, fermentation methods, and large-scale production of various pharmaceutical products like alcohol, penicillin, vaccines, and blood products, alongside an introduction to the design and operation of production fermenters.
4. Focusing on Gene Therapy and Vaccines: To explore into gene therapy, its ethical concerns, methodologies, and delivery systems, while exploring vaccine types, preparation, and immunization strategies, as well as addressing the regulatory and standardization aspects of vaccines and sera in the pharmaceutical industry.

COURSE OUTCOMES:

Upon completion of the course the student will have:

1. Understand and apply the principles biotechnology to pharmaceutical sciences, including genetic engineering and recombinant DNA technology.
2. Expertise in production of biopharmaceutical products, Protein therapeutics, monoclonal antibodies.
3. Knowledge of Gene therapy and its delivery systems with ethical concerns considerations.
4. Practical Expertise in fermentation processes, and the large-scale production of pharmaceuticals such as vaccines, hormones, and blood products.
5. Understanding concepts of Immunization and immunization products like vaccines and sera.
6. Regulatory and ethical considerations; challenges in development of biopharmaceutical products.

COURSE CONTENTS

1. Understanding Good microbiological laboratory practices while working in Microbiology laboratory, Study of various equipments such as loop, straight wire, spreader, forceps, pipette, test tube, petridish, burner etc. and apparatus used in Pharmaceutical microbiology lab such as B.O.D. incubator, laminar flow, aseptic hood, autoclave, hot air sterilizer, deep freezer, microscopes etc.
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

Note: Minimum 12 experiments must be performed

RECOMMENDED BOOKS:

1. "Biotechnology for Pharmaceutical Engineers" by M. C. P. Ma and J. C. M. Lau
2. "Molecular Biotechnology: Principles and Applications of Recombinant DNA" by Bernard R. Glick and Jack J. Pasternak
3. "Pharmaceutical Biotechnology by S. P. Vyas, V.K. Dixit
4. "Practical Biotechnology: A Guide to Biochemical Engineering" by S. L. M. Chou
5. Hugo and Russell's Pharmaceutical Microbiology Eighth edition Blackwell Publishing Ltd

6. Michael J. Pelczar Microbiology 7th Edition McGraw Hill edn.
7. Lachman Lieberman's The Theory And Practice Of Industrial Pharmacy 4Ed Edited by Khar RK et al., CBS Publisher and Distribution
8. S. J. Carter, Cooper and Gunn's Tutorial Pharmacy 12th edition, CBS Publisher and Distribution
9. "Manual of Industrial Microbiology and Biotechnology" – *Richard H. Baltz, Julian E. Davies, Arnold L. Demain* (ASM Press)

SOCIAL PHARMACY AND PUBLIC HEALTH - PRACTICALS

Total Credits 1 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

The course is designed to enable students 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.
6. Develop foundational knowledge of Pharmacoeconomics and its applications
7. Evaluate health interventions, while identifying irrational drug use practices.

COURSE OUTCOMES

Upon successful completion of the course, the student 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
6. Evaluate healthcare interventions using pharmacoeconomic principles and recognize irrational drug use in real-world scenarios.

COURSE CONTENTS

1. Perform health screening Services (Blood Pressure, Body Mass Index, Blood glucose measurements)

2. Develop Health promotion material for the prevention of communicable diseases

3. Role Play-Usage of different mental scales in screening patient screening

4. Demonstration of Vaccine Administration Techniques Using Simulation Models

5. case study → calculation of prevalence & Incidence

6. Design and Demonstrate Preventive Strategies for Major Communicable Diseases (Group Activity)

7. Present a Case Study Highlighting Cost-Benefit Analysis in Healthcare

8. Perform Cost-Effectiveness Analysis for Selected Health Interventions

9. Conduct Cost-Utility Analysis to Assess Health Program Efficiency

10. Perform Basic First Aid Techniques

11. Design Informational Leaflet on Lifestyle Modifications for Disease Prevention

12. Identify and Illustrate Irrational Drug Use with a Real-World Example

13. Demonstration and simulation of CPR/AED

14. Perform wound dressing comes with in first aid techniques

15. Hand Wash &; Hand Sanitizing techniques

SEMESTER V

BIOMEDICAL CHEMISTRY - THEORY

Total Credits 3 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES:

The primary objectives of this course are to;

1. Understand the drug metabolic pathways, mechanisms and therapeutic value of drugs.
2. Acquire the Chemistry, synthesis Understand the classification, structure, structure–activity relationships (SAR), and synthesis therapeutic uses of drugs acting on affecting the autonomic Central nervous systems.
3. Develop adequate knowledge on synthesis Know the classification, structure, SAR, and therapeutic uses synthesis of drugs acting on Cardiovascular System of anti-infective agents.
4. Gain knowledge on chemistry, synthesis Explore the classification, structure, SAR, and synthesis of the Drugs acting on blood and Renal drugs therapeutic uses of anti-biotics.
5. Know the classification, structure, SAR, and synthesis of the Autacoids and related drugs
6. To acquire insight knowledge on medicinal chemistry of anti-neoplastic agents.
7. Gain knowledge on chemistry, synthesis, SAR and therapeutic uses of Endocrine Drugs, Anti diabetic agents and Narcotic analgesics.

COURSE OUTCOMES

Upon completion of the course, students shall be able to;

1. Describe the classification, structure, structure–activity relationships (SAR) and synthesis of drugs acting the central nervous systems.
2. Explain the classification, SAR, and synthesis of Anti-Infective Chemotherapeutic Agents.
3. Describe the classification, structure, SAR, and synthesis of Antibiotics and Sulfa Drugs
4. Explore the classification, structure, SAR, and synthesis of Antineoplastic Agents
5. Explore the medicinal chemistry aspects of Endocrine Drugs, Anti diabetic agents and Narcotic analgesics

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 (*)

Unit I: Drugs Acting on the Central Nervous System **10 Hours**

- **General anesthetics**

  Halothane, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane. Methohexital sodium, Thiamylal sodium, Thiopental sodium. Ketamine hydrochloride.* Ramelteon, Remimazolam, Fospropofol, Dexmedetomidine.

- **Sedatives and Hypnotics**

  Barbital, Phenobarbital*, Mephobarbital, Amobarbital, Butabarbital, Pentobarbital, Secobarbital, Chlordiazepoxide, Diazepam*, Oxazepam, Chlorazepate, Lorazepam, Alprazolam, Zolpidem, Glutethmide, Meprobomate, Ethchlorvynol, Triclofos sodium, Paraldehyde. SAR of barbiturates, SAR of Benzodiazepines

- **Antipsychotics**

  Promazine hydrochloride, Chlorpromazine hydrochloride*, Triflupromazine, Thioridazine hydrochloride, Piperacetazine hydrochloride, Prochlorperazine maleate, Trifluoperazine hydrochloride. Chlorprothixene, Thiothixene, Loxapine succinate, Clozapine. Haloperidol, Droperidol, Risperidone, Molindone hydrochloride, Sulpieride, Brexpiprazole, Lumateperone, Pimavanserin, Samidorphan, SAR Phenothiazeines

- **Anticonvulsants**

  Phenobarbitone, Methabarbital, Phenytoin*, Mephenytoin, Ethotoin Oxazolidine diones: Trimethadione, Paramethadione, Phensuximide, Methsuximide, Ethosuximide Phenacemide, Carbamazepine* Benzodiazepines: Clonazepam, Primidone, Valproic acid , Gabapentin, Felbamate, Perampanel, Lacosamide, Retigabine. SAR of Anticonvulsants.

Unit II: Anti-Infective Chemotherapeutic Agents **12 Hours**

Antitubercular Agents

Isoniazid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.* Rifampicin, Rifabutin, Cycloserine Streptomycine, Capreomycin sulphate, pretomanid, linezolid, Clofazime, Cycloserine.

Antimalarials

Quinine sulphate, Chloroquine*, Amodiaquine, Primaquine phosphate, Pamaquine, Quinacrine hydrochloride, Mefloquine, Cycloguanil pamoate, Proguanil, Pyrimethamine, Artesunete, Artemether, Atovoquone. SAR of quinoline derivatives.

Antiprotozoals

Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine, Paramomycin, Nitazoxamide.

Antivirals

Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirding, Ribavirin, Saquinavir, Indinavir, Ritonavir, Ganciclovir, Valganciclovir, Peramivir, Lenocapavir.

Antifungals

Amphotericin-B, Nystatin, Natamycin, Griseofulvin, Clotrimazole, Econazole, Butoconazole, Oxiconazole Tioconozole, Miconazole, Ketoconazole*, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate, Poscaonazole, Issvuconazole.

Anthelmintics:

Diethylcarbamazine citrate, Thiabendazole, Mebendazole, Albendazole*, Niclosamide, Oxamniquine, Praziquantal, Ivermectin.

Urinary tract anti-infective agents

Nalidixic Acid,Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Furazolidine, Nitrofurantoin, Methanamine. Moxifloxacin, SAR of quinolones

Unit III: Antibiotics and Sulfa Drugs (8 Hours)

- **Antibiotics**

  Penicillin, Cepholosporins, β- Lactamase inhibitors, Monobactams Aminoglycosides: Streptomycin, Neomycin, Kanamycin Tetracyclines: Tetracycline,Oxytetracycline, Minocycline, Doxycycline Erythromycin Clarithromycin, Azithromycin. Chloramphenicol*, Clindamycin, Clavulanic acid, Streptomycin, Tetracycline, Doxycycline, SAR of Penicillins, *Tetracyclines* and Cephalosporins.

- **Sulfa Drugs**

  Sulphamethizole, Sulfisoxazole, Sulphapyridine, Sulphathiazole, Sulfacetamide, Sulfamethoxaole, Sulphadiazine, Mefenide acetate, Sulfasalazine. Trimethoprim, Cotrimoxazole. Dapsone*. SAR of Sulfonamides.

Unit IV: Antineoplastic Agents **6 Hours**

Meclorethamine, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin Etoposide, Vinblastin sulphate, Vincristin sulphate Cisplatin, Mitotane, Carboplatin

Unit V: Endocrine Drugs, Anti diabetic agents and Narcotic analgesics **9 Hours**

Endocrine Drugs

Sex hormones: Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol, Oestrione, Diethylstilbestrol.

Drugs for erectile dysfunction: Sildenafil, Tadalafil.

Oral contraceptives: Mifepristone, Norgestril, Levonorgestrol

Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone

Thyroid and antithyroid drugs: L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole

Anti diabetic agents:

Insulin and its preparations Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride. Biguanides: Metformin. Thiazolidinediones: Pioglitazone, Rosiglitazone. Repaglinide, Nateglinide, Acrabose, Voglibose

Narcotic analgesics

Morphine sulphate, Codeine, Meperidine hydrochloride, Anilerdine hydrochloride, Diphenoxylate hydrochloride, Loperamide hydrochloride, Fentanyl citrate*, Methadone hydrochloride, Propoxyphene hydrochloride, Pentazocine, Levorphanol tartarate. Nalorphine hydrochloride, Levallorphan tartarate, Naloxone hydrochloride. SAR of Morphine analogues

RECOMMENDED BOOKS

1. Foye's Principles of Medicinal Chemistry – Authors: Thomas L. Lemke, David A. Williams, and Virginia F. Roche
2. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry –Editors: John M. Beale Jr., John T. Thomas, and Michael H. Duckett
3. Burger's Medicinal Chemistry and Drug Discovery, **Editors**: Donald J. Abraham and John L. Griffin
4. An Introduction to Medicinal Chemistry by Graham L.Patrick.
5. **Medicinal Chemistry** by Ashutosh Kar
6. Modern Drug Synthesis" by Jie Jack Li, William M. Welch, and others
7. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
8. **Medicinal Chemistry** by Sriram & Yogeeswari
9. **Textbook of Medicinal Chemistry Vol. 1 & 2** by V. Alagarsamy
10. Text book of practical organic chemistry- A.I.Vogel
11. Goodman & Gilman's The Pharmacological Basis of Therapeutics – Laurence L. Brunton et al.

PHARMACEUTICAL ANALYSIS - THEORY

Total Credits 3 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

1. To understand the interaction of matter with electromagnetic radiations and its applications in drug analysis
2. To understand the chromatographic separation techniques and analysis of drugs.
3. To Perform quantitative & qualitative analysis of drugs using various analytical instruments.

COURSE OUTCOMES

At the end of the course, 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. Operate and perform analyses using the instruments involved in electrochemical and spectroscopic methods.
3. Describe the principles, instrumentation, and applications of various chromatographic and electrophoretic techniques.
4. Choose and justify the selection of suitable analytical techniques for specific pharmaceutical analysis requirements.
5. Analyze, interpret, and report analytical data accurately and draw meaningful conclusions.
6. Troubleshoot common problems encountered in analytical procedures and demonstrate competence in quantitative pharmaceutical analysis.

COURSE CONTENTS

UNIT I: Electrochemical Methods of analysis **10 Hours**

1. **Potentiometry:** Electrode potential, electrochemical cell, construction and working of reference and indicator electrodes including membrane electrodes, measurement of potential and pH, potentiometric titrations, methods of detecting end point and Karl Fischer titration.
2. **Conductometry**: Introduction, conductivity cell, conductometric titrations and applications.
   Polarography: Introduction, residual current, migration current, diffusion current and limiting current, DME, polarographic wave, Ilkovic's equation, effect of oxygen on polarographic wave, Polarographic maxima and suppressors and applications.
3. **Amperometry**: Introduction, reference and indicator electrode, amperometric titrations, advantages, disadvantages and pharmaceutical applications.

UNIT II: Spectroscopy **10 Hours**

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.

UNIT III: Fluorometric Analysis **07 Hours**

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.

UNIT IV: Introduction to Chromatographic Techniques **08 Hours**

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.

UNIT V **10 Hours**

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.

RECOMMENDED BOOKS (LATEST EDITIONS)

1. "Analytical Chemistry" by Gary D. Christian
2. John Dyer's **Applications of Absorption Spectroscopy of Organic Molecules.**
3. "Pharmaceutical Analysis: A Textbook" by David G. Watson
4. "Analytical Chemistry: A Modern Approach to Analytical Science" by Robert D. Braun
5. "Principles of Instrumental Analysis" by Douglas A. Skoog
6. "Modern Analytical Chemistry" by David Harvey
7. Instrumental Methods of Chemical Analysis by B.K Sharma
8. Organic spectroscopy by Y.R Sharma
9. Text book of Pharmaceutical Analysis by Kenneth A. Connors

SYSTEMIC PHARMACOLOGY AND CHEMOTHERAPY - THEORY

Total Credits 3 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

1. To provide the understanding of the neurohumoral transmission in the central nervous system and the role of different neurotransmitters and their modulators in the CNS diseases and disorders.
2. To develop understanding of details pharmacology of drugs in pathological conditions of CNS, GIT, and endocrine system along with the detailed pharmacology of such drugs.
3. To familiarize the learners with concepts of drug abuse, addiction, dependence, and tolerance their treatment of addiction and dependence
4. To impart the knowledge related to pharmacology of chemotherapeutic agents including anticancer agents and introduce them to the concept of rational use of chemotherapeutic agents.

COURSE OUTCOMES

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

1. Identify the role of neurotransmitters in the CNS diseases and disorders and describe the pharmacology of drugs acting on central neurotransmission.
2. Apply principles of chemotherapy to explain the mechanisms of actions of the chemotherapeutic agents and their use in treating different infectious diseases and cancer.
3. Recall the pharmacology of hormones and drugs acting on the diseases and disorders related to the endocrinal system including sex hormones and their modulators.
4. State the mechanisms and therapeutic uses of drugs affecting gastrointestinal function, including antiulcer agents, laxatives, antiemetics, and digestants.
5. Recognize Issues related to drug abuse, addiction, and dependence and their management.

COURSE CONTENTS

UNIT–I:

Pharmacology of drugs acting on CNS **10 Hours**

Neurohumoral transmission in the central nervous system, physiological roles of GABA, Glutamate, Glycine, Serotonin and Dopamine.

a) General anesthetics, pre-aesthetic medications, and Local anaesthetic agents.

b) Sedatives-hypnotics.

c) Opioids, opiate analgesics and antagonists.

d) Drugs used in epilepsy.

e) Drugs used in Parkinson's and Alzheimer's diseases.

UNIT-II:

Pharmacology of drugs used in Psychiatry **07 Hours**

a) Antipsychotics, antidepressants, anti-anxiety, mood stabilizers, CNS stimulants and hallucinogens.

b) Substance abuse, drug addiction, and general principles of de-addiction.

UNIT-III: **14 Hours**

Chemotherapy

i) Introduction:

a) Definitions of chemotherapy, chemotherapeutic index, antibiotics, antimicrobial agents (AMA).

b)Concept of selective targeting in chemotherapy, classification of AMAs on mechanism of action.

c) Concept of superinfection, chemoprophylaxis and combined use of antibiotics.

d) Anti-microbial resistance: Causes, mechanisms and modes of development, and preventive measures.

ii) Antimicrobial agents: Classification, mechanism, ADRs and therapeutic uses of sulphonamides, cotrimoxazole, fluoroquinolones, penicillin, cephalosporins, macrolides, tetracyclines, linezolid and aminoglycosides.

iii) Chemotherapy of diseases: Drugs used in treatment of Fungal infections, Viral infections, Helminthiasis, Urinary Tract infections, Tuberculosis, Leprosy, Malaria, Amoebiasis, and Neoplastic diseases.

UNIT-IV: **10 Hours**

Pharmacology of drugs acting on the endocrine system

a) Introduction to basic concepts of endocrinology.

b) Thyroid and anti-thyroid agents.

a) Parathormones, calcitonin and vitamin D.

b) Insulin and oral hypoglycaemic agents

c) ACTH and corticosteroids

d) Oral contraceptives

e) Drugs acting on the uterus.

UNIT-V: **04 Hours**

Drugs acting on gastrointestinal tract

a) Drugs used in Peptic Ulcer.

b) Drugs used for constipation and diarrhoea.

c) Emetics and anti-emetics.

d) Definitions and examples of digestants, carminatives, appetizers and anorectics.

RECOMMENDED BOOKS:

Updated versions of the following books are recommended

1. Rang & Dale's Pharmacology, H.P. Rang, M.M. Dale, J.M. Ritter, R.J. Flower, G. Henderson,Publisher: Elsevier

2. Katzung & Trevor's Pharmacology Examination and Board Review, Bertram G. Katzung, Marieke Kruidering-Hall, Rupa Lalchandani Tuan, Todd W. Vanderah, Anthony J. Trevor Publisher: McGrow Hills Lange.

3. Goodman & Gilman's: The Pharmacological Basis of Therapeutics, Laurence L. Brunton, Randa Hilal-Dandan, Bjorn Knollmann. Publisher: McGraw-Hill Education, Edition: 13th Edition (2017)

4. Basic and Clinical Pharmacology, Bertram Katzung, Anthony Trevor. Publisher: McGraw-Hill Education.

5. Richard Finkel, Lippincott's Illustrated Reviews: Pharmacology, Karen Whalen, Publisher: Wolters Kluwer.

6. Pharmacology and Pharmacotherapeutics, R.S. Satoskar, Nirmala N. Rege, S.D. Bhandarkar. Publisher: Elsevier India

7. Modern Pharmacology with Clinical Applications, U.D. Tripathi, U. K. Seth. Publisher: CBSPublishers & Distributors Pvt Ltd

8. Principles of Pharmacology, H.L. Sharma, K.K. Sharma, Publisher: Paras Medical Publisher.

9. Essentials of Medical Pharmacology, K.D. Tripathi., Publishers: Jaypee Brothers Medical

10. Pharmacotherapy: A Pathophysiologic Approach. Joseph T. DiPiro, Robert L. Talbert, Gary C. Yee, Gary R. Matzke. Publisher: McGraw-Hill Education

11. Modern Pharmacology with Clinical Applications, Charles R. Craig, Robert E. Stitzel. Publisher: Lippincott Williams and Wilkins publisher.

12. Integrated Pharmacology, Clive P. Page, Brian Hoffman, Michael Curtis , Michael Walker;Publisher: Mosby Elsevier.

13. Introduction to Pharmacology, S.K Kulkarni, Vallabh Prakashan.

INDUSTRIAL PHARMACOGNOSY - THEORY

Total Credits 3 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

1. To introduce industrial and commercial aspects of herbal drugs and formulations.
2. To train students in techniques for extraction, isolation, and analysis of phytoconstituents.
3. To familiarize students with national and international regulatory requirements for herbal products.
4. To provide hands-on experience in herbal drug technology through practical applications.

COURSE OUTCOMES (COS)

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

1. Describe the trade status, economic relevance, and institutional support for medicinal plant-based industries in India.
2. Explain and apply the principles of standardization and production of herbal extracts, volatile oils, and classical formulations.
3. Demonstrate analytical skills using modern spectroscopy and chromatography techniques for herbal drug analysis.
2. Isolate, characterize, and analyze important phytoconstituents used in the pharmaceutical and nutraceutical industries.
3. Interpret international regulatory requirements, safety, efficacy, and pharmacopoeial standards for herbal products.

COURSE CONTENTS

UNIT-I **8 Hours**

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, Haridra, 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-Ageng, Depigmenting, anti-acne, sunscreen, detoxifying, antiirritant, nutricosmetics.

UNIT-II **10 Hours**

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 standardised 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.

UNIT-III **12 Hours**

Modern methods of analysis of herbal drugs/ botanicals/ formulations and bioactives

Basic principles and applications in analysis of botanicals: Spectroscopic methods: UV-Visible spectroscopy, IR Spectroscopy, NMR spectroscopy and Mass spectroscopy, AAS, ICPOES, ICP-MS, Chromatographic methods: HPTLC, HPLC, UPLC, GC, GCMS, LC/MS, LC-MS/MS, GC-IRMS

UNIT-IV **08 Hours**

Isolation, Characterization, Commercial Production and analysis of bioactive phytoconstituents

Isolation, characterization with commercial production, identification and analysis of bioactive phytoconstituents: Artemisinin, Sennosides, Withanoloids, Boswellic acid, Atropine, Reserpine and Lycopene.

UNIT-V **07 Hours**

International Regulatory Perspectives

(a) Overview of global regulations for herbal products (e.g., World 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), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, Quality, Safety, Efficacy and Multidisciplinary Guidelines)

(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 BOOKS

1. Choudhary, R.D. (1996). Herbal Drug Products Industry. 1st Edn., Eastern Publishers, New Delhi.

2. Mukherjee, P.K. (2003). GMP for Botanicals: Regulatory and Quality Issues on Phytomedicine, with contributions from Robert Verpoorte. 1st Edn., Business Horizons, New Delhi.

3. Indian Herbal Pharmacopoeia (2002). Revised Edn., Indian Drug Manufacturers' Association (IDMA), Mumbai.

4. Ayurvedic Pharmacopoeia of India (API), Government of India, Ministry of AYUSH.

5. Unani Pharmacopoeia of India (UPI), Government of India, Ministry of AYUSH.

6. Indian Pharmacopoeia (IP) – Latest Edition. Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India.

7. United States Pharmacopoeia (USP) – Herbal Medicines and Dietary Supplements Section.

8. WHO Guidelines. (2003). Good Agricultural and Collection Practices (GACP) for Medicinal Plants. WHO Document

9. The Drugs and Cosmetics Act, Government of India – Schedules T, Z, E1 (latest amendments).

10. European Medicines Agency (EMA) – Herbal Monographs and Regulatory Guidelines.

11. Therapeutic Goods Administration (TGA), Australia – Australian Regulatory Guidelines for Complementary Medicines (ARGCM).

12. Natural Health Products (NHP), Canada – Regulatory Framework.

13. International Council for Harmonisation (ICH) – Q (Quality), S (Safety), E (Efficacy), and M (Multidisciplinary) Guidelines.

INNOVATION AND STARTUP ECOSYSTEM - THEORY

Total Credits 2 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES:

1. To introduce students to the fundamental concepts of innovation and entrepreneurship.
2. To familiarize students with the various components and stakeholders of a startup ecosystem.
3. To develop an understanding of the startup lifecycle, from ideation to scaling.
4. To equip students with practical skills for identifying opportunities and validating ideas.
5. To foster an entrepreneurial mindset and encourage participation in activities to integrate practical learning experiences through engagement with stakeholders.

COURSE OUTCOMES (COS):

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

1. Explain the key concepts of innovation, entrepreneurship, and the role of a supportive ecosystem.
2. Identify and analyze different types of innovation and their impact on various sectors.
3. Evaluate potential business ideas for feasibility and viability within the current market landscape.
4. Develop a preliminary business model canvas and outline a strategy for idea validation.
5. Participate effectively in innovation and entrepreneurship-related events and competitions.
6. Articulate the importance of intellectual property and funding mechanisms in the startup journey.

COURSE CONTENTS:

Unit 1:Introduction to Innovation and Entrepreneurship **6 Hours**

Defining Innovation and Entrepreneurship

What is Innovation? Types of Innovation (Product, Process, Business Model, Social).

What is Entrepreneurship? Characteristics of an Entrepreneur.

Distinction between Invention and Innovation.

The Importance of Innovation in the 21st Century

Economic growth and job creation.

Solving societal problems.

Disruptive technologies and their impact.

Case Studies of 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.

Unit 2: Ideation and Opportunity Identification **6 Hours**

Identifying Problems and Market Gaps

Problem-solving approach to entrepreneurship.

Techniques for problem identification (observation, empathy mapping, user interviews).

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's internal ideation competitions).

Unit 3: Building a Minimum Viable Product (MVP) and Validation **6 Hours**

Lean Startup Methodology

Introduction to Lean Startup principles (Build-Measure-Learn feedback loop).

The concept of MVP: why it's crucial and what it entails.

Designing and Developing an MVP

Different types of MVPs.

Tools and resources for rapid prototyping.

User experience basics for MVPs.

Validating Your Idea with Customers

Customer interviews and feedback collection.

A/B testing and split testing.

Pivoting vs. Persevering.

Practical Aspect: Participation in sessions or workshops on Prototype, MVP, product development.

Unit 4: Business Models and Startup Operations **6 Hours**

Business Model Canvas (BMC)

Introduction to the 9 building blocks of the Business Model Canvas.

Developing a BMC for a new venture.

Value Proposition Design.

Legal and Financial Aspects for Startups

Basic legal structures (Sole Proprietorship, Partnership, Private Limited Company).

Intellectual Property Rights (Patents, Trademarks, Copyrights) – importance and basics.

Introduction to startup funding: bootstrapping, angel investors, venture capital.

Team Building and Mentorship

Importance of a strong founding team.

Roles and responsibilities in a startup.

The value of mentors and advisors.

Practical Aspects: Participation in intellectual property rights or funding for startups.

Unit 5: Scaling, Ecosystem Engagement, and Future Trends 6 Hours

Growth Strategies and Scaling Up

Marketing and sales for startups.

User acquisition and retention.

Challenges of scaling and how to overcome them.

Exit strategies (Acquisition, IPO).

Engaging with the Startup Ecosystem

Networking with investors, mentors, and fellow entrepreneurs.

Participating in startup competitions and pitch events.

Leveraging incubators and accelerators.

Future Trends in Innovation and Entrepreneurship

Emerging technologies (AI, Blockchain, IoT, Sustainable Technologies).

Social entrepreneurship and impact investing.

Global startup trends.

Practical Aspect: Participation in National Innovation Day. Encouraging students to prepare and deliver a concise pitch for their developed idea, simulating a startup pitch event.

RECOMMENDED BOOKS:

1. Stay Hungry, Stay Foolish, Rashmi Bansal, Westland (HarperCollins India)
2. Connect the Dots, Rashmi Bansal, Westland (HarperCollins India)
3. Dream with Your Eyes Open, Ronnie Screwvala, Rupa Publications
4. Failing to Succeed: The Story of India's First E-Commerce Company, K. Vaitheeswaran, Rupa Publications
5. Big Billion Startup: The Untold Flipkart Story, Mihir Dalal, Pan Macmillan India

6. Innovation and Entrepreneurship, Subhendu Mishra, Pramod Kumar Patjoshi, Susanta Kumar Patnaik, Pearson India
7. Startup Ecosystem in India: Text & Cases, Dr. Ramesh Sardar, Dr. Ganesh Waghmare, Himalaya Publishing House
8. The Manual for Indian Start-Ups: Tools To Start and Scale-Up Your New Venture, Vijaya Kumar Ivaturi, Notion Publishers
9. The Dolphin and the Shark: Stories on Entrepreneurship, Namita Thapar, Penguin Business (Penguin Random House India)

Online Resources:

1. NITI Aayog, Government of India: Startup India Portal (startupindia.gov.in)
2. Ministry of Education's Innovation Cell (MIC) & IIC: Official Website (mic.gov.in) for IIC calendar, guidelines, and resources.
3. Swayam/NPTEL Courses: Relevant courses on Entrepreneurship, Innovation, and Design Thinking.
4. Blogs and Articles: TechCrunch, Entrepreneur, Harvard Business Review (HBR) articles on innovation and startups.
5. YouTube Channels: Stanford eCorner, Y Combinator, TechStars for insightful talks and workshops.

AI IN PHARMACOLOGY & DRUG SAFETY - THEORY

Total Credits 2 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

1. Teach students to use AI tools for 3-D visualization, anatomical mapping, and virtual physiology simulations.
2. Introduce AI models that predict pharmacokinetic properties and protein–ligand interactions across species.
3. Equip learners with AI platforms that accelerate drug discovery, candidate selection, and preclinical testing.
4. Familiarize students with AI techniques for predicting adverse drug reactions and chemical toxicity.
5. Explore how AI enables personalized medicine and shapes the future of pharmacology.

COURSE OUTCOMES

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

1. Create AI-generated anatomical or physiological visualizations and explain the underlying models.
2. Apply AI algorithms to forecast ADME profiles and map target interactions for small molecules in human, rat, and mouse systems.
3. Run an AI-driven workflow to identify, rank, and justify potential drug candidates.
4. Predict adverse drug reactions or toxicities for a given compound set and interpret the safety implications.
5. Design a personalized treatment concept using AI insights and discuss emerging pharmacology trends.

COURSE CONTENTS:

Unit 1 – AI-Enhanced Anatomy & Physiology **6 Hours**

- AI-Based 3D Visualization of Human Anatomy
- AI-based anatomical mapping and physiological functions
- AI-driven simulations showing real-time physiological responses
- AI-based virtual dissection and physiology simulation

Unit 2 – AI for Pharmacokinetics & Molecular Interaction **6 Hours**

- AI models predict drug absorption, distribution, metabolism, and excretion (ADME)
- Molecular interactions between target protein and small molecules
- Target Prediction of small molecules in Human, Rat, Mice model

Unit 3 – AI in Drug Discovery & Development **6 Hours**

- Introduction to AI applications in drug discovery and development
- Use of AI platforms to identify novel drug candidates
- Analysis of molecular and omics data using machine learning
- Prediction of drug-target interactions to assess efficacy
- AI-driven tools in preclinical testing and compound optimization

Unit 4 – AI in Drug Safety & Toxicology **6 Hours**

- AI applications in drug safety and pharmacovigilance
- Platforms for predicting adverse drug reactions (ADRs) and drug-drug interactions
- Machine learning models for early toxicity prediction of small molecules based on chemical structure
- Role of AI in enhancing drug safety profiles and optimizing treatment regimens

Unit 5 – AI in Personalized Medicine & Future Pharmacology **6 Hours**

- AI-driven approaches in personalized medicine and individualized therapy design
- Genomic data integration for precision drug recommendations
- Future trends in AI-powered pharmacology and therapy optimization
- Ethical, legal, and implementation challenges in AI-based personalized healthcare

RECOMMENDED BOOKS

1. Artificial Intelligence in Drug Discovery — Nathan Brown — Royal Society of Chemistry, 2020
2. Deep Learning for the Life Sciences — Bharath Ramsundar, Peter Eastman, Patrick Walters, Vijay Pande — O'Reilly Media, 2019
3. Machine Learning and Artificial Intelligence in Toxicology and Environmental Health — Zhoumeng Lin & Wei-Chun Chou (eds.) — Elsevier, 2024
4. Artificial Intelligence in Medical Imaging: Opportunities, Applications and Risks — Erik R.

Ranschaert, Sergey Morozov, Paul Algra (eds.) — Springer, 2019

5. Deep Learning in Personalized Healthcare and Decision Support — Abhinav Garg (ed.) — Elsevier, 2023

BIOMEDICAL CHEMISTRY - PRACTICALS

Total Credits 2 **Hours / Week: 4** **60 HR**

COURSE OBJECTIVES

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. Gain proficiency in various analytical techniques used in drug quality control.
5. Learn and utilize computational tools to predict physicochemical and ADME properties of drug molecules.
6. Apply molecular docking techniques to predict drug-target interactions.

COURSE OUTCOMES

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. Interpret data from drug assays to ensure quality control.
5. Calculate and analyze physicochemical and ADME properties of drug candidates using computational tools.
6. Conduct and interpret molecular docking studies to understand drug-receptor binding.

COURSE CONTENTS

1. Preparation of Drugs / Intermediates (Any 4)

a. 7-Hydroxy 4-methylcoumarin
b. Thiobarbituric acid
c. 2,3-diphenylquinoxaline
d. Sulphanilamide
e. Triphenylimidazole
f. Perform synthesis of intermediate/drug using microwave irradiation
g. Perform synthesis of intermediate/drug using microwave irradiation

2. Assay of Drugs (Any 4)

a. Dapsone
b. Metronidazole

c. Isoniozid
d. Phenobarbitone
e. Benzyl penicillin
f. Chloroquine

3. Drug Design & Computational Tools (4)

a. Calculate physicochemical and ADME properties using SwissADME (e.g. logP, molecular weight, H-bond donors/acceptors)
b. Perform basic molecular docking studies using any of open-source academic tools such as: AutoDock Vina, PyRx, SwissDock, MZDock

RECOMMENDED BOOKS (LATEST EDITIONS)

1. Current concepts in drug design by T. Durai Ananda Kumar
2. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
3. Foye's Principles of Medicinal Chemistry.
4. Burger's Medicinal Chemistry, Vol I to IV.
5. Introduction to principles of drug design- Smith and Williams.
6. Remington's Pharmaceutical Sciences.
7. Martindale's extra pharmacopoeia
8. Organic Chemistry by I. L. Finar, Vol. II.
9. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
10. Indian Pharmacopoeia.
11. Text book of practical organic chemistry- A. I. Vogel

PHARMACEUTICAL ANALYSIS - PRACTICALS

Total Credits 2 **Hours / Week: 4** **60 HR**

COURSE OBJECTIVES

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, including single and multi-component assays, identification of functional groups, and separation of mixtures.
5. Analyze and interpret experimental data to draw meaningful conclusions regarding the identity and quantity of analytes.
6. Adhere to good laboratory practices and safety protocols in handling chemicals and operating instruments.

COURSE OUTCOMES

At the end of the course, the student 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.
6. Demonstrate competence in documenting experimental procedures and results in a clear and concise manner, adhering to laboratory safety regulations.

COURSE CONTENTS (Minimum 13 experiments)

1. Determination of the endpoint of a acid base titration by potentiometric method.
2. Determination of end point of acid base titrations by conductometry.
3. Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds

4. Assay of APIs by colorimetry.
5. Assay of single component by UV- Spectrophotometer.
6. Simultaneous estimation of multicomponent formulations by UV spectrophotometer.
7. Identification of various functional groups in official compounds by FTIR as per IP.
8. Assay of quinine sulphate by fluorimetry
9. Determination of quenching effect by fluorimetry
10. Assay of sodium chloride by flame photometry
11. Assay of potassium chloride by flame photometry
12. Determination of chlorides and sulphates by nephelo turbidometry
13. Separation of amino acids by paper chromatography
14. Separation of mixture of components by thin layer chromatography
15. Demonstration experiment on GC
16. Determination of official compounds by HPLC (any one)
17. Demonstration experiment on HPTLC

RECOMMENDED BOOKS (LATEST EDITIONS)

1. "Analytical Chemistry" by Gary D. Christian
2. John Dyer's **Applications of Absorption Spectroscopy of Organic Molecules.**
3. "Pharmaceutical Analysis: A Textbook" by David G. Watson
4. "Analytical Chemistry: A Modern Approach to Analytical Science" by Robert D. Braun
5. "Principles of Instrumental Analysis" by Douglas A. Skoog
6. "Modern Analytical Chemistry" by David Harvey
7. "Chromatography: Principles and Instrumentation" by David J. W. O'Connell
8. Instrumental Methods of Chemical Analysis by B.K Sharma
9. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
10. Organic spectroscopy by Y.R Sharma
11. Text book of Pharmaceutical Analysis by Kenneth A. Connors

SYSTEMIC PHARMACOLOGY AND CHEMOTHERAPY - PRACTICALS

Total Credits 2 **Hours / Week: 4** **60 HR**

COURSE OBJECTIVES

1. To provide details on the pharmacological evaluation of the analgesic, antiepileptic, antidepressant, and other drugs acting on CNS.
2. To impart knowledge on the bioassay techniques using isolated tissue preparations and study the actions of agonists and antagonists through virtual simulations.
3. To develop skills to interpret the mechanisms of drug action in various animal models for psychotropic drugs, such as antipsychotics, antianxiety, and memory-enhancing drugs.
4. To develop practical knowledge of antibacterial sensitivity testing methods and understand the principles behind them through theoretical details and case studies.
5. To present case studies and analyse the rational use of corticosteroids in disease management and explore national health initiatives for diseases like tuberculosis, leprosy, and sexually transmitted diseases.
6. Develop critical thinking skills through the analysis of experimental data, learning how to interpret the pharmacological relevance of observed results.

COURSE OUTCOMES

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

1. Describe the experimental protocols to conduct analgesic, antiepileptic, antidepressant, and psychotropic drug activity using various models such as Eddie's hot plate, tail-flick, MES-induced seizures, and actophotometer.
2. Assess drug effects on CNS by evaluating the behaviours like learning, memory, and locomotion using interactive simulation methods.
3. Explain the principles and methods of bioassays and relevant calculations related to bioassays of oxytocin, histamine, and other drugs using 3- and 4-point bioassay methods, bracketing, and interpolation techniques via virtual experiments.
4. Acquire theoretical knowledge of cell culture, including the handling of equipment and media preparation, aiding in pharmaceutical research.
5. Analyse the results of the antibacterial sensitivity testing and its significance in the choice of chemotherapeutic agents.
6. Interpret the clinical case studies and apply the pharmacological knowledge to the rational use of corticosteroids and analyse government schemes related to public health initiatives for diseases like tuberculosis and leprosy.

COURSE CONTENTS

1. To evaluate the analgesic activity centrally acting and peripherally acting analgesics using Eddie's hot plate/tail-flick/ tail immersion/acetic acid induced writhing method using interactive computer simulation.
2. To evaluate the antiepileptic activity of phenytoin using Maximal electroconvulsive shock (MES)-induced seizures in mice using interactive computer simulations.
3. To demonstrate and study the antiepileptic activity of diazepam using pentylenetetrazol-induced seizures in mice on an interactive computer simulation.
4. To evaluate the antidepressant activity of drugs using tail suspension test using an interactive computer simulation.
5. To demonstrate and study the locomotor activity of diazepam and caffeine by using actophotometer through interactive computer simulation.
6. To evaluate the antianxiety activity of an alprazolam by using plus maze/zero maze using interactive computer simulation.
7. To test the antipsychotic activity of drugs using inhibition of conditioned response on Cook's pole climbing apparatus using interactive computer simulation experiment.
8. To study the effect of drugs on learning and memory on Morris Water maze test using interactive computer simulation.
9. To evaluate the antiulcer activity of the given test sample on indomethacin/pylorus ligation induced ulceration model.
10. To estimate the concentration of oxytocin on rat uterus by any suitable method using interactive computer-based simulation.
11. To estimate the concentration of any one agonist and one antagonist using a suitable isolated tissue preparation by 3- or 4-point bioassay with the help of hypothetical data using interactive computer simulation experiment.
12. To study bioassay of histamine using by matching/bracketing/ interpolation method on suitable isolated tissue preparation with the help of hypothetical data using interactive computer simulation experiment.
13. To study the various types of cell culture techniques, instruments/equipment, media, and growing of cell culture in a laboratory facility.
14. To study the antibacterial sensitivity testing of the urine culture using different techniques like disc diffusion methods (only theoretical details/ case studies).
15. Applications of opensource databases and opensource software packages predicting drug activity, ADME, as well as toxicity (e.g. Binding DB, SWISS Target, WAY2DRUGS-PASS online, PKCSM etc.)

RECOMMENDED BOOKS (LATEST EDITIONS/VERSIONS)

1) CAL software package: a suitable interactive simulation on which examination can be conducted.

2) Fundamentals of Experimental Pharmacology. Ghosh MN. Publisher: Hilton & Company, Kolkata.

3) Handbook of experimental pharmacology. Kulkarni SK. Publisher: Vallabh Prakashan.

4) Practical Pharmacology, Goyal RK. Publisher: B. S. Shah Publisher

INDUSTRIAL PHARMACOGNOSY - PRACTICALS

Total Credits 2 **Hours / Week: 4** **60 HR**

COURSE OBJECTIVES

1. To develop skills in chromatographic techniques for isolation and identification of phytoconstituents.
2. To enable practical understanding of separation and analysis of plant metabolites.
3. To provide knowledge on distillation and analysis of volatile oils.
4. To introduce the preparation of herbal drug monographs as per pharmacopoeial standards.
5. To promote experiential learning through traditional formulations and community-based studies.

COURSE OUTCOMES (COS)

After completion of this course, students will be able to:

1. Apply chromatographic techniques for isolation and analysis of phytoconstituents.
2. Isolate and identify key compounds from medicinal plants.
3. Distill and evaluate volatile oils for chemical constituents.
4. Prepare herbal drug monographs and assess traditional formulations.
5. Conduct community-based studies on traditional medicine practices.

COURSE CONTENTS

1. To perform column chromatography for isolation of flavonoids/ colouring matter.
2. Exercise involving isolation & identification of: Piperine, Sennoside, Withanoloids, Boswellic acid, Reserpine and Lycopene
3. Separation of sugars by paper chromatography.
4. TLC/HPTLC/HPLC of herbal extracts/ botanicals.
5. Distillation of volatile oils form Clove, Cumin, Cardamomum and their identification by TLC.
6. Preparation of monographs on herbal drugs wrt API, UPI and IP.
7. Determination of the alcohol content of Asava and Arista
8. Determination of Aldehyde content in volatile oils
9. Experiential learning-based experiments focused on the preparation and practical applications of folkloric or region-specific traditional formulations within the community.
10. Case studies analyzing community awareness and usage patterns of various traditional formulations.

RECOMMENDED BOOKS:

1. Mukherjee, P.K. (2002). Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. 1st Edn., Business Horizons Pharmaceutical Publishers, New Delhi.
2. Sinha, D., Mukherjee, S., & Chowdhury, S. (2022). Methods of Extraction of Phytochemicals. In: IGI Global. DOI: 10.4018/978-1-6684-7337-5.ch010
3. Zhang, J., Wen, C., Zhang, H., Duan, Y., & Ma, H. (2020). Recent advances in the extraction of bioactive compounds with subcritical water: A review. Trends in Food Science & Technology, 95, 183–195.

SEMESTER VI

PHARMACEUTICAL QUALITY ASSURANCE - THEORY

Total Credits 3 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

1. Differentiate QC, QA, GMP, TQM, and QbD and articulate their collective role in safeguarding pharmaceutical quality.
2. Interpret and apply ICH Q-series, ISO 9000/14000, and NABL requirements to resolve basic compliance scenarios in drug development and manufacturing.
3. Design a GMP-compliant plant layout, personnel flow, and warehousing SOP that control contamination and support traceability.
4. Perform and interpret in-process and finished-product QC tests for tablets, capsules, semi-solids, ophthalmic and parenteral forms, recommending corrective actions when limits are breached.
5. Calibrate basic instruments and validate analytical methods—drafting protocols, executing studies, and compiling reports consistent with ICH Q2.

COURSE OUTCOMES

Upon completion of the course student shall be able to:

1. Explain core quality paradigms—QA, QC, GMP—and their evolution into modern Quality Management Systems.
2. Apply TQM, QbD, and ICH guidelines to design robust pharmaceutical processes that meet global regulatory expectations.
3. Plan and manage compliant facilities, personnel, materials, and documentation to minimize risk and ensure product integrity.
4. Execute pharmacopoeial QC tests and understand concepts of Good Laboratory Practices (GLP) related to formulations, raw materials, and packaging components.
5. Perform calibration, equipment qualification, and analytical method validation in line with regulatory guidance.

COURSE CONTENTS

UNIT – I **10 Hours**

1. **Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP.**

2. **Total Quality Management (TQM):** Definition, elements, philosophies
3. **ICH Guidelines**: Purpose, Process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines.
4. **Quality by Design (QbD)**: Definition, overview, elements of QbD program, tools
5. **ISO 9000 & ISO 14000**: Overview, Benefits, Elements, steps for registration
6. **NABL accreditation**: Principles and procedures

UNIT - II **10 Hours**

1. **Organization and personnel:** Personnel responsibilities, training, hygiene and personal records.
2. **Premises:** Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.
3. **Equipment and raw materials:** Equipment selection, User requirement Specifications (URS), handling and maintenance of raw materials.
4. **Warehousing:** Good warehousing practice and materials management

UNIT – III **10 Hours**

1. **Quality Control Tests for Formulations:** In-process and finished products quality control tests for Tablets, Capsules, Ointments, Creams, Ophthalmic and Parenteral Preparations.
2. **Quality Control:** Quality control test for raw materials, containers, rubber closures and secondary packing materials.
3. **Good Laboratory Practices:** General Provisions, Organization and Personnel, Facilities Equipment, ALCOVA principles, reference standards, Testing Facilities Operation, Test and Control Articles, Records and Reports, Disqualification of Testing Facilities

UNIT – IV **08 Hours**

1. **Document maintenance in pharmaceutical industry:** Batch Formula Record, Master Formula Record, Drug Master File, SOP, Quality audit, Preparation, handling, archival and distribution of records.

2. **Complaints:** Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.

UNIT – V **07 Hours**

1. **Calibration and Validation:** Introduction, definitions, importance and general principles of calibration and validation. Calibration of weights and measures, Calibration of pH meter, Qualification of UV-Visible spectrophotometer, electronic balance, IR Spectrophotometer, HPLC.
2. General principles of Analytical method validation as per ICH Q2 Guidelines.

RECOMMENDED BOOKS:

1. Quality Assurance Guide. Organization of Pharmaceutical Products of India.
2. Weinberg, S. Good Laboratory Practice Regulations. Vol. 69. Marcel Dekker.
3. World Health Organization (WHO). Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials. Vol. I. WHO Publications.
4. Maitra, K., & Ghosh, S. K. A Guide to Total Quality Management.
5. Sharma, P. P. How to Practice GMPs.

ADVANCED PHARMACOGNOSY - THEORY

Total Credits 3 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

1. To understand integrative and reverse pharmacological approaches in natural drug discovery.
2. To apply metabolomics and systems biology tools for quality control and bioactivity assessment.
3. To explore modern AI-driven and high-throughput technologies for natural product lead identification.
4. To understand legal, ethical, and patenting frameworks in bioprospecting and natural product innovation.

COURSE OUTCOMES

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

1. Explain reverse pharmacology, traditional knowledge databases, and bioprospecting strategies.
2. Analyze herbal formulations 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.

COURSE CONTENTS:

UNIT-I **6 Hours**

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, NAPRALERT, Supernatural,

etc. Molecular docking and ADMET screening of bioactives. Concept of adjuvant therapy with herbals in metabolic and non-communicable diseases.

UNIT-II **11 Hours**

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

UNIT-III **10 Hours**

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, Novel-formulation of phytoconstituents and herbal drugs

UNIT-IV **12 Hours**

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, Galegine 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.

UNIT-V **06 Hours**

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.

RECOMMENDED BOOKS

1. Satyajit D. Sarker, Z. Latif, & A. I. Gray (2006). Natural Products: Isolation, Structure Elucidation, History. Elsevier.
2. Chen, S., & Marston, A. (Eds.). (2018). The Handbook of Natural Products Analysis. Wiley.
3. S.V. Bhat, B. A. Nagasampagi, & M. Sivakumar (2005). Chemistry of Natural Products. Springer.
4. Ikan, R. (1991). Natural Products: A Laboratory Guide (2nd ed.). Academic Press.
5. Hanessian, S. (2000). Natural Products in Medicinal Chemistry. Wiley-VCH.
6. Gräbley, S., & Thiericke, R. (1999). Drug Discovery from Nature. Springer-Verlag.
7. Narayanan, P. (2006). Intellectual Property Law. Eastern Law House.
8. Gupta, A. K. (2002). Patent Protection of Traditional Knowledge in the Indian Context. IIM Ahmedabad Working Papers.
9. Kemp, W. (1991). Spectroscopic Methods in Organic Chemistry (3rd ed.). Macmillan.

SUGGESTED READINGS

1. Balunas, M. J., & Kinghorn, A. D. (2005). Drug discovery from medicinal plants. Life Sciences, 78(5), 431–441.
2. Li, J. W.-H., & Vederas, J. C. (2009). Drug discovery and natural products: End of an era or an endless frontier? Science, 325(5937), 161–165.
3. Zhang, A., Sun, H., Wang, X. (2012). Recent advances in metabolomics in drug discovery. Trends in Analytical Chemistry, 32, 1–14.
4. Karthikeyan, A., Joseph, A., & Nair, B. G. (2024). Medicinal Plant Identification in RealTime Using Deep Learning Model. SN Computer Science, 5, 73. https://doi.org/10.1007/s42979-023-02398-5

5. Kolluri, S., Lin, J., Liu, R., Zhang, Y., & Zhang, W. (2022). Machine Learning and Artificial Intelligence in Pharmaceutical Research and Development: A Review. AAPS Journal, 24(1), 19. https://doi.org/10.1208/s12248-021-00644-3
6. Traditional Knowledge Digital Library (TKDL) – https://www.tkdl.res.in
7. AYUSH Research Portal & Guidelines – https://www.ayush.gov.in
8. National Biodiversity Authority – Nagoya Protocol – https://nbaindia.org
9. WHO – General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine – https://www.who.int
10. ICH Guidelines (Q, S, E, M Series) – https://www.ich.org
11. OECD Guidelines for Toxicological Evaluation – https://www.oecd.org
12. SwissADME, AutoDock, Cytoscape – Open-source tools for in-silico pharmacokinetics and docking – http://www.swissadme.ch
13. ICMR – Standards on Indian Medicinal Plants – https://main.icmr.nic.in
14. WIPO and WHO – Publications on herbal drug regulation and IPR – https://www.wipo.int | https://www.who.int
15. The Drugs and Cosmetics Act and Rules, Government of India – Legal Text.

BIOPHARMACEUTICS AND PHARMACOKINETICS - THEORY

Total Credits 3 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES:

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. Develop and evaluate compartmental pharmacokinetic models, and apply 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:

Upon completion of this course, 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 one- and two-compartment models by employing numerical techniques such as curve fitting, Wagner–Nelson, and Loo–Riegelman methods.
5. Design optimal dosing regimens, interpret non-linear pharmacokinetic behaviors, and utilize simulation software (WinNonlin, GastroPlus, Simcyp) for advanced PK/PD analysis.

COURSE CONTENTS

UNIT-I **10 Hours**

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

UNIT-II **10 Hours**

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.

UNIT- III **10 Hours**

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: statistical movement theory.

UNIT- IV **09 Hours**

Multicompartment models: 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.

UNIT- V **06 Hours**

Nonlinear Pharmacokinetics: Introduction, Reasons for Non-linearity, Michaelis-menton method of estimating parameters, Explanation with example of drugs.

Application of PK softwares: Introduction of various in -silico methods for calculating various Pk parameters including WinNonlin; NONMEM (Nonlinear Mixed Effects Modeling); Phoenix WinNonlin; GastroPlus; Simcyp; PK-Sim and MoBi, etc.

RECOMMENDED BOOKS

1. Biopharmaceutics and Clinical Pharmacokinetics. *Author*: Milo Gibaldi
2. Applied Biopharmaceutics and Pharmacokinetics. *Authors*: Leon Shargel, Andrew Yu
3. Biopharmaceutics and Pharmacokinetics: A Treatise. *Author*: D.M. Brahmankar and Sunil B. Jaiswal
4. Rowland and Tozer's Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications. *Authors*: Malcolm Rowland, Thomas N. Tozer
5. Pharmacokinetic-Pharmacodynamic Modeling and Simulation. *Author*: Peter Bonate
6. Modeling and Simulation in the Medical and Health Sciences. *Author*: David M. Eddy

PHARMACEUTICAL JURISPRUDENCE - THEORY

Total Credits 3 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

The Course aims to:

1. Understand the key pharmaceutical legislations and their implications on the development, approval, and marketing of pharmaceutical products.
2. Gain comprehensive knowledge of various Indian pharmaceutical Acts and laws that regulate the industry.
3. Identify and describe the roles and responsibilities of regulatory authorities and agencies involved in the manufacture, distribution, and sale of pharmaceuticals in India.
4. Comprehend and apply the professional code of ethics relevant to pharmaceutical practice.

COURSE OUTCOMES

At the end of the course, the student 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.

COURSE CONTENTS

UNIT-I **10 Hours**

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.

UNIT-II **10 Hours**

Drugs and Cosmetics Act, 1940 and its rules 1945.

- Detailed study of Schedule G, H, H1, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA)
- 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

UNIT-III **8 Hours**

- **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

UNIT-IV **08 Hours**

- **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
- **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)

UNIT-V **09 Hours**

- **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.**
- **Medical device regulations, food safety and standards.**
- **Biologics and biosimilars.**
- **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**

RECOMMENDED BOOKS: (LATEST EDITION)

1. Forensic Pharmacy by B. Suresh
2. Text book of Forensic Pharmacy by B.M. Mithal
3. Hand book of drug law-by M.L. Mehra
4. A text book of Forensic Pharmacy by N.K. Jain
5. Drugs and Cosmetics Act/Rules by Govt. of India publications.
6. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
7. Narcotic drugs and psychotropic substances act by Govt. of India publications
8. Drugs and Magic Remedies act by Govt. of India publication
9. Bare Acts of the said laws published by Government. Reference books (Theory)

INTELLECTUAL PROPERTY RIGHTS - THEORY

Total Credits 2 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

1. To introduce the fundamental concepts and types of intellectual property (IP) and highlight their importance in the pharmaceutical and healthcare sectors.
2. To 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. To provide insights into the management and commercialization of IP, including licensing, technology transfer, and joint ventures.
5. To familiarize with common IP infringement issues and remedies, using real-world case studies from the pharmaceutical industry to illustrate key principles.

COURSE OUTCOMES

After successful completion of this course, the student will be able to:

1. Understand the basic concepts and significance of intellectual property rights with respect to pharmaceutical industries.
2. Know about types of intellectual property 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.

COURSE CONTENTS

Unit I: Introduction to Intellectual Property **6 Hours**

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

Unit II: Patents – Fundamentals and Process **6 Hours**

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

Unit III: Patent Laws and Acts **6 Hours**

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.

Unit IV: Other Forms of Intellectual Property **6 Hours**

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

Unit V: IPR Management and Commercialization **6 Hours**

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.

RECOMMENDED BOOKS

1. Bouchoux, D. (2012). Intellectual property right, Cengage learning.
2. Ganguli, Prabuddha. (2017). Intellectual property right - Unleashing the knowledge economy, Tata McGraw Hill Publishing Company Ltd.
3. Johnson, M.(2021).Intellectual Property Law: Basics and Beyond. Coursera.
4. Sreenivasulu, N.S. (2013). Law Relating to Intellectual Property. Partridge Publishing India
5. Vaidhyanathan, Siva. (2017)."Intellectual Property: A Very Short Introduction". Oxford University Press.
6. B.L. Wadehra, Law Relating to Intellectual Property, Universal Law Publishing
7. V.K. Ahuja, Law Relating to Intellectual Property Rights, LexisNexis
8. P. Narayanan, Intellectual Property Law, Eastern Law House

9. T. Ramakrishna, Basic Principles and Acquisition of Intellectual Property Rights, CIPRA, NLSIU
10. World Intellectual Property Organization (WIPO): www.wipo.int
11. World Intellectual Property Organization. (2022). Introduction to Intellectual Property. https://www.wipo.int/edocs/pubdocs/en/wipo-pub-944-2022-en-world-intellectual-propertyreport-2022-the-direction-of-innovation.pdf

Elective 3 – AEC (Theory)

Total Credits 1 **Hours / Week: 1** **15 HR**

The syllabi for elective subjects are given in the appendices

ML IN PHARMACOGNOSY & BIOTECHNOLOGY

Total Credits 2 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

The course aims to:

1. Introduce students to core AI and ML tools used across nutrition, agriculture, herbal medicine, genomics, and microbiology.
2. Show how AI designs personalized diets, discovers nutraceutical actives, and checks their safety and efficacy.
3. Teach AI methods that optimize crop growth, conserve medicinal plants, and predict plant secondary metabolites.
4. Train learners to apply AI for crude-drug recognition, natural-product drug discovery, and regulatory intelligence.
5. Equip students to analyze genomic, proteomic, and microbial data with AI—covering phylogenetics, non-coding RNA, and enzyme engineering.

COURSE OUTCOMES

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

1. Produce an AI-generated diet plan and justify its predicted health benefits.
2. Build an ML model that forecasts plant growth or metabolite yield from soil, climate, or genomic inputs.
3. Classify a crude drug image set with AI and flag potential herb-drug interactions.
4. Run an AI pipeline to identify microbes or non-coding RNAs from sequence data and display a phylogenetic tree.
5. Create an AI-guided strategy to improve enzyme immobilization or automate cell-structure detection and present the results.

COURSE CONTENTS:

Unit 1 – Nutrition & Nutraceuticals **6 Hours**

- AI in nutrition planning and personalized diet recommendations.
- AI assistance in linking food components with disease phenotypes.
- AI in Nutraceutical Discovery and Personalization Machine learning for bioactive compound Screening, AI-guided formulation of personalized supplements
- Predictive analytics in efficacy and safety assessment of nutraceuticals.

Unit 2 – Agriculture & Plant Science **6 Hours**

- AI in agriculture for optimizing plant growth conditions via soil and climate analysis,
- Greenhouse automation.
- AI in Conservation of Medicinal Plants: GIS, Remote Sensing & Prediction Models.
- Prediction of Plant secondary metabolites using genomes.
- AI driven prediction of secondary metabolite structures.

Unit 3 – Herbal Medicine & Natural Products **6 Hours**

- AI in Classification of Crude Drugs using Image Recognition (Microscopy, Morphology).
- AI-driven techniques for identification of crude drugs.
- AI driven drug discovery from natural product.
- Herb Identification, Herb-Drug Interactions, Herbal formulations
- AI for Regulatory Intelligence: Machine learning to track updates in EU, ICH, and WHO herbal guidelines (T).
- AI in studying secondary metabolite production through pathways like the Shikimic acid pathway and Acetate pathway.

Unit 4 – Genomics & Molecular Biology **6 Hours**

- Introduction to AI & ML in Biology, AI in Genomics and Molecular Data Analysis
- Machine Learning in Protein Structure Prediction,
- ML-based identification of non-coding RNAs (miRNA, lncRNA, etc.).
- Basic differences between DNA, RNA, and proteins.

Unit 5 – Microbial & Cellular Informatics and Enzyme Engineering **6 Hours**

- Identification of microorganisms using gene sequences through BLAST.
- Open-Source AI Tool for Microbial Identification.
- Introduction and hands-on training on Phylogenetic tree construction.
- Prediction of secondary metabolite biosynthetic gene clusters.
- Use of deep learning for analyzing cell structures and identifying organelles automatically (T-1HRS).

• ML for optimizing enzyme loading, immobilization matrices.

RECOMMENDED BOOKS

1. Artificial Intelligence in Food Science: Transforming Food and Bioprocess Development — Tanmay Sarkar & Anandakumar Haldorai, Academic Press (Elsevier), 1st ed., 2025
2. Artificial Intelligence in Agriculture — Rajesh Singh, Anita Gehlot, Mahesh Kumar Prajapat & Bhupendra Singh, CRC Press (Taylor & Francis), 1st ed., 2022.
3. Artificial Intelligence in Drug Discovery — Nathan Brown, Royal Society of Chemistry, 1st ed., 2020
4. Deep Learning in Bioinformatics: Techniques and Applications in Practice — Habib Izadkhah, Academic Press (Elsevier), 1st ed., 2022
5. Bioinformatics, AI, and Machine Learning in Microbial Drug Development — Vagish Dwibedi, Nancy George, Santosh Kumar Rath & Swapnil Kajale (eds.), Academic Press (Elsevier), 1st ed., 2025

BIOPHARMACEUTICS AND PHARMACOKINETICS - PRACTICALS

Total Credits 1 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

1. Understand and compare 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. Calculate and interpret pharmacokinetic parameters using plasma and urinary excretion data.
4. Establish in vitro–in vivo correlations (IVIVC) for drug products based on experimental datasets.
5. Utilize software tools to simulate and analyze pharmacokinetic and pharmacodynamic data.

COURSE OUTCOMES

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

1. Compare the dissolution profiles of marketed formulations and assess the impact of dietary factors.
2. Perform dissolution tests using biorelevant media and absorption studies using ex vivo methods such as the everted sac technique.
3. Calculate AUC, MRT, absorption rate constant, elimination rate constant, and half-life using various analytical methods.
4. Assess relative bioavailability and bioequivalence of drug products using plasma and urinary excretion data.
5. Develop and validate IVIVC models and use in silico/PKPD software to estimate pharmacokinetic parameters.

COURSE CONTENTS

1. To compare dissolution profiles of marketed formulations.
2. To perform dissolution test using biorelevant dissolution medium.
3. To assess absorption of a drug using isolated everted intestine sac method
4. To assess effect of dietary factors on the dissolution of drug
5. To calculate AUC from the given data by different methods

6. To calculate MRT from the given data.
7. To assess the effect of protein binding of a drug
8. To report relative bioavailability of given drug product using urinary excretion data
9. To report relative bioavailability of given drug product using plasma data
10. Establish IVIVC from the given in -vitro and in- vivo data.
11. To calculate pharmacokinetic parameters of a drug using given plasma level data.
12. To report bioequivalence of drug products using given urinary excretion data administered
13. To Calculate absorption rate constant, elimination rate constant and elimination half life of given excretion data by sigma minus method.
14. To Calculate absorption rate constant, elimination rate constant and elimination half life of the given drug data administered by i.v. bolus injection represented by one compartment model.
15. To calculate the absorption rate constant by using curve fitting method (Methods of residual)
16. To calculate various Pharmacokinetic parameters using in - silico / PKPD softwares.

Note: Minimum 12 experiments must be performed

RECOMMENDED BOOKS

1. Applied Biopharmaceutics and Pharmacokinetics. Authors: Leon Shargel & Andrew Yu
2. Biopharmaceutics and Pharmacokinetics: A Treatise. Authors: D.M. Brahmankar & Sunil B. Jaiswal
3. Biopharmaceutics and Clinical Pharmacokinetics. Author: Milo Gibaldi
4. Practical Biopharmaceutics and Pharmacokinetics Laboratory Manual.Author: Rajesh Khar, S.P. Vyas
5. Textbook of Biopharmaceutics and Pharmacokinetics. Author: N.V.S. Murthy

Elective 4 – SEC (Practical)

Total Credits 1 **Hours / Week: 2** **30 HR**

The syllabi for elective subjects are given in the appendices

Elective 5 – VAC (Practical)

Total Credits 1 **Hours / Week: 2** **30 HR**

The syllabi for elective subjects are given in the appendices

SEMESTER VII

MODERN ANALYTICAL TECHNIQUES - THEORY

Total Credits 3 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

1. Study the basic principle, instrumentation and application of spectral techniques viz., NMR spectroscopy, Mass spectrometry.
2. Gain knowledge on the theoretical and practical aspects involved in the instruments used for the physical characterization of drugs and excipients.
3. Learn the basic principle and primary applications of Advanced chromatographic techniques used for analysis of drugs and excipients.
4. Know the different types of sample preparation techniques used during the analysis of drugs in different matrices.
5. Appreciate the importance of particle size analyzer used during formulation development in pharmaceutical industries.

COURSE OUTCOMES

Upon completion of the course students shall be able to:

1. Apply the principle of Mass and NMR spectra's 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. Understand and Apply Green Analytical Chemistry Techniques for environmental Sustainability
6. Develop the practical skills in the analysis of drugs from various matrices through sample preparation techniques.

COURSE CONTENTS

UNIT I **10 hours**

1. **Nuclear Magnetic Resonance Spectroscopy:** Principles of 1H-NMR and 13C-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 – Electron impact, chemical ionization, MALDI, FAB, API, Analyzers -Time off light and Quadrupole, Ion trap, detectors and applications.

UNIT II **08 hours**

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.

UNIT III **10 hours**

1. **UHPLC and Nano LC**: Principle, advantages over LC and applications.
2. **Principle and applications of Hyphenated techniques:** GC-MS,LC-MS/MS, ICP/MS
3. **Super Critical chromatography and Flash chromatography:** principles and applications

UNIT IV **12 Hours**

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:** 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.

UNIT V **05 Hours**

Microscopy-Based Analytical Techniques: Principle, instrumentation and applications of optical microscopy, Scanning Electron Microscopy and Transmission Electron Microscopy

FUTURE PROSPECTS:

1. Structural interpretation of NMR and Mass spectra's.
2. Different types of software for calculating the Greenness of analytical solvents
3. Circular Dichroism studies
4. Chiral Chromatography techniques
5. HPTLC-MS–Principle, instrumentation and applications

RECOMMENDED BOOKS:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic Spectroscopy by Y.R Sharma
3. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
4. Organic Spectroscopy by William Kemp
5. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
6. Spectrophotometric identification of Organic Compounds by Silverstein
7. Pharmaceutical Analysis: Modern methods Part B by J W Munson
8. Instrumental Methods of Analysis by Willard

PHARMACOVIGILANCE - THEORY

Total Credits 3 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES:

a) **Understand Pharmacovigilance Concepts:** To provide a thorough understanding of the principles and practices of pharmacovigilance in drug safety monitoring.

b) **Know the methods of Pharmacovigilance:** To understand the various definitions and types of Adverse Drug Reactions and the methods used for monitoring adverse drug reactions, assessing causality, severity and preventability and costs on hospitals, community and healthcare system. It also includes methods and models of pharmacovigilance being implemented in various countries and emerging sub-disciplines of pharmacovigilance.

c) **Explore Immunovigilance:** To examine the importance of immunovigilance in ensuring vaccine safety and monitoring adverse effects following immunization.

d) **Regulatory Frameworks:** To familiarize students with the regulatory requirements and guidelines for pharmacovigilance and immunovigilance in India and globally.

e) **Adverse Event Reporting:** To develop skills for identifying, documenting, and reporting adverse drug reactions (ADRs) and adverse events following drug use and immunization (AEFIs).

f) **Data Analysis and Risk Management:** To equip students with the knowledge to analyze pharmacovigilance data for implementing various risk management strategies

COURSE OUTCOMES

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

- **Describe Key Concepts:** Explain the fundamental concepts of pharmacovigilance and immunovigilance, including definitions, significance, and objectives
- **Analyse Regulatory Frameworks:** Evaluate the regulatory frameworks governing pharmacovigilance and immunovigilance in India and their implications for healthcare professionals
- **Identify and Report ADRs/AEFIs:** Identify, document, and report adverse drug reactions and adverse events following immunization using appropriate reporting systems

- **Assess Pharmacovigilance Data:** Analyze pharmacovigilance data to identify trends, signals, and risk factors associated with drug safety and efficacy
- **Implement Risk Management Strategies:** Develop and propose risk management strategies based on data analysis to enhance patient safety

COURSE CONTENTS

Unit-I **10 hours**

a) Anatomical, therapeutic and chemical (ATC) classification of drugs
b) International classification of diseases (ICD)
c) Daily Defined Doses (DDD)
d) International Non-proprietary Names (INN) for drugs
e) Types of Drug-related Problems (DRPs)
f) Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation

Unit-II: **10 hours**

Introduction to Pharmacovigilance

a) Definition, history, development and significance of pharmacovigilance
b) Terminologies used in pharmacovigilance
c) Key functions and objectives of pharmacovigilance
d) Methods for data collection in pharmacovigilance
e) Signal detection and analysis of pharmacovigilance data
f) Pharmacovigilance systems across the world
g) Indian and Global regulatory frameworks and agencies (WHO, USFDA, EMA, CIOMS) for pharmacovigilance and their functions
h) WHO international drug monitoring programme
i) Pharmacovigilance Program of India (PvPI), establishing pharmacovigilance centres in hospitals
j) Pharmacovigilance of complementary and alternative medicines (CAM)

Unit-III: Adverse Drug Reactions (ADRs) **08 hours**

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 for ADRs (e.g., WHO-ART, VigiBase, Vigiflow, Oracle Argus or OpenVigil software)

Unit-IV: Immunovigilance and other disciplines of pharmacovigilance 7 hours

a) Definition, scope and significance of immunovigilance, cosmetovigilance, neutraceutical-vigilance, Materiovigilance, herbovigilance, eco-pharmacovigilance and hemovigilance.
b) Vaccination failure and vaccine pharmacovigilance (vaccinovigilance)
c) Overview of adverse events following immunization (AEFIs)
d) Immunization safety monitoring systems in India

Unit-V: 10 hours

Risk Communication, Evaluation, Management and ICH Guidelines for Pharmacovigilance

a) Risk evaluation and management strategies in pharmacovigilance and immunovigilance
b) Communication in Drug Safety Crisis management
c) Communicating with Regulatory Agencies, Business Partners, Healthcare facilities
d) Analysis of real-world case studies and lessons learnt
e) Emerging trends and challenges in pharmacovigilance and immunovigilance
f) An 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) in pharmacovigilance and Schedule Y of Drugs and Cosmetics Act, 1940
m) Application of Pharmacogenomics and Pharmacometrics in Pharmacovigilance

RECOMMENDED BOOKS (LATEST EDITIONS)

1. Cobert's Manual of Drug Safety and Pharmacovigilance by Barton Cobert, William W Gregory, Jean-Loup Thomas. 3rd Edition (2019). World Scientific Publishing Company.
2. Pharmacovigilance: Critique and Ways Forward by Ralph Edwards, Marie Lindquist. Springer International Publishing
3. Pharmacovigilance Essentials: Advances, Challenges and Global Perspectives by Anoop Kumar and Mukesh Nandave. Springer (2024).

4. Mann's Pharmacovigilance by Elizabeth B. Andrews, Nicholas Moore. Wiley Blackwell.
5. An Introduction to Pharmacovigilance by Patrick Waller, Mira Harrison-Woolrych. Wiley Blackwell
6. Principles and Practice of Pharmacovigilance and Drug Safety by Jimmy Jose, Anthony R. Cox, Vibhu Paudyal. Springer International Publishing (2024).
7. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
8. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones. Bartlett Publishers.
9. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle.
10. An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers.
11. Textbook of Pharmacoepidemiology edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers.
12. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills:G. Parthasarathi, Karin Nyfort Hansen, Milap C. Nahata
13. National Formulary of India
14. Text Book of Medicine by Yashpal Munjal

COSMETICS AND COSMECEUTICALS - THEORY

Total Credits 2 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

The course aims to equip students to:

1. Recognize the fundamental concepts, classification, and different dosage forms employed in cosmetic and cosmeceutical formulations.
2. Develop knowledge of some common dermatological, hair, and oral care issues and their respective cosmetic products.
3. Acquire knowledge about the ingredients, formulation techniques, packaging, and testing of different cosmetic and personal care items.
4. Develop an understanding of herbal cosmetics and their principles of formulation.
5. Acquaint yourself with regulatory guidelines, labeling protocols, and packaging regulations for cosmetics and cosmeceuticals.
6. Research recent trends such as artificial intelligence (AI) in customized skincare and cosmetic innovation.

COURSE OUTCOMES

On the successful completion of the course, 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.

COURSE CONTENTS

UNIT I **06 Hours**

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.

UNIT II **06 Hours**

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.

UNIT III **06 Hours**

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.

UNIT IV **06Hours**

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, lipcare and cleansing.

Intimate hygiene products for males and females.

UNIT -V **06 Hours**

Regulating bodies for Cosmetics and cosmeceuticals and their roles (CDSCO and FDA). Cosmetics regulations 2020 and role of BIS, Role of certifying bodies like ECOCERT and COSMOS in herbal cosmetics. Labeling requirement of cosmetics and Packaging of cosmetics.

Use of AI in cosmetics for personalized skincare recommendations, virtual makeup try-ons, and improved product development.

RECOMMENDED BOOKS

1. Cosmetic Science and Technology" (Vol I–III) – *Edited by Mitsuo Matsumoto, Elsevier*
2. "Harry's Cosmeticology" (9th Edition) – *Edited by Meyer R. Rosen*
3. "Handbook of Cosmetic Science and Technology" – *André O. Barel, Marc Paye, Howard I. Maibach*
4. "Cosmetic Formulation of Skin, Hair, and Nails" – *Amparo Salvador, Alberto Chisvert*
5. "Herbal Cosmetics Handbook" – *H. Panda (NIIR Board)*
6. "Regulatory Affairs for Cosmetic Products in India" – *R. Udupa*
7. Introduction to Cosmetic Formulation and Technology", Authors: Gabriella Baki & Kenneth S. Alexander, Publisher: Wiley.
8. "Handbook of Cosmetic Science", Editor: H.W. Hibbert, Publisher: Springer.
9. The Chemistry and Manufacture of Cosmetics" (Vol. 1–4), Author: Maison G. deNavarre, Publisher: Allured Publishing.
10. "Cosmetic Formulation: Principles and Practice", Authors: Heather A.E. Benson, Adam C. Watkinson, Publisher: CRC Press
11. "Formulating Natural Cosmetics", Authors: Anthony Dweck, Patricia F. Santos Publisher: Allured Book.
12. "Artificial Intelligence for Cosmetics: A Practical Guide" (New/Recent Publications) Authors: Various (Available in AI & Cosmetic Science Journals or CRC compiled works)

REGULATORY AFFAIRS - THEORY

Total Credits 2 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

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

By the end of this course, 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.

COURSE CONTENTS

Unit 1: Fundamentals of Regulatory Affairs **6 Hours**

- 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).

Unit 2: Regulatory Requirements in Drug Development **6 Hours**

- 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.

Unit 3: Indian Regulatory Framework and Approval Process **6 Hours**

- 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.

Unit 4: International Regulatory Systems & Global Drug Registration **6 Hours**

- 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.

Unit 5: Clinical Trials, Ethics, and Post-Marketing Surveillance **6 Hours**

- 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,

REFERENCE BOOKS

1. Douglas J Pisano and David S. Mantus. Textbook of FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition
2. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
3. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185. Informa Health care Publishers.
4. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
5. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
6. FDA Regulatory Affairs: A guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
7. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
8. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
9. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
10. Drugs: From Discovery to Approval, Second Edition By Rick Ng
11. Regulatory Authority websites for current/ updated information.

PHARMACY PRACTICE - THEORY

Total Credits 3 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

The course aims to enable students 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

On completion of this course, the students shall 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. Participate in basic health screening activities and recognize the pharmacist's role in preventive healthcare.
6. Interpret and apply prescribing guidelines, essential drug concepts, and principles of rational drug use for optimal pharmacotherapy.

COURSE CONTENTS

Unit I – Introduction to Pharmacy Practice **8 hours**

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

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 in various levels of care

Unit II – Hospital and Community Pharmacy **10 hours**

Hospital and it's organization

- Classification of hospitals
- Organization structure of a hospital, healthcare staff involved in the hospital 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, policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescriptions, automatic stop order, and emergency drug list preparation.

Hospital Formulary

Definition of hospital formulary; contents of hospital formulary, Differentiation of hospital formulary and Drug list; preparation and revision of hospital formulary;

Drug distribution system in a hospital

Drug procurement, 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 the establishment and maintenance of a drug store
- Dispensing of proprietary products, maintenance of records of retail and wholesale drug store
- Prescription handling, labelling and patient counselling in community pharmacy
- Introduction, definition, sale and OTC medication list
- Vaccination services

Unit III – Clinical Pharmacy Services **9 hours**

- Introduction to clinical pharmacy, concept of clinical pharmacy
- Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, ward round participation, medication history and pharmaceutical care.

- Drug information services
- Drug/Medication Related Problems
- Drug and poison information services
- Therapeutic drug monitoring (TDM)

Unit IV – Patient-Oriented Services Medication adherence and non-adherence 9 hours

- Definition, Factors influencing non- adherence
- Pharmacist role in the medication adherence; monitoring of patient medication adherence
- Tools used to assess medication adherence
- Strategies to overcome non adherence

Patient counseling techniques and communication skills

- Definition of patient counseling; steps involved in patient counseling.
- Communication skills- communication with prescribers and patients.
- Types of educational materials used in patient counselling
- Barriers to effective counseling - Types and strategies to overcome the barriers

Health screening services

- Definition, importance
- Methods for screening
    - Blood pressure
    - Blood sugar
    - Body Mass Index
    - Lung function test
- Role of Pharmacist in health screening services

Unit V – Prescribing Guidelines, Essential Drug Concept and Rational Drug Therapy

9 hours

Prescribing Guidelines

- Pediatrics
- Geriatrics
- Pregnant and Lactating women

Essential drug concept

- WHO Definition
- Core Principles and key features
- Procedure involved in adding drug into essential drug list

Rational Use of Medications

- Antibiotics
- Injections
- OTC Drugs
- Consequences of irrational drug use

REFERENCE BOOKS

1. Hospital Pharmacy by William E. Hassan
2. A text book of Hospital Pharmacy by S.H.Merchant & Dr.J.S.Qadry. Revised by R.K.Goya l& R.K. Parikh
3. Practice standards and definitions: Society of Hospital Pharmacists of Australia (SHPA)
4. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall Publication
5. A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr. G. Parthasarathi, Karin Nyfort Hansen, Milap Nahata, Orient Longman Pvt. Ltd.
6. Health Education and Community Pharmacy by N.S.Parmar.
7. WHO consultative group report.
8. Drug store & Business management by Mohammed Ali & Jyoti.
9. Handbook of pharmacy – health care.Edt. Robin J Harman. The Pharmaceutical press.
10. Comprehensive Pharmacy Review – Edt. Leon Shargel. Lippincott Williams &Wilkins.

BIOSTATISTICS AND RESEARCH METHODOLOGY - THEORY

Total Credits 3 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

1. To introduce and explain foundational concepts in biostatistics, including data types, measurement scales, data collection methods, and descriptive statistics for summarizing health and pharmaceutical data.
2. To build a strong understanding of probability and statistical distributions, enabling students to apply binomial, Poisson, and normal distributions in real-world biomedical and pharmaceutical scenarios.
3. To develop the ability to analyze relationships between variables using correlation and regression techniques.
4. To enable students to perform inferential statistical analyses, including estimation, hypothesis testing (parametric and non-parametric), and selection of appropriate tests based on research questions and data types.
5. To impart comprehensive knowledge of research methodology, including study design, scientific report writing, referencing, ethical considerations like plagiarism, and advanced experimental design techniques such as factorial and response surface methods.

COURSE OUTCOMES

At the end of the course, the learners will be able to;

1. Enlist steps involved in research and explain the concept of research problem, research hypothesis and research methodology
2. Given a research problem, be able to suggest the research methodology to be adopted including research design
3. Perform calculations and procedures pertaining to descriptive statistics
4. Perform statistical calculations using calculators/ Excel/ R pertaining to statistical estimation, regression, correlation, and hypothesis testing

COURSE CONTENTS

Unit I Basic concepts of biostatistics **9 hours**

1. Statistics – Definition, Biostatistics – Definition, Variables – Meaning and types

- Discrete and continuous,

- Categorical and numerical,
- Independent and dependent

Scales of variables – Nominal, ordinal, interval and ratio scale

Data – Meaning and methods of data collection

Population and sample, Importance of sampling, Sampling methods

- Probability and non-probability sampling
    - Probability sampling - Random, systematic, stratified, cluster sampling
    - 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

Descriptive statistics

- Frequency distribution
- Measures of central tendency – Mean, Median and Mode
- Measures of dispersion – Range, variance and standard deviation. Concept of degrees of freedom

Diagrammatic representation of frequency distribution

- Bar graphs, Pie charts, Histograms

1. Use of data analysis and pivot tables in Excel for descriptive statistics

Unit II Probability and probability distributions **9 Hours**

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

Binomial distribution – Definition and real world examples, characteristics of a binomial experiment, Binomial probability equation, parameters of a binomial distribution. Pharmaceutical examples of data which can be modelled with binomial distribution.

Poisson distribution – Definition and real-world examples, characteristics of a Poisson distribution, Poisson distribution equation, parameter of a Poisson distribution. Pharmaceutical examples of data which can be modelled with Poisson distribution.

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 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

Unit III Correlation and regression analysis **9 Hours**

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-efficients Use of scatter plot Multiple correlation – Concept and applications. Use of data analysis in Excel and R for calculating correlation co-efficients

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-efficients and correlation co-efficient

Problems on simple linear regression analysis for prediciting values of dependent variables (pharmaceutical examples)

Use of data analysis in Excel and R for performing regression analysis

Multiple linear regression – Concept and applications

UNIT 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

Use of Excel and R for statistical estimation

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 (problems on t tests and ANOVA)

Use of Data Analysis in Excel for performing 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)

UNIT V Research methodology

Research – Meaning, importance and types

The research process

Types of research designs

1.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. Decision tree approach for selection of statistical tests on the basis of research question and type of data

2.Descriptive research design – Examples of application

Observational research design – Examples of application

Experimental research design – Examples of application

3Scientific report writing, plagiarism, referencing styles, selection of research journals, abstracting services and databases

4.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 BOOKS

1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. NewYork.
2. Fundamental of Statistics – Himalaya Publishing House- S.C.Guptha
3. Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam,
4. Design and Analysis of Experiments – Wiley Students Edition, Douglas and C. Montgomery

Elective 6 – AEC (Theory)

Total Credits 1 **Hours / Week: 1** **15 HR**

The syllabi for elective subjects are given in the appendices

INTELLIGENT MANUFACTURING & SMART QA IN PHARMACY

Total Credits 2 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

The course will enable students to:

1. Explain how AI and machine-learning platforms optimize dosage-form design, excipient selection, and Quality by Design (QbD) practices.
2. Demonstrate the integration of AI with Process Analytical Technology (PAT) for real-time quality control, scale-up, and smart product authentication.
3. Teach AI-based pharmacokinetic and PBPK modeling to predict absorption, distribution, metabolism, and excretion of advanced delivery systems.
4. Introduce data-driven techniques for market segmentation, consumer-behavior prediction, and personalized cosmetic/dermatology solutions.
5. Familiarize students with AI tools that streamline regulatory dossiers, enable explainable decision support, and validate new drug targets.

COURSE OUTCOMES

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

1. Build an AI model that recommends optimal tablet or capsule formulations while meeting predefined CQAs.
2. Apply ML algorithms with PAT data to detect process deviations and propose corrective actions during scale-up.
3. Generate a PBPK simulation for a controlled-release or nanotech delivery system and interpret the predicted ADME profile.
4. Analyze marketing datasets with AI to segment customers and propose a targeted product or skincare recommendation.
5. Draft an AI-supported regulatory summary that justifies target validation and addresses regional guideline requirements.

COURSE CONTENTS

Unit 1 – AI-Driven Formulation Design **6 Hours**

- Machine Learning in Tablet and Capsule Optimization
- Process optimization and formulation optimization of dosage forms

- AI-driven excipient selection, physicochemical properties, formulation optimization, and data-informed QbD
- Formulation AI Platforms provide a direct approach to optimizing the formulation processes in NDDS by predicting key parameters (e.g., release profiles, encapsulation efficiency, bioadhesion)
- Predicting Drug Release and Dissolution Profiles

Unit 2 – Process Analytics, Quality Control & Scale-Up **6 Hours**

- ML learns from historical and real-time data to improve quality predictions, process control, and compliance
- Integrated with Process Analytical Technology (PAT) tools
- AI helps define and control Critical Quality Attributes (CQAs) and Critical Process Parameters (CPPs) in line with Quality by Design (QbD) principles
- AI in process development and scale-up: using AI to optimize scale-up and technology transfer
- Smart Packaging and AI-Based Product Authentication

Unit 3 – Pharmacokinetic & Biopharmaceutic Modeling **6 Hours**

- Modeling Drug Absorption Profiles Using AI
- Pharmacokinetic Modeling and Simulations: learning to develop and apply pharmacokinetic models to predict drug ADME process
- SimCyp Simulator, advanced PBPK modeling to predict the in vivo behavior of controlled, gastroretentive, transdermal, and targeted drug delivery systems
- AI in Enhancement of Nanotechnology-Based Delivery Systems

Unit 4 – Market Analytics & Consumer-Focused AI **6 Hours**

- AI in Consumer Behavior Prediction and Market Segmentation
- Pharma marketing data analytics and customer insights
- AI/ML, virtual tools that assess skin and recommend cosmetics and detect clinical skin concerns

Unit 5 – Regulatory & Discovery Intelligence **6 Hours**

- Comparative analysis of regulatory guidelines across regions

- Leveraging AI to Streamline Regulatory Dossier Preparation and Review
- Explainable AI for Regulatory Decision Support Systems
- AI in target identification and validation: validate drug targets

RECOMMENDED BOOKS

1. Pharmaceutical Quality by Design: A Practical Approach — Shawn P. Kennedy & Anders T. Rantanen, Springer, 2nd ed., 2022
2. Physiologically Based Pharmacokinetic (PBPK) Modeling and Simulations — Sheila Annie Peters, Wiley, 1st ed., 2021
3. Artificial Intelligence in Pharmaceutical Manufacturing — Girish Malhotra, Elsevier, 1st ed., 2024
4. Machine Learning for Drug Formulation and Process Development — Vijay Kumar Thakur (ed.), CRC Press, 1st ed., 2023
5. Artificial Intelligence for Marketing: Practical Applications — Jim Sterne, Wiley, 1st ed., 2017

MODERN ANALYTICAL TECHNIQUES - PRACTICALS

Total Credits 1 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

The course aims to enable students to:

1. Interpret spectral data obtained from various analytical techniques, including NMR, mass spectrometry, X-Ray diffraction, and DSC, to elucidate the structure and properties of pharmaceutical compounds.
2. Apply modern chromatographic techniques, specifically UHPLC, for the quantification of official pharmaceutical compounds.
3. Develop and evaluate green analytical solvents for sustainable pharmaceutical analysis.
4. Formulate a protocol for conducting bioavailability and bioequivalence studies in compliance with USFDA guidelines.
5. Apply sample preparation techniques such as Solid Phase Extraction (SPE), Protein Precipitation Extraction (PPE), and Liquid-Liquid Extraction (LLE) for the quantification of pharmaceuticals in biological matrices.
6. Understand the principles and demonstrate the procedure for evaluating cell viability using the MTT assay.

COURSE OUTCOMES

Upon successful completion of this course, the student 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.
6. Explain and execute the MTT assay for evaluating cell viability in a laboratory setting.

COURSE CONTENTS (Minimum – 12 experiments)

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. Quantification of official compounds by UHPLC (any one)
7. Preparation and Evaluation of Green Analytical Solvents
8. Analytical method development by using Green chemistry
9. Quantification of pharmaceuticals in biological fluids using Solid Phase Extraction (SPE)
10. Quantification of pharmaceuticals in biological matrix by PPE
11. Quantification of pharmaceuticals in biological matrix by LLE
12. Demonstration of Cell Viability evaluation using MTT Assay

RECOMMENDED BOOKS (LATEST EDITIONS)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic Spectroscopy by Y.R Sharma
3. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
4. Organic Spectroscopy by William Kemp
5. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
6. Spectrophotometric identification of Organic Compounds by Silverstein
7. Pharmaceutical Analysis: Modern methods Part B by J W Munson
8. Instrumental Methods of Analysis by Willard

SEMESTER VIII

NDDS AND PRECISION MEDICINE - THEORY

Total Credits 3 **Hours / Week: 3** **45 HR**

COURSE OBJECTIVES

The course aims to enable students to;

1. Understand the scientific and technological foundations of advanced and novel drug delivery systems, including their classification, design rationale, materials, and formulation challenges.
2. Examine the role of polymers, lipids, and excipients in formulating biodegradable, targeted, and controlled-release drug delivery systems.
3. Analyze specialized delivery routes and carriers such as oral, mucosal, transdermal, ocular, and parenteral NDDS, 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.
6. Correlate pharmacogenomics, biomarker profiling, and AI-based analytics with patient-centric therapeutic strategies.
7. Evaluate the ethical, regulatory, and clinical considerations associated with implementing NDDS and precision medicine in healthcare systems.
8. Integrate NDDS innovations with personalized therapeutic models, especially in oncology, CNS, metabolic disorders, and hormone therapy.

COURSE OUTCOMES

Upon successful completion of the course, learners 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. Select appropriate materials—such as polymers, surfactants, and lipids—for designing site-specific or controlled-release delivery systems.
3. Design and compare oral, mucosal, parenteral, and transdermal NDDS, evaluating their mechanisms and formulation parameters.

4. Apply QbD principles and preclinical evaluation tools (e.g., IVIVC, permeability assays, PK/PD models) to assess NDDS quality and safety.
5. Demonstrate an understanding of the scope, principles, and challenges of precision medicine in modern pharmacotherapy.
6. Interpret pharmacogenomic data and biomarker information to suggest personalized treatment options in clinical case scenarios.
7. Explain the integration of AI, EHRs, and big data analytics in supporting personalized medicine and NDDS-based treatment planning.
8. Evaluate ethical and regulatory frameworks governing advanced therapeutics and genomic-based interventions in pharmacy practice.
9. Discuss case studies involving successful translation of NDDS and precision-based treatments (e.g., mRNA vaccines, ADCs, smart delivery).

COURSE CONTENTS

Unit I: Fundamentals, Polymers & Materials for NDDS **12 Hours**

- Limitations of conventional dosage forms (e.g., solubility, permeability, toxicity, first-pass metabolism)
- Classification of NDDS: Controlled Release, Targeted, Stimuli-Responsive (Smart), Chronotherapeutic, Transdermal and Mucosal, Implantable and Injectable Depot Systems, Vesicular, Polymeric, Ocular, Pulmonary, and Nasal Drug Delivery Systems

- Biodegradable and biocompatible polymers: PLA, PLGA, PCL, chitosan, gelatin
- Lipids and surfactants: lecithin, phospholipids, Span/Tween, SLNs
- Inorganic systems: silica, gold nanoparticles, iron oxide, MOFs
- Excipients in NDDS: GRAS substances, IIG database, regulatory constraints

Unit II: Oral and Mucosal Delivery Systems **6 Hours**

- Gastro-retentive systems: floating, bioadhesive, expandable systems
- Colon-targeted systems: pH-triggered, microbially-triggered, time-dependent systems
- Buccal, nasal, and pulmonary carriers: films, sprays, DPIs, liposomes
- IVIVC and biorelevant dissolution testing.

Unit III: Parenteral and Transdermal NDDS **6 Hours**

- Injectable nanosystems: liposomes, niosomes, SLNs, dendrimers, polymeric nanoparticles
- Long-acting systems: in-situ gels, microspheres, implants, ocular inserts
- Transdermal and microneedle technologies: iontophoresis, sonophoresis, dissolvable MNs
- Aseptic manufacturing, scale-up challenges, and process analytical tools (PAT)

Unit IV: Evaluation, Quality, and Translation **6 Hours**

- Preformulation and QbD: QTPP, CQAs, CPPs
- Characterization methods: particle size, zeta potential, SEM/TEM, in-vitro release, permeability assays (PAMPA, Caco-2)
- Non-clinical evaluation: PK/PD modeling, biodistribution, toxicology
- Regulatory pathways: 505(b)(2), complex generics, ICH Q8–Q10, EMA pathways
- Case studies: Liposomal Amphotericin B for Fungal Infections, mRNA-Lipid Nanoparticle Vaccines (e.g., COVID-19 Vaccines), Depot Antipsychotic Injections (e.g., Risperidone Microspheres), 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.

Unit V: Precision Medicine **15 Hours**

- **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
- **Pharmacogenomics in Drug Response and Safety**
  - Basic human genetics relevant to pharmacy
  - Genotype-phenotype relationships
  - Genetic polymorphisms: CYP450 enzymes (CYP2D6, CYP2C9, etc.)
  - FDA drug labeling and pharmacogenomic biomarkers

- Tools/databases: PharmGKB, CPIC, SNPedia

- **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
- **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 (e.g., Insilico Medicine, Deep Genomics)
  - Data security and interoperability
- **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
- **Integration of NDDS with Personalized Medicine**
  - Targeted nano-delivery in oncology
  - Antibody-drug conjugates (ADCs)
  - Smart delivery systems (stimuli-responsive, biosensors

RECOMMENDED BOOKS

1. Pathak Y, Khatri N (Eds.), *Handbook of Novel Drug Delivery Systems*, CRC Press
2. Mahendran Bhaskaran, Karri V V S Narayana Reddy, Sriram Narukulla. *Novel Drug Delivery Systems* (B.Pharm) (SEM-VII), PV Books.
3. Siepmann J, Siegel R, Rathbone MJ (Eds.), *Fundamentals & Applications of Controlled Release*, Springer
4. Burgess D (Ed.), *Injectable Dispersed Systems: Formulation, Processing and Performance*, CRC
5. Langer R, Vacanti J., *Science* articles on tissue engineering & drug delivery
6. USFDA/EMA guidance on complex products and nanomedicines

PHARMACEUTICAL MANAGEMENT - THEORY

Total Credits 2 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

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. Explore sales force management, key account management, and customer relationship management (CRM) in the pharma sector.

COURSE OUTCOMES

At the end of the course, the student 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.
6. Apply advanced sales and marketing techniques tailored to the pharmaceutical industry, focusing on product positioning, customer segmentation, and digital marketing.

COURSE CONTENTS

Unit 1: Introduction to Pharmaceutical Management **8 hours**

Introduction to management, definition, function, importance, Overview of Indian & Global pharmaceutical industry, Role and responsibilities of a pharmaceutical manager, Definition, functions and importance of Key Management Principles: Planning, organizing, leading, controlling, Decision-making and Time management

Unit 2: Marketing Management in Pharmaceuticals **10 hours**

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

Unit3: Pharmaceutical Product Management **10 hours**

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.

Unit 4: Financial planning and Human Resource Management **7 hours**

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.

Unit 5: Operations & Supply Chain Management in Pharmaceuticals **10 hours**

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

RECOMMENDED BOOKS:

1. Marketing management by Philip Kotler
2. Textbook of Pharmaceutical Management by S.K. Gupta
3. Pharmaceutical Marketing in India by Subba Rao Chaganti
4. Principles of Management by Peter Drucker
5. Pharmaceutical Supply Chain Management by Kuldeepak Singh
6. Textbook of pharmaceutical marketing management by P.K Sahoo.

CLINICAL PHARMACOTHERAPEUTICS - THEORY

Total Credits 2 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

The primary objectives of this course are to study:

1. The pathophysiology of selected disease states and the rationale for drug therapy
2. The therapeutic approach to management of these diseases
3. The importance of preparation of individualized therapeutic plans based on diagnosis
4. Needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects)
5. Summarized therapeutic approach to management of these diseases including reference to the latest available evidence

COURSE OUTCOMES

At completion of this course, it is expected that 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.

COURSE CONTENTS

Definition, etiopathogenesis, clinical manifestations, overview of management of the diseases associated with

Unit I: Cardiovascular system: 5 Hours

Hypertension, Heart Failure, myocardial infarction, Hyperlipidaemia

Unit II: Respiratory System: 2 Hours

Asthma, COPD

Unit III: Renal System: 3 Hours

Acute Renal Failure, Chronic Renal Failure, Renal Replacement Therapy

Unit IV: Endocrine System: 3 Hours

Diabetes, Thyroid disorders

Unit V: Nervous System: 5 hours

Epilepsy, stroke, Parkinsonism

Unit VI: Gastrointestinal System 2 Hours

Peptic ulcer disease, GERD

Unit VII: Diseases of bones and joints 3 Hours

Rheumatoid arthritis, Osteoarthritis

Unit VIII: Infectious Diseases: 4 Hours

Tuberculosis, Pneumonia, UTI, Malaria, HIV

Unit IX: Hematological Diseases: 3 Hours

Anemia

REFERENCE BOOKS

1. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.
2. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication

Elective 7 – AEC (Theory)

Total Credits 2 **Hours / Week: 2** **30 HR**

1. The syllabi for elective subjects are given in the appendices

Industrial pharmacy and facility design

Credits : 3 **Hours / Week : 3** **Hours /Sem: 45**

Course Objectives

The course aims to:

1. Provide comprehensive knowledge of **regulatory guidelines** (ICH, WHO, Schedule M, cGMP, SUPAC) governing formulation development, stability testing, and scale-up.
2. Develop understanding of **industrial product development processes**, including pilot plant design, scale-up considerations, and platform technologies.
3. Equip learners with the ability to plan and execute **technology transfer (TT)**, covering protocols, quality risk management, documentation, and legal frameworks.
4. Impart knowledge of **facility design principles** for sterile and non-sterile manufacturing, focusing on layout, utilities (water, steam, HVAC), cleaning, and contamination control.
5. Familiarize students with **advances in pharmaceutical facility design**, including modular cleanrooms, automation, robotics, and innovative contamination control technologies.
6. Build skills to apply **qualification, validation, and monitoring** protocols to ensure compliance, product quality, and operational efficiency in industrial settings.

Course Outcomes

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

1. **Interpret and apply** ICH, WHO, and national regulatory guidelines for formulation development, stability testing, and facility design.
2. **Plan and design** pilot plant and scale-up processes for solids, liquids, semi-solids, and specialized dosage forms, incorporating relevant documentation and SUPAC guidelines.
3. **Execute and manage** technology transfer from R&D to production, ensuring compliance with WHO TT protocols, quality risk management principles, and legal documentation requirements.
4. **Design facility layouts** for sterile and non-sterile manufacturing in compliance with Schedule M, cGMP, and global cleanroom standards.

5. **Select and validate** water purification systems, steam systems, HVAC components, and contamination control strategies for pharmaceutical production.
6. **Implement cleaning validation protocols** with appropriate acceptance criteria to maintain product quality and regulatory compliance.
7. **Integrate modern facility design concepts** such as modular cleanrooms, isolators, and automation into pharmaceutical manufacturing.
8. **Critically evaluate** industrial processes and facility designs to ensure quality, efficiency, and adaptability for current and future pharmaceutical needs.

Course contents

Unit I **[12Hours]**

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

Unit II **[09 Hours]**

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

UNIT III

Facility Considerations : Non sterile **[9Hours)**

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, SIP. 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,

Unit IV - Facility considerations : Sterile [9 Hours]

- Overview of sterile pharmaceutical manufacturing: layout as per schedule M and cGMP, clean room concept -Importance of sterility and contamination control, 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.

Unit 5 – Advances in facility design [6Hours]

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.

Recommended books:

1. **Pharmaceutical Quality by Design: A Practical Approach** *– Sarwar Beg, Md. Zaheer Abbas, Md. Akhter Hossain*
2. **ICH Quality Guidelines: An Implementation Guide** *– Andrew Teasdale, David Elder, Ray W. Greenwood*
3. **Pharmaceutical Process Scale-Up** (3rd Edition) *– Michael Levin*
4. **Pharmaceutical Production Facilities: Design and Applications** *– Graham Bunn*
5. **GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers – Leonard Steinborn**
6. **Good Design Practices for GMP Pharmaceutical Facilities – T. Michael Neubauer (ISPE)**
7. **ISPE Baseline Guide Volume 4: Water and Steam Systems – International Society for Pharmaceutical Engineering (ISPE)**
8. **Pharmaceutical Production Facilities: Design and Applications – Graham Bunn**
9. **Cleaning Validation: Practical Compliance Solutions for Pharmaceutical Manufacturing – Richard M. Francke, Heike Meissner**
10. **Pharmaceutical Facility Design – Kate McCormick**
11. **Advanced Cleanroom Technology – Tim Sandle**
12. Good Design Practices for GMP Pharmaceutical Facilities",Author: Terry Jacobs and Andrew A. Carlson, Publisher: CRC Press
13. Pharmaceutical Facilities: Design, Layouts and Validation",Author: Graham Bunn, Publisher: CRC Press / Taylor & Francis.

14. Cleanroom Technology: Fundamentals of Design, Testing and Operation", Author: William Whyte, Publisher: Wiley-Blackwell, Edition: 2nd Edition
15. Pharmaceutical Manufacturing Handbook: Production and Processes", Editor: Shayne Cox Gad, Publisher: Wiley-Interscience, Edition: 1st Edition
16. "Good Manufacturing Practices for Pharmaceuticals", Author: Joseph D. Nally, Publisher: CRC Press, Edition: 6th Edition
17. Sterile Product Development: Formulation, Process, and Regulatory Considerations", Editor: Michael J. Akers, Publisher: Informa Healthcare / CRC Press, Edition: Latest Edition

AI IN PHARMACY PRACTICE & PATIENT CARE - THEORY

Total Credits 2 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

The course aims to:

1. Introduce AI-driven simulation technologies—covering student and teacher modeling—to enhance pharmacy education.
2. Familiarize learners with key AI simulation and content-creation platforms such as Body Interact, SimX, IBM Watson Health, Synthesia, Pictory, and Animoto.
3. Explain how AI supports pharmacy automation, medication dispensing, and adherence monitoring through wearables and mobile apps.
4. Teach AI techniques for adverse drug-reaction prediction and for monitoring the safety of medicines and vaccines.
5. Develop the ability to apply AI-based big-data analytics for public-health surveillance and decision-making.

COURSE OUTCOMES

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

1. Students will design a simple AI-guided simulation scenario that adapts to learner performance and objectives.
2. Students will compare two AI simulation platforms and justify their choice for a specific pharmacy teaching case.
3. Students will map an automated dispensing workflow and recommend AI tools to improve accuracy and patient adherence tracking.
4. Students will build and interpret a basic machine-learning model that flags potential adverse drug reactions from clinical data.
5. Students will analyze public-health datasets with AI techniques to detect emerging trends and propose evidence-based interventions.

COURSE CONTENTS

Unit 1 – AI-Driven Simulation-Based Learning **6 Hours**

- Introduction to AI in healthcare and education

- Concept of simulation-based learning in pharmacy education
- **Student modeling**: adaptive feedback systems, personalized learning trajectories
- **Teacher modeling**: intelligent tutoring systems and performance prediction
- Role of Natural Language Processing (NLP) in conversational agents for learning
- Case studies: Use of AI-driven simulators in pharmacology and clinical pharmacy labs

Unit 2 – Simulation & Content-Creation Platforms **6 Hours**

- Overview of simulation platforms: design, integration, and outcomes
- **Body Interact**: virtual patient cases, clinical decision-making
- **SimX**: AR/VR-based immersive clinical training
- **IBM Watson Health**: real-time decision support and AI in disease management
- **Synthesia, Pictory, Animoto**: automated video generation for microlearning
- Applications of AI-generated content in patient counseling and drug education
- Ethics and accuracy in AI-generated educational material

Unit 3 – Pharmacy Automation & Adherence **6 Hours**

- Pharmacy Automation & Medication Dispensing
- Medication Adherence Monitoring (AI-enabled wearables, apps)
- Fundamentals of pharmacy automation systems: dispensing robots, smart carts
- AI in prescription validation, drug labeling, and inventory management
- Medication adherence tools: AI-enabled **wearables**, reminder apps, digital pills
- Case examples: Proteus Digital Health, Medisafe, and smart pill organizers
- Challenges in implementation: interoperability, privacy, and user compliance
- Role of pharmacists in interpreting AI recommendations and alerts

Unit 4 – Pharmacovigilance & Safety Monitoring **6 Hours**

- Adverse Drug Reaction (ADR) Prediction
- Leveraging AI for medicines and vaccines safety monitoring
- Introduction to pharmacovigilance and its challenges in manual reporting
- AI for signal detection in large ADR databases (e.g., VigiBase, FAERS)
- Algorithms for **ADR prediction** based on EHR, genomic, and prescription data
- Safety monitoring of **vaccines and biologics** using machine learning and real-world data

- NLP in mining social media and forums for adverse event tracking
- Integration of AI tools in national pharmacovigilance programs (e.g., PvPI)

Unit 5 – Public Health Analytics **6 Hours**

- Introduction to **AI in public health**: disease outbreak prediction, surveillance systems
- Sources of real-world health data: EHRs, claims data, mobile health apps, IoT
- Machine learning models for predicting epidemics, health risks, and patient outcomes
- Role of AI in health policy, vaccination forecasting, and healthcare resource planning
- Introduction to big-data tools (e.g., Hadoop, R, Python, Power BI) for pharmacists
- Case studies: AI for COVID-19 surveillance, antimicrobial resistance mapping

RECOMMENDED BOOKS

1. Artificial Intelligence in Education: Promises and Implications for Teaching and Learning — Wayne Holmes, Maya Bialik & Charles Fadel, Routledge/CCR, 2019 (1st ed.)
2. Pharmacy Automation — Fouad Sabry, Independently Published (Apple Books), 2025 (1st ed.)
3. Artificial Intelligence in Pharmacovigilance: A New Era for Drug Safety — Julia Appelskog, Kindle Direct Publishing, 2024 (1st ed.)
4. AI for Disease Surveillance and Pandemic Intelligence: Intelligent Disease Detection in Action — Arash Shaban-Nejad, Martin Michalowski & Simone Bianco (eds.), Springer, 2022 (1st ed.)
5. Data Science and Predictive Analytics: Biomedical and Health Applications Using R — Ivo D. Dinov, Springer, 2023 (2nd ed.)

NDDS AND PRECISION MEDICINE – Lab

Total Credits 2 **Hours / Week: 4** **60 HR**

Course Objectives

The course aims 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

Upon successful completion of the course, 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.
6. **Interpret and present experimental data** related to novel formulations in compliance with regulatory and scientific standards.

Course Content

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 raft forming systems
13. Preparation and evaluation of liposomes
14. Preparation and evaluation of niosomes
15. Preparation and evaluation of nasal spray

Note: Minimum 12 experiments must be performed

List of reference and recommended books:

1. **Practical Manual of Pharmaceutics (Advanced Drug Delivery Systems)** *– Dr. B. P. Nagori, Dr. Hitesh Patel*
2. **Pharmaceutical Drug Delivery Systems and Vehicles** *– S.P. Vyas, R.K. Khar*
3. **A Textbook of Pharmaceutics – Modern Pharmaceutics** (5th Ed.) *– G.S. Banker, C.T. Rhodes*
4. **Targeted and Controlled Drug Delivery: Novel Carrier Systems** *– S. P. Vyas, R. K. Khar*
5. **Pharmaceutical Technology: Concepts and Applications** *– S. J. Carter, Lachman, Lieberman*
6. **Controlled and Novel Drug Delivery Systems** *– N.K. Jain*

7. **Novel Drug Delivery Systems: Technology, Applications and Regulatory Aspects** – *Yie W. Chien*
8. **Novel Drug Delivery Systems: Technology, Applications and Regulatory Aspects** – *Yie W. Chien*

PHARMACEUTICAL MARKETING SKILLS - PRACTICALS

Total Credits 1 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

1. Introduce students to the fundamentals of pharmaceutical marketing, focusing on the industry-specific strategies and tactics.
2. Gain insight into the stages of a pharmaceutical product's lifecycle, from development to commercialization.
3. Discuss the critical role of regulations, ethical considerations, and compliance issues in marketing pharmaceutical products.
4. Equip students with skills to design marketing strategies for pharmaceutical products, considering various market segments and stakeholder needs.
5. Introduce various sales techniques and communication skills needed to build relationships with healthcare professionals and other stakeholders.

COURSE OUTCOMES

At the end of this course, 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

COURSE CONTENTS

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.

Elective 8 – VAC (Practical)

Total Credits 1 **Hours / Week: 2** **30 HR**

1. The syllabi for elective subjects are given in the appendices

List of Recommended Electives (AEC/SEC/VAC)

II Sem		**Elective - 1** **Practical SEC** 1. Communication Skills 2. Mental Well-Being, Stress & Conflict Management 3. Fundamental of computer operations
III Sem		**Elective - 2** **Practical AEC** 1. Nutraceutical functional foods 2. Food Analysis 3. Yoga and life sciences 4. Career Building in Cultivation of Medicinal Plants
VI Sem	**Elective - 3** **Theory AEC** 1. Green chemistry 2. Materiovigilance and hemovigilance 3. Scientific writing 4. Drug store and business management	**Elective - 4** **Practical SEC** 1. Computer aided drug design 2. Analytical method validation 3. Principles of preclinical studies 4. Omics Science **Elective - 5** **Practical VAC** 1. Professional skills 2. Process analytical technology (PAT) and QbD in formulation science 3. Futuristic Pharma through Augmented Reality and Virtual Reality (ARVR): Pharma 4.0
VII Sem	**Elective - 6** **Theory AEC** 1. cGMP 2. Pharmaceutical automation 3. Modern techniques in cellular biology 4. Medical devices	
VIII Sem	**Elective - 7** **Theory AEC** 1. Pharmaceutical packaging 2. Supply chain management 3. Industrial safety and waste management 4. Traditional healing practices of India	**Elective - 8** **Practical VAC** 1. Cleaning validation 2. Basic training in aseptic handling techniques 3. Impurity profiling 4. Herbal Cosmetics for Industry Perspective

Electives

कामये दुःखतप्तानाम् प्राणिनामार्तिनाशनम्

Pharmacy Council of India

New Delhi

Proposed Syllabus for the

Bachelor of Pharmacy

(ELECTIVES)

[As per NEP 2020]

May 2025

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

II Sem		**Elective - 1** **Practical SEC** 1. Communication Skills 2. Mental Well-Being, Stress & Conflict Management 3. Fundamental of Computer Operations
III Sem		**Elective - 2** **Practical AEC** 1. Nutraceutical functional foods 2. Food Analysis 3. Yoga and life sciences 4. Career building in Cultivation of Medicinal Plants
VI Sem	**Elective - 3** **Theory AEC** 1. Green chemistry 2. Materiovigilance and hemovigilance 3. Scientific writing 4. Drug store and business management	**Elective - 4** **Practical SEC** 1. Computer aided drug design 2. Analytical method validation 3. Principles of preclinical studies 4. Omics Science **Elective - 5** **Practical VAC** 1. Professional skills 2. Process analytical technology (PAT) and QbD in formulation science 3. Futuristic Pharma through Augmented Reality and Virtual Reality (ARVR): Pharma 4.0
VII Sem	**Elective - 6** **Theory AEC** 1. cGMP 2. Pharmaceutical automation 3. Modern techniques in cellular biology 4. Medical Devices	
VIII Sem	**Elective - 7** **Theory AEC** 1. Pharmaceutical packaging 2. Supply chain management 3. Industrial safety and waste management 4. Traditional healing practices of India	**Elective - 8** **Practical VAC** 1. Cleaning validation 2. Basic training in aseptic handling techniques 3. Impurity profiling 4. Herbal Cosmetics for Industry Perspective

SEMESTER II

Elective 1 – SEC (Practical)

COMMUNICATION SKILLS

Total Credits 1 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

1. To enhance verbal and non-verbal communication skills in academic, clinical, and professional pharmacy settings.
2. To develop competence in patient counseling, prescription communication, and interprofessional dialogue.
3. To promote empathetic and ethical communication in diverse cultural and patient contexts.
4. To use digital tools and professional formats (e.g., email, reports, posters) for effective communication.
5. To foster confidence, active listening, and clarity in pharmacy-related presentations and conversations.

COURSE OUTCOMES

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

1. Demonstrate effective verbal and non-verbal communication in clinical, retail, and academic pharmacy contexts.
2. Perform patient counseling 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.
6. Use digital tools and online platforms effectively for professional pharmacy communication and patient education.

COURSE CONTENTS

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 BOOKS

1. Communication Skills for Pharmacy Students – B. S. Rathor, CBS Publishers & Distributors
2. Communication Skills in Pharmacy Practice – E. M. Kelly & S. L. Svarstad, Lippincott Williams & Wilkins
3. Developing Communication Skills for Pharmacy – Catherine Langford, Pharmaceutical Press
4. Communication Skills – Sanjay Kumar & Pushp Lata, Oxford University Press
5. Communication Skills – B. Pharm 1st Year – S. T. Chelli, Thakur Publication
6. Patient Counselling Guidelines for Pharmacists – WHO India, World Health Organization

MENTAL WELL-BEING, STRESS & CONFLICT MANAGEMENT

Total Credits 1 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

1. To introduce students to the concepts of mental well-being and stress.
2. To equip students with techniques to manage stress, anxiety, and emotional well-being.
3. To develop conflict resolution skills for personal and professional life.
4. To encourage emotional intelligence and interpersonal communication.
5. To promote resilience and positive mindset development.

COURSE OUTCOMES

By the end of the course, 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.

COURSE CONTENTS

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 BOOKS

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

FUNDAMENTALS OF COMPUTER OPERATIONS

Total Credits 1 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

1. To introduce students to the basic operations of computers and common software applications.
2. To develop practical skills in using MS Office tools for documentation, calculations, and presentations.
3. To familiarize students with file management and digital communication tools.
4. To enhance basic internet navigation and online research skills.
5. To prepare students for the use of computers in pharmaceutical applications and data management.

COURSE OUTCOMES

By the end of the course, students will be able to:

1. Operate computers efficiently, using basic system functions and software tools.
2. Create and format documents using MS Word and design spreadsheets using MS Excel.
3. Prepare presentations using MS PowerPoint and effectively communicate via email.
4. Conduct research using internet databases and online platforms like PubMed and Google Scholar.
5. Apply computer skills in managing pharmaceutical data and documentation.

COURSE CONTENT

1. Basic operation and navigation of Windows operating system
2. Creating, renaming, moving, and deleting files and folders
3. MS Word: Formatting a pharmacy report with tables and headers
4. MS Word: Inserting equations, images, and preparing a certificate
5. MS Excel: Creating a spreadsheet for dose calculation or pharmacy sales data
6. MS Excel: Use of formulas – SUM, AVERAGE, IF, COUNT, etc.
7. MS Excel: Creating graphs and charts from experimental data

8. MS PowerPoint: Preparing a 5-slide academic presentation
9. Internet browsing and search techniques – PubMed, Google Scholar
10. Email writing: composing, attaching files, CC/BCC, etiquette
11. Introduction to online pharmaceutical software or demo billing software
12. Use of cloud storage (Google Drive) for saving pharmacy data
13. Exploring pharmacy-related mobile apps or e-health tools
14. Online learning tools: accessing NPTEL/Coursera content
15. Creating and submitting a digital assignment using MS Office tools

RECOMMENDED BOOKS

1. Fundamentals of Computers – V. Rajaraman, PHI Learning Pvt. Ltd.
2. Computer Fundamentals – P. K. Sinha & Priti Sinha, BPB Publications
3. Introduction to Computers – Peter Norton, McGraw-Hill Education
4. Computer Fundamentals and Applications – D. P. Nagpal, S. Chand Publishing
5. Computer Basics: Absolute Beginner's Guide – Michael Miller, Que Publishing
6. Operating System Concepts – Abraham Silberschatz, Peter B. Galvin & Greg Gagne, Wiley
7. Microsoft Office 365 – In Practice – Randy Nordell, McGraw-Hill Education

SEMESTER III

Elective 2 – AEC (Practical)

NUTRACEUTICALS AND FUNCTIONAL FOODS

Total Credits 1 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

1. To introduce the concept and classification of nutraceuticals and functional foods.
2. To explore the role of bioactive components in health promotion and disease prevention.
3. To familiarize students with the formulation, labeling, and quality control of nutraceuticals.
4. To understand the regulatory aspects governing nutraceuticals and dietary supplements.
5. To develop practical skills in extraction, analysis, and preparation of functional foods.

COURSE OUTCOMES

Upon successful completion of this course, 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.

COURSE CONTENTS

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 BOOKS

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

FOOD ANALYSIS

Total Credits 1 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

The primary objectives of this course are to:

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.

COURSE OUTCOMES:

Upon completion of this course the students are 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.

COURSE CONTENTS

(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.

RECOMMENDED BOOKS

1. Food Analysis – Suzanne Nielsen, Springer
2. Introduction to Food Analysis – S. Suzanne Nielsen, Springer
3. Food Analysis and Quality Control – S. S. Nielsen, CBS Publishers & Distributors
4. Food Analysis: Theory and Practice – Y. Pomeranz & Clifton E. Meloan, Springer
5. Manual of Methods of Analysis of Foods – Food Safety and Standards Authority of India (FSSAI), Government of India
6. Food Chemistry – H.-D. Belitz, Werner Grosch & Peter Schieberle, Springer
7. Food Analysis Laboratory Manual – S. Suzanne Nielsen, Springer

YOGA AND LIFE SCIENCES

Total Credits 1 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

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

By the end of the course, 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.

COURSE CONTENTS

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 OM and Gayatri 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 BOOKS

1. Light on Yoga – B. K. S. Iyengar, HarperCollins Publishers
2. The Science of Yoga – William J. Broad, Simon & Schuster
3. Yoga and Health – Swami Kuvalayananda, Kaivalyadhama Yoga Institute
4. Principles and Practice of Yoga in Health Care – Sat Bir S. Khalsa, Lorenzo Cohen, Timothy McCall & Shirley Telles, Handspring Publishing
5. Yoga: The Path to Holistic Health – B. K. S. Iyengar, Dorling Kindersley (DK)
6. Yoga Therapy: Theory and Practice – Mark Stephens, North Atlantic Books
7. Yoga and Ayurveda: Self-Healing and Self-Realization – David Frawley, Motilal Banarsidass Publishers
8. The Heart of Yoga: Developing a Personal Practice – T. K. V. Desikachar, Inner Traditions International

Career Building in Cultivation of Medicinal Plants

(Credits: 1, Total Duration: 15 Hours)

Course objectives:

1. Understand the significance and historical roots of medicinal plants
2. Analyze the structure and dynamics of the medicinal plant industry
3. Identify and describe important medicinal plants of India
4. Develop practical knowledge of sustainable and organic cultivation practices
5. Explore entrepreneurship and value chain opportunities

Program Objectives:

1. To equip learners with foundational and applied knowledge in the field of medicinal plants
2. To develop competent professionals and entrepreneurs capable of contributing to the medicinal plant industry
3. To foster interdisciplinary awareness and collaboration between agriculture, ethnobotany, pharmacognosy, and business
4. To promote sustainable and organic agricultural
5. To prepare learners for employment or self-employment

Course Outcomes / Take-Home Lessons for Students:

By the end of the course, participants will:

1. Understand the technical and commercial aspects of medicinal plant cultivation
2. Identify profitable species and sustainable methods
3. Be aware of government schemes and legal processes
4. Be equipped to launch a business or pursue a career in this field

Course Contents:

Unit I: Introduction & Industry Overview (3 hours)

- 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)

Unit II: Key Medicinal Plants & Cultivation Basics (4 hours)

- Botanical characteristics and uses of major plants: Ashwagandha, Tulsi, Aloe vera, Shatavari, Brahmi, etc.
- Regional suitability and agro-climatic zones
- Cultivation essentials: soil, propagation, irrigation, pest control, organic inputs
- Harvesting, post-harvest management and storage

Unit III: Organic Farming & Market Linkages (3 hours)

- Organic certification and sustainable farming practices
- Biodiversity conservation and agroforestry integration
- Processing, drying, packaging, branding
- Market linkages: pharma, cooperatives, online platforms, export guidelines

Unit IV: Policy, Entrepreneurship & Digital Tools (3 hours)

- 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

Unit V: Practical Exposure & Project Presentation (2 hours)

- Virtual/shortened farm/nursery visit or guest lecture (can be online)
- Group/individual project: business plan or herbal enterprise pitch presentation

Recommended readings:

1. Cultivation of Medicinal and Aromatic Crops" by N. Kumar, J. B. M. Misra, et al. (ICAR publication)
2. "Medicinal Plants: Conservation, Cultivation and Utilization" by V. Singh and A. K. Jain
3. "Handbook on Medicinal Herbs with Uses" by H. Panda (NIIR Board)
4. "Textbook of Pharmacognosy and Phytochemistry" by Biren Shah & Avinash Seth
5. "Medicinal Plants: A Global Heritage" edited by S.K. Jain
6. "Medicinal Plants Sector in India: Challenges and Opportunities" by Planning Commission/NMPB Reports
7. "Organic Farming in India: Policies and Practices" by M. K. Sharma
8. "Herbal Industry and Entrepreneurship Development" by A. S. Sandhu & A. K. Gupta
9. Planning Commission Report on "Herbal Industry in India" (Government of India, NITI Aayog)
10. NMPB (National Medicinal Plants Board) Annual Reports
11. Patwardhan, B. et al. (2005). "Ayurveda and natural products drug discovery." *Current Science*, 89(3), 289–298.
12. Sharma, A., et al. (2021). "Sustainable cultivation of medicinal plants: Practices and policies." *Journal of Ethnopharmacology*, 278, 114292.
13. World Health Organization (WHO) – "Good Agricultural and Collection Practices (GACP) for Medicinal Plants"
14. Rajendran, S. M., & Natarajan, D. (2015). "Marketing of Medicinal Plants in India: A Review." *Journal of Medicinal Plants Studies*, 3(4), 23–29.
15. Gupta, R. et al. (2020). "Use of GIS and remote sensing in medicinal plant conservation." *Ecological Indicators*, 113, 106215.
16. Chauhan, N.S. (2008). "Medicinal and Aromatic Plants Cultivation and Utilization."

SEMESTER VI
Elective 3 – AEC (Theory)

GREEN CHEMISTRY

Total Credits 1 **Hours / Week: 1** **15 HR**

COURSE OBJECTIVES

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.

COURSE OUTCOMES

Upon successful completion of this course, the student 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.

COURSE CONTENTS

UNIT 1: Introduction to Green Chemistry in Pharmacy **5 Hours**

1. Definition and scope of green chemistry in pharmaceutical sciences
2. Principles of Green Chemistry with pharmaceutical examples
3. Comparison of traditional vs. green chemical approaches in drug synthesis
4. Environmental impact of pharmaceutical manufacturing
5. Overview of pharmaceutical pollutants and their life cycle
6. Metrics: Atom economy, E-factor, Process Mass Intensity (PMI)

UNIT 2: Green Techniques in Pharmaceuticals Synthesis 5 Hours

1. Green Solvents and use of green solvents (e.g. water, supercritical fluids, ionic liquids) in drug synthesis. Solvent-free reactions in pharmaceutical synthesis.
2. Green Catalysis and Reaction Enhancement in pharmaceutical green chemistry -. Overview of catalysis in pharmaceutical green chemistry, Photochemical Transformations, Phase Transfer Catalysis
3. Microwave assisted reactions: Merit and demerits of its use, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis.

UNIT 3: Green Chemistry in Industrial and Regulatory 5 Hours

1. Green chemistry in pharmaceutical manufacturing processes
2. Ultrasound assisted reactions: Types of Sono chemical 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)

RECOMMENDED BOOKS

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. Ahluwalia, V.K. and Kidwai, M., 2012. New trends in green chemistry. Springer Science & Business Media.
4. V.K. Ahluwalia, Green Chemistry: A Textbook [1 st Ed.], An Alpha Science International Ltd. Oxford, U.K.
5. Green Chemistry in the Pharmaceutical Industry, Edited by Peter J. Dunn, Andrew Wells, and Michael T. Williams, 2010.
6. 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.
7. Scalable Green Chemistry: Case Studies from the Pharmaceutical Industry, Edited by Stefan Koenig, 2013.

MATERIOVIGILANCE AND HEMOVIGILANCE

Total Credits 1 **Hours / Week: 1** **15 HR**

COURSE OBJECTIVES

1. To understand the concepts and need for materiovigilance and hemovigilance in healthcare.
2. To familiarize with regulatory frameworks, reporting systems, and global initiatives.
3. To identify and evaluate adverse events associated with medical devices and blood products.
4. To develop competencies in reporting, investigation, and documentation.
5. To promote a culture of safety and vigilance in clinical practice.

COURSE OUTCOMES

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

1. **Describe the principles, scope, and significance of vigilance systems** (materiovigilance, and hemovigilance) in ensuring patient and public health safety.
2. **Explain the structure and function of the Materiovigilance Programme of India (MvPI)** and demonstrate the process of identifying, documenting, and reporting adverse events related to medical devices.
3. **Outline the framework of the Hemovigilance Programme of India (HvPI)** and categorize various types of transfusion-related adverse events using national reporting formats and protocols.
4. **Compare global and national vigilance systems** and apply methods for risk assessment, signal detection, and root cause analysis in the context of medical device and blood safety.
5. **Demonstrate accurate reporting practices** through hands-on exercises, and describe the role of healthcare professionals in promoting vigilance, quality assurance, and ethical patient care.
6. **Obtain Skill sets** - Analytical and Critical Thinking, Documentation and Reporting, communication, team learning

UNIT I: Introduction to Vigilance Systems **6 hours**

- 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

UNIT II: Materiovigilance – Principles and Practices **6 hours**

- 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

UNIT III: Hemovigilance – Principles and Practices **6 hours**

- 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.

UNIT IV: Global Regulations, Risk Assessment & Root Cause Analysis **6 hours**

- 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

UNIT V: Reporting Systems, Quality Assurance, and Professional Role 6 hours

- 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

RECOMMENDED BOOKS

1. Thota Janaki Ramaiah-*Textbook of Pharmacovigilance,* Paras Medical Publisher
2. B. K. Sharma - *Practical Manual of Pharmacovigilance,* CBS Publishers
3. Bertil Jacobson - *Medical Device Safety: The Regulation of Medical Devices for Public Health and Safety,* CRC Press
4. Jack Wong - *Handbook of Medical Device Regulatory Affairs in Asia,* Pan Stanford Publishing
5. Denise M. Harmening - *Modern Blood Banking and Transfusion Practices,* F.A. Davis Company
6. World Health Organization (WHO)- *Blood Safety: Basic Elements*

OTHER RESOURCES

1. Materiovigilance Programme of India (MvPI) Guidelines
   Published by: Indian Pharmacopoeia Commission (IPC)
2. WHO Global Model Regulatory Framework for Medical Devices
3. US FDA MAUDE Database
4. Hemovigilance Programme of India (HvPI) Guidelines
   Published by: National Institute of Biologicals (NIB)
5. SHOT Reports (UK - Serious Hazards of Transfusion)
   WHO Guidelines on Blood Transfusion Safety

SCIENTIFIC WRITING

Total Credits 1 **Hours / Week: 1** **15 HR**

COURSE OBJECTIVES

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

Upon completion of this course, students should 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
6. Develop the ability to give and receive constructive feedback

COURSE CONTENTS

Unit I: **Introduction to Scientific Writing** **2 hours**

· Overview of the course

· Principles of scientific writing

· Overview of scientific research

· Introduction to Microsoft tools and its application

Unit II: **Writing Literature Reviews & Scientific Papers** **5 hours**

· Structure and format of literature reviews

· Conducting a literature review

· Analyzing literature and developing themes

· Writing a compelling introduction

· Developing a clear methodology

· Results and analysis

Unit III: **Communicating Results and Data** **3 hours**

· Understanding data presentation

· Developing tables and figures

· Using effective graphic design

Unit IV: **Scientific Citation and Referencing** **3 hours**

· Understanding citation styles

· Citation and plagiarism

· Referencing in scientific writing

Unit V: **Ethical Issues in Scientific Writing & Peer Review and Revision** **2 hours**

· Ethical principles in scientific writing

· Misconduct and fraud in scientific writing

· Peer review and publication ethics

· Providing Constructive feedback

· Responding to feedback

DRUG STORE AND BUSINESS MANAGEMENT

Total Credits 1 **Hours / Week: 1** **15 HR**

COURSE OBJECTIVES

By the end of the course, the students will be able 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

After successful completion of the course, 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.

COURSE CONTENTS

Unit 1: Introduction to Trade and Industry **3 Hours**

- 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

Unit 2: Drug Store Management **3 Hours**

- Selection of site, space, and layout of a drug store
- 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

Unit 3: Inventory Control and Sales Promotion **3 Hours**

- 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

Unit 4: Financial Management and Bookkeeping **3 Hours**

- 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)

Unit 5: Pharmaceutical Marketing and Entrepreneurship **3 Hours**

- 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)

RECOMMENDED BOOKS

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

SEMESTER VI

Elective 4 – SEC (Practical)

COMPUTER AIDED DRUG DESIGN

Total Credits 1 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

The primary objectives of this course are to;

1. Know about various CADD based software.
2. Identify various data bases and sources.
3. Learn various CADD techniques and their applications

Course Outcomes (COs):

Upon completion of the course, students shall be able to;

1. Draw 2D structure and convert to 3D structure
2. Enumerate various ADMET parameters by using CADD software
3. Learn Hit identification with Docking, virtual screening by using CADD software
4. Understand the QSAR based experiments by using CADD software

COURSE CONTENTS (Any 12 Experiments)

1. **Target Identification & Preparation**
   - Use databases like **UniProt** or **PDB** to retrieve protein structures.
   - Clean and prepare the protein using **PyMOL**, **Chimera**, or **AutoDock Tools**.
   - Predict active sites using tools like **CASTp** or **DoGSiteScorer**.
2. **Ligand Design & Optimization**
   - Sketch ligands using **ChemSketch** or **MarvinSketch etc**.
   - Optimize geometry with **Avogadro** or **Gaussian**.
   - Generate 3D conformers and perform energy minimization.
3. **Molecular Docking**
   - Perform docking using **AutoDock Vina**, **Schrödinger Glide**, or **SwissDock**.
   - Analyze binding poses and interactions using **PyMOL** or **Discovery Studio Visualizer**.
   - Score and rank ligands based on binding affinity.
4. **Pharmacophore Modeling**
   - Identify key features using **LigandScout** or **Pharmit**.
   - Build and validate pharmacophore models.
   - Use models for virtual screening of compound libraries.

5. **QSAR Modeling**

- Use **PaDEL-Descriptor** or **KNIME** to calculate molecular descriptors.
- Build regression/classification models using **Python (scikit-learn)** or **R**.
- Validate models with cross-validation and external test sets.

6. **ADMET Prediction**

- Predict absorption, distribution, metabolism, excretion, and toxicity using:
- **SwissADME**
- **admetSAR**
- **pkCSM**

7. **Molecular Dynamics Simulations**

- Set up and run simulations using **GROMACS** or **AMBER**.
- Analyze RMSD, RMSF, hydrogen bonds, and binding stability.
- Visualize trajectories with **VMD** or **PyMOL**.

Suggested Software Toolkit

Category	**Tools/Software**
Protein Prep	PyMOL, Chimera, AutoDock Tools etc.
Ligand Design	ChemSketch, Avogadro, MarvinSketch, etc.
Docking	AutoDock Vina, PyRx, SwissDock, MZDock, Glide etc.
Pharmacophore Modelling	LigandScout, Pharmit, Phase etc
QSAR	PaDEL, KNIME, Python (RDKit), Phase etc
ADMET	SwissADME, Mol inspiration, pkCSM, admetSAR, Qikprop etc.
MD Simulations	GROMACS, AMBER, VMD, DESMOND etc.

ANALYTICAL METHOD VALIDATION

Total Credits 1 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

The primary objectives of this course are to:

1. Understand the construction and working of various analytical instruments.
2. Know the principle and mechanism of instrumentation.
3. Understand the different modern techniques of drug analysis.
4. Appreciate the advantages of instrumental methods of analysis.

COURSE OUTCOMES

Upon completion of this course the students are able to:

1. Gain knowledge on method development and optimization.
2. Understand the application of validation parameters
3. Execute the operation and troubleshoot of analytical instrumentation.
4. Understand to interpret and report analytical data.
5. Acquire theoretical knowledge to practical scenarios.

COURSE CONTENTS (Any 12 Experiments)

1. Development of a UV-Visible spectrophotometric method for the assay of paracetamol API.
2. Construction of calibration curve for a model API using UV-Visible spectrophotometry.
3. Determination of solid dosage form by using dissolution method.
4. Analytical method development and validation of Atenolol/metformin by using HPLC.
5. Investigation of different columns for HPLC separation of a Multi-component Drug Mixture.
6. Optimization of mobile Phase composition for HPLC analysis of a selected drugs.
7. Optimization of Flow rate and temperature in HPLC for paracetamol/ caffeine.
8. Selection of wavelength for spectrophotometric analysis by HPLC of Marketed drugs.
9. Determination of λmax and calibration curve for qualitative analysis of paracetamol.
10. Determination of pH on Retention time in RP-HPLC.
11. Validation of HPLC method : Determination of LOD and LOQ for paracetamol by HPLC

12. Preliminary Investigation of forced Degradation studies on Ibuprofen by HPLC.
13. Method development for related substances of a drug substance using HPLC.
14. Determination of residual solvent analysis for ethanol/acetone in API by using Gas Chromatography.
15. Development of titrimetric method for the assay of marketed drugs(Ascorbic acid/sodium bicarbonate).

RECOMMENDED BOOKS

1. Validation of Analytical Procedures and Methodology – Satinder Ahuja, CBS Publishers & Distributors
2. Handbook of Analytical Instruments – R. S. Khandpur, McGraw-Hill Education India
3. Quality Assurance and Quality Management in Pharmaceutical Industry – Y. Anjaneyulu, PharmaMed Press
4. Pharmaceutical Analysis Vol. II – Dr. A. H. Beckett & J. B. Stenlake (adapted by Indian publishers), CBS Publishers & Distributors

PRINCIPLES OF PRECLINICAL STUDIES

Total Credits 1 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

1. To introduce the role of preclinical studies in drug discovery and development.
2. To familiarize students with laboratory animal handling, ethics, and protocols.
3. To explore the basic principles of pharmacokinetics and toxicology in animal models.
4. To study the regulatory guidelines and standards for preclinical research.
5. To develop skills in interpreting preclinical data for further clinical trials.

COURSE OUTCOMES

By the end of the course, students will be able to:

1. Explain the role of preclinical studies in drug development.
2. Handle laboratory animals according to ethical and legal guidelines.
3. Analyze pharmacokinetic data from animal studies.
4. Design and interpret toxicological studies for drug safety.
5. Apply knowledge of preclinical data in clinical trial design.

COURSE CONTENTS

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 BOOKS

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

OMICS SCIENCE

Credit 1 15 Hr

Unit 1: Introduction to OMICS and Drug Discovery

- Introduction to OMICS: Definition and scope
- Importance of OMICS in drug discovery an development
- Overview of drug discovery pipeline
- Systems biology and its integration with OMICS
- Ethical and regulatory considerations in OMICS research

Unit 2: Genomics and Pharmacogenomics

- Introduction to genomics and genome sequencing technology
- Genomic approaches in drug target identification
- Gene expression profiling (Microarray and RNA-Seq)
- Pharmacogenomics: Concepts and clinical relevance
- Cancer genomics, understanding pathogenesis and identification of disease genes

Unit 3: Transcriptomics

- Introduction to transcriptome and its significance
- mRNA, non-coding RNAs (miRNA, lncRNA) in disease and therapy
- RNA-Seq workflow and data analysis
- Transcriptomics in biomarker discovery and drug response studies
- Early production of adverse drug target effect

Unit 4: Proteomics

- Introduction to proteomics: Scope and challenges
- Protein separation techniques (2D-PAGE, SDS-PAGE, LC-MS/MS)
- Mass spectrometry-based proteomics
- Protein identification, quantification, and PTM analysis
- Clinical proteomics and biomarker discovery
- Role of proteomics in target validation and mechanism of action

Unit 5: Metabolomics and Lipidomics troduction to metabolomics: Primary and secondary metabolites ample preparation and analysis (NMR, GC-MS, LC-MS)

- targeted metabolomics, untargeted metabolomics,
- Lipidomics and its relevance in metabolic diseases
- Integration of metabolomics in systems pharmacology
- Challenges and potential applications

Unit 6: Integrative OMICS and Future Directions

- Systems biology and multi-omics data integration
- Computational tools and bioinformatics in OMICS
- Single cell omics
- Emerging trends: Epigenomics, glycomics, microbiomics
- Case studies on multi-omics-driven drug development

SEMESTER VI
Elective 5 – VAC (Practical)

PROFESSIONAL SKILLS

Total Credits 1 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

1. To develop effective verbal skills for professional settings.
2. To train students in workplace etiquette, interview techniques, and team collaboration.
3. To enhance problem-solving, time management, and critical thinking skills.
4. To promote personal grooming, digital professionalism, and social media etiquette.
5. To prepare students for professional challenges through experiential learning and role play.

COURSE OUTCOMES

By the end of this course, students will be able to:

1. Demonstrate professional in interviews, emails, and meetings.
2. Develop and present an industry-standard resume and online professional profile.
3. Exhibit confidence in group discussions, presentations, and interviews.
4. Apply time management, decision-making, and conflict-resolution strategies.
5. Maintain workplace ethics, etiquette, and a professional demeanor across formats.

COURSE CONTENTS

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 BOOKS

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. Business Communication by Meera Banerjee & P.D. Chaturvedi**,** Pearson Education
5. Effective Technical Communication by M. Ashraf Rizvi**,** Tata McGraw-Hill Education
6. Communication Skills for Professionals by Nira Konar**,** PHI Learning Pvt. Ltd.
7. The Art of Public Speaking by Stephen E. Lucas**,** McGraw-Hill Education

PROCESS ANALYTICAL TECHNOLOGY (PAT) AND QBD IN FORMULATION SCIENCE

Total Credits 1 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

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

At the end of the 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.

COURSE CONTENTS

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 BOOKS

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.

FUTURISTIC PHARMA THROUGH AUGMENTED REALITY AND VIRTUAL REALITY (ARVR): PHARMA 4.0

Total Credits 1 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

1. To introduce students to the fundamentals of AR/VR technologies and their applications in the pharmaceutical sector.
2. To provide hands-on exposure to AR/VR tools used in manufacturing, training, simulation, and patient education.
3. To develop skills in using immersive platforms for enhancing pharmaceutical research, formulation, and communication.
4. To explore Pharma 4.0 integration including AI, IoT, and AR/VR in smart manufacturing and regulatory compliance.

COURSE OUTCOMES

Upon successful completion of this course, 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.

COURSE CONTENTS

Module 1: Introduction to AR/VR & Tools **4 Hours**

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)

Module 2: AR/VR in Pharmaceutical Education and Training 6 Hours

3. Simulation of Anatomy, Physiology, and Drug Mechanism in 3D
    - Use of apps for visualizing drug-receptor interaction
    - Virtual dissection and interactive physiology
4. Virtual Lab Training for Pharmaceutics & Industrial Pharmacy
    - Simulated tablet compression and coating machines
    - Training modules on aseptic techniques using VR
5. Interactive Role-Play: 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

Module 3: AR/VR in Manufacturing & Pharma 4.0 8 Hours

6. Digital Twin Concept & Virtual Plant Walkthrough
    - Create mock layouts of pharma production plants in AR
    - Navigate a cleanroom and observe equipment placement virtually
7. Smart Maintenance and SOP Training via AR
    - Scan QR codes on lab equipment to display AR-based SOPs
    - Create 3D step-by-step tutorials for equipment calibration
8. Hands-on with Pharma IoT: Integrating AR with Sensors and QR-based Inventory
    - Demo on connecting real-world temperature/humidity sensors with AR dashboards
    - Simulate live monitoring of warehousing systems
9. Pharma 4.0 Compliance and Regulatory Perspectives
    - Virtual audit readiness

- Simulate documentation and equipment validation trails using AR mock-ups

Module 4: AR/VR for Patient-Centric Applications 6 Hours

10. Creating AR Patient Leaflets and Drug Delivery Tutorials

- Develop AR content showing how to use inhalers, injectables, or devices
- Overlay content on medicine boxes or instruction cards

11. AR/VR for Mental Health, Pain, and Rehabilitation Therapy

- Explore real case studies: VR for phobia therapy, chronic pain, etc.
- Simulate scenarios for relaxation therapy (guided VR mindfulness)

12. Demo: Digital Adherence Tools with AR Guidance

- Show real-time AR reminders linked to prescription schedules
- Use AI avatars for personalized patient nudges

Module 5: Project-Based Integration & Evaluation 6 Hours

1. Mini Project: Create an AR/VR-Based Solution

- Example: VR tour of GMP plant, AR-based patient education module
- Use Unity or online tools like CoSpaces / ZapWorks

RECOMMENDED BOOKS

1. 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.

SEMESTER VII

Elective 6 – AEC (Theory)

cGMP

Total Credits 1 **Hours / Week: 1** **15 HR**

COURSE OBJECTIVES

1. To understand the structure, purpose, and implementation of Standard Operating Procedures (SOPs) in pharmaceutical settings.
2. To develop knowledge of training and development systems, including need assessment and training evaluation in the pharmaceutical industry.
3. To gain a comprehensive understanding of current Good Manufacturing Practices (cGMP) and key FDA guidelines relevant to pharmaceutical quality assurance.
4. To explore the core quality systems such as Quality Management System (QMS), CAPA, deviation handling, and non-conformance management in pharmaceutical operations.
5. To learn the procedures for handling customer complaints, investigating quality issues, and ensuring product safety and compliance.
6. To prepare for and manage regulatory audits and inspections, including FDA audits, and respond appropriately to audit findings.

COURSE OUTCOMES

Upon completion of the course student shall 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.

COURSE CONTENTS

UNIT I Standard Operating Procedures (SOP), Systems for Training & Development in Pharmaceuticals **3 Hours**

- 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.

Unit II A comprehensive review of cGMP and various important FDA guidelines 3 Hours

- List of major guidelines referred in pharmaceuticals
- Effectively reading and understanding the guidelines

Unit III Important Quality Assurance and cGMP systems adopted in Pharmaceuticals 3 Hours

- 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

UNIT IV Handling of Customer Complaints 3 Hours

- Introduction to complaints, Types of complaints
- Understanding Manufacturing defects and Quality issues
- Handling and investigation of customer complaints

UNIT V Regulatory Audits 3 Hours

- 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.

RECOMMENDED BOOKS

Good Manufacturing Practices for Pharmaceuticals – Joseph D. Nally, CRC Press

Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials (Vol. 1 & 2) – World Health Organization (WHO), WHO Press

Pharmaceutical Quality Assurance – Manohar A. Potdar, Nirali Prakashan

Guidance for Industry: Quality Systems Approach to Pharmaceutical CGMP Regulations – U.S. FDA, CDER/CDRH Guidance Document

Pharmaceutical Production and Packaging Technologies – Michael J. Groves, CRC Press

Pharmaceutical Quality by Design: A Practical Approach – Walkiria S. Schlindwein & Mark Gibson, Wiley

CGMP Guidelines for Pharmaceuticals – R. M. Mehta, New Age International Publishers

Fundamentals of Quality Assurance in the Pharmaceutical Industry – Sarwar Beg, Elsevier India

PHARMACEUTICAL AUTOMATION

Total Credits 1 **Hours / Week: 1** **15 HR**

COURSE OBJECTIVES

1. To provide fundamental knowledge about automation technologies used in the pharmaceutical industry.
2. To familiarize students with automated systems in manufacturing, quality control, and packaging processes.
3. To introduce concepts of process instrumentation, SCADA, PLC, and robotics in pharma operations.
4. To develop understanding of laboratory automation, LIMS, and PAT systems.
5. To explore regulatory guidelines and emerging trends in pharmaceutical automation.

COURSE OUTCOMES

After successful completion of this course, 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.

COURSE CONTENTS

Unit 1: Introduction to Automation in Pharmaceuticals **3 Hours**

- 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

Unit 2: Automated Manufacturing Systems **3 Hours**

- 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

Unit 3: Process Control and Instrumentation **3 Hours**

- 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)

Unit 4: Quality Control and Laboratory Automation **3 Hours**

- 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

Unit 5: Regulatory Aspects and Emerging Trends **3 Hours**

- Regulatory expectations: USFDA, WHO, EMA on automation & electronic systems
- 21 CFR Part 11 – electronic records and signatures
- Data integrity and ALCOA+ principles
- Emerging trends: IoT, Industry 4.0, cloud-based manufacturing, AI in pharma
- Case studies: automated systems in top pharma companies

RECOMMENDED BOOKS

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

MODERN TECHNIQUES IN CELLULAR BIOLOGY

Total Credits 1 **Hours / Week: 1** **15 HR**

COURSE OBJECTIVES

The course aims to equip students 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

Upon successful completion of this course, 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.

COURSE CONTENTS

Unit 1 – CRISPR & Genome Editing **3 Hours**

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 evaluate off-target detection strategies before a mini-lab in which they design a gRNA and screen predicted off-targets.

Unit 2 – Flow Cytometry & Cell Sorting **3 Hours**

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.

Unit 3 – Live-Cell Imaging **3 Hours**

This unit covers phase-contrast, DIC and fluorescence time-lapse microscopy, stressing environmental control through on-stage incubators and microfluidic perfusion. Students deploy fluorescent reporters such as GFP fusions and calcium biosensors to track motility, division and signalling, learn to minimise phototoxicity and manage large image datasets, then conduct a 12-hour GFP-cell time-lapse demo.

Unit 4 – Single-Cell RNA-Seq & Multi-Omics **3 Hours**

Participants examine single-cell isolation by droplets, microwells or FACS, walk through barcoding, library preparation and sequencing, and run a basic bioinformatics pipeline for quality control, normalisation, clustering and UMAP/t-SNE visualisation. They identify cell types, trajectories and rare populations, glimpse CITE-seq and spatial transcriptomics, and explore a public scRNA-seq dataset in R/Python during a workshop.

Unit 5 – Advanced Fluorescence & Super-Resolution Microscopy **3 Hours**

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.

RECOMMENDED BOOKS

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.

MEDICAL DEVICES

Credit 2 **30 Hrs**

Course Objectives:

Upon successful completion of this course, students will:

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: By the end of this course, 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 policies on market dynamics.

2. Design Medical Devices with Safety and Efficacy: Apply design principles to develop medical devices that are safe, effective, and compliant with regulatory standards.

3. Select Appropriate Materials for Medical Applications: Evaluate and choose suitable biomaterials for medical devices, ensuring biocompatibility and functionality.

4. Implement Quality Management Systems: Apply ISO 13485 standards and risk management processes to ensure the quality and safety of medical devices.

5. Navigate Regulatory Pathways for Device Approval: Understand and apply the regulatory processes for medical device approval in India, the US, the EU, and other regions.
6. Develop Strategies for Post-Market Surveillance: Design and implement strategies for monitoring the performance and safety of medical devices post-launch.
7. Integrate Emerging Technologies in Medical Devices: Incorporate advancements in sensors, electronics, and software into the design and development of innovative medical devices.
8. Address Ethical Considerations in Device Development: Identify and address ethical issues related to the development, testing, and use of medical devices.

Subject Contents:

Unit I: Introduction to Medical Devices: (6 Hrs)

- History and Overview of Medical Device Industry and evolving market Trends (India + WW)
- GOI's initiatives and National Medical Device Policy.
- Regulatory frameworks (CDSCO; State FDA; USFDA; EU-CE, etc.)
- Medical device design and development process
- Definition and Classification of Medical Devices (India; US; EU)

Unit II: Medical Device Design, Biomaterials and Biocompatibility: (6 Hrs)

- Medical Device Design principles and methodologies, safety analysis
- Properties and selection of materials & biomaterials for devices
- Tissue engineering and regenerative medicine
- Biocompatibility Testing and Standards (ISO 10993)

Unit III: Manufacturing and Quality Systems: (based on ISO 13485 Fifth Sch of IMDR 2017) (6 Hrs)

- Good Manufacturing Practices (GMP) & Infrastructure requirements
- Quality assurance and quality control in Medical Devices
- Supply chain management (warehousing distribution)
- Risk Management (ISO 14971)

Unit IV: Regulatory Affairs, Regulatory strategies for global market access (6Hrs)

- Medical device regulations and standards (IMDR 2017)
- Understanding Regional Differences in Regulatory Pathways
- Regulatory submissions and approvals (India)
- Post-market surveillance and vigilance (India)
- Global Regulatory Requirements (USFDA, CE Mark, etc.)
- Case Studies of Global Regulatory Challenges

Unit V: Biomedical Engineering; Instrumentation: Emerging Technologies (6 Hrs)

- Principles of biomedical sensors and transducers
- Medical imaging techniques (X-ray, CT, MRI, ultrasound)
- Telemedicine and remote monitoring
- Integration of Electronics and Software in Medical Devices
- Wearable Devices and Remote Monitoring
- Ethical issues in device development and use

References:

1) MEDICAL DEVICES RULES, 2017 MINISTRY OF HEALTH AND FAMILY WELFARE (Department of Health and Family Welfare) NOTIFICATION New Delhi, the 31st January, 2017 https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical%20De vices%20Rules,%202017.pdf
2) https://www.ema.europa.eu/en/human-regulatory-overview/medical-devices?utm_source=chatgpt.com
3) SMedical devices — Application of risk management to medical devices https://www.iso.org/obp/ui/en/#iso:std:iso:14971:ed-3:v1:en

SEMESTER VIII

Elective 7 – AEC (Theory)

PHARMACEUTICAL PACKAGING

Total Credits 2 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

The course aims:

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

COURSE OUTCOMES

After completing the course, 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.

COURSE CONTENTS

Unit – I - General Information on Packaging **6 Hours**

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.

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).

Unit – II – Pharmaceutical Packaging – Design and Development 6 Hours

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).

Unit –III- Formulation Packaging Interaction 6 Hours

1. Polymer Chemistry Science and Stability Aspects
2. Extractable and Leachables
3. Methods to study formulation packaging interaction
4. Suitability considerations for pharmaceutical packaging

Unit – IV – Quality Assurance, Control and Regulatory Aspects 6 Hours

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,

Unit – V -Advances in Pharmaceutical Packaging 6 Hours

1. Labelling- Types of label (including Bar code, Hologram, RF, structured program, in-mould and decorative labeling) – 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 labeling

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).

RECOMMENDED BOOKS

1. The Wiley Encyclopedia of Packaging Technology, Author: AI Brody & K S Marsh,Publisher: John Wiley & Sons, New York, Edition: Latest
2. The Theory and Practice of Industrial Pharmacy, Author: Leon Lachman, H A Lieberman, J L Kanig, Publisher: Lea & Febiger, Philadelphia., Edition: Latest
3. Packaging of Cosmetics and Toiletries, Author: T C KacChesney, Publisher: Newness-Butterworth, London, Edition: Latest
4. Remington: The Science and Practice of Pharmacy, Author: Loyd V. Allen Jr., Publisher: Mack Publishing Co.

SUPPLY CHAIN MANAGEMENT

Total Credits 2 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

The course aims 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

Upon successful completion of this course, participants 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.

COURSE CONTENTS

Unit 1: Introduction to Supply Chain Management **6 Hours**

- Introduction to SCM: Definition, scope, Importance of SCM, in global business, Key components and stakeholders, Supply Chain Strategies, Process and barriers of supply chain management.
- Supply Chain Models: SCOR Model (Plan, Source, Make, Deliver, Return)

  CSCMP Supply Chain Process Standards.
- Supply Chain Network Design, Facility location and layout, Transportation planning.

- Supply Chain Performance Metrics, Key Performance Indicators (KPIs)
- Performance measurement tools
- Case Study: SCM in Practice with Real-world examples

Unit 2: Procurement and Supplier Management 6 Hours

- Procurement Fundamentals, Role of procurement in SCM, sourcing strategies
- Supplier selection criteria, supplier performance evaluation, Collaboration and communication.
- Global Sourcing, Challenges and opportunities, Cultural considerations, Legal and ethical issues
- E-Procurement, Electronic procurement systems, Benefits and challenges
- Case Study: Procurement Excellence, Best practices.

Unit 3: Logistics and Distribution Management 6 Hours

- Logistics Fundamentals, Definition and scope, Importance in SCM
- Transportation Management, Modes of transportation, Routing and scheduling, Freight cost analysis
- Inventory Management of pharmaceuticals, Inventory types and functions, Inventory control techniques, Economic Order Quantity (EOQ)
- Introduction to warehouse functions, Management and Distribution channels and distribution strategies for vaccines and biologicals.
- Case Study: Logistics and transportation Optimization process, Knowledge and skill sets needed for optimization.

Unit 4: Technology and Innovation in SCM 6 Hours

- Information Technology in SCM, Role of IT in SCM planning and operations management for pharmaceuticals.
- Enterprise Resource Planning (ERP) systems, operations system, Supply Chain Management Softwares.
- Big Data and Analytics, Importance of data in SCM.
- Artificial Intelligence and Machine Learning, AI/ML applications in SCM, smart logistics.

- Demand forecasting, Autonomous vehicles
- Security and transparency with special emphasis to cybersecurity.

Unit 5: Sustainability and Risk Management in SCM 6 Hours

- Sustainable Supply Chain Management, Green logistics, Circular economy

  Environmental impact assessment.
- Ethical Sourcing, Fair trade practices, Labor standards, Supplier audits.
- Risk Management in SCM, Risk identification and assessment, Risk mitigation strategies, Crisis management with special emphasis to Pharmaceutical products.
- Regulatory Compliance, International trade regulations, Customs and import/export laws, Compliance standards.
- Cold chain management, its need, challenges and opportunities in Pharmaceutical products.
- Case Study: Risk and Sustainability Challenges

RECOMMENDED BOOKS

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. APICS. (2022). APICS Dictionary (16th ed.). APICS.
5. Coyle, Bardi, Longley, THE MANAGEMENT OF BUSINESS LOGISTICS- A SUPPLY CHAIN PERSPECTIVE, Thompson Press, 2006.

INDUSTRIAL SAFETY AND WASTE MANAGEMENT

Total Credits 2 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

1. To understand the principles of industrial safety and accident prevention in pharmaceutical industries.
2. To analyze workplace hazards and implement risk management systems.
3. To provide foundational knowledge of industrial waste types and their environmental impacts.
4. To familiarize students with waste treatment technologies and regulatory frameworks.
5. To promote sustainable waste management practices in line with national and global standards.

COURSE OUTCOMES

After completing this course, 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.

COURSE CONTENTS

Unit 1: Introduction to Industrial Safety **6 Hours**

- 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)
- OSHA guidelines and ISO safety standards

Unit 2: Risk Assessment and Hazard Management **6 Hours**

- 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

Unit 3: Waste Management – Fundamentals **6 Hours**

- 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

Unit 4: Waste Treatment Technologies **6 Hours**

- 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

Unit 5: Regulatory and Sustainable Practices **6 Hours**

- 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

RECOMMENDED BOOKS

1. Industrial Safety and Environment by A.K. Gupta, Laxmi Publications
2. Industrial Safety Management by L.M. Deshmukh, McGraw-Hill Education

3. Waste Management Practices: Municipal, Hazardous, and Industrial by John Pichtel, CRC Press
4. Safety, Health and Environment for Engineers and Scientists by Michel W. First, John Wiley & Sons
5. Industrial Waste Management Handbook by Kanti L. Shah, McGraw-Hill Education
6. Biomedical Waste Management in India by Sunil Kumar, Elsevier
7. Pharmaceutical Engineering by C.V.S. Subrahmanyam, Vallabh Prakashan

TRADITIONAL HEALING PRACTICES OF INDIA

Total Credits 2 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

1. To provide a foundational understanding of Indian traditional medicine systems
2. To familiarize students with the core principles and diagnostic methods of Ayurveda, Siddha, Unani, Naturopathy, and Homeopathy
3. To document and critically analyze tribal and folk healing traditions
4. To explore the spiritual and religious dimensions of traditional healing
5. To encourage scientific validation and policy-level integration of traditional health knowledge

COURSE OUTCOMES

At the end of the course, the student 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.

COURSE CONTENTS

Unit I: **6 Hours**

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

Unit II: **6 Hours**

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

Unit III: **6 Hours**

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

Unit IV: **6 Hours**

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

Unit V: **6 Hours**

Spiritual and Religious Healing: Role of Yoga, Pranayama, and meditation

Healing through Mantras, rituals, and astrology

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 BOOKS

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

SEMESTER VIII

Elective 8 – VAC (Practical)

CLEANING VALIDATION

Total Credits 1 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

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

By the end of the course, 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.

COURSE CONTENTS

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 BOOKS

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
7. Pharmaceutical Validation Handbook – Syed Imtiaz Haider, CRC Press

BASIC TRAINING IN ASEPTIC HANDLING TECHNIQUES

Total Credits 1 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

The objectives are to:

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

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.

COURSE CONTENTS

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 BOOKS

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.

IMPURITY PROFILING

Total Credits 1 **Hours / Week: 2** **30 HR**

COURSE OBJECTIVES

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

At the end of the course, the student 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.

COURSE CONTENTS

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 BOOKS

1. Impurities Evaluation of Pharmaceuticals by Steven Gorog, Marcel Dekker Inc.
2. ICH Quality Guidelines: An Implementation Guide by Andrew Teasdale, Wiley
3. Pharmaceutical Analysis by Ashutosh Kar, New Age International Publishers
4. A Textbook of Pharmaceutical Analysis by K.A. Connors, Wiley India Pvt. Ltd.
5. Handbook of Isolation and Characterization of Impurities in Pharmaceuticals by Satinder Ahuja, Academic Press (Elsevier)
6. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D. Sethi, CBS Publishers & Distributors
7. The Analysis of Drugs in Biological Fluids by Joseph Chamberlain, CRC Press

HERBAL COSMETICS FOR INDUSTRY PERSPECTIVES

(Credits: 2, Total Duration: 30 Hours)

Course Objectives:

In this subject the students shall learn about the various requirements for setting up an herbal cosmetics industry. This shall focus on materials, infrastructure, GMP, legal and regulatory requisites along with developing entrepreneurial attitude and skills.

Program Objectives:

1. To provide foundational knowledge of the herbal cosmetics industry
2. To nurture an entrepreneurial mindset
3. To develop competence in financial planning and marketing strategies
4. To ensure awareness and understanding of legal and regulatory frameworks
5. To impart skills in quality assurance and safety evaluation of herbal cosmetics

Course Outcomes / Take-Home Lessons for Students:

By the end of this course, 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.

Course Contents:

1. **Unit I: Introduction to the requirements for an herbal cosmetics industry (6 hours)**

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.

2. **Unit II: Fundamentals of Entrepreneurship (6 hours)**

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

3. **Unit III: Financial Management and Marketing Strategies (6 hours)**

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

4. **Unit IV: Legal and Regulatory Framework (8 hours)**

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

5. **Unit V: Quality and safety evaluation of herbal cosmetics (4 hours)**

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)

Recommended reading:

- Drugs and Cosmetics Act, 1940 & Rules, 1945
- **Guidelines from Ministry of AYUSH (**ayush.gov.in)
- **Bureau of Indian Standards (BIS) – IS Codes for Cosmetics**

- Herbal Cosmetics Handbook (Formulae, Manufacturing Processes with Machinery & Equipment Details) 5th Revised Edition (2021) Author: Dr. Himadri Panda ISBN: 9788195370108

Appendix-2

Format for Calling of Public Comments

S.No.	Page No. of the proposed syllabus	Content/Topic	Comments/ Suggestions	Reasons/Justification for changes