Pharmacy Council of India
New Delhi
Proposed Syllabus for the Bachelor of Pharmacy
(GENERAL STREAM)
[As per NEP 2020]

May 2025

PREFACE

The National Education Policy 2020 proposes the revision and revamping of all aspects of the education structure, including the school regulation and governance, to create a new system which is aligned with the aspirational goals of 21st century education along with India's tradition, culture and value system. Built on the foundational pillars of access, equity, quality, affordability and accountability, NEP strives to transform India into a vibrant knowledge society to become a global knowledge superpower (**Vishwa guru**).

In Higher Education, NEP 2020 provides valuable insights and recommendations on various aspects of education that include multidisciplinary and holistic education, institutional autonomy, promotion of quality research, continuous professional development of teachers, integration of technology, internationalization of higher education, valid reliable and blended assessment and availability of content in Indian languages and National Credit Framework.

The world is undergoing rapid changes in the knowledge landscape. Worldwide the scientific and technological advances, such as the rise of big data, machine learning, and artificial intelligence, would take over many unskilled jobs. With the changing employment landscape and global ecosystem, it is becoming critical that children not only learn, but more importantly learn how to learn**.** This is aligned with the thoughts of a great Indian Philosopher, Swami Vivekanand who said "Education is the manifestation of perfection already existing in the man"

Today, India is one of the youngest nations in the world with more than 62% population in the working age group (15-59 years), and over 54% population below 25 years of age. India needs to equip its workforce with knowledge and employable skills so that they can contribute substantially to the economic growth and development of the country. Countries with higher levels and standards of skills adjust more effectively to the challenges and opportunities in domestic and international job markets. **The Skill India Mission** launched by Government of India in 2015, is a comprehensive initiative aimed at enhancing the skills of youth, equipping with vocational and technical training, to meet job market demands and boost overall economic productivity.

India's pharmaceutical industry has gained international recognition as the **"*Pharmacy of the World*,"** for its imperative role in supplying vaccines, essential medicines, and medical supplies during COVID-19. Ranking third globally in drug and pharmaceutical production by volume, India exports to approximately 200 countries. The pharmaceutical sector is expected to reach $100 billion by 2025 owing to the robust domestic manufacturing base with over 10,500 manufacturing facilities. Many are these are US-FDA compliant, WHO-GMP approved and European Directorate of Quality Medicines (EDQM) approved plants which cater to the international Market. India offers 60,000 generic brands across 60 therapeutic categories and 500+ Active Pharmaceutical Ingredients (API), contributing to **'Make in India'** initiative launched 2014. **Startup India** is a flagship initiative launched by the Government in January 2016, to build a strong eco-system for nurturing innovation and startups. This will encourage

entrepreneurship in Pharmacy professionals with innovative ideas. It becomes very important to bring in positive reforms in the pharmacy education.

Salient Features

In Pharmacy education, we propose one General Pharmacy branch with two more specialization viz. Industrial Pharmacy catering to manufacturing need of different drugs and dosage forms and Clinical Pharmacy specifically catering to pharmacological aspect of medicines and patient counselling regarding treatment. Initial four semesters in all the 3 branches are common with basic courses. The specialization commencing post 5th semester which is selected by the students as per their liking and aptitude. The total credits allotted are in the range of 170-180 as per NEP. Flexibility is given to Higher Education Institutes as per their subjects of interest. Major, Minor courses, Value added courses, skill enhancement and ability enhancement courses are included in the syllabus as per requirement in pharmacy education. Lot of emphasis is given to experiential learning with two mandatory internships.

The Multidisciplinary approach can be achieved by collaborating with various streams of Arts, Science and Commerce such as Law: Pharmaco-Legal, Economics- Pharamacoeconomics, Instrumentation engineering :Medical Devices and Bulk drugs industry set up, Medicine: Clinical studies, Data Management, Forensic sciences: Legal, Ayurveda: Integrated Health Care education and Ayush Approach, Computer engineering: AI/ML/Data Sciences/Analytics, Statistics: Biostatistics, Industrial Chemistry: Process development, Physics: Biophysics, nano-technology for drug development, Management: Product Marketing, Nutrition: Nutraceuticals, Sports: Sports Medicines, Botany: Pharmacognostic studies of plants.

The NEP policy is expected to bring long-lasting positive impact in the education system and making India a global hub of skilled manpower during the '**Amrit Kaal'**, leading up to **Viksit Bharat** by 2047. A vibrant, socially engaged, cooperative communities, happier, cohesive, cultured, productive, innovating, progressive & Prosperous nation.

Index

SALIENT FEATURES

1. **Two specializations (Industrial Pharmacy and Clinical Pharmacy) apart from one regular General Pharmacy course are proposed.**
2. **Specialization will be from 5th Semester onward.**
3. **Number of credits would be in the range of 170-180.**
4. **Flexibility to HEI to add some of the courses of their interests.**
5. **Emphasis on Experiential Learning given.**
6. **Majors and Minors, Value added courses, Skill Enhancement and Ability Enhancement courses are also included apart from other practical courses.**
7. **Two mandatory internships included.**
8. **Emphasis on Research project at UG level in two semesters.**
9. **Artificial Intelligence and similar New age Technologies are also embedded in the curriculum**

NEP Structure - General Stream

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	L3	L 3	L3	L 3		L 3	
	General Pharmacy	Physical Pharmaceutics	Dosage Form :Sterile	Herbal Drug Technology	Biomedical Chemistry	Pharmaceutical Quality Assurance	—-	Biostatistics Research methodology	21
MJ-2	P 2	P 2	P2	P2	P2	P 2		P2	
	General Pharmacy Lab	Physical Pharmaceutics Lab	Dosage Form : Sterile Lab	Herbal Drug Technology Lab	Biomedical Chemistry Lab	Pharmaceutical Quality Assurance Lab	—-	HEI to decide	14
MJ-3	L 3	L 3	L 3	L 3	L 3		L3	L2	
	Pharmaceutical Inorganic and Analytical Chemistry	Pharmaceutical Organic Chemistry	Chemistry of Aromatic and Heterocyclic Compounds	Medicinal Chemistry	Pharma-ceutical Analysis	—-	Modern analytical techniques	HEI to decide	20
MJ-4	P2	P 2	P2	P2	P 2		P2		
	Pharmaceutical Inorganic and Analytical Chemistry LAB	Pharmaceutical Organic Chemistry LAB	Chemistry of Aromatic and Heterocyclic Compounds Lab	Medicinal Chemistry Lab	Pharmaceutical Analysis Lab	—-	Modern analytical techniques Lab	—-	12
MJ-5	L 3	L 3	L 3	L3	L3		L3	--	
	Human Anatomy, Physiology and Pathophysiology I	Human Anatomy, Physiology and Pathophysiology 2	General Pharmacology and Recent advances	Systematic Pharmacology and Autacoids	Systematic Pharmacology and Chemotherapy	—-	Pharmacovigilance & Materio Vigilance	—-	18
	P 2	P 2	P2	P2	P2		--	--	

MJ-6	Human Anatomy, Physiology and Pathophysiology Lab	Human Anatomy, Physiology and Pathophysiology 2 LAB	General Pharmacology and Recent advances LAB	Systematic Pharmacology and Autacoids Lab	Systematic Pharmacology and Chemotherapy	—-	—-	—-	**10**
	L 3	L 3			L 3	L3			
MJ-7	Introduction To Pharmacognosy	Pharmacognosy And Phytochemistry Lab	—--	—--	Industrial Pharma-cognosy	Advanced Pharmaco-gnosy	—-	—-	**12**
	P2	P2			P2	L3			
MJ-8	Introduction To Pharmacognosy Lab	Pharmacognosy And Phytochemistry	—-	—-	Industrial Pharmacognosy Lab	Biopharma-ceutics and Pharmaco-kinetics	—-	—-	**9**
	20	**20**	**15**	**15**	**20**	**11**	**8**	**7**	**116**
MN-1		L3	L2	L2			L2	L2	
	—--	Biochemistry	Pharmaceutical Microbiology	Pharmaceutical Biotechnology	—-	—-	Elective HEI to decide	Elective-HEI to decide	**11**
MN-2		P2		P 2				P 1	
	—-	Biochemistry Lab	—-	Pharmaceutical Biotechnology and Microbiology lab	—-	—-	—-	HEI to Decide	**5**

MN-3	AI & Python Programming for Pharmacy I	AI & Python Programming for Pharmacy II	AI in Formulation & Pre-formulation	AI in Pharma Chemistry, Analysis & Bioinformatics	AI in Pharmacology & Drug Safety	ML in Pharmacognosy & Biotech Discovery	Intelligent Manufacturing & Smart QA in Pharmacy	AI in Pharmacy Practice & Patient Care	**8**
MD	L2 &P1		L1	L2		L2	L2	L 2	
	Healthcare Psychology and Communication Skill		Pharmaceutical Mathematics	Social Pharmacy & Public Health		Pharmaceutical Jurisprudence	Cosmetics and Cosmeceuticals	Pharmaceutical Management	**11**
AEC		—-	P1			L 1	L 1	P 1	
			HEI to Decide			HEI to Decide	HEI to Decide	HEI to Decide	**4**
SEC		P1		L2		P 1	P2	P 1	
		HEI to Decide	—-	**Drug Design and Discovery**	—-	HEI to Decide	Cosmetics and Cosmeceuticals Lab	Pharmaceutical marketing Skills Lab	**7**
VAC			L1	L 1	L2	P 1	P 1	--	**6**
		—-	Ethics & Universal Human Values	Environmental Science	Innovation And Startup Ecosystem	HEI to Decide	HEI to Decide		
Internship	----	----	----	**Mandatory 4**	----	**Mandatory 4**	----	----	**8**
Research	—-	—-	—-	—-	—-	—-	Research Project 6	Research Project 6	**12**

							HEI to Decide	HEI to Decide	
Total Cr	~~22~~ (23)	26	20	24+4	22	16+4	16+6	14+6	~~180~~ (181)

SEMESTER I

GENERAL PHARMACY (THEORY)

Total Credits 3 **Hours / Week: /3L+1T** **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 India 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. Know the basics and development of pharmacy profession and its scope.
2. Refer various Pharmacopoeias formulation and quality control of various types of dosage forms.
3. Recognize the structure of a prescriptions and professional way to handle prescriptions with patient counselling.
4. Do the pharmaceutical calculations in formulation and preparation of various types of dosage forms.
5. Gain fundamental knowledge of active pharmaceutical ingredients (API), pharmaceutical excipients and their role in different dosage form
6. Know about basic methods of preparation of solid, liquid and semisolid dosage forms

COURSE CONTENT

UNIT – 1 **09Hrs**

Introduction to Profession of Pharmacy

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

  Evolution, Development and Milestones

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

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

- **Pharmacopoeias:** **03Hrs**

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

- **Prescription** **02Hr**

  Structure and Format/ Parts of Prescription, Handling of Prescription,
  Latin Terminology related to prescription

UNIT – II **09Hrs**

Pharmaceutical Calculations and Dosage Forms

- **Pharmaceutical Calculations:** **(03Hrs)**

  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:** **02Hrs**

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

- **Introduction to Dosage Forms** **04Hrs**

  Introduction to Routes of administration**,**
  Classification of Dosage Forms.
  Introduction to Active Pharmaceutical Ingredient and Excipients: Definition, Ideal Characteristics and Importance.

UNIT – III **09Hrs**

Solid Dosage Forms

- **Powders:** **02Hrs**

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

- **Tablets:** **04Hrs**

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

- **Capsules** **03Hrs**

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

UNIT – IV **09Hrs**

Liquid Dosage Forms

- **Monophasic Liquids:** **05Hrs**

  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:** **02Hrs**

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

b) **Emulsions:** **02Hrs**

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

UNIT – V **09Hrs**

Semisolid Dosage Forms and Suppositories

- **Semisolid Dosage Forms:** **05Hrs**

  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** **04Hrs**

  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

GENERAL PHARMACY (PRACTICAL)

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

COURSE OBJECTIVE:

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 pediatric 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. Discuss the principles and conduct pharmaceutical calculations involving dilution and allegation.
2. Prepare monophasic dosage forms like solutions, syrups, linctuses, and elixirs by pharmacopeial techniques.
3. Demonstrate and distinguish between different biphasic preparations such as suspensions and emulsions based on method, stability, and use.
4. Formulate and test solid dosage forms like powders, granules, and suppositories for their intended therapeutic applications.
5. Prepare and design semisolid preparations like ointments, liniments, and paints with appropriate excipients and methods.
6. Develop and standardize patient-friendly preparations such as mouthwashes, gargles, and pediatric elixirs with accuracy in terms of dose and compliance.

1.PHARMACEUTICAL CALCULATIONS

Solutions based on allegation and dilution methods

2.SOLUTIONS

a) Strong solution of ammonium acetate

b) Cresol with soap solution

c) Lugol’s solution

3.SYRUPS

a) Simple Syrup IP& USP

b) Compound syrup of Ferrous Phosphate BPC

4.LINCTUS

Terpin Hydrate Linctus IP

5.ELIXIRS

a) Piperazine citrate elixir

b) Paracetamol paediatric elixir

6.THROAT PAINT

Iodine Throat Paint (Mandles Paint)

7.SUSPENSIONS

a) Calamine lotion IP

b) Magnesium Hydroxide mixture

c) Aluminimum 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

c) Dusting powder

d) Divided powders

10.SUPPOSITORIES

a) Glycerogelatin suppository

b) Coca butter suppository

c) Zinc Oxide suppository

11.SEMISOLIDS

a) Sulphur ointment IP

b) Non-staining-iodine ointment with methyl salicylate BPC

12. GARGLES & MOUTHWASHES

a) Iodine gargle

b) Chlorhexidine mouthwash

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. PrabhuShnakar, 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

PHARMACEUTICAL INORGANIC AND ANALYTICAL CHEMISTRY-THEORY

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

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. Describe and differentiate various analytical techniques used in pharmaceutical analysis, including titrimetric methods, and their specific applications in quality assessment.
2. Identify sources and types of errors in pharmaceutical analysis, and apply strategies to minimize these

errors, demonstrating knowledge of accuracy, precision, and significant figures.

3. Understand the role of Pharmacopoeias in pharmaceutical regulation, including methods for identifying and testing impurities in pharmaceutical products.
4. Apply concepts of acid-base chemistry and buffer systems to pharmaceutical formulations, with a focus on calculations related to pH and isotonicity for IV fluids and ophthalmic solutions.
5. Explain the principles and applications of various titrimetric methods, including the preparation and standardization of titrants and interpret the results to quantify analytes.
6. 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.

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 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. **Pharmacopoeia**: 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.

PHARMACEUTICAL INORGANIC AND ANALYTICAL CHEMISTRY (PRACTICAL)

Total Credits: 2 **4 hours/week**

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. Select appropriate analytical techniques for the analysis of inorganic compounds based on specific criteria and contexts
2. Gain skills in performing the titrimetric analysis using various volumetric techniques
3. Perform the preparation of various pharmaceutical inorganic compounds
4. Demonstrate the physicochemical properties of pharmaceutical inorganic compounds
5. Analyze the importance of determining the quality of pharmaceutical products and substances.

COURSE CONTENTS

Limit tests

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

1. **Preparation of inorganic pharmaceuticals**

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

2. Test for Purity

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

3. Assay of the following inorganic compounds including standardization of titrant

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)

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

HUMAN ANATOMY, PHYSIOLOGY AND PATHOPHYSIOLOGY-I (THEORY)

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

COURSE OBJECTIVES:

- To understand the structural and functional organization of human anatomy and physiology at different levels including subcellular, cellular, tissue and organ systems.
- To explain the physiological mechanisms and normal functioning of major body systems and relevant neurological and biochemical control mechanisms.
- To familiarise the learners with the pathological changes leading to diseases and disorders.
- Correlate anatomical and physiological concepts with disease pathophysiology of diseases like hypertension, anaemia, peptic ulcer, COPD etc.
- To familiarise learners with the anatomical and medical terminology and develop analytical skills to understand the disease mechanisms.

COURSE OUTCOMES:

Upon completion of this course the student should be able to

- Explain the gross morphology, structures and functions of various organs and organ systems of the human body.
- Describe the various homeostatic mechanisms and their imbalances.
- Describe the aetiology and pathogenesis of the selected disease states
- Know the signs and symptoms, risk factors, diagnosis, prevention, treatment strategies and complications of the diseases.
- Understand coordinated working pattern of different organs of each system

COURSE CONTENTS:

UNIT-I **10 Hours**

a) **Introduction to human body**

Definition and scope of anatomy, physiology and pathophysiology. Levels of structural organization and body systems, homeostasis, basic anatomical terminology and anatomical positions.

b) **Cellular level of organization**

Structure and functions of cell, transport across cell membrane, cell division, cell junctions.

c) **Basic Principles of Cell injury and adaptation:** Causes of cellular injury and pathogenesis (cell membrane damage, mitochondrial damage, ribosomal damage, nuclear damage). Morphology of cell injury – adaptive changes (atrophy,hypertrophy, hyperplasia, metaplasia,

dysplasia).

d) Tissue level of organization

Classification of tissues: structure, location and functions of epithelial, muscular, nervous and connective tissues.

Unit-II **10 Hours**

a) Skeletal system

Divisions of skeletal system, types of bones, salient features and functions of bonesof axial and appendicular skeletal system

b) Joints

Structural and functional classification, types of joint movements and their articulations

c) Pathophysiology of the diseases of bones and joints: Rheumatoid arthritis,osteoarthritis, osteoporosis and gout

d) Organization of skeletal muscles: names and locations of major skeletal muscles, physiology of muscle contraction, neuromuscular junction.

Unit-III **10 Hours**

a) Body fluids and blood

Body fluids, composition and functions of blood, hemopoiesis, formation of haemoglobin, mechanisms of coagulation, blood grouping, Rh factors, transfusion, Reticuloendothelial system, pathophysiology of blood related disorders like anaemia, leukaemia, haemophilia, coagulopathy.

b) Lymphatic system

Lymphatic organs and tissues, lymphatic vessels, lymph circulation and functions of lymphatic system, pathophysiology of lymphadenopathy

c) Basic mechanism involved in the process of inflammation and repair: Introduction, Clinical signs of inflammation, Different types of Inflammation, Mechanism of Inflammation, Mediators of inflammation.

Unit-IV **07 Hours**

a) Cardiovascular system

Vascular system: Types of blood vessels and their structure and functions, blood circulation.

Heart – anatomy of heart, 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), cardiac arrest, rheumatic heart disease, cardiac arrhythmia.

Unit-V **08 Hours**

a) Digestive system

Anatomy of GI Tract with special reference to anatomy and functions of stomach, (Acid production and regulation of acid through parasympathetic nervous system, role of pepsin in protein digestion), small intestine, large intestine, anatomy and functions of salivary glands, pancreas, liver and gall bladder, movements of GIT, digestion and absorption of nutrients.

b) Pathophysiology of peptic ulcer, pancreatitis, inflammatory bowel disease, gastritis, hepatitis, cirrhosis of liver.

c) Respiratory system: Anatomy and Physiology of respiratory system, mechanism of respiration andregulation of respiration

d) Lung volumes and capacities, transport of respiratory gases, artificial respiration, and resuscitation methods.

e) Cough, chronic bronchitis, bronchial asthma, COPD, Pneumonia.

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.

HUMAN ANATOMY, PHYSIOLOGY AND PATHOPHYSIOLOGY-I (PRACTICAL)

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

COURSE OBJECTIVES:

This subject is designed to impart fundamental knowledge on the structure and functions of the various organ systems of the human body and the pathophysiology of various diseases affecting these organ systems. It also helps in understanding both homeostatic mechanisms and the study of various causes of diseases and reactions of the body to such disease producing causes.

COURSE OUTCOMES:

Upon completion of this course the student should be able to

1. To understand and describe the principles and applications of microscopy techniques.
2. Explain the gross morphology, structures and functions of various organs and organ systems of the human body.
3. To estimate various hematological parameters and to 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 complications of the diseases.
6. Understand coordinated working patterns of different organs of each system
7. Perform the various experiments related to special senses and nervous system

COURSE CONTENT:

Practical HAPP allows the verification of physiological processes discussed in theory classes through experiments on living tissues, simulated animal models, charts, models or and models with the help of human volunteers

1. Principle and applications of compound microscopes/phase contrast/Electron Microscopy (SEM/TEM)
2. Microscopic study of epithelial, connective, muscular and nervous tissues
3. Identification of axial bones and appendicular bones

4. Estimation of hemoglobin content
5. Determination of bleeding time and clotting time and demonstration of complete blood count by cell analyzer
6. Estimation of white blood cell (WBC) count
7. Estimation of red blood corpuscles (RBC) count
8. Estimation of differential leukocyte (DLC) count
9. Determination of blood groups and erythrocyte sedimentation rate (ESR). Students should study sample hematological test reports.
10. Learning through charts and models – Heart and blood vessels
11. Learning through charts and models – Respiratory system
12. Learning through charts and models – Digestive system
13. Determination of heart rate, pulse rate, respiratory rate and tidal volumes
14. Recording blood pressure and studying the components of ECG.
15. Students may undertake case studies of some of the diseases prescribed in the theory syllabus above.

RECOMMENDED BOOKS:

For Anatomy and Physiology:

1. Textbook of Human Histology by Inderbir Singh, Jaypee Brother's medical publishers, New Delhi.
2. Textbook of Practical Physiology by C.L. Ghai, Jaypee
3. Laboratory Manual and Journal of Physiology. Dr. V. G. Ranade, Pune Vidhyarthee Prakashan.
4. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee Brother's medical publishers, New Delhi.
5. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterjee, Academic Publishers Kolkata

INTRODUCTION TO PHARMACOGNOSY (Theory)

Credits3 **45 Hours**

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:

CO1: Describe the historical development, classification, and scope of Pharmacognosy.

CO2: Explain cultivation, processing, and conservation techniques for medicinal plants.

CO3: Apply quality evaluation methods to crude drugs using organoleptic, microscopic, and chemical parameters.

CO4: Identify primary and secondary metabolites with their therapeutic relevance.

CO5: Recognize traditional systems of medicine and commonly used phyto-therapeutic agents.

COURSE CONTENT

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

UNIT-II **08 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 **10 Hours**

Quality control of Drugs of Natural Origin:

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

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.

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.,

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.
9. Ansari, S.H. Essentials of Pharmacognosy, 2nd Edition, Birla Publications, New Delhi,2007.
10. Iyengar, M.A. Anatomy of Crude Drugs.

INTRODUCTION TO PHARMACOGNOSY (PRACTICAL)

Credits 2 **4 Hours/Week**

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 (COs)

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

CO1: Identify crude drugs using transverse section microscopy.

CO2: Perform chemical tests to detect key phytoconstituents.

CO3: Analyze physicochemical parameters of crude drugs.

CO4: Collect and identify medicinal plants and prepare voucher specimens.

CO5: Apply pharmacognostic knowledge for herbal drug standardization.

COURSE CONTENT:

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.**

HEALTH CARE PSYCHOLOGY AND COMMUNICATION SKILLS

Credits 2 **30 Hr**

COURSE OBJECTIVES

By the end of this course, students will be able to:

1. Understand key psychological principles that influence health, illness behaviour, and healthcare delivery.
2. Develop effective interpersonal and professional communication skills applicable in healthcare settings.
3. Explore psychological responses to illness, stress, trauma, and treatment from both patient and provider perspectives.
4. Cultivate empathy, cultural competence, and ethical communication within multidisciplinary healthcare teams.
5. Apply psychological insights and communication strategies in real-life healthcare situations such as patient counselling, crisis intervention, and collaborative care.

COURSE OUTCOMES

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

1. **CO1**: Demonstrate understanding of how psychological factors affect patient behaviour, treatment compliance, and recovery.
2. **CO2**: Communicate effectively with patients, families, and healthcare professionals using verbal and non-verbal techniques.
3. **CO3**: Apply empathy, emotional intelligence, and active listening to enhance therapeutic relationships.
4. **CO4**: Evaluate real-world healthcare interactions from a psychological and communicative lens.
5. **CO5**: Design context-sensitive, ethical communication strategies for patient education and public health advocacy.

COURSE CONTENT:

Unit I: Introduction to Psychology in Healthcare

- 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

- 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

- 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

- 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

- 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

Practical Component (Activities & Skill Development)

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.

AI & PYTHON PROGRAMMING FOR PHARMACY I

Credits 2 **30 Hr**

COURSE OBJECTIVES

By the end of this course, students will be able to:

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. **CO1:** Describe the evolution, key approaches, and knowledge-representation methods of AI.
2. **CO2:** Differentiate and choose appropriate ML paradigms (supervised, unsupervised, reinforcement) and implement basic algorithms
3. **CO3:** Analyze pharmaceutical case studies and justify AI/ML techniques that improve efficiency in drug development, manufacturing, or pharmacovigilance
4. **CO4:** Write well-structured Python programs employing variables, control flow, collections, functions, and file/exception handling to solve defined tasks.
5. **CO5:** Integrate AI/ML algorithms with Python to design and execute a mini-project addressing a real pharmacy challenge, and interpret the results critically

COURSE CONTENT:

Unit 1 – Foundations of Artificial Intelligence

- 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

- 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

- 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

- 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

- 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.

SEMESTER II

PHYSICAL PHARMACEUTICS (THEORY)

Total Credits 3 **Hours /week 3L+1T** **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) This subject will create foundation for understanding of formulation and development concepts.

COURSE OUTCOMES:

Upon completion of this course, the students will able:

1) To understand the principles and theory behind various processes and operations in pharmaceutical manufacturing.

2) To analyse the physicochemical properties of various materials and its relation with formulation, quality and stability of dosage form.

3) To know the principle and working of various equipment used in pharmaceuticals operations and processes.

4) To develop ability of practically determining and establishing various parameters behind pharmaceutical processes.

5) To optimize pharmaceutical processes with respect to various parameters for desired outcome.

COURSE CONTENT

Unit I **[9 Hrs]**

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.

Different clarification and filtration equipment's (Filter media and Filter aids) and its application.

Unit II **[9 Hrs]**

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 **[9 Hrs]**

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\, phase inversion.)

Equipments used for solid and Liquid Mixing

Unit IV **[9 Hrs]**

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 **[9 Hrs]**

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 (Brookfield powder flow tester)

.

Equipments used for Size reduction (based upon principles of Impact, Attrition, cutting and crushing) and size separation

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

PHYSICAL PHARMACEUTICS (PRACTICAL)

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

COURSE OBJECTIVES:

Upon completion of this course, the students will able:

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, filtration efficiency, and powder properties.

6. To inspire creativity in the design of formulation approaches and choosing appropriate processing equipment depending on experimental results.

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.
6. Develop formulation strategies or test setups by combining understanding of pharmaceutical principles and equipment use.

COURSE CONTENT

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 and microscopic method

9.Determination of densities and derived properties of powders (Bulk density, tapped density, hausners ration, carr's compressibility index) true density and porosity

10. Determine the angle of repose and influence of glidents on angle of repose.

11. Demonstration of Pharmaceutical Machinery such as, all type of Stirrers/ Impellers, Homogenizer, Sonicators, Planetoary Mixers

12.Factors affecting Rate of Filtration using filter aids and filter media (Surface area, Concentration and Thickness/ viscosity)

13.Determining the solubility of drug at different buffer/pH at room temperature

14.Determination of Partition coefficient of drug in n-octanol and water system

Note: 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, AultonPharmacceutics: 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 (THEORY)

Total Credits: 3 **3 hours/ Week** **45 hours**

COURSE OBJECTIVES

This course provides a comprehensive introduction to the fundamental principles of organic chemistry. It focuses on the classification and systematic nomenclature of simple organic compounds, the nature and role of reaction intermediates, and the methods of synthesis. Emphasis is placed on understanding key chemical reactions and the mechanisms underlying them.

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

COURSE OUTCOMES

1. To outline the classification, structure, and IUPAC nomenclature of aliphatic organic compounds, benzene, and its derivatives.
2. To describe the fundamental chemical reactions and reaction mechanisms of organic compounds.
3. To illustrate the methods of preparation for various classes of organic compounds using standard laboratory procedures.
4. To analyze the kinetics, reactivity, and stereochemical aspects of chemical reactions involving alkyl halides and carbonyl compounds.
5. 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: Basics of organic chemistry **12 hours**

1. Introduction to organic chemistry including versatility of carbon like tetravalency, catenation and atomic size of carbon **(1 hr)**
2. Classification and nomenclature of aliphatic organic compounds (IUPAC) **(2 hrs)**
3. Definition and types of basic organic chemical reactions such as addition, elimination, substitution and rearrangement reactions, each illustrated with an example **(2 hrs)**
4. Definition types and stability of reactive intermediates with examples (Free radicals, carbocations and carbanions) **(3 hrs)**
5. Electron displacement effects and their importance (Electromeric, Inductive, Mesomeric and Hyper conjugative effect) **(2 hrs)**
6. Definition and types of hybridization and its significance in alkanes, alkenes and alkynes **(2 hrs)**

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

1. **Alkanes** **3 hours**
   a. Methods of preparation of alkanes by Wurtz reaction, Kolbe's Reaction, Clemmensen reduction and Wolf-Kishner reduction **(1 hr)**
   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 hrs)**
2. **Cycloalkanes** **2 hours**

   Study of Baeyer's strain theory and its limitations, Coulson-Moffitt's modification and Sachse - Mohr's theory.
3. **Alkenes** **3 hours**
   a. Methods of preparation of alkenes by dehydration of alcohols, dehydrohalogenation of alkyl halides, dehalogenation of vicinal dihalides and Wittig reaction **(1 hr)**
   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 **(2 hrs)**

4. **Conjugated dienes** **2 hours**

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-III: Chemistry of alkyl halides **8 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 **(3 hrs)**
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 hrs)**
3. Zaitsev's Rule (Saytzeff's) with examples. Difference between E_1 and E_2 reactions. Substitution Vs Elimination reactions **(1 hr)**
4. Pharmaceutical applications of alkyl halides (Chloroform, Iodoform, Tricholoroethylene) **(1 hr)**

UNIT-IV: Chemistry of benzene and its derivatives **10 hours**

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

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

1. Methods to prepare carbonyl compounds by oxidation of alcohols, Reimer-Tiemann reaction and Friedel-Crafts acylation reaction **(2 hrs)**
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) **(3 hrs)**

RECOMMENDED BOOKS

1. Organic Chemistry, by Robert Thornton Morrison, Robert Neilson Boyd and Saibal Kanti Bhattacharjee, Pearson Education India, 7th edition, 2010 (ISBN 9788131704813).
2. Organic Chemistry, Vol. 1, by IL FINAR, Pearson Books, 6th Edition, 2002, (ISBN-13. 978-8177585421).
3. A Text Book of Organic Chemistry, by B S Bahl and Arun Bahl,S Chand and Company, 22nd Edition, 2017, (ISBN 9352531965).
4. Principles of Pharmaceutical Organic Chemisty, by Rama Rao Nadendla, PharmMed Press, 2nd edition, 2018, (ISBN 978-93-5230-197-3).
5. Text Book of Organic Chemistry, by Sony PL and Chawla HM, Sultan Chand and Sons, 16th edition, 2007, (ISBN 9788180547676).

PHARMACEUTICAL ORGANIC CHEMISTRY (PRACTICAL)

Total Credits: 2 **4 hours/week**

COURSE OBJECTIVES

This course aims to equip students with fundamental skills in the identification, characterization, and synthesis of simple organic compounds. Emphasis is placed on experimental techniques such as solubility testing, melting and boiling point determination, elemental analysis, and functional group identification through characteristic chemical tests. The course also includes practical training in the synthesis of organic compounds and their derivatives. By the end of this course, students will be able to:

1. Understand and follow essential laboratory safety protocols, including the proper handling of chemicals, glassware, and laboratory equipment.
2. Gain hands-on experience in identifying and analyzing organic compounds by observing their physical and chemical behavior, particularly the reactivity of functional groups.
3. Apply fundamental modeling techniques using ball-and-stick models to visualize molecular structures.

4. Master basic purification techniques such as crystallization to isolate and refine organic compounds.

COURSE OUTCOMES

1. To recall and outline the preliminary qualitative tests used for identifying water-insoluble and immiscible organic compounds.
2. To understand the synthesis methods for preparing simple organic compounds and their derivatives.
3. To apply crystallization techniques to purify organic compounds effectively.
4. To analyze experimentally to detect elements and functional groups to identify unknown organic compounds.
5. To 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

1. Text Book of Organic Chemistry, by Sony PL and Chawla HM, Sultan Chand and Sons, 16th edition, 2007, (ISBN 9788180547676).
2. Practical Organic Chemistry, by Mann and Saunders, Pearson Education India, 4th Edition, 2009, (ISBN 13. 978-8131727102).
3. Advanced Practical Organic Chemistry, by N.K. Vishnoi, Vikas Publishing, 3rd Edition, 2010, (ISBN 13: 978-8125931287).
4. Introduction to Organic Laboratory Techniues: A Small Scale Approach, by Donald L. Pavia, Gary M. Lampman, George S. Kriz, Brooks/Cole, 3rd Edition, 2010, (ISBN 978-0538733281).
5. Vogel's Text Book of Practical organic Chemistry, by B S Furniss, Pearson India, 5th edition, 2003, (ISBN-10. 9788177589573).

HUMAN ANATOMY, PHYSIOLOGY AND PATHOPHYSIOLOGY- II (THEORY)

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

COURSE OBJECTIVES:

This subject is designed to impart fundamental knowledge on the structure and functions of the various organ systems of the human body and the pathophysiology of various diseases affecting these organ systems. It also helps in understanding both homeostatic mechanisms and the study of various causes of diseases and reactions of the body to such disease producing causes.

COURSE OUTCOMES:

Upon completion of this course the student should be able to

- Explain the gross morphology, structures and functions of various organs and organ systems of the human body.
- Describe the various homeostatic mechanisms and their imbalances.
- Describe the aetiology and pathogenesis of the selected disease states
- Know the signs and symptoms, risk factors, diagnosis, prevention, treatment strategies and complications of the diseases.
- Understand coordinated working pattern of different organs of each system
- Perform the various experiments related to special senses and nervous system

COURSE CONTENTS

UNIT-I **08 Hours**

a) Nervous system

Organization of nervous system, neuron, neuroglia, classification and properties of nerve fibre, nerve electrophysiology, synapse, neurotransmitters and their receptors and neurohumoral transmission including ion channel opening, signal transduction, second messengers.

UNIT-II **10 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) Diseases of Peripheral and Central Nervous System:

Pathophysiology of neurodegenerative diseases (Alzheimer's disease, Parkinson's disease), traumatic injuries (spinal cord injury, brain injury), infections (Meningitis, Encephalitis), vascular disorders (stroke), demyelinating diseases (Multiple sclerosis), and mental health conditions (Depression and Schizophrenia). Pathophysiology of Epilepsy and Migraine. Pathophysiology of peripheral neuropathies.

UNIT-III **10 Hours**

a) Urinary system

Anatomy of urinary tract, kidney and nephrons, functions of kidney and urinary tract, physiology of urine formation, micturition reflex and role of kidneys in acid base balance, renin-angiotensin axis

b) Pathophysiology of glomerulonephritis, acute and chronic renal failure, renal calculi.

Special Senses: Anatomy and physiology of eye, ear, nose, tongue and skin

Definitions and pathophysiology of - Myopia. Hypermetropia, loss of accommodation, glaucoma, cataract, vertigo, hearing impairment, otitis.

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. Pathophysiology of diabetes, thyroid disorders, pituitary disorders, adrenal disorders.

b) 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. Diseases of sex hormones: PCOD, menstrual disorders, male and female infertility.

Unit-V **7 Hours**

Pathophysiology of

a) Neoplasms: Classification, aetiology, and pathogenesis of cancer.

b) An overview of Mutagenicity and Teratogenicity

c) Infectious diseases**:** Meningitis, typhoid, malaria, leprosy, tuberculosis, dengue chikungunya, COVID-19, amoebiasis, septicaemia etc.

d) Sexually transmitted diseases: AIDs, chlamydia, syphilis, gonorrhoea, etc.

RECOMMENDED BOOKS (LATEST EDITIONS):

a) For Anatomy and Physiology (Latest Editions):

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

c) 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.

HUMAN ANATOMY, PHYSIOLOGY AND PATHOPHYSIOLOGY- II (PRACTICAL)

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

COURSE OBJECTIVES

This subject is designed to impart fundamental knowledge on the structure and functions of the various organ systems of the human body and the pathophysiology of various diseases affecting these organ systems. It also helps in understanding both homeostatic mechanisms and the study of various causes of diseases and reactions of the body to such disease producing causes.

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

COURSE CONTENT:

Practical HAPP allows the verification of physiological processes discussed in theoryclasses through experiments on living tissues, simulated animal models, charts, and models with the help of human volunteers.

1. Learning through charts and models – Nervous system
2. To demonstrate the general neurological examination and calculation of GCSScore
3. To record body temperature and demonstrate the reflex activity
4. Understanding EEG as a diagnostic tool
5. Learning through charts, models and open-source digitalapplications – Special senses.
    - To demonstrate the function of olfactory nerve
    - To examine the different types of taste.
    - To demonstrate the visual acuity
    - To demonstrate the reflex activity
6. Learning through charts and models – Urinary system
7. Learning through charts and models – Endocrine system
8. Learning through charts and models – Reproductive system
9. Recording of body mass index (BMI) and basal metabolic rate (BMR).
10. Study of family planning devices and pregnancy diagnosis test.
11. Understanding the significance of liver function tests with the help of a clinicaldiagnostic report,
12. Understanding the significance of kidney function tests with the help of a clinicaldiagnostic report
13. Understanding the significance of lipid profile tests with the help of a clinicaldiagnostic report
14. Students may undertake case studies of some of the diseases prescribed in the theory syllabus above.

RECOMMENDED BOOKS:

For Anatomy and Physiology:

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.

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 (Lippincot Williams &Wilkins)
3. Pathophysiology – Principles of disease byMarhta J. Miller

PHARMACOGNOSY AND PHYTOCHEMISTRY (Theory)

Credits 3 **45 Hours**

COURSE OBJECTIVES

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

COURSE OUTCOMES (COS)

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

CO1: Describe biosynthetic pathways and genetic tools in phytoconstituent production.

CO2: Classify and explain primary and secondary metabolite-containing drugs.

CO3: Apply traditional and modern methods of extraction and isolation.

CO4: Perform qualitative and quantitative analysis of plant metabolites.

CO5: Evaluate identity, purity, and quality of herbal raw materials

COURSE CONTENT:

UNIT-I **06 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 **08 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 **15 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 **08 Hours**

Isolation, Identification and characterization of Drugs and Botanicals

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, 20019**
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.

PHARMACOGNOSY AND PHYTOCHEMISTRY (PRACTICAL)

Credits 2 **04**

Hours/Week

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.

5. To enable evaluation of herbal materials using spectrophotometric methods and standard comparisons.

COURSE OUTCOMES (COS)

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

CO1: Identify crude drugs through specific chemical tests.

CO2: Perform quantitative microscopy to measure diagnostic plant features.

CO3: Conduct sensory, morphological, chemical, and powder microscopic evaluation of medicinal plants.

CO4: Estimate phytoconstituent content using gravimetric analysis techniques.

CO5: Evaluate and compare herbal raw materials using spectrophotometry and pharmacopoeial standards.

COURSE CONTENT

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 (THEORY)

Total Credits: 3 **3 hours/ Week** **45 hours**

COURSE OBJECTIVES

Biochemistry is the study of living matter by combining biology and chemistry.

1. Students learn about the metabolism of carbohydrates, lipids, and proteins, and how hormones control metabolism.
2. Students learn how genetic errors can cause diseases, and how these errors are inherited.
3. Students learn about the organization of DNA in a genome, how it is replicated and repaired, and how genetic information is expressed as proteins.
4. Students learn about enzymes, enzyme kinetics and biological functions of coenzymes

COURSE OUTCOMES

1. To recall the classification, biological role, properties and significance of carbohydrates, lipids, nucleic acids, amino acids and proteins.
2. To outline the concepts of bioenergetics and metabolism of carbohydrates
3. To apply the concept of enzyme kinetics in design of drugs, study the diagnostic and therapeutic application of enzymes.
4. To distinguish the process of DNA replications, transcription and translation
5. To discuss the causes, manifestation and diagnosis of metabolic disorders.

COURSE CONTENTS

UNIT-I **8 Hours**

1. **Biomolecules:** Introduction, classification, chemical nature and biological role of carbohydrate, lipids, nucleic acids, amino acids and proteins.
2. **Bioenergetics:** Concept of free energy, endergonic and exergonic reaction, Relationship between free energy, enthalpy and entropy; Redox potential.
3. Energy rich compounds; classification;

UNIT-II **10 hours**

1. **Carbohydrate metabolism:**
    a. Glycolysis – Pathway, energetic and significance
    b. Citric acid cycle – Pathway, energetic and significance

c. Glucose-6-phosphate its participation between Glycolysis and pentose phosphate pathway.

d. Glycogen metabolism Pathways and glycogen storage diseases (GSD)

e. Gluconeogenesis – Pathway and its significance

f. Hormonal regulation of blood glucose level and Diabetes mellitus

2. Biological Oxidation

a. Electron transport chain (ETC) and its mechanism:

b. Oxidative phosphorylation & its mechanism and substrate level phosphorylation, Inhibitors ETC and oxidative phosphorylation/Uncouplers.

UNIT-III **10 hours**

1. Lipid metabolism:

a. β-Oxidation of saturated fatty acid (Palmitic acid)

b. Formation and utilization of ketone bodies; ketoacidosis.

c. De novo synthesis of fatty acids (Palmitic acid)

d. Biological significance of cholesterol.

e. Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, fatty liver and obesity.

2. Amino acid metabolism:

a. General reactions of amino acid metabolism: Transamination, deamination and decarboxylation, urea cycle and its disorders.

b. Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenyketonuria, Albinism, alkeptonuria, tyrosinemia)

c. Significance of biological subvstances; 5-HT, molatonin, dopamine, noradrenaline, adrenaline.

d. Catabolism of heme; hyperbilirubinemia and jaundice.

UNIT-IV **10 hours**

Nucleic acid metabolism and genetic information transfer

a. Biosynthesis of purine and pyrimidine nucleotides.

b. Catabolism of purine nucleotides and Hyperuricemia and Gout disease.

c. Organization of mammalian genome (replication, transcription, translation)

d. Genetic code and inhibitors of protein synthesis.

UNIT-V **07 hours**

Enzymes

a. Introduction, properties, nomenclature and IUB classification of enzymes.

b. Enzyme kinetics (Michaelis plot, Line Weaver Burke plot)

c. Enzyme inhibitors with examples.

d. Regulation of enzymes: enzyme induction and repression, allosteric enzymes regulation.

e. Therapeutic and diagnostic application of enzymes and isoenzymes.

f. Biochemical functions of coenzymes.

RECOMMENDED BOOKS:-

1. Lehninger principles of Biochemistry byDavid Nelson, Michael Cox, and Aaron Hoskins. Macmillan Publishing Company. Eight edition, 2021 ISBN-13:978-1319381493
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. Mc Graw Hill Education .Thirty-Second Edition, 2023, ISBN 1260469948 · 9781260469943
3. Biochemistry by U. Satyanarayana, U. Chakrapani, Elsevier Health Sciences, 5th edition, 2020. ISBN: 9788131262535
4. A Textbook of Biochemistry, A. V. S. S. Rama Rao UBS Publishers' Distributors Pvt. Limited, 10th Edition, 2006, ISBN 8174765697, 9788174765697
5. Fundamentals of Biochemistry by Deb, A. C. New Central Book Agency (P) Limited, Edition 7th .2014.ISBN:9788173811449, 817381144X
6. Biochemistry by Berg, Jeremy M. Tymoczko, John L., Gatto, Gregory J, Stryer, Lubert. United Kingdom: Macmillan Learning, 7th International ed 2015.ISBN: 9781429276351 (hbk) 1429276355 (hbk)
7. Outlines of Biochemistry by Erice Conn, Paul Stumpf. John Wiley & Sons Publishers, 5TH Edition 2009 ISBN8126509309, 9788126509300

BIOCHEMISTRY – PRACTICALS

Total Credits: 2 **4 hours/week**

COURSE OBJECTIVES

Biochemistry Practicals able to carry out the qualitative analysis of different nutrients such as carbohydrates, protein and lipids. Objectives of the course are:

1. Students learn about safety and precautionary measures, how to handle glassware and minor equipment, and how to prepare laboratory reagents and standard chemical solutions
2. Students learn to analyze carbohydrates, proteins, urine, blood creatinine, blood sugar, and serum total cholesterol
3. Students learn about enzymatic hydrolysis of starch, effect of temperature and effect of substrate concentrate on amylase activity.

COURSE OUTCOMES

1. To recall the qualitative analysis of carbohydrates and proteins
2. To explain the principle involved in estimation of blood glucose and its clinical significance
3. To experiment with determination ofof reducing sugars by DNSA method
4. To test for abnormal constituents present in urine and study their clinical significance.
5. To discuss the amount of proteins, creatinine and cholesterol in blood and study their clinical significance.

COURSE CONTENTS

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 abnormal constituents.
4. Proteins (Biuret method)
5. Determination of blood creartinine
6. Determination of blood sugar
7. Determination of serum total cholesterol
8. Study of 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.

RECOMMENDED BOOKS:

a. Practical biochemistry BY RC Gupta and S Bhargava. New Delhi : CBS Publishers & Distributors Pvt. Ltd, 2023. 6TH Edition ISBN: 9789354660221
b. An Introduction to Practical Biochemistry BY David T. Plummer. Mcgraw hill; 2016 3rd Edition ISBN: 9780070994874
c. Practical Biochemistry for Medical Students. by Rajagopal, G., Ramakrishnan, S., Orient Longman, 1983 ISBN 0861314158, 9780861314157.
d. Practical Clinical Biochemistry. By Harold Varley. CBS Publishers & Distributors Ltd 2005 4th edition. ISBN: 9788123909691.

AI & PYTHON PROGRAMMING FOR PHARMACY II

Credits 2 **30 Hr**

COURSE OBJECTIVES

By the end of this course, students will be able to:

1. Teach the basics of matrices, determinants, eigenvalues / eigenvectors, and core calculus needed for AI and pharmacokinetic modeling.
2. Show how matrix multiplication drives neural-network forward and backward propagation.
3. Use linear algebra and differential equations to build and interpret simple pharmacokinetic models.
4. Explain AI tools that automate dispensing, manage inventory, and spot medication errors in pharmacy practice.
5. Explore AI-based clinical decision support and adherence-tracking systems that improve patient outcomes.

COURSE OUTCOMES

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

1. CO1: Students will calculate determinants, eigenvalues, and perform key matrix operations to prepare data for AI tasks.
2. CO2: Students will solve basic differentiation, integration, and differential-equation problems applied to drug-level prediction.
3. CO3: Students will implement a small neural network and clearly describe how matrix multiplication enables training.
4. CO4: Students will evaluate a pharmacy workflow and recommend AI solutions for dispensing, inventory control, and error prevention.

5. CO5: Students will interpret results from a clinical decision support or adherence-monitoring tool and suggest optimized medication therapy.

COURSE CONTENT:

Unit 1

Matrices and Determinants, Eigenvalues and Eigenvectors

Unit 2

Calculus: Differentiation and Integration, Differential Equation

AI algorithms often represent data as vectors and matrices, making linear algebra essential for data manipulation , analysis. And developing pharmacokinetics model

Unit 3

Matrix Multiplication: This is fundamental for operations in neural networks, enabling forward and backward propagation during model training.

Unit 4

Automated Dispensing and Inventory Management, Predictive Analytics for Inventory, Medication Error Detection, Medication Adherence:

- AI-powered systems can automate tasks like prescription filling (Electronic Prescription), medication packaging (Barcoding), and labelling, reducing errors and minimizing pharmacists' time in interacting with patients.
- AI algorithms can analyse patient data, including medical records and medication profiles, to identify potential drug interactions, adverse reactions, and incorrect dosages, helping prevent medication errors.
- AI-powered systems can track patient adherence & non-adherence to their medication regimen , provide reminders and personalized notifications to promote compliance

Unit 5

Clinical Decision Support Systems (CDSS): AI can be used to develop CDSS that help pharmacists make more informed decisions about medication therapy, leading to improved patient outcomes.

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

SEMESTER III

DOSAGE FORMS : STERILE (THEORY)

Total Credits 3 **Hours / Week : 45 /3L+1T**

COURSE OBJECTIVES :

The objectives of the course to study;

1) To provide students with a systematic understanding of the principles, practices, and regulations involved in the development and evaluation of sterile pharmaceutical products.

2) Various pre-formulation considerations of API and Excipients for development sterile formulations.

3) Various methods and approaches used for formulation and packaging of sterile products.

4) Evaluation of various sterile formulations as per regulatory requirements.

5) Area designing and facilities required for manufacturing as per cGMP guidelines.

COURSE OUTCOMES:

Upon completion of the course the student will have

1. Fundamental Knowledge of sterile dosage forms, including different types such as large volume parenterals (LVP), small volume parenterals (SVP), sterile powders, and ophthalmic preparations.
2. Understand the Pre-Formulation Principles relevant to parenteral formulations, including the selection and role of additives, containers, and closures for effective formulation design.
3. Knowledge of step-by-step procedures involved in the manufacturing, aseptic processing, sterilization, and packaging of sterile dosage forms, with an emphasis on quality evaluation methods.
4. Understand the Regulatory Guidelines as per current Good Manufacturing Practices (cGMP) related to sterile product facilities, including clean room requirements, environmental control, and disinfection practices, along with the preparation for regulatory audits.
5. Specific knowledge on the formulation, evaluation, and regulatory requirements of ophthalmic products.
6. Training of Students with Practical Skills in sterile product development, focusing on key evaluation methods such as clarity, leakage, injectability, and sterility testing.

COURSE CONTENT

UNIT I **[9 Hrs]**

Introduction to sterile dosage forms

A. Definition, Concept and Advantages& disadvantages
B. Types of Parenteral Route of Administration, Advantages and LimitationsTypes of parenteral formulation (depending on volume and dosage form) Advantages and Limitations

C. General Requirements (Sterility, Pyrogen, Particulate Matter, Isotonicity, Specific Gravity, Chemical Purity, Stability)

D. Water for Injection and its Types, Pharmacopoeial Requirements, Preparation and Storage (SOPs and Industrial Documentation).

UNIT II **[8 Hrs]**

Pre-formulation of parenterals

A. Physico-chemical Properties related to Parenteral Formulation

Formulation consideration Vehicles, Co-solvents, Surfactants, Buffers, Tonicity adjuster, Chelating agents, Preservatives, Stabilizers, Antioxidants.

B. Containers and Closures – Selection Factors, Types, Materials – Advantages and Limitations, Evaluation,.

UNIT III **[10 Hrs]**

Formulation and packaging evaluation

A. Steps Involved in Parenteral Manufacturing (LVP, SVP, Suspension, Emulsion) along with DMF

B. Aseptic Processing

C. Sterile Powder for reconstitution and Lyophilization

D. Evaluation Methods (Mainly through Practical) – Clarity, Leakage, Injectability, Syringability, Endotoxin, Sterility, Particulate matter fill volume , extractable volume)

E. Filling and Sealing of Vials, Ampoules, Form, Fill and Seal Technology

F. Labeling

UNIT IV **[9 Hrs]**

Facilities and regulatory guidelines

A. cGMP Guidelines on Parenteral Facilities, Clean Room Design: Engineering Concepts, Equipments, Personnel, Environment Control. Clean room design Softwares (DIT /Autodesk) and certification system.

B. Isolation Technology

C. Disinfection and Sanitation

D. CMC Documentation for Parenteral Section, List of SOPs and Audit Preparation – Case Study

UNIT V **[9 Hrs]**

Ophthalmic formulation, control and evaluation

A. Definition and Classification (various types such as Liquid Ophthalmic Drug Forms, Solid Ophthalmic Drug Forms, Semisolid Ophthalmic Drug Forms)

B. Formulation Consideration (Physiological and pharmaceutical factors)
C. Excipients for Ophthalmic formulations
D. (improvement of residence time and permeability)
E. Evaluation and Quality Control
F. Introduction to specialized ophthalmic products Ocular insert , mini disk, artificial tears, collagen shield , contact lenses

RECOMMENDED BOOKS:

1. Pharmaceutical Dosage Forms – Parenteral Medication Vol. 1-3, Edited by Kenneth E. Avis, Herbert A. Lieberman and Leon Lachman
2. Sterile Dosage Forms: Their Preparation and Clinical Application" by Salvatore J. Turco and Robert E. King
3. Pharmaceutical Quality Control. Akers MJ 2002 Dekker New York
4. Handbook of Pharmaceutical Excipients, Edited by Paul J Sheskey, Bruno C Hancock, Gary P Moss, David J Goldfarb
5. Injectable Dispersed Systems – Formulations, Processing and Performance Edited by Diane J. Burgess, CRC Press
6. Kenneth E. Avis, Herbert A. Lieberman, Leon Lachman- *Pharmaceutical Dosage Forms – Parenteral Medications (Vol. 1–3),* Marcel Dekker
7. Leon Lachman, H.A. Lieberman, Joseph B. Schwartz, *The Theory and Practice of Industrial Pharmacy* (3rd Ed.)
8. Remington (Editor: Adejare, A.), *The Science and Practice of Pharmacy* (23rd Edition)
9. Aulton, M.E. & Taylor, K.M.G., *Aulton's Pharmaceutics – The Design and Manufacture of Medicines*

DOSAGE FORMS: STERILE (PRACTICAL)

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

COURSE OBJECTIVE

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

1. Understand the principles of formulation and evaluation of sterile dosage forms such as injections, eye drops, and parenteral nutrition.

2. Use aseptic practices, sterility testing procedures, and SOPs to guarantee product safety and efficacy.

3. Explain the physical and chemical parameters influencing the stability and compatibility of sterile preparations.

4. Assess various packaging materials like glass, plastic, and rubber closures used for parenteral products.

5. Create technical documents like dossiers, SOPs, and plant layouts as per regulatory standards.

6. Prove to be able to perform quality control tests like LAL testing, measurement of tonicity, and injectability tests.

COURSES OUTCOME

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

1. Define the minimum requirements, compositions, and forms of sterile drug products such as injections and eye drops

2. Formulate and test sterile preparations like calcium gluconate, ascorbic acid injection, and total parenteral nutrition with proper aseptic procedures.

3. Conduct analytical experiments like tonicity determination, LAL test, and sterility testing by direct inoculation and membrane filtration.

4. Evaluate the integrity and suitability of packaging materials such as rubber closures, plastic bottles, and glass ampoules for sterile products.

5. Create standard operating procedures (SOPs) for aseptic area operations and assemble a dossier for a parenteral product.

6. Conduct practical evaluations of injectability and syringability of formulations to ensure that they meet pharmacopoeial requirements

COURSE CONTENT

1. To prepare and evaluate calcium gluconate injection
2. To prepare and evaluate Ascorbic Acid injection
3. To prepare and evaluate Ringer lactate LVP alongwith measurement of tonicity
4. To carry out the sterility test by direct inoculation method of marketed formulation

5. To carry out LAL test of marketed formulation
6. To prepare and evaluate eye drop
7. To carry out evaluation test for plastic as a packaging material for parenteral formulation
8. To perform evaluation of Glass as packaging material for parenteral formulation
9. To perform various evaluation test on rubber closures for parenteral formulation
10. To check syringability and injectability of the formulation
11. To prepare a complete Dossier for parenteral formulation
12. To develop SOP for working in aseptic area
13. To prepare total parenteral nutrition infusion
14. To perform a sterility test by membrane filtration method
15. To draw the plant layout of the parenteral formulation department.

Note: Minimum 12 experiments must be performed

RECOMMENDED BOOKS

1. **N.K. Jain-** *Pharmaceutical Product Development*
2. **Kenneth E. Avis, Herbert A. Lieberman, Leon Lachman-** *Pharmaceutical Dosage Forms – Parenteral Medications (Vol. 1–3)*
3. **Michael J. Akers-** *Sterile Drug Products: Formulation, Packaging, Manufacturing and Quality*
4. **Paul J. Sheskey et al.-** *Handbook of Pharmaceutical Excipients*
5. **Diane J. Burgess (Ed.)-** *Injectable Dispersed Systems – Formulation, Processing and Performance*
6. **Swarbrick, J. (Ed.)-** *Encyclopedia of Pharmaceutical Technolog*

CHEMISTRY OF AROMATIC AND HETEROCYCLIC COMPOUNDS (THEORY)

Total Credits: 3 **3 hours/ Week** **45 hours**

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

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: (3 hrs)**
   a. Methods to prepare carboxylic acids (Oxidation of alcohols, carbonation of Grignard reagent, Kolbe-Schmidt reaction) **(1 hr)**
   b. Study of acidity of carboxylic acids and effect of substituents on acidity **(1 hr)**
   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) **(1hr)**
2. **Aliphatic and aromatic amines (4 hrs)**
   a. Methods to prepare amines (Reduction of nitro compound, reduction of nitriles and Hofmann degradation of amides) **(1 hr)**
   b. Study of basicity of amines and effect of substituents on basicity **(1 hr)**
   c. Study of mechanism and synthetic applications of diazonium salts including Sandmeyer's and azo-dye coupling reaction **(2 hrs)**
3. **Alcohols and Phenols: (4 hrs)**

a. Classification of alcohols, methods to prepare alcohols (oxymercuration - demercuration, reduction of carbonyl compounds) **(1 hr)**

b. Acidity of alcohols **(1 hr)**

c. Definition of phenols, method to prepare phenols by cumene process. Comparison of the acidity of phenol vs alcohol **(1 hr)**

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) **(1 hr)**

4. **Chemistry of polynuclear hydrocarbons: (4 hrs.)**

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

UNIT III Geometrical isomerism: 06 hours

1. Nomenclature of geometrical isomers (Cis & Trans, E & Z, Syn & Anti system) **(2 hrs)**
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 **(2 hrs)**

UNIT IV Chemistry of five membered heterocycles 10 hours

1. IUPAC nomenclature and classification of heterocyclic compounds as per the Hansch-Widman system **(4 hrs)**
2. Relative aromaticity and reactivity of pyrrole, furan and thiophene **(1 hr)**
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) **(1 hr)**

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 **(3 hrs)**
2. Chemical structures of Indole, pyrimidine, benzimidazole, purine, azepine, pyrazole, oxazole, Phenothiazine, benztriazole, quinoxaline **(1 hr)**
3. Basicity of imidazole, pyridine and quinolone **(1 hr)**
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 **(2 hrs)**

RECOMMENDED BOOKS

1. Organic Chemistry, by Robert Thornton Morrison, Robert Neilson Boyd and Saibal Kanti Bhattacharjee, Pearson Education India, 7th edition, 2010, (ISBN 9788131704813).
2. Organic Chemistry, Vol. 1, by IL FINAR, Pearson Books, 6th Edition, 1 January 2002, (ISBN-13. 978-8177585421).
3. Organic Chemistry, Stereochemistry and Natural Products, Vol. 2, by IL FINAR, 6th Edition, 1 January 2002, Pearson Books, (ISBN-13. 978-8177585421).
4. Pharmaceutical Organic Chemistry (Part-1 Heterocyclic and Natural Products), by Rama Rao Nadendla, Vallabh Publications, 2nd Edition, 2018.
5. Heterocyclic Chemistry, By Thomas L Gilchrist, Prentice Hall Publication, 3rd Edition, 1997, (ISBN-13. 978-0582278431).
6. Principles of Pharmaceutical Organic Chemisty, by Rama Rao Nadendla, PharmMed Press, 2nd Edition, 2018, (ISBN 978-93-5230-197-3).

CHEMISTRY OF AROMATIC AND HETEROCYCLIC COMPOUNDS (PRACTICAL)

Total Credits: 2 **4 hours/week**

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

1. To draw organic compound structures using chemical drawing tools.
2. To explain and apply techniques for purification and characterization of organic compounds.
3. To synthesize organic compounds through practical laboratory methods.
4. To analyze and separate binary organic mixtures using suitable experimental techniques.
5. **To estimate molecular properties of aromatic organic and heterocyclic compounds.**

COURSE CONTENTS

1. Prepare, purify and characterize (by physical constant/TLC/IR) 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. Benzil from benzoin by oxidation reaction.

g. Synthesis of 3,5-dimethyl pyrazole from acetylacetone.

h. Synthesis of benzimidazole from ortho phenylene diamine

i. Synthesis of phenothiazine from diphenyl amine

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 4th Edition, 2009, (ISBN: 13. 978-8131727102).

2) Introduction to Organic Laboratory Techniues: A Small Scale Approach, by Donald L. Pavia, Gary M. Lampman, George S. Kriz,Brooks/Cole, 3rd Edition, 2010, (ISBN: 978-0538733281).

3) Heterocyclic Chemistry, by Raj K Bansal, New Age International, 5th Edition, 2020, (8122412122).

GENERAL PHARMACOLOGY AND RECENT ADVANCES (THEORY)

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

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 to drug 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.

d) Novel Drug Delivery Systems and Basic concepts of nano pharmacology.

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

protein binding and its therapeutic importance.

c) Drug biotransformation, microsomal, non-microsomal metabolism and cytochrome P450 enzyme system, phase I and II reactions, first-pass metabolism, entero-hepatic cycling, concept of prodrugs.

d) Drug excretion and its kinetics.

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

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.

GENERAL PHARMACOLOGY AND RECENT ADVANCES (PRACTICAL)

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

COURSE OBJECTIVES

- To understand the historical and foundational aspects of experimental pharmacology
- To develop knowledge and practical awareness of ethical and regulatory standards in laboratory animal care and use, as outlined in CCSEA guidelines
- To acquire skills in pharmacological data acquisition and analysis
- 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,
- 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

- Identify and describe the pharmacological actions of drugs on different physiological systems and understand their therapeutic relevance.
- Design basic pharmacological experiments and analyse the results to determine drug efficacy and safety.
- Apply the knowledge of drug mechanisms and interactions to predict clinical outcomes.
- Develop skills for documentation, data collection, and report preparation of experimental pharmacological investigations.
- Understand the importance of pharmacology in drug development, clinical research, and its application in medical practice

CONTENTS OF COURSE

1. To describe the contributions of renowned pharmacologists and their discoveries based on pharmacological experiments (Any 5 Noble Laureates whose research contributed to the development of Pharmacology).

2. To study various laboratory safety precautions, hazards, personal hygiene, commonly used tools, devices and instruments in experimental pharmacology.
3. To study common experimental animals including transgenic animals along with their applications in the pharmacological experiments in current drug discovery paradigm.
4. To study concept of 3Rs along with the maintenance and experimentation on laboratory animals as per the CCSEA guidelines.
5. To demonstrate collection/isolation of the following biological samples- blood, cerebrospinal fluid, DNA and RNA using computer simulations and audiovisual aids.
6. To study important anaesthetics and euthanasia procedures for experimental animals.
7. To demonstrate different routes drug administration using computer simulation and understand the significance of each route along with the maximum administrable dose.
8. To study preparation of different types of physiological salt solutions (PSS), cell culture media and to understand the role of each ingredient used in PSS preparation.
9. To study the instrumentation used for isolated tissue experiments (students organ bath assembly) and recent development in recording of the responses of isolated tissues.
10. To record the dose response curve of any two agonists on suitable isolated tissue preparation using computer simulation experiment.
11. To study the potentiating effect of physostigmine on DRC of acetyl choline through interactive computer simulation.
12. To study antagonizing effect of d-tubocurarine on the DRCs of acetylcholine through interactive computer simulation.
13. To determine of PD2 of given agonists using isolated tissue preparation using computer simulation experiment.
14. To study and determine various pharmacokinetic parameters (Cmax, tmax, KE, t1/2, Vd, Clt, AUC, AUMC) from a given hypothetical data.
15. To estimate LD 50 by using the given of hypothetical data using computer simulation experimentation (as per OECD 425 guideline using opensource AOT software).
16. 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 Publisher

5. OECD guidelines for toxicity and Safety Pharmacology
6. ICH guideline 7A and 7B.

PHARMACEUTICAL MICROBIOLOGY
(THEORY)

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

COURSE OBJECTIVES:

The objectives of the course to study;

1) Various microorganisms used for used for the production of alcohol, antibiotics, vaccines, vitamins enzymes etc.

2) Fundamentals of microbiology and its utilization in pharmaceutical field.

3) Various routes of microbial contaminations and methods to control it.

4) The theory and equipment used for sterilization.

5) Various methods of evaluation and testing of microbial contamination.

COURSE OUTCOMES:

Upon completion of this course, the students should:

1) Identify, grow and differentiate pharmaceutically useful microorganisms.

2) Understands the importance and implementation of sterilization in pharmaceutical processing and industry

3) Ability to carry out and interpret microbiological standardization of Pharmaceuticals.

4) Understanding and implementation of various measures to prevent microbial contamination.

5) Know various facilities and areas for pharmaceutical manufacturing as per regulatory agencies.

6) Understand the cell culture technology and its applications in pharmaceutical industries.

COURSE CONTENT

UNIT I **[6 Hrs]**

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.
- Antibiotics produced by microbiology (Production and uses of Penicillin, streptomycin, cephalosporin)

UNIT II **[6 Hrs]**

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.

UNIT III **6 Hrs**

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 Hrs**

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 Hrs**

Microbiological quality control

- Microbial limit tests and Microbial assay and effectiveness (Agar cup plate and inoculation method)
- Sterility testing of products according to IP, BP and USP
- 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)

PHARMACEUTICAL MATHEMATICS

Credit 1 **15Hrs**

COURSE OBJECTIVES:

1. To apply algebraic methods in pharmaceutical calculations and pharmacokinetics.
2. To solve linear systems using matrices and determinants in drug modeling.
3. To use calculus and differential equations in analyzing drug kinetics.

COURSE OUTCOMES

1.Apply algebraic methods including partial fractions, logarithms, and functions to solve problems in pharmaceutical calculations and pharmacokinetics.
2.Solve systems of linear equations using matrices and determinants to model and analyze pharmacokinetic and drug distribution processes.
3.Use concepts of calculus and differential equations to interpret drug concentration-time relationships and evaluate rates of drug absorption and elimination.**COURSE CONTENT**

UNIT I **4 Hr**

Partial Fractions, Logarithms, and Functions:

Rational, proper, improper fractions- Decomposition into partial fractions, Logarithms- laws, characteristic and mantissa , Real-valued functions, types- Limits and continuity

UNIT II **4 Hr**

Matrices and Determinants: Matrix types, operations, inverse- Determinants: minors, cofactors, Solving linear equations- Cramer's rule

UNIT III **4 Hr**

Calculus and Analytical Geometry:

Differentiation-standard functions, product&quotient rules, maxima& minima, Integration- basic methods, definite integrals Analytical geometry- distance, slope, line equations

UNIT IV **3 Hr**

Differential Equations:
Differential equations - order and degree, separable, linear, exact

REFFERENCE BOOKS

1. Higher Engineering Mathematics by B.S. Grewal
2.Pharmaceutical Mathematics - B. S. Mathur
3. Pharmaceutical Statistics - Sandhya Bhat and Indra Prakash Yadav

ETHICS AND UNIVERSAL HUMAN VALUES

Credit 1 — 15 Hr

COURSE OBJECTIVE:

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 CONTENT:

UNIT I: Introduction to Value Education

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

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

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 FORMULATION & PREFORMULATION

Credits 2 **30 Hr**

COURSE OBJECTIVES

By the end of this course, students will be able to:

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. CO1: Students will describe the role of AI across pre-formulation workflows.
2. CO2: Students will generate regression models that estimate solubility, melting, and boiling points from molecular descriptors.
3. CO3: Students will apply ML tools to analyze fluid flow, particle separation, and predict viscosity curves.
4. CO4: Students will implement an AI-based control strategy that identifies process faults before they occur.
5. CO5: Students will develop neural-network models that accurately predict stability and release profiles under varied conditions.

COURSE CONTENT:

Unit 1

- Introduction to AI in Pre formulation Studies

Unit 2

- AI-Driven Strategies to Address Poor Solubility and bioavailability enhancement
- Regression model for predict melting/boiling points from molecular descriptors

Unit 3

- Artificial Intelligence with predictive learning to analyze fluid dynamics, particle behavior, and separation techniques
- AI/ML Algorithms for Predicting Viscosity and Rheological Behavior

Unit 4

- Process Optimization and Control: using AI to predict & prevent equipment failures & improve product quality

Unit 5

- Artificial neural network-based degradation pathways and shelf life prediction at various conditions
- Machine learning algorithm to predict drug release kinetics

RECOMMENDED BOOKS

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

SEMESTER IV

HERBAL DRUG TECHNOLOGY (Theory)

Credits 3 **45 Hours**

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 (COS): 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 CONTENT:

UNIT-I **09 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 12 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 **05 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

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). *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

HERBAL DRUG TECHNOLOGY (Practical)

Credits 2 **4 hours/Week**

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 (COS):

After successful completion, students will be able to:

CO1: Perform seed germination and plant tissue culture of medicinal plants.

CO2: Prepare and standardize various herbal extracts and phytochemical-rich fractions.

CO3: Formulate and evaluate herbal cosmetics and dosage forms.

CO4: Prepare and characterize phytosome-based herbal delivery systems.

CO5: Evaluate quality of marketed herbal formulations following pharmacopoeial **guidelines.**

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 Bacopa

d) 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 (THEORY)

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

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. Elucidate the mechanisms of action of various drug classes, including those affecting the autonomic nervous system, cardiovascular system, blood and renal function, and autacoids.
4. Apply the principles of structure-activity relationships (SAR) to predict and explain the pharmacological activity of selected drug classes.
5. Describe the synthesis of selected drugs from different therapeutic categories, focusing on key reaction steps and chemical transformations.
6. 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, explain their mechanisms of action, 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; stereochemical considerations
- **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, bromide, 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. **Congestive Heart Failure (CHF) Drugs:** 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 Drugs 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*, Phenidamine 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 and analgesics:** 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. An Introduction to Medicinal Chemistry – Graham L. Patrick
2. Foye's Principles of Medicinal Chemistry – David A. Williams, Thomas L. Lemke
3. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry – John H. Block, John M. Beale
4. Drug Design and Development: From Practice to Concept – Robin Ganellin
5. Goodman & Gilman's The Pharmacological Basis of Therapeutics – Laurence L. Brunton et al.
6. Antibiotics and Antibiotic Resistance – Vincent Courcelle and Patrice Nordmann

MEDICINAL CHEMISTRY (PRACTICAL)

Total Credits: 2 **4 hours/week**

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

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. Phenothiazine
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. Ketamine hydrochloride
    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. Textbook of medicinal chemistry by Alagarsamy V
4. Indian pharmacopoeia

SYSTEMATIC PHARMACOLOGY AND AUTACOIDS (THEORY)

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

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 class of drugs
3. To provide understanding of the classification and pharmacology of drugs acting on Peripheral nervous system, cardiovascular system, urinary system and autacoid 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.

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 the 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 covered in the course

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,

bradykinin and substance P.

b) Histamine and antihistamines.

c) 5-HT, its agonists and antagonists, drugs used in migraine.

d) Non-steroidal anti-inflammatory drugs, antipyretics and analgesics.

e) Anti-gout and Antirheumatic drugs including Disease Modifying Antirheumatic Drugs (DMARDs).

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.

SYSTEMATIC PHARMACOLOGY AND AUTACOIDS (PRACTICAL)

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

COURSE OBJECTIVES

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

- To describe the drug effects on blood pressure, heart rate, and understand their relevance to cardiovascular pharmacotherapy through virtual simulations.
- To evaluate the pharmacological management of asthma, analyse drug actions on the respiratory system, and correlate them with clinical data.
- To interpret experimental data, calculate and analyse PA2 values, plot standard curves, and estimate drug effects using hypothetical data from computer simulations.

- To present the case studies and explore drug interactions and rational drug management in cardiovascular situations and asthma, applying pharmacological knowledge to patient care.
- To demonstrate competence in various pharmacological measurements, such as intraocular pressure estimation, nitric oxide estimation in plasma, and spirometry.
- 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.
- 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 interaction/ rational drug management of asthma (Drug-drug) 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.
4. Practical Pharmacology, Goyal R K. Publisher: B. S. Shah Publisher

PHRMACEUTICAL BIOTECHNOLOGY (THEORY)

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

COURSE OBJECTIVES:

The objectives of the course to study;

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.

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 CONTENT

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 **[6 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.

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.

Unit V **[6 Hours]**

Vaccine types and generations, Immunization, Immunology of vaccines. Preparation, evaluation and standardization of vaccines and sera. Regulatory consideration of vaccines and Sera. Marketed products of vaccines and sera, Challenges to vaccine and sera success, 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

PHARMACEUTICAL BIOTECHNNOLOGY AND MICROBIOLOGY (PRACTICAL)

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

COURSE OBJECTIVES :

The objectives of the course to study;

4. To provide fundamental knowledge on biotechnology concepts, including protein therapeutics, monoclonal antibodies, enzyme immobilization, and their pharmaceutical applications.
5. Knowledge of genetic engineering and recombinant DNA technology for pharmaceutical applications.
6. 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.
7. 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 CONTENT

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 A John Wiley & Sons, 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 (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 CONTENT:

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 Drug Use, 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/)

DRUG DESIGN AND DISCOVERY (THEORY)

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

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 modelling 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. Drug development pipeline: From target to market
3. Disease linkage and types of biological targets
4. Challenges in Drug Discovery
5. 2D & 3D representations of chemical structure
6. Molecular properties/descriptor and Lipinski's Rule of Five
7. Computer Aided Drug Design (CADD) and Its applications
8. Various software and modules used in CADD and its applications (Both open source and commercial)
9. Chemical and Biological databases including natural, small molecule and protein databases like PubChem, ChEMBL, DrugBank, Zinc, Coconut, RCSB, NCBI etc.
10. Energy minimization and force fields
11. Drug – receptor interactions

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

1. Target identification using public databases
2. 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 modelling
3. Prediction of binding energy of ligand-receptor complex
4. Molecular similarity and similarity searching
5. Molecular dynamics
6. Drug repurposing
7. Case studies:

a. Imatinib, Oseltamivir, Atorvastatin, Sildenafil, drugs for neglected diseases

b. Biosimilars: Trastuzumab

8. 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-MODELMolecular 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- SwissADME, pkCSM, Qikprop*, ProTox 3.0likeness

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

RECOMMENDED 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

ENVIRONMENTAL SCIENCES (Theory)

Credit 1 **15 hours**

COURSE OBJECTIVES:

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 OUTCOME:

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 CONTENT:

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

AI IN PHARMA CHEMISTRY, ANALYSIS & BIOINFORMATICS

Credits 2 **30 Hr**

COURSE OBJECTIVES

By the end of this course, students will be able to:

1. Introduce AI tools and databases that speed drug discovery, including ADMET, QSAR, and drug-repurposing workflows.
2. Explain deep-learning algorithms used in bioinformatics and their role in target identification and hit expansion.
3. Teach AI-guided enzyme design and engineering techniques for improved catalytic performance.
4. Demonstrate AI systems that predict stereochemistry, plan syntheses, and forecast solubility and stability of compounds.
5. Develop practical skills in applying AI to pharmaceutical analysis, process control, and spectroscopic data interpretation.

COURSE OUTCOMES

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

1. CO 1: Students will retrieve data from major biological repositories and run an AI model to predict ADMET or activity for a lead molecule.
2. CO 2: Students will execute a deep-learning pipeline that aligns protein sequences, models a structure, and proposes ligands in silico.
3. CO 3: Students will build an AI model that suggests enzyme mutations and evaluate its predictions against experimental benchmarks.
4. CO 4: Students will generate an AI-driven synthetic route with predicted stereochemical outcomes and reaction conditions for a target drug.
5. CO 5: Students will apply chemometric and six-sigma AI tools to interpret spectroscopic or chromatographic data and verify product quality.

COURSE CONTENT:

Unit 1

Role of Artificial intelligence (AI) in accelerating drug discovery

a. Introduction to Databases and Resources for major repository of biological data to carry out protein structure predictions.

b. Artificial Intelligence in ADMET prediction, Insilico prediction of activity, Drug design, QSAR studies, Drug Repurposing,

Unit 2

Artificial Intelligence in Bioinformatics: Algorithms, Applications, and Advances, Deep learning-based methods to drug discovery

Unit 3

Enzyme Design & Engineering

Artificial Intelligence in prediction of stereochemical outcomes of reactions and symmetric synthesis by analyzing reaction conditions and catalysts, Reaction Prediction & Synthesis Planning

Unit 4

AI models to predict properties, concepts, and their applications. AI-Driven Prediction of Solubility & Stability of Inorganic Compounds, Study of inorganic drug interactions via molecular simulations and their parameters,

Unit 5

Artificial Intelligence in Pharmaceutical Quantitative and Qualitative Analysis, Leveraging AI and machine learning in six-sigma documentation for pharmaceutical quality assurance, Process Analytical Technology, AI in Analytical Instrumentation and Quality Control, Role of Artificial Intelligence in Spectroscopic Data Analysis and Error Detection, Chemometric assisted quantitative estimation of drug in formulation by Spectroscopy, Artificial Intelligence in Interpretation of Advanced Spectroscopic and Chromatographic Data, Interpretation of NMR spectra for structural elucidation using AI

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. Enzyme Engineering: Selective Catalysts for Applications in Biotechnology, Organic Chemistry, and Life Science— Zhoutong Sun & Ge Qu (eds.) — Wiley-VCH, 2023
4. Machine Learning in Chemistry: The Impact of Artificial Intelligence — Hugh M. Cartwright (ed.) — Royal Society of Chemistry, 2020
5. Chemometrics in Spectroscopy (2nd Ed.) — Howard Mark & Jerry Workman Jr. — Academic Press/Elsevier, 2018

SEMESTER V

BIOMEDICAL CHEMISTRY (Theory)

Credits 3 **45 Hours**

Course Objectives: The primary objectives of this course are to;

1. Study the basic principles and fundamental concepts of medicinal Chemistry
2. Understand the drug metabolic pathways, mechanisms and therapeutic value of drugs.
3. Understand the classification, structure, structure–activity relationships (SAR), and synthesis of drugs affecting the autonomic nervous systems.
4. Know the classification, structure, SAR, and synthesis of drugs acting on **Cardiovascular System**
5. Explore the classification, structure, SAR, and synthesis of the Drugs acting on blood **and Renal** drugs
6. Know the classification, structure, SAR, and synthesis of the Autacoids and related drugs

Course Outcomes (COs): Upon completion of the course, students shall be able to;

CO 1: Describe the classification, structure, structure–activity relationships (SAR) and synthesis of drugs acting the central nervous systems.

CO-2: Explain the classification, SAR, and synthesis of **Anti-Infective Chemotherapeutic Agents**.

CO 3: Explain the classification, structure, SAR, and synthesis of Antibiotics **and Sulfa Drugs**

CO 4: Explore the classification, structure, SAR, and synthesis of Antineoplastic Agents

CO 5: Explore the classification, structure, SAR, and synthesis of the **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

Isoniozid*, 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, Sulphamethizine, 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
Current concepts in drug design by T. Durai Ananda Kumar
Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry
Organic medicinal and Pharmaceutical Chemistry.
Foye's Principles of Medicinal Chemistry.
Burger's Medicinal Chemistry, Vol I to IV.
Introduction to principles of drug design- Smith and Williams.
Remington's Pharmaceutical Sciences.
Martindale's extra pharmacopoeia
Organic Chemistry by I.L. Finar, Vol. II.
The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
Indian Pharmacopoeia.
Text book of practical organic chemistry- A.I.Vogel
An Introduction to Medicinal Chemistry – Graham L. Patrick
Foye's Principles of Medicinal Chemistry – David A. Williams, Thomas L. Lemke
Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry – John H. Block, John M. Beale
Drug Design and Development: From Practice to Concept – Robin Ganellin
1. Goodman & Gilman's The Pharmacological Basis of Therapeutics – Laurence L. Brunton et al.
2. Antibiotics and Antibiotic Resistance – Vincent Courcelle and Patrice Nordmann

BIOMEDICAL CHEMISTRY (PRACTICAL)

Total Credits: 2 **2 hours/week**

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 (THEORY)

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

COURSE OBJECTIVES

Upon completion of the course the student shall be able to

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

COURSE OUTCOMES

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

PHARMACEUTICAL ANALYSIS (PRACTICAL)

Total Credits: 2 **4 hours/week**

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

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

1. Determination of the endpoint of a weak acid and strong base by potentiometric titration.
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 injection by flame photometry
11. Assay of potassium chloride injection 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 GLC

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

SYSTEMATIC PHARMACOLOGY AND CHEMOTHERAPY (Theory)

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

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 and 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: 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.

SYSTEMATIC PHARMACOLOGY AND CHEMOTHERAPYI (PRACTICAL)

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

COURSE OBJECTIVES

- To provide details on the pharmacological evaluation of the analgesic, antiepileptic, antidepressant, and other drugs acting on CNS.
- To impart knowledge on the bioassay techniques using isolated tissue preparations and study the actions of agonists and antagonists through virtual simulations.
- 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.
- To develop practical knowledge of antibacterial sensitivity testing methods and understand the principles behind them through theoretical details and case studies.

- 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.
- 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:

- 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.
- Assess drug effects on CNS by evaluating the behaviours like learning, memory, and locomotion using interactive simulation methods.
- 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.
- Acquire theoretical knowledge of cell culture, including the handling of equipment and media preparation, aiding in pharmaceutical research.
- Analyse the results of the antibacterial sensitivity testing and its significance in the choice of chemotherapeutic agents.
- 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 (Theory)

Credits 3 **45 Hours**

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. CO1: Describe the trade status, economic relevance, and institutional support for medicinal plant-based industries in India.
2. CO2: Explain and apply the principles of standardization and production of herbal extracts, volatile oils, and classical formulations.
3. CO3: Demonstrate analytical skills using modern spectroscopy and chromatography techniques for herbal drug analysis.
4. CO4: Isolate, characterize, and analyze important phytoconstituents used in the pharmaceutical and nutraceutical industries.
5. CO5: Interpret international regulatory requirements, safety, efficacy, and pharmacopoeial standards for herbal products.

COURSE CONTENT

UNIT-I 08 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, working 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*.

INDUSTRIAL PHARMACOGNOSY (Practical)

Credits 2 **04 Hours/ week**

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:

CO1: Apply chromatographic techniques for isolation and analysis of phytoconstituents.

CO2: Isolate and identify key compounds from medicinal plants.

CO3: Distill and evaluate volatile oils for chemical constituents.

CO4: Prepare herbal drug monographs and assess traditional formulations.

CO5: Conduct community-based studies on traditional medicine practices.

COURSE CONTENT

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.

INNOVATION AND STARTUP ECOSYSTEM

Credits 2 **30 hours**

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:

CO1: Explain the key concepts of innovation, entrepreneurship, and the role of a supportive ecosystem.

CO2: Identify and analyze different types of innovation and their impact on various sectors.

CO3: Evaluate potential business ideas for feasibility and viability within the current market landscape.

CO4: Develop a preliminary business model canvas and outline a strategy for idea validation.

CO5: Participate effectively in innovation and entrepreneurship-related events and competitions.

CO6: 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

Credits 2 **30 Hr**

COURSE OBJECTIVES

By the end of this course, students will be able to:

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. CO 1: Students will create AI-generated anatomical or physiological visualizations and explain the underlying models.

2. CO 2: Students will apply AI algorithms to forecast ADME profiles and map target interactions for small molecules in human, rat, and mouse systems.

3. CO 3: Students will run an AI-driven workflow to identify, rank, and justify potential drug candidates.

4. CO 4: Students will predict adverse drug reactions or toxicities for a given compound set and interpret the safety implications.

5. CO 5: Students will design a personalized treatment concept using AI insights and discuss emerging pharmacology trends.

COURSE CONTENT:

Unit 1 – AI-Enhanced Anatomy & Physiology

- 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

- 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

- AI in Drug Discovery and Development
- AI platforms to identify drug candidates, analyze molecular data, and predict interactions to assess drug efficacy
- AI in Drug Discovery and Preclinical Testing

Unit 4 – AI in Drug Safety & Toxicology

- AI in Drug Safety; AI platform to predict adverse drug reactions (ADRs) and interactions, enhancing the safety profile of medications and ensuring more effective treatment regimens.
- Toxicity prediction of small molecules based on chemical structure

Unit 5 – AI in Personalized Medicine & Future Pharmacology

- AI in Personalized Medicine & Future of Pharmacology

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

SEMESTER VI

PHARMACEUTICAL QUALITY ASSURANCE (THEORY)

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

COURSE OBJECTIVES

Upon completion of the course student shall be able to:

1. Understand the cGMP aspects in a pharmaceutical industry
2. Appreciate the importance of documentation
3. Understand the scope of quality certifications applicable to pharmaceutical industries
4. Understand the responsibilities of QA & QC departments

COURSE OUTCOMES

1. Students will be able to define and differentiate between Quality Control, Quality Assurance, and GMP, and explain their importance in the pharmaceutical industry.
2. Students will be able to apply the principles of TQM and QbD to optimize pharmaceutical manufacturing processes and ensure product quality.
3. Students will be able to interpret and apply ICH guidelines to pharmaceutical development and manufacturing.
4. Students will be able to describe the requirements and benefits of ISO 9000, ISO 14000, and NABL accreditation in ensuring quality and compliance.
5. Students will be able to evaluate and ensure the quality of pharmaceutical manufacturing environments, equipment, raw materials, and warehousing practices.
6. Students will be able to perform and document the calibration and validation of pharmaceutical equipment and analytical methods according to industry standards.

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, ICHQ1 and ICH Q3 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, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.
4. **Warehousing:** Good warehousing practice, materials management

UNIT – III **10 Hours**

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

UNIT – IV **08 Hours**

1. **Complaints:** Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.
2. **Document maintenance in pharmaceutical industry:** Batch Formula Record, Master Formula Record, Drug Master File, CTD & eCTD, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

UNIT – V **07 Hours**

1. **Calibration and Validation:** Introduction, definition and general principles of calibration. Calibration of pH meter, Qualification of UV-Visible spectrophotometer,

electronic balance, IR Spectrophotometer, Fluorimeter, HPLC.

2. General principles of Analytical method Validation as per ICH and USFDA 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.

PHARMACEUTICAL QUALITY ASSURANCE (PRACTICAL)

Total Credits: 2 **4 hours/week**

COURSE OBJECTIVES

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

1. Understand the principles and procedures involved in in-process and finished product quality control testing for solid oral dosage forms (tablets and capsules).
2. Describe the quality control tests applicable to semi-solid preparations and pharmaceutical raw materials/APIs.
3. Explain the quality control testing requirements for primary (glass containers for parenterals) and secondary (cartons/paperboard) packaging materials, as well as rubber closures.
4. Develop Standard Operating Procedures (SOPs) for the operation and maintenance of selected analytical instruments used in pharmaceutical quality control.
5. Explain the principles and perform the calibration of common analytical instruments such as pH meter and analytical balance.
6. Describe the calibration procedures for advanced analytical instruments like UV-Vis Spectrophotometer, FTIR Spectrophotometer, Spectrofluorimeter, and HPLC.
7. Understand the principles and prepare protocols for analytical method validation according to ICH/USFDA guidelines.

COURSE OUTCOMES

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

1. Perform and interpret in-process and finished product quality control tests for tablets and capsules, ensuring compliance with pharmacopoeial standards.
2. Apply appropriate quality control tests to evaluate the quality of semi-solid preparations and pharmaceutical raw materials/APIs.
3. Evaluate the suitability of primary and secondary packaging materials and rubber closures for pharmaceutical products based on relevant quality control tests.
4. Formulate and document Standard Operating Procedures (SOPs) for the effective operation and maintenance of key analytical instruments.
5. Calibrate and verify the performance of fundamental analytical instruments like pH

meters and analytical balances to ensure accurate measurements.

6. Describe and understand the significance of calibration procedures for sophisticated analytical instruments and develop protocols for analytical method validation in accordance with regulatory guidelines.

COURSE CONTENTS

1. In-process quality control and finished products quality control test for tablets.
2. In process quality control and finished products quality control test for capsules.
3. Quality control test for semisolid preparations.
4. Quality control test for raw materials/API's
5. Quality control test for glass containers used for parenterals packaging.
6. Quality control tests for secondary packaging materials – Carton/paper board.
7. Quality control test for rubber closures.
8. Preparation of SOP for operation and maintenance of any two analytical instruments.
9. Calibration of pH meter
10. Calibration of analytical balance
11. Calibration of UV-Vis Spectrophotometer
12. Calibration of FTIR spectrophotometer
13. Calibration of Spectrofluorimeter
14. Calibration of HPLC instrument
15. Protocol preparation for the analytical method validation as per ICH/USFDA guidelines.

RECOMMENDED BOOKS: (LATEST EDITION)

1. Ghosh, S. G. ISO 9000 and Total Quality Management.
2. World Health Organization (WHO). The International Pharmacopoeia. Volumes I-IV.
3. Good Laboratory Practices. Marcel Dekker Series.
4. ICH Guidelines. ISO 9000 and ISO 14000 Guidelines.

5. Indian Pharmacopoeia. Government of India.

ADVANCED PHARMACOGNOSY (TRENDS IN DRUG DISCOVERY FROM NATURAL RESOURCES) (Theory)

Credit 3 **45 Hours**

Upon completion, students will be able to:

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

COURSE OUTCOMES (COS):

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

- **CO1:** Explain reverse pharmacology, traditional knowledge databases, and bioprospecting strategies.
- **CO2:** Analyze herbal formulations using metabolomics, spectral libraries, and chemoinformatics tools.
- **CO3:** Employ modern in-silico and AI techniques in lead identification and optimization from natural products.
- **CO4:** Evaluate preclinical safety, pharmacokinetics, and efficacy of bioactive leads.
- **CO5:** Interpret global IP frameworks and develop strategies for patenting herbal products and protecting traditional knowledge.

- **PO4:** Demonstrate critical understanding of IPR, biopiracy, and global legal frameworks governing natural product patenting.
- **PO5:** Undertake independent research projects aligned with innovation,
- entrepreneurship, and translational pharmacognosy.

COURSE CONTENT:

UNIT-I **06 Hours**

Reverse Pharmacology and Integrative Approaches

Reverse pharmacology and integrative approaches from the AYUSH perspective. Ethnopharmacological approach to bioprospecting. Traditional medicine databases: TKDL, 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 of 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.

10. Balunas, M. J., & Kinghorn, A. D. (2005). Drug discovery from medicinal plants. *Life Sciences, 78*(5), 431–441.
11. 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.
12. Zhang, A., Sun, H., Wang, X. (2012). Recent advances in metabolomics in drug discovery. *Trends in Analytical Chemistry, 32*, 1–14.
13. Karthikeyan, A., Joseph, A., & Nair, B. G. (2024). Medicinal Plant Identification in Real-Time Using Deep Learning Model. *SN Computer Science, 5*, 73. https://doi.org/10.1007/s42979-023-02398-5
14. 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
15. Traditional Knowledge Digital Library (TKDL) – https://www.tkdl.res.in
16. AYUSH Research Portal & Guidelines – https://www.ayush.gov.in
17. National Biodiversity Authority – Nagoya Protocol – https://nbaindia.org
18. WHO – *General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine* – https://www.who.int
19. ICH Guidelines (Q, S, E, M Series) – https://www.ich.org
20. OECD Guidelines for Toxicological Evaluation – https://www.oecd.org
21. SwissADME, AutoDock, Cytoscape – Open-source tools for in-silico pharmacokinetics and docking – http://www.swissadme.ch
22. ICMR – *Standards on Indian Medicinal Plants* – https://main.icmr.nic.in
23. WIPO and WHO – Publications on herbal drug regulation and IPR – https://www.wipo.int | https://www.who.int
24. The Drugs and Cosmetics Act and Rules, Government of India – Legal Text.

BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

Total Credits 3 **Hours / Week : 45 /3L+1T**

COURSE OBJECTIVES :

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

1. Recall the biopharmaceutics and pharmacokinetics principles and how they contribute to drug absorption, distribution, metabolism, and excretion.
2. Recognize the physicochemical and biological properties influencing drug bioavailability and protein binding.

3. Explain, analyze compartmental models describing drug kinetics and apply mathematical equations to pharmacokinetic calculations.
4. Assess bioavailability and bioequivalence studies and understand the significance of in-vitro/in-vivo correlations.
5. Implement the principles of multiple dosing and compute parameters like loading dose, maintenance dose, and steady-state levels.
6. Discuss non-linear pharmacokinetics and the employment of software tools to PK data analysis and simulation.

COURSE OUTCOMES:

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

1. Explain the pharmacokinetic and pharmacodynamic parameters from plasma drug concentration-time curves.
2. Explain and compare the factors affecting drug absorption, distribution, and protein binding with clinical significance.
3. Compare absolute and relative bioavailability and develop protocols for bioequivalence studies.
4. Numerically solve pharmacokinetic equations for one- and two-compartment models via curve fitting, Wagner-Nelson, and Loo-Riegelman methods.
5. Compute and interpret loading doses, maintenance doses, and steady-state concentrations in multiple dosing regimens.
6. Describe the importance of non-linear pharmacokinetics and apply simulation software such as WinNonlin, GastroPlus, and Simcyp for PK modeling.

COURSE CONTENT

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

2 Credits **30 Hours**

COURSE OBJECTIVES:

Upon completion of the course, the student shall be able to understand:

1. To understand the laws and regulations related to the profession of pharmacy in India.
2. To familiarize students with the legal responsibilities and ethical practices of pharmacists.
3. To provide knowledge about various drug regulatory frameworks and their application.
4. The Pharmaceutical legislations and their implications in the development and
5. marketing of pharmaceuticals.
6. The regulatory authorities and agencies governing the manufacture and sale of Pharmaceutical
7. The code of ethics during the pharmaceutical practice

COURSES OUTCOMES (COS)

1. Describe the origin and nature of pharmacy law in India
2. Acquire knowledge about various acts related to practice standards in pharmacy
3. Discuss pharmaceutical legislations and their implications in the development of marketing of pharmaceuticals
4. Interpret the act and rules regulating the profession and practice of pharmacy in India
5. Discuss the application of acts with special reference to the schedule
6. Interpret the fundamentals of Drugs and Magic remedy act from the perspective of pharmacy

COURSE CONTENT:

Unit I – Introduction to Pharmaceutical Legislation (6 Hours)

- Definition and scope of pharmaceutical jurisprudence
- History and evolution of pharmacy laws in India
- Objectives and significance of drug legislation
- Overview of regulatory bodies:
    - **CDSCO** (Central Drugs Standard Control Organization)
    - **PCI** (Pharmacy Council of India)
    - **State Pharmacy Councils**

Unit II – The Pharmacy Act, 1948 and Related Laws (6 Hours)

- Objectives and salient features of the Pharmacy Act, 1948
- Constitution and functions of PCI
- Education regulations, approval of institutions, and registration of pharmacists
- Offences and penalties under the Act
- Introduction to the **Education Regulations (ER-2020)**

Unit III – The Drugs and Cosmetics Act, 1940 and Rules, 1945 (6 Hours)

- Objectives and scope
- Definitions: drug, cosmetic, patent medicine, etc.
- Provisions relating to manufacture, sale, and distribution
- Schedules to the Act (esp. Schedule M, H, H1, X, and Y)
- Licensing requirements for retail and wholesale
- Labeling and packaging rules
- Offences and penalties
- Cosmetics Rule 2020
- Medical Devices Rules 2017

Unit IV – Other Relevant Acts and Rules (6 Hours)

- Narcotic Drugs and Psychotropic Substances Act, 1985
- Key provisions and pharmacist's role
- Drugs Price Control Order (DPCO), 2013

- Price control and NPPA
- Medicinal and Toilet Preparations (Excise Duties) Act, 1955
- Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954
- Overview of Biomedical Waste Management Rules

Unit V – Code of Ethics and Professional Practice (6 Hours)

- Code of Pharmaceutical Ethics by PCI
- Role and responsibilities of a pharmacist in society and healthcare
- Misconduct and disciplinary actions
- Legal provisions related to clinical trials and ethics committees (overview of ICMR & GCP guidelines)
- Intellectual property rights (IPR) basics relevant to pharmacy

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)

ML IN PHARMACOGNOSY & BIOTECH DISCOVERY

Credits 2 30 Hr

COURSE OBJECTIVES

By the end of this course, students will be able 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. CO 1: Learners will produce an AI-generated diet plan and justify its predicted health benefits.
2. CO 2: Learners will build an ML model that forecasts plant growth or metabolite yield from soil, climate, or genomic inputs.
3. CO 3: Learners will classify a crude drug image set with AI and flag potential herb-drug interactions.
4. CO 4: Learners will run an AI pipeline to identify microbes or non-coding RNAs from sequence data and display a phylogenetic tree.
5. CO 5: Learners will create an AI-guided strategy to improve enzyme immobilization or automate cell-structure detection and present the results.

COURSE CONTENT:

Unit 1 – Nutrition & Nutraceuticals

- 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

- 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

- 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

- 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

- 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

SEMESTER VII

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

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 assay**s **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

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

MODERN ANALYTICAL TECNIQUES (PRACTICAL)

Total Credits: 2 **2 hours/week**

COURSE OBJECTIVES

Upon completion of this course, the student will be able 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

1. Interpretation of Proton NMR spectra of known compound (any two)
2. Interpretation of Carbon NMR spectra of known compound (any one)
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. Protocol preparation for conduct of Bioavailability and bioequivalence study as per USFDA Guidelines.
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

PHARMACOVIGILANCE AND MATERIOVIGILANCE (THEORY)

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

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 OUTCOME

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: 30**

COURSE OBJECTIVES:

By completing this course, students will be able 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. Categorize cosmetics and cosmeceuticals according to areas of application and forms of dosage, and outline their formulation excipients. (Understanding – L2)
2. Describe the formulation, preparation, packaging, and assessment of skin, hair, and oral cosmetics, including herbal ones.
3. Show awareness of shampoos, soap, lotion, and decorative cosmetics preparation methods and assessment criteria.
4. Identify and describe the functional function of cosmetic ingredients in treating common skin, hair, and oral diseases.
5. Describe the regulatory agencies (CDSCO, FDA, BIS, ECOCERT, COSMOS), their functions, and labeling/packaging specifications for cosmetic products.
6. Discuss the function of AI in contemporary cosmetic science for individualized skincare, product formulation, and virtual use.

COURSE CONTENT

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 State FDA). Role of BIS in cosmetics regulations, 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)

COSMETICS AND COSMECEUTICALS (PRACTICAL)

Total Credits 2 **Hours / Week: 04**

COURSE OBJECTIVE:

At the completion of this course, students should be able:

1.To provide hands-on experience of developing, preparing, and assessing cosmetic and personal care products.

2.To build an understanding of the scientific concepts and regulatory aspects of cosmetic product production.

3.To offer practical skills in handling herbal, traditional, and semi-solid cosmetic formulations.

4.To reinforce the student's proficiency in sensory evaluation and stability testing of cosmetic products.

5.To enhance awareness regarding labeling standards and consumer safety for cosmetic products.

6.To develop the skill to formulate market-relevant and patient-compatible cosmetic products with suitable excipients and actives.

COURSE OUTCOMES:

At the completion of this course, students should be able to:

1.Describe the composition and role of actives employed in different cosmetic products.

2.Prepare and analyze simple cosmetic products such as cold cream, vanishing cream, lipstick, and shampoo by following standard methods.

3.Design and formulate plant-based cosmetics like tooth gels, hair serum, and face packs by utilizing natural actives.

4.Examine label content of commercial cosmetics to determine legal and regulatory needs.

5.Test functional and aesthetic characteristics of cosmetics such as nail lacquer remover, mascara, and cleansing gel using sensory and performance tests.

6.Formulate and evaluate moisturizing lotions and other skin care products with skin compatibility and stability.

COURSE CONTENT

1) Preparation and evaluation of cold cream and vanishing cream

2) Preparations and evaluation of Lipstick and Lipbalm

3) To prepare and evaluate shampoo

4) Formulation and Evaluation of Herbal Tooth Gel using clove oil

5) Formulation and evaluation of mouthwash and Gargle

6) Formulation and Evaluation of Herbal Hair Serum

7) To study the inner and outer label of marketed cosmetic formulations (at least two different types of cosmetics)

8) To prepare and evaluate solid soap

9) Formulation and evaluation of eye mascara

10) To prepare and evaluate nail lacquer remover

11) To prepare and evaluate cleansing gel

12) Formulation and Evaluation of Herbal Face Pack

13) Preparation and evaluation of Moisturizing lotion

Note: Minimum 12 experiments must be performed

RECOMMENDED BOOKS

1. "Harry's Cosmeticology" (9th Edition) **– *Meyer R. Rosen***
2. "Cosmetic and Toiletry Formulations" (Vol 1–3) **– *Ernest W. Flick***
3. "Handbook of Cosmetic Science and Technology" **– *A.O. Barel, M. Paye, H.I. Maibach***
4. "Textbook of Cosmetology" **– *B.M. Mittal & R.N. Saha***
5. "Herbal Cosmetics Handbook" **– *H. Panda (NIIR Board)***
6. "Cosmeceuticals and Active Cosmetics" **– *R.M. Draelos & L.D. Bissett***
7. "Cosmetic Product Testing: A Comprehensive Guide" **– *W. Wagg.***

INTELLIGENT MANUFACTURING & SMART QA IN PHARMACY

Credits 2 **30 Hr**

COURSE OBJECTIVES

By the end of this course, students will be able 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. CO 1: Learners will build an AI model that recommends optimal tablet or capsule formulations while meeting predefined CQAs.
2. CO 2: Learners will apply ML algorithms with PAT data to detect process deviations and propose corrective actions during scale-up.
3. CO 3: Learners will generate a PBPK simulation for a controlled-release or nanotech delivery system and interpret the predicted ADME profile.
4. CO 4: Learners will analyze marketing datasets with AI to segment customers and propose a targeted product or skincare recommendation.
5. CO 5: Learners will draft an AI-supported regulatory summary that justifies target validation and addresses regional guideline requirements.

COURSE CONTENT:

Unit 1 – AI-Driven Formulation Design

- 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

- 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

- 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

- 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

- 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

SEMESTER VIII

BIOSTATISTICS AND RESEARCH METHODOLOGY

CREDITS 3 **45Hours**

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

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 CONTENT

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

PHARMACEUTICAL MANAGEMENT

Credits 2 **30 Hrs**

COURSE OBJECTIVE

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 OUTCOME

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 CONTENT

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.

PHARMACEUTICAL MARKETING SKILLS FOR INDUSTRIAL PHARMACY LAB

CREDIT 1 **15 Hr**

COURSE OBJECTIVE

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 Outcome:

By 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 CONTENT

1. To study Indian and Global Pharmaceutical Marketing
2. Marketing Communication: To learn about various marketing communication styles.
2. To carry out primary Market Research on Pharmaceuticals & Data Analysis
3. To carry out primary Market Research on OTC products & Data Analysis
4. To learn Marketing Communication skills /Presentation on Pharmaceutical product detailing for healthcare Professionals
5. To learn Marketing Communication skills /Presentation on Pharmaceutical product detailing for consumers/ Design Patient education Program
6. Presentation on OTC products for health care professionals and consumers
7. To design Product Promotion schemes/ Create brand strategy
8. To develop sales strategy for pharmaceutical product focussing on distribution channels and promotional tactics (For Retailers / Distributors)

9. To Design a mock-up or prototype of an E Commerce website for Pharmacy.
10. To design Digital Marketing (Online) campaign for pharmaceutical/ cosmetics utilising social media, Email Marketing and Search Engine Optimization Techniques
11. To create product positioning for a new product including USP

AI IN PHARMACY PRACTICE & PATIENT CARE

Credits 2 **30 Hr**

COURSE OBJECTIVES

By the end of this course, students will be able 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. CO 1: Students will design a simple AI-guided simulation scenario that adapts to learner performance and objectives.
2. CO 2: Students will compare two AI simulation platforms and justify their choice for a specific pharmacy teaching case.
3. CO 3: Students will map an automated dispensing workflow and recommend AI tools to improve accuracy and patient adherence tracking.
4. CO 4: Students will build and interpret a basic machine-learning model that flags potential adverse drug reactions from clinical data.
5. CO 5: Students will analyze public-health datasets with AI techniques to detect emerging trends and propose evidence-based interventions.

COURSE CONTENT:

Unit 1 – AI-Driven Simulation-Based Learning

- AI modeling technologies in simulation-based learning, including student modeling and teacher modeling
- AI-assisted simulation games-based education

Unit 2 – Simulation & Content-Creation Platforms

- Body Interact, SimX, IBM Watson Health, Synthesia, Pictory, Animoto

Unit 3 – Pharmacy Automation & Adherence

- Pharmacy Automation & Medication Dispensing
- Medication Adherence Monitoring (AI-enabled wearables, apps)

Unit 4 – Pharmacovigilance & Safety Monitoring

- Adverse Drug Reaction (ADR) Prediction
- Leveraging AI for medicines and vaccines safety monitoring

Unit 5 – Public Health Analytics

- AI in public health surveillance
- Real-World Big Data Analytics

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.)

List of Recommended Electives (AEC/SEC/VAC/MD courses)

1 Credit electives (15 Hrs /, 1Hr/Week)	**2 Credit electives (30 Hrs /, 2Hr/Week)**
Domain:Pharmaceutical Chemistry	
• Basics of use of AI in Drug Discovery • Green Chemistry • Biosimilars	Omics Science Impurity Profiling Biological targets Pharmaceutical Bioanalysis • Applications of Artificial Intelligence in Drug Discovery • Advanced Medicinal Chemistry • Advanced Pharmaceutical Organic Chemistry
Domain: Pharmaceutics	
• Drug Store Business Management • Industrial safety • Supply Chain Management	• Packaging • Pharmaceutical automation and Documentation • c-GMP
Domain: Pharmacology	
• Health and wellness • Nutrition and Diet	• Pharmacy Practice • Lifestyle and Holistic Medicine • Molecular Pharmacology • Pharmacovigilance Materiovigilance
Domain: Pharmacognosy	
• Panchagavya Ayurveda Formulations • Cultivation of Medicinal Plants and Career Building	• Medicinal Plants for Everyday Health: A multidisciplinary approach • Herbal Cosmetics for industry perspective • Traditional Healing Practices of India • Bioeconomy and Biomanufacturing: Role of Traditional Medicine and Natural Products • Pharmacognosy and Artificial Intelligence • Herbal drugs value addition and amelioration
Domain : Miscellaneous	
• Scientific Writing	• Intellectual Property Right in Pharma • Medical Devices • Regulatory Sciences