

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

1. write the structure, name and the type of isomerism of the organic compound
2. write the reaction, name the reaction and orientation of reactions
3. account for reactivity/stability of compounds,
4. prepare organic compounds

General methods of preparation and reactions of compounds superscripted with asterisk (\*) to be explained

To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

#### UNIT I

10 Hours

- **Benzene and its derivatives**

- A. Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule
- B. Reactions of benzene - nitration, sulphonation, halogenation- reactivity, Friedelcrafts alkylation- reactivity, limitations, Friedelcrafts acylation.
- C. Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction
- D. Structure and uses of DDT, Saccharin, BHC and Chloramine

#### UNIT II

10 Hours

- **Phenols\*** - Acidity of phenols, effect of substituents on acidity, qualitative tests, Structure and uses of phenol, cresols, resorcinol, naphthols
- **Aromatic Amines\*** - Basicity of amines, effect of substituents on basicity, and synthetic uses of aryl diazonium salts
- **Aromatic Acids\*** –Acidity, effect of substituents on acidity and important reactions of benzoic acid.

#### UNIT III

**10 Hours**

- **Fats and Oils**

- a. Fatty acids – reactions.

- b. Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils.
- c. Analytical constants – Acid value, Saponification value, Ester value, Iodine value, Acetyl value, Reichert Meissl (RM) value – significance and principle involved in their determination.

UNIT IV

08 Hours

- **Polynuclear hydrocarbons:**

- a. Synthesis, reactions
- b. Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene, Diphenylmethane, Triphenylmethane and their derivatives

UNIT V

07 Hours

- **Cyclo alkanes\***

Stabilities – Baeyer's strain theory, limitation of Baeyer's strain theory, Coulson and Moffitt's modification, Sachse Mohr's theory (Theory of strainless rings), reactions of cyclopropane and cyclobutane only

**TOTAL: 45 h**

**COURSE OUTCOME:**

At the end of this course the students will be able to,

- CO1: Define various terminologies used in Organic chemistry along with their reactions and reactivity in Aromatic compounds.
- CO2: Give special emphasis on mechanisms and orientation of chemical reactions of Aromatic compounds
- CO3: Classify and Explain the properties, Analysis and significance of organic and biochemical compounds
- CO4: Identify the compounds by qualitative tests, Application and Uses some official organic compounds.

- I Experiments involving laboratory techniques
- Recrystallization
  - Steam distillation
- II Determination of following oil values (including standardization of reagents)
- Acid value
  - Saponification value
  - Iodine value
- III Preparation of compounds
- Benzanilide/Phenyl benzoate/Acetanilide from Aniline/ Phenol /Aniline by acylation reaction.
  - 2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline/
  - Acetanilide by halogenation (Bromination) reaction.
  - 5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid / Nitro benzene by nitration reaction.
  - Benzoic acid from Benzyl chloride by oxidation reaction.
  - Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.
  - 1-Phenyl azo-2-naphthol from Aniline by diazotization and coupling reactions.
  - Benzil from Benzoin by oxidation reaction.
  - Dibenzal acetone from Benzaldehyde by Claisen Schmidt reaction
  - Cinnamic acid from Benzaldehyde by Perkin reaction
  - *P*-Iodo benzoic acid from *P*-amino benzoic acid

**TOTAL: 4 h/Week**

**COURSE OUTCOME:**

At the end of this course the students will be able to,

- CO1: Outline the synthetic procedures of some important medicinal compounds derivatives
- CO2: Discuss the Experiments involving laboratory techniques on Determination of following oil values (including standardization of reagents)

**REFERENCE BOOKS:**

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar , Volume-I
3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
4. Organic Chemistry by P.L.Soni
5. Practical Organic Chemistry by Mann and Saunders.
6. Vogel's text book of Practical Organic Chemistry
7. Advanced Practical organic chemistry by N.K.Vishnoi.
8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.

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

1. Understand various physicochemical properties of drug molecules in the designing the dosage forms
2. Know the principles of chemical kinetics & to use them for stability testing and determination of expiry date of formulations
3. Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.

### UNIT-I

**10 Hours**

**Solubility of drugs:** Solubility expressions, mechanisms of solute solvent interactions, ideal solubility parameters, solvation & association, quantitative approach to the factors influencing solubility of drugs, diffusion principles in biological systems. Solubility of gas in liquids, solubility of liquids in liquids, (Binary solutions, ideal solutions) Raoult's law, real solutions. Partially miscible liquids, Critical solution temperature and applications. Distribution law, its limitations and applications

### UNIT-II

**10Hours**

**States of Matter and properties of matter:** State of matter, changes in the state of matter, latent heats, vapour pressure, sublimation critical point, eutectic mixtures, gases, aerosols – inhalers, relative humidity, liquid complexes, liquid crystals, glassy states, solid-crystalline, amorphous & polymorphism.

**Physicochemical properties of drug molecules:** Refractive index, optical rotation, dielectric constant, dipole moment, dissociation constant, determinations and applications

### UNIT-III

**08 Hours**

**Surface and interfacial phenomenon:** Liquid interface, surface & interfacial tensions,

surface free energy, measurement of surface & interfacial tensions, spreading coefficient, adsorption at liquid interfaces, surface active agents, HLB Scale, solubilisation, detergency, adsorption at solid interface.

UNIT-IV

08Hours

**Complexation and protein binding:** Introduction, Classification of Complexation, Applications, methods of analysis, protein binding, Complexation and drug action, crystalline structures of complexes and thermodynamic treatment of stability constants.

UNIT-V

07 Hours

**pH, buffers and Isotonic solutions:** Sorensen's pH scale, pH determination (electrometric and calorimetric), applications of buffers, buffer equation, buffer capacity, buffers in pharmaceutical and biological systems, buffered isotonic solutions.

**TOTAL: 45 h**

**COURSE OUTCOME:**

At the end of this course the students will be able to,

- CO1: Define about the basics and theories of solubility, solvation, solubility of gases in liquids, liquids in liquids, various laws, states of matter, physico chemical properties of drug, surface and interfacial phenomenon, complexation, protein binding, buffers and pH.
- CO2: Describe about the various solubilities and factors affecting them, various states of matter, physicochemical properties of drug, surface and interfacial phenomenon, complexation and protein binding and pH
- CO3: Identify the various techniques for measuring solubility, types of states of matter, surface and interfacial tension, methods of complexation and protein binding, buffers
- CO4: Explain about the applications of solubility, uses of states of matter, surface and interfacial tension, complexation, protein binding, buffers and pH.

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

1. Determination the solubility of drug at room temperature
2. Determination of pKa value by Half Neutralization/ Henderson Hasselbalch equation.
3. Determination of Partition co- efficient of benzoic acid in benzene and water
4. Determination of Partition co- efficient of Iodine in  $\text{CCl}_4$  and water
5. Determination of % composition of NaCl in a solution using phenol-water system by CST method
6. Determination of surface tension of given liquids by drop count and drop weight method
7. Determination of HLB number of a surfactant by saponification method
8. Determination of Freundlich and Langmuir constants using activated char coal
9. Determination of critical micellar concentration of surfactants
10. Determination of stability constant and donor acceptor ratio of PABA-Caffeine complex by solubility method
11. Determination of stability constant and donor acceptor ratio of Cupric-Glycine complex by pH titration method

**TOTAL: 4 h/Week**

**COURSE OUTCOME:**

At the end of this course the students will be able to,

- CO1: Determination of solubility parameters of the drug and percentage composition of phenol and water system, Solubility parameters of the drug, the surface tension of given liquids by drop count and drop weight method method
- CO2: Find out the HLB determination, CMC and refractive index of given sample of liquids.
- CO3: Estimate the stability constants, freundlich and langmuirs adsorption constants.
- CO4: Report the partition co efficient and pka value of the drug

**REFERENCE BOOKS:**

1. Physical Pharmacy by Alfred Martin
2. Experimental Pharmaceutics by Eugene, Parott.
3. Tutorial Pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical Calculations, Lea &Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, MarcelDekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical Dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C and ManavalanR.
8. Laboratory Manual of Physical Pharmaceutics, C.V.S. Subramanyam, J. Thimma settee
9. Physical Pharmaceutics by C.V.S. Subramanyam
10. Test book of Physical Phramacy, by Gaurav Jain & Roop K. Khar

BP 303 T.	<b>PHARMACEUTICAL MICROBIOLOGY (Theory)</b>	
-----------	---	--

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

1. Understand methods of identification, cultivation and preservation of various microorganisms
2. To understand the importance and implementation of sterilization in pharmaceutical processing and industry
3. Learn sterility testing of pharmaceutical products.
4. Carried out microbiological standardization of Pharmaceuticals.
5. Understand the cell culture technology and its applications in pharmaceutical industries.

### **Unit I**

**10 Hours**

Introduction, history of microbiology, its branches, scope and its importance.

Introduction to Prokaryotes and Eukaryotes

Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count).

Study of different types of phase contrast microscopy, dark field microscopy and electron microscopy.

### **Unit II**

**10 Hours**

Identification of bacteria using staining techniques (simple, Gram's & Acid fast staining) and biochemical tests (IMViC).

Study of principle, procedure, merits, demerits and applications of physical, chemical gaseous, radiation and mechanical method of sterilization.

Evaluation of the efficiency of sterilization methods.

Equipments employed in large scale sterilization.

Sterility indicators.

### **Unit III**

**10 Hours**

Study of morphology, classification, reproduction/replication and cultivation of Fungi and Viruses. Classification and mode of action of disinfectants

Factors influencing disinfection, antiseptics and their evaluation. For bacteriostatic and bactericidal actions

Evaluation of bactericidal & Bacteriostatic.

Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP.

Unit IV

08 Hours

Designing of aseptic area, laminar flow equipments; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification.

Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids.

Assessment of a new antibiotic.

Unit V

07Hours

Types of spoilage, factors affecting the microbial spoilage of pharmaceutical products, sources and types of microbial contaminants, assessment of microbial contamination and spoilage.

Preservation of pharmaceutical products using antimicrobial agents, evaluation of microbial stability of formulations.

Growth of animal cells in culture, general procedure for cell culture, Primary, established and transformed cell cultures.

Application of cell cultures in pharmaceutical industry and research.

**TOTAL: 45 h**

**COURSE OUTCOME:**

At the end of this course the students will be able to,

- CO1: Outline the Prokaryotes and Eukaryotes, microbes and their taxonomy of bacteria, rickettsiae, spirochetes and viruses. .ultra-structure and morphological classification of bacteria, nutritional requirements, culture media growth, growth curve, isolation and preservation methods for pure cultures, total & viable count staining ,
- CO2: Explain physical, chemical gaseous, radiation and mechanical method of sterilization. Evaluation of the efficiency of sterilization methods. Equipments employed in large scale sterilization. Sterility indicators.
- CO3: Classify Fungi reproduction/replication and cultivation of and Viruses. mode of action of disinfectants Factors influencing disinfection, antiseptics and their evaluation. For bacteriostatic and bactericidal actions Evaluation of bactericidal & Bacteriostatic. Sterility testing of pharmaceutical products
- CO4: Explain the Designing of aseptic area, laminar flow equipments; Methods for standardization of antibiotics, vitamins and amino acids. Assessment of a new antibiotic. Evaluation of microbial stability of formulations. Growth of animal cells in culture, general procedure for cell culture, Primary, established and transformed cell cultures. Application of cell cultures in pharmaceutical industry and research.

BP 307P.	PHARMACEUTICAL MICROBIOLOGY (Practical)
----------	---

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

1. Introduction and study of different equipments and processing, e.g., B.O.D. incubator, laminar flow, aseptic hood, autoclave, hot air sterilizer, deep freezer, refrigerator, microscopes used in experimental microbiology.
2. Sterilization of glassware, preparation and sterilization of media.
3. Sub culturing of bacteria and fungus. Nutrient stabs and slants preparations.
4. Staining methods- Simple, Grams staining and acid fast staining (Demonstration with practical).
5. Isolation of pure culture of micro-organisms by multiple streak plate technique and other techniques.
6. Microbiological assay of antibiotics by cup plate method and other methods
7. Motility determination by Hanging drop method.
8. Sterility testing of pharmaceuticals.
9. Bacteriological analysis of water
10. Biochemical test.

**TOTAL: 4 h/Week**

**COURSE OUTCOME:**

At the end of this course the students will be able to,

- CO1: Outline the sterilization of nutrient agar simple staining method Gram's staining method, Acid fast staining method
- CO2: Experiment with the Isolation of pure culture of micro-organisms
- CO3: Analyze the of actinomycetes from soil and motility by hanging drop technique,
- CO4: Explain the concepts of Microbiological assay of antibiotics by cup plate method and other method. Sterility testing of pharmaceuticals Discuss about the and disinfectant by rideal walker co-efficient method.

**REFERENCE BOOKS:**

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4<sup>th</sup> edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.

8. Pepler: Microbial Technology.
9. I.P., B.P., U.S.P.- latest editions.
10. Ananthnarayan : Text Book of Microbiology, Orient-Longman, Chennai
11. Edward: Fundamentals of Microbiology.
12. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
13. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company

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

1. To know various unit operations used in Pharmaceutical industries.
2. To understand the material handling techniques.
3. To perform various processes involved in pharmaceutical manufacturing process.
4. To carry out various test to prevent environmental pollution.
5. To appreciate and comprehend significance of plant lay out design for optimum use of resources.
6. To appreciate the various preventive methods used for corrosion control in Pharmaceutical industries.

#### UNIT-I

10 Hours

- **Flow of fluids:** Types of manometers, Reynolds number and its significance, Bernoulli's theorem and its applications, Energy losses, Orifice meter, Venturimeter, Pitot tube and Rotometer.
- **Size Reduction:** Objectives, Mechanisms & Laws governing size reduction, factors affecting size reduction, principles, construction, working, uses, merits and demerits of Hammer mill, ball mill, fluid energy mill, Edge runner mill & end runner mill.
- **Size Separation:** Objectives, applications & mechanism of size separation, official standards of powders, sieves, size separation Principles, construction, working, uses, merits and demerits of Sieve shaker, cyclone separator, Air separator, Bag filter & elutriation tank.

#### UNIT-II

10 Hours

- **Heat Transfer:** Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers.
- **Evaporation:** Objectives, applications and factors influencing evaporation, differences between evaporation and other heat process. principles, construction, working, uses, merits and demerits of Steam jacketed kettle, horizontal tube evaporator, climbing film evaporator, forced circulation evaporator, multiple effect evaporator & Economy of multiple effect evaporator.
- **Distillation:** Basic Principles and methodology of simple distillation, flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation.

### UNIT- III

08 Hours

- **Drying:** Objectives, applications & mechanism of drying process, measurements & applications of Equilibrium Moisture content, rate of drying curve. principles, construction, working, uses, merits and demerits of Tray dryer, drum dryer spray dryer, fluidized bed dryer, vacuum dryer, freeze dryer.
- **Mixing:** Objectives, applications & factors affecting mixing, Difference between solid and liquid mixing, mechanism of solid mixing, liquids mixing and semisolids mixing. Principles, Construction, Working, uses, Merits and Demerits of Double cone blender, twin shell blender, ribbon blender, Sigma blade mixer, planetary mixers, Propellers, Turbines, Paddles & Silverson Emulsifier,

### UNIT-IV

08 Hours

- **Filtration:** Objectives, applications, Theories & Factors influencing filtration, filter aids, filter medias. Principle, Construction, Working, Uses, Merits and demerits of plate & frame filter, filter leaf, rotary drum filter, Meta filter & Cartridge filter, membrane filters and Seidtz filter.
- **Centrifugation:** Objectives, principle & applications of Centrifugation, principles, construction, working, uses, merits and demerits of Perforated basket centrifuge, Non-perforated basket centrifuge, semi continuous centrifuge & super centrifuge.

### UNIT- V

07 Hours

- **Materials of pharmaceutical plant construction, Corrosion and its prevention:** Factors affecting during materials selected for Pharmaceutical plant construction, Theories of corrosion, types of corrosion and there prevention. Ferrous and nonferrous metals, inorganic and organic non metals, basic of material handling systems.

**TOTAL: 45 h**

### **COURSE OUTCOME:**

At the end of this course the students will be able to,

- CO1: Define the various unit operations involved in pharmaceutical industries ,corrosion control and material handling system.
- CO2: Write the construction and working of various equipments used in unit operation.
- CO3: Explain the principle involved in the various unit operation process .
- CO4: Describe the principle ,classification and applications of various unit operation process.

**REFERENCE BOOKS:**

1. Introduction to chemical engineering – Walter L Badger & Julius Banchero, Latest edition.
  2. Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson- Latest edition.
  3. Unit operation of chemical engineering – McCabe Smith, Latest edition.
  4. Pharmaceutical engineering principles and practices – C.V.S Subrahmanyam et al., Latest edition.
  5. Remington practice of pharmacy- Martin, Latest edition.
  6. Theory and practice of industrial pharmacy by Lachmann., Latest edition.
  7. Physical pharmaceuticals- C.V.S Subrahmanyam et al., Latest edition.
- Cooper and Gunn's Tutorial pharmacy, S.J. Carter, Latest edition.

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

- I. Determination of radiation constant of brass, iron, unpainted and painted glass.
- II. Steam distillation – To calculate the efficiency of steam distillation.
- III. To determine the overall heat transfer coefficient by heat exchanger.
- IV. Construction of drying curves (for calcium carbonate and starch).
- V. Determination of moisture content and loss on drying.
- VI. Determination of humidity of air – i) From wet and dry bulb temperatures –use of Dew point method.
- VII. Description of Construction working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier.
- VIII. Size analysis by sieving – To evaluate size distribution of tablet granulations – Construction of various size frequency curves including arithmetic and logarithmic probability plots.
- IX. Size reduction: To verify the laws of size reduction using ball mill and determining Kicks, Rittinger's, Bond's coefficients, power requirement and critical speed of Ball Mill.
- X. Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such other major equipment.
- XI. Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration and Thickness/ viscosity
- XII. To study the effect of time on the Rate of Crystallization.
- XIII. To calculate the uniformity Index for given sample by using Double Cone Blender.

**TOTAL: 4 h/Week**

**COURSE OUTCOME:**

At the end of this course the students will be able to,

- CO1: Record the radiation constant of brass, efficiency of steam distillation, heat transfer coefficient, drying, humidity, rate of crystallisation, uniformity of index, rate of filtration.
- CO2: Compute interpret drying curves, moisture content, humidity of air, heat transfer coefficient, size analysis by sieving, laws of size reduction.
- CO3: Demonstrate tablet machine, size reduction equipment, dryer, coating machine, dehumidifier.
- CO4: Estimate radiation constant, rate of filtration, efficiency of steam distillation, evaporation, rate of crystallisation.