



## **Chebrolu Hanumaiah Institute of Pharmaceutical Sciences**

Chandramoulipuram, Chowdavaram, Guntur – 522019, Andhra Pradesh.

(Sponsored by Nagarjuna Education Society)

Approved by AICTE & PCI, Affiliated to Acharya Nagarjuna University.

Recognised by Govt. of Andhra Pradesh, An ISO 9001:2015 Certified Institute.

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**Course:** Bachelor of Pharmacy

**Duration:** 4 years

### **Programme outcomes:**

- 1) To provide essential knowledge pertaining to key principles involved in various Physicochemical and biological aspects of drugs and their implications.
- 2) To inculcate fundamental aspects about the genesis and importance of various materials used in formulation development and also for their pre-formulatory and biopharmaceutical assessment.
- 3) To impart essential skills required for the development of various formulations and to provide necessary training on basic skills to handle machinery and instruments needed for their fabrication, evaluation and marketing.
- 4) To ensure sustainability and perfection in aspects relating to pharmacodynamic and pharmacokinetic drug screening, usage of simulated practices for studying therapeutic ability of drugs.
- 5) To imbibe the prominence of a pharmacist in health care sector as a clinical pharmacist, community pharmacist etc. powered with good communication skills, hospital training and also by conducting health awareness programs to general public.

## SEMESTER - I

### BP101T. HUMAN ANATOMY AND PHYSIOLOGY-I (Theory)

#### Course Objectives:

This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

#### Course Content:

##### Unit I

10 hours

- Introduction to human body

Definition and scope of anatomy and physiology, levels of structural organization and body systems, basic life processes, homeostasis, basic anatomical terminology.

- Cellular level of organization

Structure and functions of cell, transport across cell membrane, cell division, cell junctions. General principles of cell communication, intracellular signaling pathway activation by extracellular signal molecule, Forms of intracellular signaling: a) Contact-dependent b) Paracrine c) Synaptic d) Endocrine

- Tissue level of organization

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

#### Learning Outcomes:

Upon completion of this course the student should be able to

- Identify the various tissues and organs of different systems of human body.
- Appreciate coordinated working pattern of different organs of each system

##### Unit II

10 hours

- Integumentary system

Structure and functions of skin

- Skeletal system

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

Organization of skeletal muscle, physiology of muscle contraction, neuromuscular junction

- Joints

Structural and functional classification, types of joints movements and its articulation

#### Learning Outcomes:

Upon completion of this course the student should be able to

- Explain the gross morphology, structure and functions of various organs of the human body.
- Identify the various tissues and organs of different systems of human body.
- Perform the various experiments related to special senses and nervous system.
- Appreciate coordinated working pattern of different organs of each system

##### Unit III

10 hours

- Body fluids and blood

- Body fluids, composition and functions of blood, hemopoiesis, formation of hemoglobin, anemia, mechanisms of coagulation, blood grouping, Rh factors, transfusion, its significance and disorders of blood, Reticulo endothelial system.
- Lymphatic system

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

**Learning Outcomes:**

Upon completion of this course the student should be able to

- Explain the gross morphology, structure and functions of various organs of the human body.
- Describe the various homeostatic mechanisms and their imbalances.
- Identify the various tissues and organs of different systems of human body.
- Appreciate coordinated working pattern of different organs of each system

**Unit IV**

08 hours

Peripheral nervous system:

Classification of peripheral nervous system: Structure and functions of sympathetic and parasympathetic nervous system.

Origin and functions of spinal and cranial nerves.

- Special senses

Structure and functions of eye, ear, nose and tongue and their disorders.

**Learning Outcomes:**

Upon completion of this course the student should be able to

- Explain the gross morphology, structure and functions of various organs of the human body.
- Identify the various tissues and organs of different systems of human body.
- Perform the various experiments related to special senses and nervous system.
- Appreciate coordinated working pattern of different organs of each system

**Unit V**

07 hours

- Cardiovascular system

Heart – anatomy of heart, blood circulation, blood vessels, structure and functions of artery, vein and capillaries, elements of conduction system of heart and heart beat, its regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of blood pressure, pulse, electrocardiogram and disorders of heart.

**Learning Outcomes:**

Upon completion of this course the student should be able to

- Explain the gross morphology, structure and functions of various organs of the human body.
- Describe the various homeostatic mechanisms and their imbalances.
- Identify the various tissues and organs of different systems of human body.
- Perform the various experiments related to special senses and nervous system.
- Appreciate coordinated working pattern of different organs of each system

**BP107P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)**

4 Hours/week

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject.

1. Study of compound microscope.
2. Microscopic study of epithelial and connective tissue
3. Microscopic study of muscular and nervous tissue
4. Identification of axial bones
5. Identification of appendicular bones
6. Introduction to hemocytometry.
7. Enumeration of white blood cell (WBC) count
8. Enumeration of total red blood corpuscles (RBC) count
9. Determination of bleeding time
10. Determination of clotting time
11. Estimation of hemoglobin content
12. Determination of blood group.
13. Determination of erythrocyte sedimentation rate (ESR).
14. Determination of heart rate and pulse rate.
15. Recording of blood pressure.

**Recommended Books (Latest Editions):**

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
4. Text book of Medical Physiology- Arthur C, Guyton and John.E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
6. Textbook of Human Histology by Inderbir Singh, Jaypee brother's medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother's medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

**Reference Books (Latest Editions):**

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

## **BP102T. PHARMACEUTICAL ANALYSIS (Theory)**

### **Course Objectives:**

This course deals with the fundamentals of analytical chemistry and principles of electrochemical analysis of drugs

### **Course Content:**

#### **Unit-I**

10 Hours

- a) Pharmaceutical analysis- Definition and scope
  - i. Different techniques of analysis
  - ii. Methods of expressing concentration
  - iii. Primary and secondary standards.
  - iv. Preparation and standardization of various molar and normal solutions- Oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulphate, sulphuric acid, potassium permanganate and ceric ammonium sulphate
- b) Errors: Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures

Pharmacopoeia, Sources of impurities in medicinal agents, limit tests.

### **Learning Outcomes:**

Upon completion of the course student shall be able to

- Understand the principles of analysis
- Carryout various volumetric and electrochemical titrations
- Develop analytical skills

#### **Unit-II**

10 Hours

- Acid base titration: Theories of acid base indicators, classification of acid base titrations and theory involved in titrations of strong, weak, and very weak acids and bases, neutralization curves
- Non aqueous titration: Solvents, acidimetry and alkalimetry titration and estimation of Sodium benzoate and Ephedrine HCl

### **Learning Outcomes:**

Upon completion of the course student shall be able to

- Understand the principles of volumetric analysis
- Carryout various volumetric titrations
- Develop analytical skills

#### **UNIT-III**

10 Hours

- Precipitation titrations: Mohr's method, Volhard's, Modified Volhard's, Fajans method, estimation of sodium chloride.
- Complexometric titration: Classification, metal ion indicators, masking and demasking reagents, estimation of Magnesium sulphate, and calcium gluconate.
- Gravimetry: Principle and steps involved in gravimetric analysis. Purity of the precipitate: co-precipitation and post precipitation, Estimation of barium sulphate.

### **Learning Outcomes:**

Upon completion of the course student shall be able to

- Understand the principles of volumetric analysis
- Carryout various volumetric titrations
- Develop analytical skills

#### **Unit-IV**

08 Hours

Redox titrations

- a. Concepts of oxidation and reduction
- b. Types of redox titrations (Principles and applications)

Cerimetry, Iodimetry, Iodometry, Bromatometry, Dichrometry, Titration with potassium iodate

#### **Learning Outcomes:**

Upon completion of the course student shall be able to

- Understand the principles of volumetric analysis
- Carryout various volumetric titrations
- Develop analytical skills

#### **Unit-V**

07 Hours

- Electrochemical methods of analysis
- Conductometry- Introduction, Conductivity cell, Conductometric titrations, applications.
- Potentiometry - Electrochemical cell, construction and working of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine end point of potentiometric titration and applications.
- Polarography - Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications

#### **Learning Outcomes:**

Upon completion of the course student shall be able to

- Understand the principles of electro chemical analysis
- Carryout various electrochemical titrations
- Develop analytical skills

**BP108P. PHARMACEUTICAL ANALYSIS (Practical)**

4 Hours / Week

- I. Limit Test of the following
  1. Chloride
  2. Sulphate
  3. Iron
  4. Arsenic
- II Preparation and standardization of
  1. Sodium hydroxide
  2. Sulphuric acid
  3. Sodium thiosulfate
  4. Potassium permanganate
  5. Ceric ammonium sulphate
- III Assay of the following compounds along with Standardization of Titrant
  1. Ammonium chloride by acid base titration
  2. Ferrous sulphate by Cerimetry
  3. Copper sulphate by Iodometry
  4. Calcium gluconate by complexometry
  5. Hydrogen peroxide by Permanganometry
  6. Sodium benzoate by non-aqueous titration
  7. Sodium Chloride by precipitation titration
- IV Determination of Normality by electro-analytical methods
  1. Conductometric titration of strong acid against strong base
  2. Conductometric titration of strong acid and weak acid against strong base
  3. Potentiometric titration of strong acid against strong base

**Recommended Books: (Latest Editions)**

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry
4. Bentley and Driver's Textbook of Pharmaceutical Chemistry
5. John H. Kennedy, Analytical chemistry principles
6. Indian Pharmacopoeia.

## **BP103T. PHARMACEUTICS- I (Theory)**

### **Course Objectives:**

This course is designed to impart a fundamental knowledge on the preparatory pharmacy with arts and science of preparing the different conventional dosage forms.

### **Course Content:**

#### **UNIT – I**

10 Hours

- Historical background and development of profession of pharmacy: History of profession of Pharmacy in India in relation to pharmacy education, industry and organization, Pharmacy as a career, Pharmacopoeias: Introduction to IP, BP, USP and Extra Pharmacopoeia.
- Dosage forms: Introduction to dosage forms, classification and definitions
- Prescription: Definition, Parts of prescription, handling of Prescription and Errors in prescription.
- Posology: Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area.

### **Learning Outcomes:**

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

- Know the history of profession of pharmacy
- Understand the basics of different dosage forms and pharmaceutical calculations
- Understand the professional way of handling the prescription

#### **UNIT – II**

10 Hours

- Pharmaceutical calculations: Weights and measures – Imperial & Metric system, Calculations involving percentage solutions, alligation, proof spirit and isotonic solutions based on freezing point and molecular weight.
- Powders: Definition, classification, advantages and disadvantages, Simple & compound powders – official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.

Liquid dosage forms: Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques

### **Learning Outcomes:**

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

- Understand the basics of different dosage forms and pharmaceutical calculations
- Preparation of various conventional dosage forms

#### **UNIT – III**

08 Hours

- Monophasic liquids: Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions.
- Biphasic liquids:
- Suspensions: Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome.
- Emulsions: Definition, classification, emulsifying agent, test for the identification of type of Emulsion, Methods of preparation & stability problems and methods to overcome.



**Learning Outcomes:**

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

- Understand the basics of different dosage forms
- Preparation of various conventional dosage forms

**UNIT – IV**

08 Hours

- Suppositories: Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories.
- Pharmaceutical incompatibilities: Definition, classification, physical, chemical and therapeutic incompatibilities with examples.

**Learning Outcomes:**

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

- Understand the basics of different dosage forms and pharmaceutical incompatibilities.
- Preparation of various conventional dosage forms

**UNIV – V**

07 Hours

- Semisolid dosage forms: Definitions, classification, mechanisms and factors influencing dermal penetration of drugs. Preparation of ointments, pastes, creams and gels. Excipients used in semi solid dosage forms. Evaluation of semi solid dosages forms

**Learning Outcomes:**

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

- Understand the basics of different dosage forms Preparation of various conventional dosage forms

**BP109P. PHARMACEUTICS I (Practical)**

3 Hours / week

1. Syrups
  - a) Syrup IP'66
  - b) Compound syrup of Ferrous Phosphate BPC'68
2. Elixirs
  - a) Piperazine citrate elixir
  - b) Paracetamol pediatric elixir
3. Linctus
  - a) Terpin Hydrate Linctus IP'66
  - b) Iodine Throat Paint (Mandles Paint)
4. Solutions
  - a) Strong solution of ammonium acetate
  - b) Cresol with soap solution
  - c) Lugol's solution
5. Suspensions
  - a) Calamine lotion
  - b) Magnesium Hydroxide mixture
  - c) Aluminium Hydroxide gel
6. Emulsions
  - a) Turpentine Liniment
  - b) Liquid paraffin emulsion
7. Powders and Granules
  - a) ORS powder (WHO)
  - b) Effervescent granules
  - c) Dusting powder
  - d) Divided powders
8. Suppositories
  - a) Glycero gelatin suppository
  - b) Cocoa butter suppository
  - c) Zinc Oxide suppository
8. Semisolids
  - a) Sulphur ointment
  - b) Non staining-iodine ointment with methyl salicylate
  - c) Carbopal gel
9. Gargles and Mouthwashes
  - a) Iodine gargle
  - b) Chlorhexidine mouthwash

**Recommended Books: (Latest Editions)**

1. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and Walkins, New Delhi.
2. Carter S.J., Cooper and Gunn's-Dispensing for Pharmaceutical Students, CBS publishers, New Delhi.
3. M.E. Aulton, Pharmaceutics, The Science & Dosage Form Design, Churchill Livingstone, Edinburgh.
4. Indian pharmacopoeia.
5. British pharmacopoeia.
6. Lachmann. Theory and Practice of Industrial Pharmacy, Lea & Febiger Publisher, The University of Michigan.
7. Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott Williams, New Delhi.
8. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, CBS Publications, New Delhi.
9. E.A. Rawlins, Bentley's Text Book of Pharmaceutics, English Language Book Society, Elsevier Health Sciences, USA.
10. Isaac Ghebre Sellassie: Pharmaceutical Pelletization Technology, Marcel Dekker, INC, New York.
11. Dilip M. Parikh: Handbook of Pharmaceutical Granulation Technology, Marcel Dekker, INC, New York.
12. Françoise Nieloud and Gilberte Marti-Mestres: Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC, New York.

## **BP104T. PHARMACEUTICAL INORGANIC CHEMISTRY (Theory)**

### **Course Objectives:**

This subject deals with the monographs of inorganic drugs and pharmaceuticals.

### **Course Content:**

#### **UNIT I**

10 Hours

- Impurities in pharmaceutical substances: History of Pharmacopoeia, Sources and types of impurities, principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals, modified limit test for Chloride and Sulphate

General methods of preparation, assay for the compounds superscripted with asterisk (\*), properties and medicinal uses of inorganic compounds belonging to the following classes

#### **Learning Outcomes:**

Upon completion of course student shall be able to

- Know the sources of impurities and methods to determine the impurities in inorganic drugs and pharmaceuticals

#### **UNIT II**

10 Hours

- Acids, Bases and Buffers: Buffer equations and buffer capacity in general, buffers in pharmaceutical systems, preparation, stability, buffered isotonic solutions, measurements of tonicity, calculations and methods of adjusting isotonicity.
- Major extra and intracellular electrolytes: Functions of major physiological ions, Electrolytes used in the replacement therapy: Sodium chloride\*, Potassium chloride, Calcium gluconate\* and Oral Rehydration Salt (ORS), Physiological acid base balance.
- Dental products: Dentifrices, role of fluoride in the treatment of dental caries, Desensitizing agents, Calcium carbonate, Sodium fluoride, and Zinc eugenol cement.

#### **Learning Outcomes:**

Upon completion of course student shall be able to

- Understand the medicinal and pharmaceutical importance of inorganic compounds

#### **UNIT III**

10 Hours

- Gastrointestinal agents

Acidifiers: Ammonium chloride\* and Dil. HCl

Antacid: Ideal properties of antacids, combinations of antacids, Sodium Bicarbonate\*, Aluminum hydroxide gel, Magnesium hydroxide mixture

Cathartics: Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite

Antimicrobials: Mechanism, classification, Potassium permanganate, Boric acid, Hydrogen peroxide\*, Chlorinated lime\*, Iodine and its preparations

#### **Learning Outcomes:**

Upon completion of course student shall be able to

- Understand the medicinal and pharmaceutical importance of inorganic compounds

#### **UNIT IV**

08 Hours

- Miscellaneous compounds

Expectorants: Potassium iodide, Ammonium chloride\*. Emetics: Copper sulphate\*, Sodium potassium tartarate Haematinics: Ferrous sulphate\*, Ferrous gluconate

Poison and Antidote: Sodium thiosulphate\*, Activated charcoal, Sodium nitrite<sup>333</sup>

Astringents: Zinc Sulphate, Potash Alum

**Learning Outcomes:**

Upon completion of course student shall be able to

- Understand the medicinal and pharmaceutical importance of inorganic compounds

**UNIT V**

07 Hours

- Radiopharmaceuticals: Radio activity, Measurement of radioactivity, Properties of  $\alpha$ ,  $\beta$ ,  $\gamma$  radiations, Half life, radio isotopes and study of radio isotopes - Sodium iodide I131, Storage conditions, precautions & pharmaceutical application of radioactive substances.

**Learning Outcomes:**

Upon completion of course student shall be able to

- Understand the medicinal and pharmaceutical importance of inorganic compounds

## **BP110P. PHARMACEUTICAL INORGANIC CHEMISTRY (Practical) 4 Hours / Week**

### **I. Limit tests for following ions**

- Limit test for Chlorides and Sulphates
- Modified limit test for Chlorides and Sulphates
- Limit test for Iron
- Limit test for Heavy metals
- Limit test for Lead
- Limit test for Arsenic

### **II. Identification test**

- Magnesium hydroxide
- Ferrous sulphate
- Sodium bicarbonate
- Calcium gluconate
- Copper sulphate

### **III. Test for purity**

- Swelling power of Bentonite
- Neutralizing capacity of aluminum hydroxide gel
- Determination of potassium iodate and iodine in potassium Iodide

### **IV. Preparation of inorganic pharmaceuticals**

- Boric acid
- Potash alum
- Ferrous sulphate

### **Recommended Books (Latest Editions)**

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London, 4th edition.
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry, 3rd Edition
4. M.L Schroff, Inorganic Pharmaceutical Chemistry
5. Bentley and Driver's Textbook of Pharmaceutical Chemistry
6. Anand & Chatwal, Inorganic Pharmaceutical Chemistry
7. Indian Pharmacopoeia

## **BP105T.COMMUNICATION SKILLS (Theory)**

### **Course Objectives:**

This course will prepare the young pharmacy student to interact effectively with doctors, nurses, dentists, physiotherapists and other health workers. At the end of this course the student will get the soft skills set to work cohesively with the team as a team player and will add value to the pharmaceutical business.

### **Course content:**

#### **UNIT – I**

07 Hours

- Communication Skills: Introduction, Definition, The Importance of Communication, The Communication Process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context
- Barriers to communication: Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers
- Perspectives in Communication: Introduction, Visual Perception, Language, Other factors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment

### **Learning Outcomes:**

Upon completion of the course the student shall be able to

- Understand the behavioural needs for a Pharmacist to function effectively in the areas of pharmaceutical operation
- Communicate effectively (Verbal and Non Verbal)
- Effectively manage the team as a team player
- Develop Leadership qualities and essentials

#### **UNIT – II**

07 Hours

- Elements of Communication: Introduction, Face to Face Communication - Tone of Voice, Body Language (Non-verbal communication), Verbal Communication, Physical Communication
- Communication Styles: Introduction, The Communication Styles Matrix with example for each -Direct Communication Style, Spirited Communication Style, Systematic Communication Style, Considerate Communication Style

### **Learning Outcomes:**

Upon completion of the course the student shall be able to

- Understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation
- Communicate effectively (Verbal and Non Verbal)
- Effectively manage the team as a team player
- Develop Leadership qualities and essentials

#### **UNIT – III**

07 Hours

- Basic Listening Skills: Introduction, Self-Awareness, Active Listening, Becoming an Active Listener, Listening in Difficult Situations
- Effective Written Communication: Introduction, When and When Not to Use Written Communication - Complexity of the Topic, Amount of Discussion' Required, Shades of Meaning, Formal Communication

- Writing Effectively: Subject Lines, Put the Main Point First, Know Your Audience, Organization of the Message

**Learning Outcomes:**

Upon completion of the course the student shall be able to

- Understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation
- Communicate effectively (Verbal and Non Verbal)
- Effectively manage the team as a team player
- Develop Leadership qualities and essentials

**UNIT – IV**

05 Hours

- Interview Skills: Purpose of an interview, Do's and Dont's of an interview
- Giving Presentations: Dealing with Fears, Planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery

**Learning Outcomes:**

Upon completion of the course the student shall be able to

- Understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation
- Communicate effectively (Verbal and Non Verbal)
- Effectively manage the team as a team player
- Develop interview skills
- Develop Leadership qualities and essentials

**UNIT – V**

04 Hours

- Group Discussion: Introduction, Communication skills in group discussion, Do's and Dont's of group discussion

**Learning Outcomes:**

Upon completion of the course the student shall be able to

- Understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation
- Communicate effectively (Verbal and Non Verbal)
- Effectively manage the team as a team player
- Develop Leadership qualities and essentials

## **BP111P.COMMUNICATION SKILLS (Practical)**

2 Hours / week

The following learning modules are to be conducted using wordsworth® English language lab software

Basic communication covering the following topics

- Meeting People
- Asking Questions
- Making Friends
- What did you do?
- Do's and Dont's

Pronunciations covering the following topics

- Pronunciation (Consonant Sounds)
- Pronunciation and Nouns
- Pronunciation (Vowel Sounds)

Advanced Learning

- Listening Comprehension / Direct and Indirect Speech
- Figures of Speech
- Effective Communication
- Writing Skills
- Effective Writing
- Interview Handling Skills
- E-Mail etiquette
- Presentation Skills

### **Recommended Books: (Latest Edition)**

1. Basic communication skills for Technology, Andreja. J. Ruther Ford, 2nd Edition, Pearson Education, 2011
2. Communication skills, Sanjay Kumar, Pushpalata, 1stEdition, Oxford Press, 2011
3. Organizational Behaviour, Stephen .P. Robbins, 1stEdition, Pearson, 2013
4. Brilliant- Communication skills, Gill Hasson, 1stEdition, Pearson Life, 2011
5. The Ace of Soft Skills: Attitude, Communication and Etiquette for success, Gopala Swamy Ramesh, 5thEdition, Pearson, 2013
6. Developing your influencing skills, Deborah Dalley, Lois Burton, Margaret, Green hall, 1st Edition Universe of Learning LTD, 2010
7. Communication skills for professionals, Konar nira, 2ndEdition, New arrivals – PHI, 2011
8. Personality development and soft skills, Barun K Mitra, 1stEdition, Oxford Press, 2011
9. Soft skill for everyone, Butter Field, 1st Edition, Cengage Learning india pvt.ltd, 2011
10. Soft skills and professional communication, Francis Peters SJ, 1stEdition, Mc Graw Hill Education, 2011
11. Effective communication, John Adair, 4thEdition, Pan Mac Millan,2009
12. Bringing out the best in people, Aubrey Daniels, 2ndEdition, Mc Graw Hill, 1999



## **BP 106RBT.REMEDIAL BIOLOGY (Theory)**

### **Course Objectives:**

To learn and understand the components of living world, structure and functional system of plant and animal kingdom.

### **UNIT I**

07 Hours

Living world:

- Definition and characters of living organisms
- Diversity in the living world
- Binomial nomenclature
- Five kingdoms of life and basis of classification. Salient features of Monera, Protista, Fungi, Animalia and Plantae, Virus,

Morphology of Flowering plants

- Morphology of different parts of flowering plants – Root, stem, inflorescence, flower, leaf, fruit, seed.
- General Anatomy of Root, stem, leaf of monocotyledons & Dicotyledones.

### **Learning Outcomes:**

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

- Know the classification and salient features of five kingdoms of life
- Understand the basic components of anatomy & physiology of plant

### **UNIT II**

07 Hours

Body fluids and circulation

- Composition of blood, blood groups, coagulation of blood
- Composition and functions of lymph
- Human circulatory system
- Structure of human heart and blood vessels
- Cardiac cycle, cardiac output and ECG

Digestion and Absorption

- Human alimentary canal and digestive glands
- Role of digestive enzymes
- Digestion, absorption and assimilation of digested food

Breathing and respiration

- Human respiratory system
- Mechanism of breathing and its regulation
- Exchange of gases, transport of gases and regulation of respiration
- Respiratory volumes

### **Learning Outcomes:**

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

- Know and understand the basic components of anatomy & physiology of animal with special reference to human

### **UNIT III**

07 Hours

Excretory products and their elimination

- Modes of excretion
- Human excretory system- structure and function
- Urine formation

- Rennin angiotensin system

Neural control and coordination

- Definition and classification of nervous system
- Structure of a neuron
- Generation and conduction of nerve impulse
- Structure of brain and spinal cord
- Functions of cerebrum, cerebellum, hypothalamus and medulla oblongata

Chemical coordination and regulation

- Endocrine glands and their secretions
- Functions of hormones secreted by endocrine glands

Human reproduction

- Parts of female reproductive system
- Parts of male reproductive system
- Spermatogenesis and Oogenesis
- Menstrual cycle

### **Learning Outcomes:**

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

- Know and understand the basic components of anatomy & physiology of animal with special reference to human

## **UNIT IV**

05 Hours

Plants and mineral nutrition:

- Essential mineral, macro and micronutrients
- Nitrogen metabolism, Nitrogen cycle, biological nitrogen fixation

Photosynthesis

- Autotrophic nutrition, photosynthesis, Photosynthetic pigments, Factors affecting photosynthesis.

### **Learning Outcomes:**

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

- Understand the basic components of anatomy & physiology of plant

## **UNIT V**

04 Hours

Plant respiration: Respiration, glycolysis, fermentation (anaerobic).

Plant growth and development

- Phases and rate of plant growth, Condition of growth, Introduction to plant growth regulators

Cell - The unit of life

- Structure and functions of cell and cell organelles. Cell division

Tissues

- Definition, types of tissues, location and functions.

### **Learning Outcomes:**

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

- Understand the basic components of anatomy & physiology of plant

### **Text Books**

- a. Text book of Biology by S. B. Gokhale

- b. A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.

**Reference Books**

- a. A Text book of Biology by B.V. Sreenivasa Naidu
- b. A Text book of Biology by Naidu and Murthy
- c. Botany for Degree students By A.C.Dutta.
- d. Outlines of Zoology by M. Ekambaranatha ayyer and T. N. Ananthkrishnan.
- e. A manual for pharmaceutical biology practical by S.B. Gokhale and C. K. Kokate

**BP112RBP.REMEDIAL BIOLOGY (Practical)**

30 Hours

1. Introduction to experiments in biology
  - a. Study of Microscope
  - b. Section cutting techniques
  - c. Mounting and staining
  - d. Permanent slide preparation
2. Study of cell and its inclusions
3. Study of Stem, Root, Leaf, seed, fruit, flower and their modifications
4. Detailed study of frog by using computer models
5. Microscopic study and identification of tissues pertinent to Stem, Root Leaf, seed, fruit and flower
6. Identification of bones
7. Determination of blood group
8. Determination of blood pressure
9. Determination of tidal volume

**Reference Books**

1. Practical human anatomy and physiology. by S.R.Kale and R.R.Kale.
2. A Manual of pharmaceutical biology practical by S.B.Gokhale, C.K.Kokate and S.P.Shriwastava.
3. Biology practical manual according to National core curriculum .Biology forum of Karnataka. Prof .M.J.H.Shafi

## **BP 106RMT.REMEDIAL MATHEMATICS (Theory)**

### **Course Objectives:**

This is an introductory course in mathematics. This subject deals with the introduction to Partial fraction, Logarithm, matrices and Determinant, Analytical geometry, Calculus, differential equation and Laplace transform.

### **Course Content:**

#### **UNIT – I**

06 Hours

- Partial fraction

Introduction, Polynomial, Rational fractions, Proper and Improper fractions, Partial fraction, Resolving into Partial fraction, Application of Partial Fraction in Chemical Kinetics and Pharmacokinetics

- Logarithms

Introduction, Definition, Theorems/Properties of logarithms, Common logarithms, Characteristic and Mantissa, worked examples, application of logarithm to solve pharmaceutical problems.

- Function:

Real Valued function, Classification of real valued functions,

- Limits and continuity :

Introduction, Limit of a function, Definition of limit of a function ( $\epsilon - \delta$  definition),

$$\lim_{x \rightarrow a} \left( \frac{x^n - a^n}{x - a} \right) = na^{n-1}, \quad \lim_{\theta \rightarrow 0} \frac{\sin \theta}{\theta} = 1$$

### **Learning Outcomes:**

Upon completion of the course the student shall be able to:-

- Know the theory and their application in Pharmacy
- Solve the different types of problems by applying theory
- Appreciate the important application of mathematics in Pharmacy

#### **UNIT –II**

06 Hours

- Matrices and Determinant:

Introduction matrices, Types of matrices, Operation on matrices, Transpose of a matrix, Matrix Multiplication, Determinants, Properties of determinants, Product of determinants, Minors and co-Factors, Adjoint or adjugate of a square matrix, Singular and non-singular matrices, Inverse of a matrix, Solution of system of linear of equations using matrix method, Cramer's rule, Characteristic equation and roots of a square matrix, Cayley–Hamilton theorem, Application of Matrices in solving Pharmacokinetic equations

### **Learning Outcomes:**

Upon completion of the course the student shall be able to:-

- Know the theory and their application in Pharmacy
- Solve the different types of problems by applying theory
- Appreciate the important application of mathematics in Pharmacy

#### **UNIT – III**

06 Hours

- Calculus

Differentiation : Introductions, Derivative of a function, Derivative of a constant, Derivative of a product of a constant and a function, Derivative of the sum or difference of two functions, Derivative of the product of two functions (product formula), Derivative of the quotient of two

functions (Quotient formula) – Without Proof, Derivative of  $x^n$  w.r.t  $x$ , where  $n$  is any rational number, Derivative of  $e^x$ , Derivative of  $\log_e x$ , Derivative of  $a^x$ , Derivative of trigonometric functions from first principles (without Proof), Successive Differentiation, Conditions for a function to be a maximum or a minimum at a point. Application

**Learning Outcomes:**

Upon completion of the course the student shall be able to:-

- Know the theory and their application in Pharmacy
- Solve the different types of problems by applying theory
- Appreciate the important application of mathematics in Pharmacy

**UNIT – IV**

06 Hours

- Analytical Geometry

Introduction: Signs of the Coordinates, Distance formula,

Straight Line : Slope or gradient of a straight line, Conditions for parallelism and perpendicularity of two lines, Slope of a line joining two points, Slope – intercept form of a straight line

Integration:

Introduction, Definition, Standard formulae, Rules of integration, Method of substitution, Method of Partial fractions, Integration by parts, definite integrals, application

**Learning Outcomes:**

Upon completion of the course the student shall be able to:-

- Know the theory and their application in Pharmacy
- Solve the different types of problems by applying theory
- Appreciate the important application of mathematics in Pharmacy

**UNIT-V**

06 Hours

- Differential Equations : Some basic definitions, Order and degree, Equations in separable form, Homogeneous equations, Linear Differential equations, Exact equations, Application in solving Pharmacokinetic equations

- Laplace Transform : Introduction, Definition, Properties of Laplace transform, Laplace Transforms of elementary functions, Inverse Laplace transforms, Laplace transform of derivatives, Application to solve Linear differential equations, Application in solving Chemical kinetics and Pharmacokinetics equations

**Learning Outcomes:**

Upon completion of the course the student shall be able to:-

- Know the theory and their application in Pharmacy
- Solve the different types of problems by applying theory
- Appreciate the important application of mathematics in Pharmacy

**Recommended Books (Latest Edition)**

1. Differential Calculus by Shanthinarayan
2. Pharmaceutical Mathematics with application to Pharmacy by Panchaksharappa Gowda D.H.
3. Integral Calculus by Shanthinarayan
4. Higher Engineering Mathematics by Dr.B.S.Grewal

## SEMESTER - II

### BP 201T. HUMAN ANATOMY AND PHYSIOLOGY-II (Theory)

#### Course Objectives:

This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

#### Course Content:

Unit I 10 hours

- Nervous system

Organization of nervous system, neuron, neuroglia, classification and properties of nerve fibre, electrophysiology, action potential, nerve impulse, receptors, synapse, neurotransmitters.

Central nervous system: Meninges, ventricles of brain and cerebrospinal fluid. structure and functions of brain (cerebrum, brain stem, cerebellum), spinal cord (gross structure, functions of afferent and efferent nerve tracts, reflex activity)

#### Learning Outcomes:

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

- Explain the gross morphology, structure and functions of various organs of the human body.
- Identify the various tissues and organs of different systems of human body.
- Appreciate coordinated working pattern of different organs of each system
- Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

Unit II 06 hours

- Digestive system

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

- Energetics

Formation and role of ATP, Creatinine Phosphate and BMR.

#### Learning Outcomes:

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

- Explain the gross morphology, structure and functions of various organs of the human body.
- Identify the various tissues and organs of different systems of human body.
- Appreciate coordinated working pattern of different organs of each system
- Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

Unit III 10 hours

- Respiratory system

Anatomy of respiratory system with special reference to anatomy of lungs, mechanism of respiration, regulation of respiration

Lung Volumes and capacities transport of respiratory gases, artificial respiration, and resuscitation methods.

- Urinary system

Anatomy of urinary tract with special reference to anatomy of kidney and nephrons, functions of kidney and urinary tract, physiology of urine formation, micturition reflex and role of kidneys in acid base balance, role of RAS in kidney and disorders of kidney.

**Learning Outcomes:**

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

- Explain the gross morphology, structure and functions of various organs of the human body.
- Identify the various tissues and organs of different systems of human body.
- Appreciate coordinated working pattern of different organs of each system
- Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

Unit IV

10 hours

- 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 and their disorders.

**Learning Outcomes:**

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

- Explain the gross morphology, structure and functions of various organs of the human body.
- Identify the various tissues and organs of different systems of human body.
- Appreciate coordinated working pattern of different organs of each system
- Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

Unit V

09 hours

- 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

- Introduction to genetics

Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance

**Learning Outcomes:**

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

- Explain the gross morphology, structure and functions of various organs of the human body.
- Identify the various tissues and organs of different systems of human body.
- Appreciate coordinated working pattern of different organs of each system
- Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.



**BP 207 P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)**

4 Hours/week

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject.

1. To study the integumentary and special senses using specimen, models, etc.,
2. To study the nervous system using specimen, models, etc.,
3. To study the endocrine system using specimen, models, etc
4. To demonstrate the general neurological examination
5. To demonstrate the function of olfactory nerve
6. To examine the different types of taste.
7. To demonstrate the visual acuity
8. To demonstrate the reflex activity
9. Recording of body temperature
10. To demonstrate positive and negative feedback mechanism.
11. Determination of tidal volume and vital capacity.
12. Study of digestive, respiratory, cardiovascular systems, urinary and reproductive systems with the help of models, charts and specimens.
13. Recording of basal mass index .
14. Study of family planning devices and pregnancy diagnosis test.
15. Demonstration of total blood count by cell analyser
16. Permanent slides of vital organs and gonads.

**Recommended Books (Latest Editions)**

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,Riverview, MI USA
4. Text book of Medical Physiology- Arthur C,Guyton andJohn.E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
6. Textbook of Human Histology by Inderbir Singh, Jaypee brothers medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brothers medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

**Reference Books:**

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

## **BP202T. PHARMACEUTICAL ORGANIC CHEMISTRY –I (Theory)**

### **Course Objectives:**

This subject deals with classification and nomenclature of simple organic compounds, structural isomerism, intermediates forming in reactions, important physical properties, reactions and methods of preparation of these compounds. The syllabus also emphasizes on mechanisms and orientation of reactions.

### **Course Content:**

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

07 Hours

- Classification, nomenclature and isomerism

Classification of Organic Compounds

Common and IUPAC systems of nomenclature of organic compounds (up to 10 Carbons open chain and carbocyclic compounds)

Structural isomerisms in organic compounds

### **Learning Outcomes:**

Upon completion of the course the student shall be able to

- Write the structure, name and the type of isomerism of the organic compound

#### UNIT-II

10 Hours

- Alkanes\*, Alkenes\* and Conjugated dienes\*

SP<sup>3</sup> hybridization in alkanes, Halogenation of alkanes, uses of paraffins. Stabilities of alkenes, SP<sup>2</sup> hybridization in alkenes

E1 and E2 reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and evidences. E1 versus E2 reactions, Factors affecting E1 and E2 reactions. Ozonolysis, electrophilic addition reactions of alkenes, Markownikoff's orientation, free radical addition reactions of alkenes, Anti Markownikoff's orientation.

Stability of conjugated dienes, Diel-Alder, electrophilic addition, free radical addition reactions of conjugated dienes, allylic rearrangement

### **Learning Outcomes:**

Upon completion of the course the student shall be able to

- Write the structure, name and the type of isomerism of the organic compound
- Write the reaction, name the reaction and orientation of reactions
- Account for reactivity/stability of compounds,
- Identify/confirm the identification of organic compound

#### UNIT-III

10 Hours

- Alkyl halides\*

SN<sup>1</sup> and SN<sup>2</sup> reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations.

SN<sup>1</sup> versus SN<sup>2</sup> reactions, Factors affecting SN<sup>1</sup> and SN<sup>2</sup> reactions

Structure and uses of ethylchloride, Chloroform, trichloroethylene, tetrachloroethylene, dichloromethane, tetrachloromethane and iodoform.

- Alcohols\*- Qualitative tests, Structure and uses of Ethyl alcohol, Methyl alcohol, chlorobutanol, Cetosteryl alcohol, Benzyl alcohol, Glycerol, Propylene glycol

**Learning Outcomes:**

Upon completion of the course the student shall be able to

- Write the structure, name and the type of isomerism of the organic compound
- Write the reaction, name the reaction and orientation of reactions
- Account for reactivity/stability of compounds,
- Identify/confirm the identification of organic compound

UNIT-IV

10 Hours

- Carbonyl compounds\* (Aldehydes and ketones)

Nucleophilic addition, Electromeric effect, aldol condensation, Crossed Aldol condensation, Cannizzaro reaction, Crossed Cannizzaro reaction, Benzoin condensation, Perkin condensation, qualitative tests, Structure and uses of Formaldehyde, Paraldehyde, Acetone, Chloral hydrate, Hexamine, Benzaldehyde, Vanilin, Cinnamaldehyde.

**Learning Outcomes:**

Upon completion of the course the student shall be able to

- Write the structure, name and the type of isomerism of the organic compound
- Write the reaction, name the reaction and orientation of reactions
- Account for reactivity/stability of compounds,
- Identify/confirm the identification of organic compound

UNIT-V

08 Hours

- Carboxylic acids\*

Acidity of carboxylic acids, effect of substituents on acidity, inductive effect and qualitative tests for carboxylic acids, amide and ester

Structure and Uses of Acetic acid, Lactic acid, Tartaric acid, Citric acid, Succinic acid. Oxalic acid, Salicylic acid, Benzoic acid, Benzyl benzoate, Dimethyl phthalate, Methyl salicylate and Acetyl salicylic acid

- Aliphatic amines\* - Basicity, effect of substituent on Basicity. Qualitative test, Structure and uses of Ethanolamine, Ethylenediamine, Amphetamine

**Learning Outcomes:**

Upon completion of the course the student shall be able to

- Write the structure, name and the type of isomerism of the organic compound
- Write the reaction, name the reaction and orientation of reactions
- Account for reactivity/stability of compounds,
- Identify/confirm the identification of organic compound

**BP208P. PHARMACEUTICAL ORGANIC CHEMISTRY -I (Practical) 4 Hours / week**

**I. Systematic qualitative analysis of unknown organic compounds like**

1. Preliminary test: Color, odour, aliphatic/aromatic compounds, saturation and unsaturation, etc.
2. Detection of elements like Nitrogen, Sulphur and Halogen by Lassaigne's test
3. Solubility test
4. Functional group test like Phenols, Amides/ Urea, Carbohydrates, Amines, Carboxylic acids, Aldehydes and Ketones, Alcohols, Esters, Aromatic and Halogenated Hydrocarbons, Nitro compounds and Anilides.
5. Melting point/Boiling point of organic compounds
6. Identification of the unknown compound from the literature using melting point/boiling point.
7. Preparation of the derivatives and confirmation of the unknown compound by melting point/boiling point.
8. Minimum 5 unknown organic compounds to be analysed systematically.

**II. Preparation of suitable solid derivatives from organic compounds**

**III. Construction of molecular models**

**Recommended Books (Latest Editions)**

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.
9. Reaction and reaction mechanism by Ahluwaliah/Chatwal.

## **BP203 T. BIOCHEMISTRY (Theory)**

### **Course Objectives:**

Biochemistry deals with complete understanding of the molecular levels of the chemical process associated with living cells. The purpose of the subject is providing biochemical facts and the principles to understand metabolism of nutrient molecules in physiological and pathological conditions. It is also emphasizing on genetic organization of mammalian genome and hetero & autocatalytic functions of DNA.

### **Course Content:**

#### UNIT I

08 Hours

- Biomolecules

Introduction, classification, chemical nature and biological role of carbohydrate, lipids, nucleic acids, amino acids and proteins.

- Bioenergetics

Concept of free energy, endergonic and exergonic reaction, Relationship between free energy, enthalpy and entropy; Redox potential.

Energy rich compounds; classification; biological significances of ATP and cyclic AMP

### **Learning Outcomes:**

Upon completion of course student shall able to

- Understand the metabolism of nutrient molecules in physiological and pathological conditions.

#### UNIT II

10 Hours

- Carbohydrate metabolism

Glycolysis – Pathway, energetics and significance Citric acid cycle- Pathway, energetics and significance

HMP shunt and its significance; Glucose-6-Phosphate dehydrogenase (G6PD) deficiency

Glycogen metabolism Pathways and glycogen storage diseases (GSD) Gluconeogenesis- Pathway and its significance

Hormonal regulation of blood glucose level and Diabetes mellitus

Oxidative phosphorylation & its mechanism and substrate level phosphorylation

Inhibitors ETC and oxidative phosphorylation/Uncouplers

### **Learning Outcomes:**

Upon completion of course student shall able to

- Understand the metabolism of nutrient molecules in physiological and pathological conditions.

#### UNIT III

10 Hours

- Lipid metabolism

$\beta$ -Oxidation of saturated fatty acid (Palmitic acid)

Formation and utilization of ketone bodies; ketoacidosis De novo synthesis of fatty acids (Palmitic acid)

Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D

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

- Amino acid metabolism

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

Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenylketonuria, Albinism, alpeptonuria, tyrosinemia)

Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline

Catabolism of heme; hyperbilirubinemia and jaundice

**Learning Outcomes:**

Upon completion of course student shall be able to

- Understand the metabolism of nutrient molecules in physiological and pathological conditions.

UNIT IV

10 Hours

- Nucleic acid metabolism and genetic information transfer

Biosynthesis of purine and pyrimidine nucleotides

Catabolism of purine nucleotides and Hyperuricemia and Gout disease Organization of mammalian genome

Structure of DNA and RNA and their functions DNA replication (semi conservative model)

Transcription or RNA synthesis

Genetic code, Translation or Protein synthesis and inhibitors

**Learning Outcomes:**

Upon completion of course student shall be able to

- Understand the metabolism of nutrient molecules in physiological and pathological conditions.
- Understand the genetic organization of mammalian genome and functions of DNA in the synthesis of RNAs and proteins.

UNIT V

07 Hours

- Enzymes

Introduction, properties, nomenclature and IUB classification of enzymes Enzyme kinetics (Michaelis plot, Line Weaver Burke plot)

Enzyme inhibitors with examples

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

Therapeutic and diagnostic applications of enzymes and isoenzymes Coenzymes –Structure and biochemical functions

**Learning Outcomes:**

Upon completion of course student shall be able to

- Understand the catalytic role of enzymes, importance of enzyme inhibitors in design of new drugs, therapeutic and diagnostic applications of enzymes.

**BP 209 P. BIOCHEMISTRY (Practical)**

4 Hours / Week

1. Qualitative analysis of carbohydrates (Glucose, Fructose, Lactose, Maltose, Sucrose and starch)
2. Identification tests for Proteins (albumin and Casein)
3. Quantitative analysis of reducing sugars (DNSA method) and Proteins (Biuret method)
4. Qualitative analysis of urine for abnormal constituents
5. Determination of blood creatinine
6. Determination of blood sugar
7. Determination of serum total cholesterol
8. Preparation of buffer solution and measurement of pH
9. Study of enzymatic hydrolysis of starch
10. Determination of Salivary amylase activity
11. Study the effect of Temperature on Salivary amylase activity.
12. Study the effect of substrate concentration on salivary amylase activity.

**Recommended Books (Latest Editions)**

1. Principles of Biochemistry by Lehninger.
2. Harper's Biochemistry by Robert K. Murray, Daryl K. Granner and Victor W. Rodwell.
3. Biochemistry by Stryer.
4. Biochemistry by D. Satyanarayan and U.Chakrapani
5. Textbook of Biochemistry by Rama Rao.
6. Textbook of Biochemistry by Deb.
7. Outlines of Biochemistry by Conn and Stumpf
8. Practical Biochemistry by R.C. Gupta and S. Bhargavan.
9. Introduction of Practical Biochemistry by David T. Plummer. (3rd Edition)
10. Practical Biochemistry for Medical students by Rajagopal and Ramakrishna.
11. Practical Biochemistry by Harold Varley.

## **BP 204T.PATHOPHYSIOLOGY (THEORY)**

### **Course Objectives:**

Pathophysiology is the study of causes of diseases and reactions of the body to such disease producing causes. This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications and understanding of basic pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge required to practice medicine safely, confidently, rationally and effectively.

### **Course content:**

#### Unit I

10Hours

- Basic principles of Cell injury and Adaptation:

Introduction, definitions, Homeostasis, Components and Types of Feedback systems, Causes of cellular injury, Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage), Morphology of cell injury – Adaptive changes (Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia), Cell swelling, Intra cellular accumulation, Calcification, Enzyme leakage and Cell Death Acidosis & Alkalosis, Electrolyte imbalance

- Basic mechanism involved in the process of inflammation and repair:

Introduction, Clinical signs of inflammation, Different types of Inflammation, Mechanism of Inflammation – Alteration in vascular permeability and blood flow, migration of WBC's, Mediators of inflammation, Basic principles of wound healing in the skin, Pathophysiology of Atherosclerosis

### **Learning Outcomes:**

Upon completion of the subject student shall be able to –

- Describe the etiology and pathogenesis of the selected disease states;

#### Unit II

10Hours

- Cardiovascular System:
- Hypertension, congestive heart failure, ischemic heart disease (angina, myocardial infarction, atherosclerosis and arteriosclerosis)
- Respiratory system: Asthma, Chronic obstructive airways diseases.
- Renal system: Acute and chronic renal failure.

### **Learning Outcomes:**

Upon completion of the subject student shall be able to –

- Describe the etiology and pathogenesis of the selected disease states;
- Name the signs and symptoms of the diseases; and
- Mention the complications of the diseases

#### Unit III

10Hours

- Haematological Diseases:
- Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalasemia, hereditary acquired anemia, hemophilia
- Endocrine system: Diabetes, thyroid diseases, disorders of sex hormones
- Nervous system: Epilepsy, Parkinson's disease, stroke, psychiatric disorders: depression, schizophrenia and Alzheimer's disease.
- Gastrointestinal system: Peptic Ulcer

### **Learning Outcomes:**



Upon completion of the subject student shall be able to –

- Describe the etiology and pathogenesis of the selected disease states;
- Name the signs and symptoms of the diseases; and
- Mention the complications of the diseases

#### Unit IV

8 Hours

- Inflammatory bowel diseases, jaundice, hepatitis (A, B, C, D, E, F) alcoholic liver disease.
- Disease of bones and joints: Rheumatoid arthritis, osteoporosis and gout
- Principles of cancer: classification, etiology and pathogenesis of cancer
- Diseases of bones and joints: Rheumatoid Arthritis, Osteoporosis, Gout
- Principles of Cancer: Classification, etiology and pathogenesis of Cancer

#### **Learning Outcomes:**

Upon completion of the subject student shall be able to –

- Describe the etiology and pathogenesis of the selected disease states;
- Name the signs and symptoms of the diseases; and
- Mention the complications of the diseases

#### Unit V

7 Hours

- Infectious diseases: Meningitis, Typhoid, Leprosy, Tuberculosis Urinary tract infections
- Sexually transmitted diseases: AIDS, Syphilis, Gonorrhoea

#### **Learning Outcomes:**

Upon completion of the subject student shall be able to –

- Describe the etiology and pathogenesis of the selected disease states;
- Name the signs and symptoms of the diseases; and
- Mention the complications of the diseases

#### **Recommended Books (Latest Editions)**

1. Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins & Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier; 2014.
2. Harsh Mohan; Text book of Pathology; 6th edition; India; Jaypee Publications; 2010.
3. Laurence B, Bruce C, Bjorn K. ; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12th edition; New York; McGraw-Hill; 2011.
4. Best, Charles Herbert 1899-1978; Taylor, Norman Burke 1885-1972; West, John B (John Burnard); Best and Taylor's Physiological basis of medical practice; 12th ed; united states;
5. William and Wilkins, Baltimore; 1991 [1990 printing].
6. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston; Davidson's Principles and Practice of Medicine; 21st edition; London; ELBS/Churchill Livingstone; 2010.
7. Guyton A, John .E Hall; Textbook of Medical Physiology; 12th edition; WB Saunders Company; 2010.
8. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; 9th edition; London; McGraw-Hill Medical; 2014.
9. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia; WB Saunders Company; 1997.

10. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3rd edition; London; Churchill Livingstone publication; 2003.

**Recommended Journals**

- The Journal of Pathology. ISSN: 1096-9896 (Online)
- The American Journal of Pathology. ISSN: 0002-9440
- Pathology. 1465-3931 (Online)
- International Journal of Physiology, Pathophysiology and Pharmacology. ISSN: 1944-8171 (Online)
- Indian Journal of Pathology and Microbiology. ISSN-0377-4929.

## **BP205 T. COMPUTER APPLICATIONS IN PHARMACY (Theory)**

### **Course Objectives:**

This subject deals with the introduction Database, Database Management system, computer application in clinical studies and use of databases.

### **Course content:**

UNIT – I 06 hours

Number system: Binary number system, Decimal number system, Octal number system, Hexadecimal number systems, conversion decimal to binary, binary to decimal, octal to binary etc, binary addition, binary subtraction – One's complement, Two's complement method, binary multiplication, binary division

### **Learning Outcomes:**

Upon completion of the course the student shall be able to

- Know the various types of application of computers in pharmacy

UNIT –II 06 hours

Web technologies: Introduction to HTML, XML, CSS and Programming languages, introduction to web servers and Server Products

Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database

### **Learning Outcomes:**

Upon completion of the course the student shall be able to

- Know the various types of databases
- Know the various applications of databases in pharmacy

UNIT – III 06 hours

Application of computers in Pharmacy – Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology and adherence monitoring

Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System

### **Learning Outcomes:**

Upon completion of the course the student shall be able to

- Know the various types of application of computers in pharmacy

UNIT – IV 06 hours

Bioinformatics: Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine Discovery

### **Learning Outcomes:**

Upon completion of the course the student shall be able to

- Know the various types of application of computers in pharmacy
- Know the various types of databases
- Know the various applications of databases in pharmacy

UNIT-V 06 hours

Computers as data analysis in Preclinical development: Chromatographic data analysis(CDS), Laboratory Information management System (LIMS) and Text Information Management System(TIMs)

**Learning Outcomes:**

Upon completion of the course the student shall be able to

- Know the various types of application of computers in pharmacy
- Know the various types of databases
- Know the various applications of databases in pharmacy

**BP210P. COMPUTER APPLICATIONS IN PHARMACY (Practical)**

1. Design a questionnaire using a word processing package to gather information about a particular disease.
2. Create a HTML web page to show personal information.
3. Retrieve the information of a drug and its adverse effects using online tools
4. Creating mailing labels Using Label Wizard , generating label in MS WORD
5. Create a database in MS Access to store the patient information with the required fields Using access
6. Design a form in MS Access to view, add, delete and modify the patient record in the database
7. Generating report and printing the report from patient database
8. Creating invoice table using – MS Access
9. Drug information storage and retrieval using MS Access
10. Creating and working with queries in MS Access
11. Exporting Tables, Queries, Forms and Reports to web pages
12. Exporting Tables, Queries, Forms and Reports to XML pages

**Recommended books (Latest edition):**

1. Computer Application in Pharmacy – William E.Fassett –Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.
2. Computer Application in Pharmaceutical Research and Development –Sean Ekins –
3. Wiley-Interscience, A John Willey and Sons, INC., Publication, USA
4. Bioinformatics (Concept, Skills and Applications) – S.C.Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002(INDIA)
5. Microsoft office Access - 2003, Application Development Using VBA, SQL Server, DAP and Infopath – Cary N.Prague – Wiley Dreamtech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi – 110002

## **BP 206 T. ENVIRONMENTAL SCIENCES (Theory)**

### **Course Objectives:**

Environmental Sciences is the scientific study of the environmental system and the status of its inherent or induced changes on organisms. It includes not only the study of physical and biological characters of the environment but also the social and cultural factors and the impact of man on environment.

### **Course content:**

#### Unit-I

10hours

The Multidisciplinary nature of environmental studies

Natural Resources

Renewable and non-renewable resources:

Natural resources and associated problems

- a) Forest resources; b) Water resources; c) Mineral resources; d) Food resources; e) Energy resources; f) Land resources: Role of an individual in conservation of natural resources.

### **Learning Outcomes:**

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

- Create the awareness about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the environment.
- Motivate learner to participate in environment protection and environment improvement.
- Acquire skills to help the concerned individuals in identifying and solving environmental problems.
- Strive to attain harmony with Nature.

#### Unit-II

10hours

Ecosystems

- Concept of an ecosystem.
- Structure and function of an ecosystem.
- Introduction, types, characteristic features, structure and function of the ecosystems: Forest ecosystem; Grassland ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)

### **Learning Outcomes:**

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

- Create the awareness about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the environment.
- Motivate learner to participate in environment protection and environment improvement.
- Acquire skills to help the concerned individuals in identifying and solving environmental problems.
- Strive to attain harmony with Nature.

#### Unit- III

10hours

Environmental Pollution: Air pollution; Water pollution; Soil pollution

### **Learning Outcomes:**

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

- Create the awareness about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the environment.
- Motivate learner to participate in environment protection and environment improvement.
- Acquire skills to help the concerned individuals in identifying and solving environmental problems.
- Strive to attain harmony with Nature.

**Recommended Books (Latest edition):**

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
5. Clark R.S., Marine Pollution, Clarendon Press Oxford
6. Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p
7. De A.K., Environmental Chemistry, Wiley Eastern Ltd.
8. Down of Earth, Centre for Science and Environment

## SEMESTER - III

### BP301T. PHARMACEUTICAL ORGANIC CHEMISTRY –II (Theory)

#### Course Objectives:

This subject deals with general methods of preparation and reactions of some organic compounds. Reactivity of organic compounds are also studied here. The syllabus emphasizes on mechanisms and orientation of reactions. Chemistry of fats and oils are also included in the syllabus.

#### Course Content:

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

#### Learning Outcomes:

Upon completion of the course the student shall be able to

- Write the structure, name and the type of isomerism of the organic compound
- Write the reaction, name the reaction and orientation of reactions
- Account for reactivity/stability of compounds,
- Prepare organic compounds

#### 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.

#### Learning Outcomes:

Upon completion of the course the student shall be able to

- Write the structure, name and the type of isomerism of the organic compound
- Write the reaction, name the reaction and orientation of reactions
- Account for reactivity/stability of compounds,
- Prepare organic compounds

#### 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.

**Learning Outcomes:**

Upon completion of the course the student shall be able to

- Write the structure, name and the type of isomerism of the organic compound
- Write the reaction, name the reaction and orientation of reactions
- Account for reactivity/stability of compounds,
- Prepare organic compounds

UNIT IV

08 Hours

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

**Learning Outcomes:**

Upon completion of the course the student shall be able to

- Write the structure, name and the type of isomerism of the organic compound
- Write the reaction, name the reaction and orientation of reactions
- Account for reactivity/stability of compounds,
- Prepare organic compounds

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

**Learning Outcomes:**

Upon completion of the course the student shall be able to

- Write the structure, name and the type of isomerism of the organic compound
- Write the reaction, name the reaction and orientation of reactions
- Account for reactivity/stability of compounds,
- Prepare organic compounds



**BP305P. PHARMACEUTICAL ORGANIC CHEMISTRY -II (Practical) 4 Hrs/week**

- 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

**Recommended Books (Latest Editions)**

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.

## **BP302T. PHYSICAL PHARMACEUTICS-I (Theory)**

### **Course Objectives:**

The course deals with the various physical and physicochemical properties, and principles involved in dosage forms/formulations. Theory and practical components of the subject help the student to get a better insight into various areas of formulation research and development, and stability studies of pharmaceutical dosage forms.

### **Course Content:**

#### 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

### **Learning Outcomes:**

Upon the completion of the course student shall be able to

- Understand various physicochemical properties of drug molecules in the designing the dosage forms
- Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.

#### 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

### **Learning Outcomes:**

Upon the completion of the course student shall be able to

- Understand various physicochemical properties of drug molecules in the designing the dosage forms
- Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.

#### 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.

### **Learning Outcomes:**

Upon the completion of the course student shall be able to

- Understand various physicochemical properties of drug molecules in the designing the dosage forms

- Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.

#### 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.

#### **Learning Outcomes:**

Upon the completion of the course student shall be able to

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

#### 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.

#### **Learning Outcomes:**

Upon the completion of the course student shall be able to

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

**BP306P. PHYSICAL PHARMACEUTICS – I (Practical)**

4 Hrs/week

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 CCl<sub>4</sub> 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

**Recommended Books: (Latest Editions)**

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. PHARMACEUTICAL MICROBIOLOGY (Theory)**

### **Course Objectives:**

Study of all categories of microorganisms especially for the production of alcohol, antibiotics, vaccines, vitamins enzymes etc.

### **Course content:**

#### 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.

### **Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Understand methods of identification, cultivation and preservation of various microorganisms
- Learn sterility testing of pharmaceutical products.
- Understand the cell culture technology and its applications in pharmaceutical industries.

#### 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.

### **Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Understand methods of identification, cultivation and preservation of various microorganisms
- To understand the importance and implementation of sterilization in pharmaceutical processing and industry
- Learn sterility testing of pharmaceutical products.

#### 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.

**Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Understand methods of identification, cultivation and preservation of various microorganisms
- To understand the importance and implementation of sterilization in pharmaceutical processing and industry
- Learn sterility testing of pharmaceutical products.
- Carried out microbiological standardization of Pharmaceuticals.

## 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.

**Learning Outcomes:**

Upon completion of the subject student shall be able to;

- To understand the importance and implementation of sterilization in pharmaceutical processing and industry
- Learn sterility testing of pharmaceutical products.
- Carried out microbiological standardization of Pharmaceuticals.

## 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.

**Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Understand methods of identification, cultivation and preservation of various microorganisms
- Carried out microbiological standardization of Pharmaceuticals.
- Understand the cell culture technology and its applications in pharmaceutical industries.

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

4 Hrs/week

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.

**Recommended Books (Latest edition)**

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th 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

## **BP 304 T. PHARMACEUTICAL ENGINEERING (Theory)**

### **Course Objectives:**

This course is designed to impart a fundamental knowledge on the art and science of various unit operations used in pharmaceutical industry.

### **Course content:**

#### **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.

### **Learning Outcomes:**

Upon completion of the course student shall be able:

- To know various unit operations used in Pharmaceutical industries.
- To understand the material handling techniques.
- To perform various processes involved in pharmaceutical manufacturing process.
- To carry out various test to prevent environmental pollution.

#### **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

### **Learning Outcomes:**

Upon completion of the course student shall be able:

- To know various unit operations used in Pharmaceutical industries.
- To understand the material handling techniques.
- To perform various processes involved in pharmaceutical manufacturing process.
- To carry out various test to prevent environmental pollution.

#### **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

**Learning Outcomes:**

Upon completion of the course student shall be able:

- To know various unit operations used in Pharmaceutical industries.
- To understand the material handling techniques.
- To perform various processes involved in pharmaceutical manufacturing process.
- To carry out various test to prevent environmental pollution.

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.

**Learning Outcomes:**

Upon completion of the course student shall be able:

- To know various unit operations used in Pharmaceutical industries.
- To understand the material handling techniques.
- To perform various processes involved in pharmaceutical manufacturing process.
- To carry out various test to prevent environmental pollution.

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.

**Learning Outcomes:**

Upon completion of the course student shall be able:

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

**BP308P - PHARMACEUTICAL ENGINEERING (Practical)**

4 Hours/week

1. Determination of radiation constant of brass, iron, unpainted and painted glass.
2. Steam distillation – To calculate the efficiency of steam distillation.
3. To determine the overall heat transfer coefficient by heat exchanger.
4. Construction of drying curves (for calcium carbonate and starch).
5. Determination of moisture content and loss on drying.
6. Determination of humidity of air – i) From wet and dry bulb temperatures –use of Dew point method.
7. Description of Construction working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier.
8. VIII. Size analysis by sieving – To evaluate size distribution of tablet granulations – Construction of various size frequency curves including arithmetic and logarithmic probability plots.
9. 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.
10. Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such other major equipment.
11. Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration and Thickness/ viscosity
12. To study the effect of time on the Rate of Crystallization.
13. To calculate the uniformity Index for given sample by using Double Cone Blender.

**Recommended Books: (Latest Editions)**

1. Introduction to chemical engineering – Walter L Badger & Julius Banchemo, 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 pharmaceutics- C.V.S Subrahmanyam et al., Latest edition.
8. Cooper and Gunn's Tutorial pharmacy, S.J. Carter, Latest edition.

## SEMESTER - IV

### BP401T. PHARMACEUTICAL ORGANIC CHEMISTRY –III (Theory)

#### Course Objectives:

This subject imparts knowledge on stereo-chemical aspects of organic compounds and organic reactions, important named reactions, chemistry of important hetero cyclic compounds. It also emphasizes on medicinal and other uses of organic compounds.

#### Course Content:

Note: To emphasize on definition, types, mechanisms, examples, uses/applications

UNIT-I 10 Hours

Stereo isomerism

Optical isomerism –

Optical activity, enantiomerism, diastereoisomerism, meso compounds Elements of symmetry, chiral and achiral molecules

DL system of nomenclature of optical isomers, sequence rules, RS system of nomenclature of optical isomers

Reactions of chiral molecules

Racemic modification and resolution of racemic mixture. Asymmetric synthesis: partial and absolute

#### Learning Outcomes:

At the end of the course, the student shall be able to

- Explain the stereo chemical aspects of organic compounds and stereo chemical reactions

UNIT-II 10 Hours

Geometrical isomerism

Nomenclature of geometrical isomers (Cis Trans, EZ, Syn Anti systems)

Methods of determination of configuration of geometrical isomers.

Conformational isomerism in Ethane, n-Butane and Cyclohexane.

Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity.

Stereospecific and stereoselective reactions

#### Learning Outcomes:

At the end of the course, the student shall be able to

- Explain the stereo chemical aspects of organic compounds and stereo chemical reactions

UNIT-III 10 Hours

Heterocyclic compounds:

Nomenclature and classification

Synthesis, reactions and medicinal uses of following compounds/derivatives Pyrrole, Furan, and Thiophene

Relative aromaticity and reactivity of Pyrrole, Furan and Thiophene

#### Learning Outcomes:

At the end of the course, the student shall be able to

- Understand the methods of preparation and properties of organic compounds
- Know the medicinal uses and other applications of organic compounds

#### UNIT-IV

8 Hours

Synthesis, reactions and medicinal uses of following compounds/derivatives Pyrazole, Imidazole, Oxazole and Thiazole.

Pyridine, Quinoline, Isoquinoline, Acridine and Indole. Basicity of pyridine Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives

#### **Learning Outcomes:**

At the end of the course, the student shall be able to

- Understand the methods of preparation and properties of organic compounds
- Know the medicinal uses and other applications of organic compounds

#### UNIT-V

07 Hours

Reactions of synthetic importance

Metal hydride reduction ( $\text{NaBH}_4$  and  $\text{LiAlH}_4$ ), Clemmensen reduction, Birch reduction, Wolff Kishner reduction.

Oppenauer-oxidation and Dakin reaction.

Beckmanns rearrangement and Schmidt rearrangement. Claisen-Schmidt condensation

#### **Learning Outcomes:**

At the end of the course, the student shall be able to

- Understand the methods of preparation and properties of organic compounds
- Know the medicinal uses and other applications of organic compounds

#### **Recommended Books (Latest Editions)**

1. Organic chemistry by I.L. Finar, Volume-I & II.
2. A text book of organic chemistry – Arun Bahl, B.S. Bahl.
3. Heterocyclic Chemistry by Raj K. Bansal
4. Organic Chemistry by Morrison and Boyd
5. Heterocyclic Chemistry by T.L. Gilchrist

## **BP402T. MEDICINAL CHEMISTRY – I (Theory)**

### **Course Objectives:**

This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

### **Course Content:**

Study of the development of the following classes of drugs, Classification, mechanism action, uses of drugs mentioned in the course, Structure activity relationship of select class of drugs as specified in the course and synthesis of drugs superscripted (\*)

#### UNIT- I

10 Hours

Introduction to Medicinal Chemistry

History and development of medicinal chemistry Physicochemical properties in relation to biological action

Ionization, Solubility, Partition Coefficient, Hydrogen bonding, Protein binding, Chelation, Bioisosterism, Optical and Geometrical isomerism.

Drug metabolism

Drug metabolism principles- Phase I and Phase II.

Factors affecting drug metabolism including stereo chemical aspects.

### **Learning Outcomes:**

Upon completion of the course the student shall be able to

- Understand the chemistry of drugs with respect to their pharmacological activity

#### UNIT- II

10 Hours

Drugs acting on Autonomic Nervous System Adrenergic Neurotransmitters:

Biosynthesis and catabolism of catecholamine.

Adrenergic receptors (Alpha & Beta) and their distribution.

Sympathomimetic agents: SAR of Sympathomimetic agents

Direct acting: Nor-epinephrine, Epinephrine, Phenylephrine\*, Dopamine,

Methyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline, Salbutamol\*, Bitolterol, Naphazoline, Oxymetazoline and Xylometazoline.

- Indirect acting agents: Hydroxyamphetamine, Pseudoephedrine, Propylhexedrine.
- Agents with mixed mechanism: Ephedrine, Metaraminol.

Adrenergic Antagonists:

Alpha adrenergic blockers: Tolazoline\*, Phentolamine, Phenoxybenzamine, Prazosin, Dihydroergotamine, Methysergide.

Beta adrenergic blockers: SAR of beta blockers, Propranolol\*, Metibranolol, Atenolol, Betazolol, Bisoprolol, Esmolol, Metoprolol, Labetolol, Carvedilol.

### **Learning Outcomes:**

Upon completion of the course the student shall be able to

- Understand the chemistry of drugs with respect to their pharmacological activity
- Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
- Know the Structural Activity Relationship (SAR) of different class of drugs

- Write the chemical synthesis of some drugs

### UNIT-III

10 Hours

Cholinergic neurotransmitters:

Biosynthesis and catabolism of acetylcholine.

Cholinergic receptors (Muscarinic & Nicotinic) and their distribution.

Parasympathomimetic agents: SAR of Parasympathomimetic agents

Direct acting agents: Acetylcholine, Carbachol\*, Bethanechol, Methacholine, Pilocarpine.

Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible): Physostigmine, Neostigmine\*, Pyridostigmine, Edrophonium chloride, Tacrine hydrochloride, Ambenonium chloride, Isoflurophate, Echothiophate iodide, Parathione, Malathion.

Cholinesterase reactivator: Pralidoxime chloride.

Cholinergic Blocking agents: SAR of cholinolytic agents

Solanaceous alkaloids and analogues: Atropine sulphate, Hyoscyamine sulphate, Scopolamine hydrobromide, Homatropine hydrobromide, Ipratropium bromide\*.

Synthetic cholinergic blocking agents: Tropicamide, Cyclopentolate hydrochloride, Clidinium bromide, Dicyclomine hydrochloride\*, Glycopyrrolate, Methantheline bromide, Propantheline bromide, Benztropine mesylate, Orphenadrine citrate, Biperidine hydrochloride, Procyclidine hydrochloride\*, Tridihexethyl chloride, Isopropamide iodide, Ethopropazine hydrochloride.

#### **Learning Outcomes:**

Upon completion of the course the student shall be able to

- Understand the chemistry of drugs with respect to their pharmacological activity
- Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
- Know the Structural Activity Relationship (SAR) of different class of drugs
- Write the chemical synthesis of some drugs

### UNIT- IV

08 Hours

Drugs acting on Central Nervous System

#### A. Sedatives and Hypnotics:

Benzodiazepines: SAR of Benzodiazepines, Chlordiazepoxide, Diazepam\*, Oxazepam, Chlorazepate, Lorazepam, Alprazolam, Zolpidem

Barbiturates: SAR of barbiturates, Barbitol\*, Phenobarbital, Mephobarbital, Amobarbital, Butobarbital, Pentobarbital, Secobarbital

Miscellaneous:

Amides & imides: Glutethimide.

Alcohol & their carbamate derivatives: Meprobamate, Ethchlorvynol. Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

#### B. Antipsychotics

Phenothiazines: SAR of Phenothiazines - Promazine hydrochloride, Chlorpromazine hydrochloride\*, Triflupromazine, Thioridazine hydrochloride, Piperacetazine hydrochloride, Prochlorperazine maleate, Trifluoperazine hydrochloride.

Ring Analogues of Phenothiazines: Chlorprothixene, Thiothixene, Loxapine succinate, Clozapine.

Fluro buterophenones: Haloperidol, Droperidol, Risperidone.

Beta amino ketones: Molindone hydrochloride.

Benzamides: Sulpieride.

C. Anticonvulsants:

SAR of Anticonvulsants, mechanism of anticonvulsant action

Barbiturates: Phenobarbitone, Methabarbital. Hydantoins: Phenytoin\*, Mephenytoin, Ethotoin

Oxazolindione: Trimethadione, Paramethadione Succinimides:

Phensuximide, Methsuximide, Ethosuximide\* Urea and monoacylureas: Phenacemide, Carbamazepine\* Benzodiazepines: Clonazepam

Miscellaneous: Primidone, Valproic acid, Gabapentin, Felbamate\

### **Learning Outcomes:**

Upon completion of the course the student shall be able to

- Understand the chemistry of drugs with respect to their pharmacological activity
- Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
- Know the Structural Activity Relationship (SAR) of different class of drugs
- Write the chemical synthesis of some drugs

UNIT – V

07 Hours

Drugs acting on Central Nervous System

General anesthetics:

Inhalation anesthetics: Halothane\*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane.

Ultra short acting barbiturates: Methohexital sodium\*, Thiopental sodium, Thiopental sodium.

Dissociative anesthetics: Ketamine hydrochloride.\*

Narcotic and non-narcotic analgesics

Morphine and related drugs: SAR of Morphine analogues, Morphine sulphate, Codeine, Meperidine hydrochloride, Anileridine hydrochloride, Diphenoxylate hydrochloride, Loperamide hydrochloride, Fentanyl citrate\*, Methadone hydrochloride\*, Propoxyphene hydrochloride, Pentazocine, Levorphanol tartarate.

Narcotic antagonists: Nalorphine hydrochloride, Levallorphan tartarate, Naloxone hydrochloride.

Anti-inflammatory agents: Sodium salicylate, Aspirin, Mefenamic acid\*, Meclofenamate, Indomethacin, Sulindac, Tolmetin, Zomepirac, Diclofenac, Ketorolac, Ibuprofen\*, Naproxen, Piroxicam, Phenacetin, Acetaminophen, Antipyrine, Phenylbutazone.

### **Learning Outcomes:**

Upon completion of the course the student shall be able to

- Understand the chemistry of drugs with respect to their pharmacological activity
- Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
- Know the Structural Activity Relationship (SAR) of different class of drugs
- Write the chemical synthesis of some drugs

**BP406P. MEDICINAL CHEMISTRY – I (Practical)**

4 Hours/Week

**I** Preparation of drugs/ intermediates

1. 1,3-pyrazole
2. 1,3-oxazole
3. Benzimidazole
4. Benzotriazole
5. 2,3- diphenyl quinoxaline
6. Benzocaine
7. Phenytoin
8. Phenothiazine
9. Barbiturate

**II** Assay of drugs

- 1 Chlorpromazine
- 2 Phenobarbitone
- 3 Atropine
- 4 Ibuprofen
- 5 Aspirin
- 6 Furosemide

**III** Determination of Partition coefficient for any two drugs**Recommended Books (Latest Editions)**

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.
7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.



## **BP 403 T. PHYSICAL PHARMACEUTICS-II (Theory)**

### **Course Objectives:**

The course deals with the various physical and physicochemical properties, and principles involved in dosage forms/formulations. Theory and practical components of the subject help the student to get a better insight into various areas of formulation research and development, and stability studies of pharmaceutical dosage forms.

### **Course Content:**

#### UNIT-I

07 Hours

Colloidal dispersions: Classification of dispersed systems & their general characteristics, size & shapes of colloidal particles, classification of colloids & comparative account of their general properties. Optical, kinetic & electrical properties. Effect of electrolytes, coacervation, peptization & protective action.

### **Learning Outcomes:**

Upon the completion of the course student shall be able to

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

#### UNIT-II

10 Hours

Rheology: Newtonian systems, law of flow, kinematic viscosity, effect of temperature, non-Newtonian systems, pseudoplastic, dilatant, plastic, thixotropy, thixotropy in formulation, determination of viscosity, capillary, falling Sphere, rotational viscometers

Deformation of solids: Plastic and elastic deformation, Heckel equation, Stress, Strain, Elastic Modulus

### **Learning Outcomes:**

Upon the completion of the course student shall be able to

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

#### UNIT-III

10 Hours

Coarse dispersion: Suspension, interfacial properties of suspended particles, settling in suspensions, formulation of flocculated and deflocculated suspensions. Emulsions and theories of emulsification, microemulsion and multiple emulsions; Stability of emulsions, preservation of emulsions, rheological properties of emulsions and emulsion formulation by HLB method.

### **Learning Outcomes:**

Upon the completion of the course student shall be able to

- Understand various physicochemical properties of drug molecules in the designing the dosage forms

- Know the principles of chemical kinetics & to use them for stability testing and determination of expiry date of formulations
- Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.

#### UNIT-IV

10Hours

Micromeritics: Particle size and distribution, mean particle size, number and weight distribution, particle number, methods for determining particle size by different methods, counting and separation method, particle shape, specific surface, methods for determining surface area, permeability, adsorption, derived properties of powders, porosity, packing arrangement, densities, bulkiness & flow properties.

#### **Learning Outcomes:**

Upon the completion of the course student shall be able to

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

#### UNIT-V

10 Hours

Drug stability: Reaction kinetics: zero, pseudo-zero, first & second order, units of basic rate constants, determination of reaction order. Physical and chemical factors influencing the chemical degradation of pharmaceutical product: temperature, solvent, ionic strength, dielectric constant, specific & general acid base catalysis, Simple numerical problems. Stabilization of medicinal agents against common reactions like hydrolysis & oxidation. Accelerated stability testing in expiration dating of pharmaceutical dosage forms. Photolytic degradation and its prevention

#### **Learning Outcomes:**

Upon the completion of the course student shall be able to

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

**BP 407P. PHYSICAL PHARMACEUTICS- II (Practical)**

3 Hrs/week

1. Determination of particle size, particle size distribution using sieving method
2. Determination of particle size, particle size distribution using Microscopic method
3. Determination of bulk density, true density and porosity
4. Determine the angle of repose and influence of lubricant on angle of repose
5. Determination of viscosity of liquid using Ostwald's viscometer
6. Determination sedimentation volume with effect of different suspending agent
7. Determination sedimentation volume with effect of different concentration of single suspending agent
8. Determination of viscosity of semisolid by using Brookfield viscometer
9. Determination of reaction rate constant first order.
10. Determination of reaction rate constant second order
11. Accelerated stability studies

**Recommended Books: (Latest Editions)**

1. Physical Pharmacy by Alfred Martin, Sixth edition
2. Experimental pharmaceuticals 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, Marcel Dekkar 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 Manavalan R.

## **BP 404 T. PHARMACOLOGY-I (Theory)**

### **Course Objectives:**

The main purpose of the subject is to understand what drugs do to the living organisms and how their effects can be applied to therapeutics. The subject covers the information about the drugs like, mechanism of action, physiological and biochemical effects (pharmacodynamics) as well as absorption, distribution, metabolism and excretion (pharmacokinetics) along with the adverse effects, clinical uses, interactions, doses, contraindications and routes of administration of different classes of drugs.

### **Course Content:**

#### UNIT-I

08 hours

##### 1. General Pharmacology

- a. Introduction to Pharmacology- Definition, historical landmarks and scope of pharmacology, nature and source of drugs, essential drugs concept and routes of drug administration, Agonists, antagonists( competitive and non competitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy.
- b. Pharmacokinetics- Membrane transport, absorption, distribution, metabolism and excretion of drugs .Enzyme induction, enzyme inhibition, kinetics of elimination

### **Learning Outcomes:**

Upon completion of this course the student should be able to

- Understand the basic pharmacology.
- Apply the basic pharmacological knowledge in the prevention and treatment of various diseases.

#### UNIT-II

12 Hours

##### General Pharmacology

- a. Pharmacodynamics- Principles and mechanisms of drug action. Receptor theories and classification of receptors, regulation of receptors. drug receptors interactions signal transduction mechanisms, G-protein–coupled receptors, ion channel receptor, transmembrane enzyme linked receptors, transmembrane JAK-STAT binding receptor and receptors that regulate transcription factors, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action.
- b. Adverse drug reactions.
- c. Drug interactions (pharmacokinetic and pharmacodynamic)
- d. Drug discovery and clinical evaluation of new drugs -Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.

### **Learning Outcomes:**

Upon completion of this course the student should be able to

- Explain the mechanism of drug action at organ system/sub cellular/ macromolecular levels.
- Apply the basic pharmacological knowledge in the prevention and treatment of various diseases.
- Appreciate correlation of pharmacology with other bio medical sciences

### UNIT-III

10 Hours

2. Pharmacology of drugs acting on peripheral nervous system
  - a. Organization and function of ANS.
  - b. Neurohumoral transmission, co-transmission and classification of neurotransmitters.
  - c. Parasympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics.
  - d. Neuromuscular blocking agents and skeletal muscle relaxants (peripheral).
  - e. Local anesthetic agents.
  - f. Drugs used in myasthenia gravis and glaucoma

#### **Learning Outcomes:**

Upon completion of this course the student should be able to

- Understand the pharmacological actions of different categories of drugs
- Explain the mechanism of drug action at organ system/sub cellular/ macromolecular levels.
- Apply the basic pharmacological knowledge in the prevention and treatment of various diseases.
- Observe the effect of drugs on animals by simulated experiments
- Appreciate correlation of pharmacology with other bio medical sciences

### UNIT-IV

08 Hours

3. Pharmacology of drugs acting on central nervous system
  - a. Neurohumoral transmission in the C.N.S. special emphasis on importance of various neurotransmitters like with GABA, Glutamate, Glycine, serotonin, dopamine.
  - b. General anesthetics and pre-anesthetics.
  - c. Sedatives, hypnotics and centrally acting muscle relaxants.
  - d. Anti-epileptics
  - e. Alcohols and disulfiram

#### **Learning Outcomes:**

Upon completion of this course the student should be able to

- Understand the pharmacological actions of different categories of drugs
- Explain the mechanism of drug action at organ system/sub cellular/ macromolecular levels.
- Apply the basic pharmacological knowledge in the prevention and treatment of various diseases.
- Observe the effect of drugs on animals by simulated experiments
- Appreciate correlation of pharmacology with other bio medical sciences

### UNIT-V

07 Hours

3. Pharmacology of drugs acting on central nervous system
  - a. Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens.
  - b. Drugs used in Parkinsons disease and Alzheimer's disease.
  - c. CNS stimulants and nootropics.
  - d. Opioid analgesics and antagonists
  - e. Drug addiction, drug abuse, tolerance and dependence.

**Learning Outcomes:**

Upon completion of this course the student should be able to

- Understand the pharmacological actions of different categories of drugs
- Explain the mechanism of drug action at organ system/sub cellular/ macromolecular levels.
- Apply the basic pharmacological knowledge in the prevention and treatment of various diseases.
- Observe the effect of drugs on animals by simulated experiments
- Appreciate correlation of pharmacology with other bio medical sciences

**BP 408**

## **PHARMACOLOGY-I (Practical)**

4Hrs/Week

1. Introduction to experimental pharmacology.
2. Commonly used instruments in experimental pharmacology.
3. Study of common laboratory animals.
4. Maintenance of laboratory animals as per CPCSEA guidelines.
5. Common laboratory techniques. Blood withdrawal, serum and plasma separation, anesthetics and euthanasia used for animal studies.
6. Study of different routes of drugs administration in mice/rats.
7. Study of effect of hepatic microsomal enzyme inducers on the phenobarbitone sleeping time in mice.
8. Effect of drugs on ciliary motility of frog oesophagus
9. Effect of drugs on rabbit eye.
10. Effects of skeletal muscle relaxants using rota-rod apparatus.
11. Effect of drugs on locomotor activity using actophotometer.
12. Anticonvulsant effect of drugs by MES and PTZ method.
13. Study of stereotypy and anti-catatonic activity of drugs on rats/mice.
14. Study of anxiolytic activity of drugs using rats/mice.
15. Study of local anesthetics by different methods

Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos

### **Recommended Books (Latest Editions)**

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology
6. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert,
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,

## **BP 405 T.PHARMACOGNOSY AND PHYTOCHEMISTRY I (Theory)**

### **Course Objectives:**

The subject involves the fundamentals of Pharmacognosy like , classification of crude drugs, their identification and evaluation, phytochemicals present in them and their medicinal properties.

### **Course Content:**

#### **UNIT-I**

10 Hours

Introduction to Pharmacognosy:

- a. Definition, history, scope and development of Pharmacognosy
- b. Sources of Drugs – Plants, Animals, Marine & Tissue culture
- c. Organized drugs, unorganized drugs (dried latex, dried juices, dried extracts, gums and mucilages, oleoresins and oleo- gum -resins).

Classification of drugs:

Alphabetical, morphological, taxonomical, chemical, pharmacological, chemo and sero taxonomical classification of drugs

Quality control of Drugs of Natural Origin:

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

Quantitative microscopy of crude drugs including lycopodium spore method, leaf constants, camera lucida and diagrams of microscopic objects to scale with camera lucida.

### **Learning Outcomes:**

Upon completion of the course, the student shall be able

- To know the techniques in the cultivation and production of crude drugs
- To know the crude drugs, their uses and chemical nature
- Know the evaluation techniques for the herbal drugs
- To carry out the microscopic and morphological evaluation of crude drugs

#### **UNIT-II**

10 Hours

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

Cultivation and Collection of drugs of natural origin Factors influencing cultivation of medicinal plants. Plant hormones and their applications.

Polyploidy, mutation and hybridization with reference to medicinal plants

Conservation of medicinal plants

### **Learning Outcomes:**

Upon completion of the course, the student shall be able

- To know the techniques in the cultivation and production of crude drugs
- To know the crude drugs, their uses and chemical nature
- Know the evaluation techniques for the herbal drugs
- To carry out the microscopic and morphological evaluation of crude drugs

#### **UNIT-III**

07 Hours

Plant tissue culture:

Historical development of plant tissue culture, types of cultures, Nutritional requirements, growth and their maintenance.

Applications of plant tissue culture in pharmacognosy. Edible vaccines



**Learning Outcomes:**

Upon completion of the course, the student shall be able

- To know the techniques in the cultivation and production of crude drugs
- To know the crude drugs, their uses and chemical nature
- Know the evaluation techniques for the herbal drugs
- To carry out the microscopic and morphological evaluation of crude drugs

## UNIT IV

10 Hours

Pharmacognosy in various systems of medicine:

Role of Pharmacognosy in allopathy and traditional systems of medicine namely, Ayurveda, Unani, Siddha, Homeopathy and Chinese systems of medicine.

Introduction to secondary metabolites:

Definition, classification, properties and test for identification of Alkaloids, Glycosides, Flavonoids, Tannins, Volatile oil and Resins

**Learning Outcomes:**

Upon completion of the course, the student shall be able

- To know the techniques in the cultivation and production of crude drugs
- To know the crude drugs, their uses and chemical nature
- Know the evaluation techniques for the herbal drugs
- To carry out the microscopic and morphological evaluation of crude drugs

## UNIT V

08 Hours

Study of biological source, chemical nature and uses of drugs of natural origin containing following drugs

Plant Products:

Fibers - Cotton, Jute, Hemp

Hallucinogens, Teratogens, Natural allergens

Primary metabolites:

General introduction, detailed study with respect to chemistry, sources, preparation, evaluation, preservation, storage, therapeutic used and commercial utility as Pharmaceutical Aids and/or Medicines for the following Primary metabolites:

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, Chaulmoogra oil, Wool Fat, Bees Wax

Marine Drugs:

Novel medicinal agents from marine sources

**Learning Outcomes:**

Upon completion of the course, the student shall be able

- To know the techniques in the cultivation and production of crude drugs
- To know the crude drugs, their uses and chemical nature
- Know the evaluation techniques for the herbal drugs
- To carry out the microscopic and morphological evaluation of crude drugs

**BP408 P. PHARMACOGNOSY AND PHYTOCHEMISTRY I (Practical) 4 Hours/Week**

1. Analysis of crude drugs by chemical tests: (i) Tragacanth (ii) Acacia (iii) Agar (iv) Gelatin (v) starch (vi) Honey (vii) Castor oil
2. Determination of stomatal number and index
3. Determination of vein islet number, vein islet termination and palisade ratio.
4. Determination of size of starch grains, calcium oxalate crystals by eye piece micrometer
5. Determination of Fiber length and width
6. Determination of number of starch grains by Lycopodium spore method
7. Determination of Ash value
8. Determination of Extractive values of crude drugs
9. Determination of moisture content of crude drugs
10. Determination of swelling index and foaming

**Recommended Books: (Latest Editions)**

1. W.C. Evans, 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 Edn., Lea and Febiger, Philadelphia, 1988.
3. Text Book of Pharmacognosy by T.E. Wallis
4. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
5. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
6. Herbal drug industry by R.D. Choudhary (1996), 1st Edn, Eastern Publisher, New Delhi.
7. Essentials of Pharmacognosy, Dr. S.H. Ansari, 2nd edition, Birla publications, New Delhi, 2007
8. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae
9. Anatomy of Crude Drugs by M.A. Iyengar

## SEMESTER - V

### BP501T. MEDICINAL CHEMISTRY – II (Theory)

#### Course Objectives:

This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

#### Course Content:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (\*)

#### UNIT- I

10 Hours

Antihistaminic agents: Histamine, receptors and their distribution in the human body

H1-antagonists: Diphenhydramine hydrochloride\*, Dimenhydrinate, Doxylamines succinate, Clemastine fumarate, Diphenylpyraline 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

H2-antagonists: Cimetidine\*, Famotidine, Ranitidin.

Gastric Proton pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole

Anti-neoplastic agents:

Alkylating agents: Meclorothamine\*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepea

Antimetabolites: Mercaptopurine\*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate\*, Azathioprine

Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate Miscellaneous: Cisplatin, Mitotane.

#### Learning Outcomes:

Upon completion of the course the student shall be able to

- Understand the chemistry of drugs with respect to their pharmacological activity
- Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
- Know the Structural Activity Relationship of different class of drugs
- Study the chemical synthesis of selected drugs

#### UNIT – II

10 Hours

Anti-anginal:

Vasodilators: Amyl nitrite, Nitroglycerin\*, Pentaerythritol tetranitrate, Isosorbide dinitrite\*, Dipyridamole.

Calcium channel blockers: Verapamil, Bepridil hydrochloride Diltiazem hydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine.

Diuretics:

Carbonic anhydrase inhibitors: Acetazolamide\*, Methazolamide, Dichlorphenamide.

Thiazides: Chlorthiazide\*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide,  
Loop diuretics: Furosemide\*, Bumetanide, Ethacrynic acid. Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride. Osmotic Diuretics: Mannitol

Anti-hypertensive Agents: Timolol, Captopril, Lisinopril, Enalapril, Benazepril hydrochloride, Quinapril hydrochloride, Methyldopate hydrochloride,\* Clonidine hydrochloride, Guanethidine monosulphate, Guanabenz acetate, Sodium nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.

### **Learning Outcomes:**

Upon completion of the course the student shall be able to

- Understand the chemistry of drugs with respect to their pharmacological activity
- Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
- Know the Structural Activity Relationship of different class of drugs
- Study the chemical synthesis of selected drugs

### UNIT- III

10 Hours

Anti-arrhythmic Drugs: Quinidine sulphate, Procainamide hydrochloride, Disopyramide phosphate\*, Phenytoin sodium, Lidocaine hydrochloride, Tocainide hydrochloride, Mexiletine hydrochloride, Lorcaïnide hydrochloride, Amiodarone, Sotalol.

Anti-hyperlipidemic agents: Clofibrate, Lovastatin, Cholesteramine and Cholestipol

Coagulant & Anticoagulants: Menadione, Acetomenadione, Warfarin\*, Anisindione, clopidogrel

Drugs used in Congestive Heart Failure: Digoxin, Digitoxin, Nesiritide, Bosentan, Tezosentan.

### **Learning Outcomes:**

Upon completion of the course the student shall be able to

- Understand the chemistry of drugs with respect to their pharmacological activity
- Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
- Know the Structural Activity Relationship of different class of drugs
- Study the chemical synthesis of selected drugs

### UNIT- IV

08 Hours

Drugs acting on Endocrine system

Nomenclature, Stereochemistry and metabolism of steroids

Sex hormones: Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol, Oestrione, Diethyl stilbestrol.

Drugs for erectile dysfunction: Sildenafil, Tadalafil.

Oral contraceptives: Mifepristone, Norgestrel, Levonorgestrol

Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone

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

### **Learning Outcomes:**

Upon completion of the course the student shall be able to

- Understand the chemistry of drugs with respect to their pharmacological activity
- Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
- Know the Structural Activity Relationship of different class of drugs
- Study the chemical synthesis of selected drugs

UNIT – V

07 Hours

Antidiabetic agents:

Insulin and its preparations

Sulfonyl ureas: Tolbutamide\*, Chlorpropamide, Glipizide, Glimepiride. Biguanides: Metformin.

Thiazolidinediones: Pioglitazone, Rosiglitazone. Meglitinides: Repaglinide, Nateglinide.

Glucosidase inhibitors: Acarbose, Voglibose.

Local Anesthetics: SAR of Local anesthetics

Benzoic Acid derivatives; Cocaine, Hexylcaine, Meprylcaine, Cyclomethycaine, Piperocaine.

Amino Benzoic acid derivatives: Benzocaine\*, Butamben, Procaine\*, Butacaine, Propoxycaine, Tetracaine, Benoxinate.

Lidocaine/Anilide derivatives: Lignocaine, Mepivacaine, Prilocaine, Etidocaine.

Miscellaneous: Phenacaine, Dipiperodon, Dibucaine.\*

### **Learning Outcomes:**

Upon completion of the course the student shall be able to

- Understand the chemistry of drugs with respect to their pharmacological activity
- Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
- Know the Structural Activity Relationship of different class of drugs
- Study the chemical synthesis of selected drugs

### **Recommended Books (Latest Editions)**

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.
7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1 to 5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

**BP 502 T. Industrial Pharmacy-I (Theory)**

3 hours/ week

**Course Objectives:**

This Course enables the student to understand and appreciate the influence of pharmaceutical additives and various pharmaceutical dosage forms on the performance of the drug product.

**Course content:**

## UNIT-I

07 Hours

Preformulation Studies: Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances.

- a. Physical properties: Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism
- b. Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization BCS classification of drugs & its significant

Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.

**Learning Outcomes:**

Upon completion of the course the student shall be able to

- Know various considerations in development of pharmaceutical dosage forms

## UNIT-II

10 Hours

## Tablets:

- a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling.
- b. Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating.
- c. Quality control tests: In process and finished product tests

Liquid orals: Formulation and manufacturing consideration of syrups and elixirs suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia

**Learning Outcomes:**

Upon completion of the course the student shall be able to

- Know the various pharmaceutical dosage forms and their manufacturing techniques.
- Know various considerations in development of pharmaceutical dosage forms
- Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality

## UNIT-III

08 Hours

## Capsules:

- a. Hard gelatin capsules: Introduction, Production of hard gelatin capsule shells. size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules.
- b. Soft gelatin capsules: Nature of shell and capsule content, size of capsules, importance of base adsorption and minim/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules and their applications.

Pellets: Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets

**Learning Outcomes:**

Upon completion of the course the student shall be able to

- Know the various pharmaceutical dosage forms and their manufacturing techniques.
- Know various considerations in development of pharmaceutical dosage forms
- Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality

## UNIT-IV

10 Hours

Parenteral Products:

- a. Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity
- b. Production procedure, production facilities and controls, aseptic processing
- c. Formulation of injections, sterile powders, large volume parenterals and lyophilized products.
- d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests of parenteral products.

Ophthalmic Preparations: Introduction, formulation considerations; formulation of eye drops, eye ointments and eye lotions; methods of preparation; labeling, containers; evaluation of ophthalmic preparations

**Learning Outcomes:**

Upon completion of the course the student shall be able to

- Know the various pharmaceutical dosage forms and their manufacturing techniques.
- Know various considerations in development of pharmaceutical dosage forms
- Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality

## UNIT-V

10 Hours

Cosmetics: Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens.

Pharmaceutical Aerosols: Definition, propellants, containers, valves, types of aerosol systems; formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies.

Packaging Materials Science: Materials used for packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.

**Learning Outcomes:**

Upon completion of the course the student shall be able to

- Know the various pharmaceutical dosage forms and their manufacturing techniques.
- Know various considerations in development of pharmaceutical dosage forms
- Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality

**BP 506 P. Industrial Pharmacy I (Practical)**

4 Hours/week

1. Preformulation studies on paracetamol/asparin/or any other drug
2. Preparation and evaluation of Paracetamol tablets
3. Preparation and evaluation of Aspirin tablets
4. Coating of tablets- film coating of tables/granules
5. Preparation and evaluation of Tetracycline capsules
6. Preparation of Calcium Gluconate injection
7. Preparation of Ascorbic Acid injection
8. Quality control test of (as per IP) marketed tablets and capsules
9. Preparation of Eye drops/ and Eye ointments
10. Preparation of Creams (cold / vanishing cream)
11. Evaluation of Glass containers (as per IP)

**Recommended Books: (Latest Editions)**

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman & J.B. Schwartz
2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman
3. Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman
4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition
5. Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS)
6. Theory and Practice of Industrial Pharmacy by Liberman & Lachman
7. Pharmaceutics- The science of dosage form design by M.E. Aulton, Churchill Livingstone, Latest edition
8. Introduction to Pharmaceutical Dosage Forms by H. C. Ansel, Lea & Febiger, Philadelphia, 5th edition, 2005
9. Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.



## **BP503.T. PHARMACOLOGY-II (Theory)**

### **Course Objectives:**

This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on different systems of body and in addition, emphasis on the basic concepts of bioassay.

### **Course Content:**

#### UNIT-I

10hours

1. Pharmacology of drugs acting on cardio vascular system
  - a. Introduction to hemodynamic and electrophysiology of heart.
  - b. Drugs used in congestive heart failure
  - c. Anti-hypertensive drugs.
  - d. Anti-anginal drugs.
  - e. Anti-arrhythmic drugs.
  - f. Anti-hyperlipidemic drugs.

### **Learning Outcomes:**

Upon completion of this course the student should be able to

- Understand the mechanism of drug action and its relevance in the treatment of different diseases
- Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments
- Demonstrate the various receptor actions using isolated tissue preparation
- Appreciate correlation of pharmacology with related medical sciences

#### UNIT-II 10hours

1. Pharmacology of drugs acting on cardio vascular system
  - a. Drug used in the therapy of shock.
  - b. Hematinics, coagulants and anticoagulants.
  - c. Fibrinolytics and anti-platelet drugs
  - d. Plasma volume expanders
2. Pharmacology of drugs acting on urinary system
  - a. Diuretics
  - b. Anti-diuretics.

### **Learning Outcomes:**

Upon completion of this course the student should be able to

- Understand the mechanism of drug action and its relevance in the treatment of different diseases
- Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments
- Demonstrate the various receptor actions using isolated tissue preparation
- Appreciate correlation of pharmacology with related medical sciences

#### UNIT-III 10hours

3. Autocoids and related drugs
  - a. Introduction to autacoids and classification
  - b. Histamine, 5-HT and their antagonists.

- c. Prostaglandins, Thromboxanes and Leukotrienes.
- d. Angiotensin, Bradykinin and Substance P.
- e. Non-steroidal anti-inflammatory agents
- f. Anti-gout drugs
- g. Antirheumatic drugs

**Learning Outcomes:**

Upon completion of this course the student should be able to

- Understand the mechanism of drug action and its relevance in the treatment of different diseases
- Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments
- Demonstrate the various receptor actions using isolated tissue preparation
- Appreciate correlation of pharmacology with related medical sciences

UNIT-IV      08hours

4. Pharmacology of drugs acting on endocrine system
  - a. Basic concepts in endocrine pharmacology.
  - b. Anterior Pituitary hormones- analogues and their inhibitors.
  - c. Thyroid hormones- analogues and their inhibitors.
  - d. Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D.
  - e. Insulin, Oral Hypoglycemic agents and glucagon.
  - f. ACTH and corticosteroids.

**Learning Outcomes:**

Upon completion of this course the student should be able to

- Understand the mechanism of drug action and its relevance in the treatment of different diseases
- Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments
- Demonstrate the various receptor actions using isolated tissue preparation
- Appreciate correlation of pharmacology with related medical sciences

UNIT-V      07hours

5. Pharmacology of drugs acting on endocrine system
  - a. Androgens and Anabolic steroids.
  - b. Estrogens, progesterone and oral contraceptives.
  - c. Drugs acting on the uterus.
6. Bioassay
  - a. Principles and applications of bioassay.
  - b. Types of bioassay
  - c. Bioassay of insulin, oxytocin, vasopressin, ACTH, d-tubocurarine, digitalis, histamine and 5-HT

**Learning Outcomes:**

Upon completion of this course the student should be able to

- Understand the mechanism of drug action and its relevance in the treatment of different diseases

- Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments
- Demonstrate the various receptor actions using isolated tissue preparation
- Appreciate correlation of pharmacology with related medical sciences

**BP 507 P. PHARMACOLOGY-II (Practical)**

4Hrs/Week

1. Introduction to in-vitro pharmacology and physiological salt solutions.
2. Effect of drugs on isolated frog heart.
3. Effect of drugs on blood pressure and heart rate of dog.
4. Study of diuretic activity of drugs using rats/mice.
5. DRC of acetylcholine using frog rectus abdominis muscle.
6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively.
7. Bioassay of histamine using guinea pig ileum by matching method.
8. Bioassay of oxytocin using rat uterine horn by interpolation method.
9. Bioassay of serotonin using rat fundus strip by three point bioassay.
10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
11. Determination of PA<sub>2</sub> value of prazosin using rat anococcygeus muscle (by Schilds plot method).
12. Determination of PD<sub>2</sub> value using guinea pig ileum.
13. Effect of spasmogens and spasmolytics using rabbit jejunum.
14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
15. Analgesic activity of drug using central and peripheral methods

Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos

**Recommended Books (Latest Editions)**

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill.
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins.
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology.
6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert.
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.

## **BP504 T. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)**

### **Course Objectives:**

The main purpose of subject is to impart the students the knowledge of how the secondary metabolites are produced in the crude drugs, how to isolate and identify and produce them industrially. Also this subject involves the study of producing the plants and phytochemicals through plant tissue culture, drug interactions and basic principles of traditional system of medicine

### **Course Content:**

#### UNIT-I

7 Hours

Metabolic pathways in higher plants and their determination

- a) Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway.
- b) Study of utilization of radioactive isotopes in the investigation of Biogenetic studies.

### **Learning Outcomes:**

Upon completion of the course, the student shall be able

- To understand the preparation and development of herbal formulation.
- To understand the herbal drug interactions
- To carryout isolation and identification of phytoconstituents

#### UNIT-II

14 Hours

General introduction, composition, chemistry & chemical classes, biosources, therapeutic uses and commercial applications of following secondary metabolites:

Alkaloids: Vinca, Rauwolfia, Belladonna, Opium,

Phenylpropanoids and Flavonoids: Lignans, Tea, Ruta

Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis

Volatile oils: Mentha, Clove, Cinnamon, Fennel, Coriander,

Tannins: Catechu, Pterocarpus

Resins: Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony

Glycosides: Senna, Aloes, Bitter Almond

Iridoids, Other terpenoids & Naphthaquinones: Gentian, Artemisia, taxus, carotenoids

### **Learning Outcomes:**

Upon completion of the course, the student shall be able

- To understand the preparation and development of herbal formulation.
- To understand the herbal drug interactions
- To carryout isolation and identification of phytoconstituents

#### UNIT-III

06 Hours

Isolation, Identification and Analysis of Phytoconstituents

a. Terpenoids: Menthol, Citral, Artemisin

b. Glycosides: Glycyrrhetic acid & Rutin

c. Alkaloids: Atropine, Quinine, Reserpine, Caffeine

d. Resins: Podophyllotoxin, Curcumin

### **Learning Outcomes:**

Upon completion of the course, the student shall be able

- To understand the preparation and development of herbal formulation.
- To understand the herbal drug interactions
- To carryout isolation and identification of phytoconstituents

#### UNIT-IV

10 Hours

Industrial production, estimation and utilization of the following phytoconstituents: Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine

#### **Learning Outcomes:**

Upon completion of the course, the student shall be able

- To understand the preparation and development of herbal formulation.
- To understand the herbal drug interactions
- To carryout isolation and identification of phytoconstituents

#### UNIT V

8 Hours

Basics of Phytochemistry

Modern methods of extraction, application of latest techniques like Spectroscopy, chromatography and electrophoresis in the isolation, purification and identification of crude drugs.

#### **Learning Outcomes:**

Upon completion of the course, the student shall be able

- To know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents
- To understand the preparation and development of herbal formulation.
- To understand the herbal drug interactions
- To carryout isolation and identification of phytoconstituents

**BP 508 P. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical) 4 Hours/Week**

1. Morphology, histology and powder characteristics & extraction & detection of: Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander
2. Exercise involving isolation & detection of active principles
  - a. Caffeine - from tea dust.
  - b. Diosgenin from Dioscorea
  - c. Atropine from Belladonna
  - d. Sennosides from Senna
3. Separation of sugars by Paper chromatography
4. TLC of herbal extract
5. Distillation of volatile oils and detection of phytoconstituents by TLC
6. Analysis of crude drugs by chemical tests: (i) Asafoetida (ii) Benzoin (iii) Colophony (iv) Aloes (v) Myrrh

**Recommended Books: (Latest Editions)**

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Saunders & Co., London, 2009.
2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
6. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.
7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
10. The formulation and preparation of cosmetic, fragrances and flavours.
11. Remington's Pharmaceutical sciences.
12. Text Book of Biotechnology by Vyas and Dixit.
13. Text Book of Biotechnology by R.C. Dubey.

## **BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)**

### **Course Objectives:**

This course is designed to impart basic knowledge on important legislations related to the profession of pharmacy in India.

### **Course Content:**

#### UNIT-I

10 Hours

Drugs and Cosmetics Act, 1940 and its rules 1945:

Objectives, Definitions, Legal definitions of schedules to the Act and Rules

Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties.

Manufacture of drugs – Prohibition of manufacture and sale of certain drugs,

Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

### **Learning Outcomes:**

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

- The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
- Various Indian pharmaceutical Acts and Laws
- The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
- The code of ethics during the pharmaceutical practice

#### UNIT-II

10 Hours

Drugs and Cosmetics Act, 1940 and its rules 1945.

Detailed study of Schedule G, H, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA) Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties

Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties.

Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors

### **Learning Outcomes:**

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

- The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
- Various Indian pharmaceutical Acts and Laws
- The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
- The code of ethics during the pharmaceutical practice

#### UNIT-III

10 Hours

- Pharmacy Act –1948: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and Penalties



- Medicinal and Toilet Preparation Act –1955: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.
- Narcotic Drugs and Psychotropic substances Act-1985 and Rules: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties

**Learning Outcomes:**

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

- The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
- Various Indian pharmaceutical Acts and Laws
- The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
- The code of ethics during the pharmaceutical practice

UNIT-IV

08 Hours

- Study of Salient Features of Drugs and Magic Remedies Act and its rules: Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties
- Prevention of Cruelty to animals Act-1960: Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties
- National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO)-2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

**Learning Outcomes:**

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

- The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
- Various Indian pharmaceutical Acts and Laws
- The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
- The code of ethics during the pharmaceutical practice

UNIT-V

07 Hours

- Pharmaceutical Legislations – A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee
- Code of Pharmaceutical ethics Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath
- Medical Termination of Pregnancy Act
- Right to Information Act

- Introduction to Intellectual Property Rights (IPR)

**Learning Outcomes:**

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

- The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
- Various Indian pharmaceutical Acts and Laws
- The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
- The code of ethics during the pharmaceutical practice

**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)

## SEMESTER - IV

### BP601T. MEDICINAL CHEMISTRY – III (Theory)

#### Course Objectives:

This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasis on modern techniques of rational drug design like quantitative structure activity relationship (QSAR), Prodrug concept, combinatorial chemistry and Computer aided drug design (CADD). The subject also emphasizes on the chemistry, mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR), therapeutic uses and synthesis of important drugs.

#### Course Content:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted by (\*)

#### UNIT – I

10 Hours

##### Antibiotics

Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.

$\beta$ -Lactam antibiotics: Penicillin, Cephalosporins,  $\beta$ -Lactamase inhibitors, Monobactams

Aminoglycosides: Streptomycin, Neomycin, Kanamycin

Tetracyclines: Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

#### Learning Outcomes:

Upon completion of the course student shall be able to

- Understand the importance of drug design and different techniques of drug design.
- Understand the chemistry of drugs with respect to their biological activity.
- Know the metabolism, adverse effects and therapeutic value of drugs.
- Know the importance of SAR of drugs.

#### UNIT – II

10 Hours

##### Antibiotics

Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.

Macrolide: Erythromycin Clarithromycin, Azithromycin.

Miscellaneous: Chloramphenicol\*, Clindamycin.

Prodrugs: Basic concepts and application of prodrugs design.

Antimalarials: Etiology of malaria.

Quinolines: SAR, Quinine sulphate, Chloroquine\*, Amodiaquine, Primaquine phosphate, Pamaquine\*, Quinacrine hydrochloride, Mefloquine.

Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil.

Miscellaneous: Pyrimethamine, Artesunate, Artemether, Atovoquone.

#### Learning Outcomes:

Upon completion of the course student shall be able to

- Understand the importance of drug design and different techniques of drug design.
- Understand the chemistry of drugs with respect to their biological activity.
- Know the metabolism, adverse effects and therapeutic value of drugs.
- Know the importance of SAR of drugs.

### UNIT – III

10 Hours

#### Anti-tubercular Agents

Synthetic anti tubercular agents: Isoniozid\*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.\*

Anti tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine Streptomycine, Capreomycin sulphate.

#### Urinary tract anti-infective agents

Quinolones: SAR of quinolones, Nalidixic Acid, Norfloxacin, Enoxacin, Ciprofloxacin\*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin

Miscellaneous: Furazolidine, Nitrofurantoin\*, Methanamine.

#### Antiviral agents:

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

#### **Learning Outcomes:**

Upon completion of the course student shall be able to

- Understand the importance of drug design and different techniques of drug design.
- Understand the chemistry of drugs with respect to their biological activity.
- Know the metabolism, adverse effects and therapeutic value of drugs.
- Know the importance of SAR of drugs.

### UNIT – IV

08 Hours

#### Antifungal agents:

Antifungal antibiotics: Amphotericin-B, Nystatin, Natamycin, Griseofulvin.

Synthetic Antifungal agents: Clotrimazole, Econazole, Butoconazole, Oxiconazole Tioconazole, Miconazole\*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate\*.

Anti-protozoal Agents: Metronidazole\*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine.

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

#### Sulphonamides and Sulfones

Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide\*, Sulphapyridine, Sulfamethoxazole\*, Sulphadiazine, Mefenide acetate, Sulfasalazine.

Folate reductase inhibitors: Trimethoprim\*, Cotrimoxazole.

Sulfones: Dapsone\*.

#### **Learning Outcomes:**

Upon completion of the course student shall be able to

- Understand the importance of drug design and different techniques of drug design.
- Understand the chemistry of drugs with respect to their biological activity.
- Know the metabolism, adverse effects and therapeutic value of drugs.
- Know the importance of SAR of drugs.

### UNIT – V

07 Hours

## Introduction to Drug Design

Various approaches used in drug design.

Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammett's electronic parameter, Taft's steric parameter and Hansch analysis. Pharmacophore modeling and docking techniques.

Combinatorial Chemistry: Concept and applications of combinatorial chemistry: solid phase and solution phase synthesis.

### **Learning Outcomes:**

Upon completion of the course student shall be able to

- Understand the importance of drug design and different techniques of drug design.
- Understand the chemistry of drugs with respect to their biological activity.
- Know the metabolism, adverse effects and therapeutic value of drugs.
- Know the importance of SAR of drugs.

**BP607P. MEDICINAL CHEMISTRY- III (Practical)**

4 Hours / week

- I Preparation of drugs and intermediates
  - 1 Sulphanilamide
  - 2 7-Hydroxy, 4-methyl coumarin
  - 3 Chlorobutanol
  - 4 Triphenyl imidazole
  - 5 Tolbutamide
  - 6 Hexamine
- II Assay of drugs
  - 1 Isonicotinic acid hydrazide
  - 2 Chloroquine
  - 3 Metronidazole
  - 4 Dapsone
  - 5 Chlorpheniramine maleate
  - 6 Benzyl penicillin
- III Preparation of medicinally important compounds or intermediates by Microwave irradiation technique
- IV Drawing structures and reactions using chem draw®
- V Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinskies RO5)

**Recommended Books (Latest Editions)**

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.
7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

## **BP602 T. PHARMACOLOGY-III (Theory)**

### **Course Objectives:**

This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on respiratory and gastrointestinal system, infectious diseases, immunopharmacology and in addition, emphasis on the principles of toxicology and chronopharmacology.

### **Course Content:**

#### UNIT-I

10hours

1. Pharmacology of drugs acting on Respiratory system
  - a. Anti -asthmatic drugs
  - b. Drugs used in the management of COPD
  - c. Expectorants and antitussives
  - d. Nasal decongestants
  - e. Respiratory stimulants
2. Pharmacology of drugs acting on the Gastrointestinal Tract
  - a. Antiulcer agents.
  - b. Drugs for constipation and diarrhoea.
  - c. Appetite stimulants and suppressants.
  - d. Digestants and carminatives.
  - e. Emetics and anti-emetics.

### **Learning Outcomes:**

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

- Understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
- Comprehend the principles of toxicology and treatment of various poisonings and
- Appreciate correlation of pharmacology with related medical sciences.

#### UNIT-II

10hours

3. Chemotherapy
  - a. General principles of chemotherapy.
  - b. Sulfonamides and cotrimoxazole.
  - c. Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolins, tetracycline and aminoglycosides

### **Learning Outcomes:**

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

- Understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
- Comprehend the principles of toxicology and treatment of various poisonings and
- Appreciate correlation of pharmacology with related medical sciences.

#### UNIT-III 10hours

#### 3. Chemotherapy

- a. Antitubercular agents
- b. Antileprotic agents

- c. Antifungal agents
- d. Antiviral drugs e. Anthelmintics
- e. Antimalarial drugs
- f. Antiamoebic agents

**Learning Outcomes:**

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

- Understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
- Comprehend the principles of toxicology and treatment of various poisonings and
- Appreciate correlation of pharmacology with related medical sciences.

UNIT-IV

08hours

Chemotherapy

Urinary tract infections and sexually transmitted diseases.

Chemotherapy of malignancy.

- 4. Immunopharmacology
  - a. Immunostimulants
  - b. Immunosuppressant

Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

**Learning Outcomes:**

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

- Understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
- Comprehend the principles of toxicology and treatment of various poisonings and
- Appreciate correlation of pharmacology with related medical sciences.

UNIT-V

07hours

- 5. Principles of toxicology
  - a. Definition and basic knowledge of acute, subacute and chronic toxicity.
  - b. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity
  - c. General principles of treatment of poisoning
  - d. Clinical symptoms and management of barbiturates, morphine, organophosphorus compound and lead, mercury and arsenic poisoning.
- 6. Chronopharmacology
  - a. Definition of rhythm and cycles.
  - b. Biological clock and their significance leading to chronotherapy.

**Learning Outcomes:**

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

- Understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
- Comprehend the principles of toxicology and treatment of various poisonings and
- Appreciate correlation of pharmacology with related medical sciences.



**BP 608 P. PHARMACOLOGY-III (Practical)**

4Hrs/Week

1. Dose calculation in pharmacological experiments
2. Antiallergic activity by mast cell stabilization assay
3. Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.
4. Study of effect of drugs on gastrointestinal motility
5. Effect of agonist and antagonists on guinea pig ileum
6. Estimation of serum biochemical parameters by using semi- autoanalyser
7. Effect of saline purgative on frog intestine
8. Insulin hypoglycemic effect in rabbit
9. Test for pyrogens ( rabbit method)
10. Determination of acute oral toxicity (LD50) of a drug from a given data
11. Determination of acute skin irritation / corrosion of a test substance
12. Determination of acute eye irritation / corrosion of a test substance
13. Calculation of pharmacokinetic parameters from a given data
14. Biostatistics methods in experimental pharmacology( student's t test, ANOVA)
15. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)

\*Experiments are demonstrated by simulated experiments/videos

**Recommended Books (Latest Editions)**

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology
6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert,
8. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
9. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,
10. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

## **BP 603 T. HERBAL DRUG TECHNOLOGY (Theory)**

### **Course Objectives:**

This subject gives the student the knowledge of basic understanding of herbal drug industry, the quality of raw material, guidelines for quality of herbal drugs, herbal cosmetics, natural sweeteners, nutraceutical etc. The subject also emphasizes on Good Manufacturing Practices (GMP), patenting and regulatory issues of herbal drugs

Course content:

#### UNIT-I

11 Hours

Herbs as raw materials

Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation Source of Herbs

Selection, identification and authentication of herbal materials Processing of herbal raw material

Biodynamic Agriculture

Good agricultural practices in cultivation of medicinal plants including Organic farming. Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.

Indian Systems of Medicine

- a. Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy
- b. Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika, Churna, Lehya and Bhasma.

### **Learning Outcomes:**

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

- Understand raw material as source of herbal drugs from cultivation to herbal drug product
- Know the herbal cosmetics, natural sweeteners, nutraceuticals

#### UNIT-II

7 Hours

Nutraceuticals

General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases.

Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina

Herbal-Drug and Herb-Food Interactions: General introduction to interaction and classification.

Study of following drugs and their possible side effects and interactions: Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.

### **Learning Outcomes:**

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

- Understand raw material as source of herbal drugs from cultivation to herbal drug product
- Know the herbal cosmetics, natural sweeteners, nutraceuticals
- Appreciate patenting of herbal drugs, GMP

#### UNIT-III

10 Hours

Herbal Cosmetics

Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products.

Herbal excipients:

Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes.

Herbal formulations :

Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes

**Learning Outcomes:**

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

- Understand raw material as source of herbal drugs from cultivation to herbal drug product
- Know the herbal cosmetics, natural sweeteners, nutraceuticals
- Appreciate patenting of herbal drugs, GMP

UNIT- IV

10 Hours

Evaluation of Drugs WHO & ICH guidelines for the assessment of herbal drugs Stability testing of herbal drugs.

Patenting and Regulatory requirements of natural products:

- i. Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy
- ii. Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.

Regulatory Issues - Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.

**Learning Outcomes:**

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

- Know the WHO and ICH guidelines for evaluation of herbal drugs
- Know the herbal cosmetics, natural sweeteners, nutraceuticals
- Appreciate patenting of herbal drugs, GMP

UNIT-V

07 Hours

General Introduction to Herbal Industry

Herbal drugs industry: Present scope and future prospects.

A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.

Schedule T – Good Manufacturing Practice of Indian systems of medicine

Components of GMP (Schedule – T) and its objectives

Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.

**Learning Outcomes:**

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

- Understand raw material as source of herbal drugs from cultivation to herbal drug product

- Know the WHO and ICH guidelines for evaluation of herbal drugs
- Know the herbal cosmetics, natural sweeteners, nutraceuticals
- Appreciate patenting of herbal drugs, GMP .

**BP 609 P. HERBAL DRUG TECHNOLOGY (Practical)**

4 hours/ week

1. To perform preliminary phytochemical screening of crude drugs.
2. Determination of the alcohol content of Asava and Arista
3. Evaluation of excipients of natural origin
4. Incorporation of prepared and standardized extract in cosmetic formulations like creams, lotions and shampoos and their evaluation.
5. Incorporation of prepared and standardized extract in formulations like syrups, mixtures and tablets and their evaluation as per Pharmacopoeial requirements.
6. Monograph analysis of herbal drugs from recent Pharmacopoeias
7. Determination of Aldehyde content
8. Determination of Phenol content
9. Determination of total alkaloids

**Recommended Books: (Latest Editions)**

1. Textbook of Pharmacognosy by Trease & Evans.
2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
3. Pharmacognosy by Kokate, Purohit and Gokhale
4. Essential of Pharmacognosy by Dr.S.H.Ansari
5. Pharmacognosy & Phytochemistry by V.D.Rangari
6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
7. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

## **BP 604 T. BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)**

### **Course Objectives:**

This subject is designed to impart knowledge and skills of Biopharmaceutics and pharmacokinetics and their applications in pharmaceutical development, design of dose and dosage regimen and in solving the problems arising therein.

### **Course Content:**

#### UNIT-I

10 Hours

Introduction to Biopharmaceutics

Absorption; Mechanisms of drug absorption through GIT, factors influencing drug absorption through GIT, absorption of drug from Non per oral extra-vascular routes, 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

### **Learning Outcomes:**

Upon completion of the course student shall be able to:

- Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
- Understand various pharmacokinetic parameters, their significance & applications.

#### UNIT- II

10 Hours

Elimination: Drug metabolism and basic understanding 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, measurement of bioavailability, in-vitro drug dissolution models, in-vitro-in-vivo correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.

### **Learning Outcomes:**

Upon completion of the course student shall be able to:

- Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
- To understand the concepts of bioavailability and bioequivalence of drug products and their significance.
- Understand various pharmacokinetic parameters, their significance & applications.

#### UNIT- III

10 Hours

Pharmacokinetics: Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra vascular administrations. Pharmacokinetics parameters -  $KE$ ,  $t_{1/2}$ ,  $V_d$ ,  $AUC$ ,  $K_a$ ,  $Cl_t$  and  $CLR$ - definitions methods of eliminations, understanding of their significance and application

### **Learning Outcomes:**

Upon completion of the course student shall be able to:

- Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.

- Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
- To understand the concepts of bioavailability and bioequivalence of drug products and their significance.
- Understand various pharmacokinetic parameters, their significance & applications.

#### UNIT- IV

08 Hours

Multicompartment models: Two compartment open model. IV bolus

Kinetics of multiple dosing, steady state drug levels, calculation of loading and maintenance doses and their significance in clinical settings.

#### **Learning Outcomes:**

Upon completion of the course student shall be able to:

- Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
- Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
- To understand the concepts of bioavailability and bioequivalence of drug products and their significance.
- Understand various pharmacokinetic parameters, their significance & applications.

#### UNIT- V

07 Hours

Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity.

Michaelis-menton method of estimating parameters, Explanation with example of drugs.

#### **Learning Outcomes:**

Upon completion of the course student shall be able to:

- Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
- Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
- To understand the concepts of bioavailability and bioequivalence of drug products and their significance.
- Understand various pharmacokinetic parameters, their significance & applications.

#### **Recommended Books: (Latest Editions)**

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition, Prentice-Hall International edition. USA
4. Bio pharmaceuticals and Pharmacokinetics-A Treatise, By D. M. Brahmkar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: By Milo Gibaldi Donald, R. Merceel Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick

8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and
9. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
10. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
11. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
12. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania

## **BP 605 T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)**

### **Course Objectives:**

- Biotechnology has a long promise to revolutionize the biological sciences and technology.
- Scientific application of biotechnology in the field of genetic engineering, medicine and fermentation technology makes the subject interesting.
- Biotechnology is leading to new biological revolutions in diagnosis, prevention and cure of diseases, new and cheaper pharmaceutical drugs.
- Biotechnology has already produced transgenic crops and animals and the future promises lot more.
- It is basically a research-based subject.

### Unit I

10 Hours

- a. Brief introduction to Biotechnology with reference to Pharmaceutical Sciences.
- b. Enzyme Biotechnology- Methods of enzyme immobilization and applications.
- c. Biosensors- Working and applications of biosensors in Pharmaceutical Industries.
- d. Brief introduction to Protein Engineering.
- e. Use of microbes in industry. Production of Enzymes- General consideration - Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase.
- f. Basic principles of genetic engineering.

### **Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Understanding the importance of Immobilized enzymes in Pharmaceutical Industries
- Genetic engineering applications in relation to production of pharmaceuticals
- Appreciate the use of microorganisms in fermentation technology

### Unit II

10 Hours

- a. Study of cloning vectors, restriction endonucleases and DNA ligase.
- b. Recombinant DNA technology. Application of genetic engineering in medicine.
- c. Application of r DNA technology and genetic engineering in the production of:
  - i. Interferon
  - ii) Vaccines- hepatitis- B
  - iii) Hormones-Insulin.
- d. Brief introduction to PCR

### **Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Understanding the importance of Immobilized enzymes in Pharmaceutical Industries
- Genetic engineering applications in relation to production of pharmaceuticals

### Unit III

10 Hours

Types of immunity- humoral immunity, cellular immunity

- a. Structure of Immunoglobulins
- b. Structure and Function of MHC
- c. Hypersensitivity reactions, Immune stimulation and Immune suppressions.
- d. General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity.
- e. Storage conditions and stability of official vaccines
- f. Hybridoma technology- Production, Purification and Applications



g. Blood products and Plasma Substitutes.

**Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Understanding the importance of Immobilized enzymes in Pharmaceutical Industries
- Genetic engineering applications in relation to production of pharmaceuticals
- Importance of Monoclonal antibodies in Industries

**Unit IV**

08 Hours

- a. Immuno blotting techniques- ELISA, Western blotting, Southern blotting.
- b. Genetic organization of Eukaryotes and Prokaryotes
- c. Microbial genetics including transformation, transduction, conjugation, plasmids and transposons.
- d. Introduction to Microbial biotransformation and applications.
- e. Mutation: Types of mutation/mutants.

**Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Understanding the importance of Immobilized enzymes in Pharmaceutical Industries
- Genetic engineering applications in relation to production of pharmaceuticals
- Importance of Monoclonal antibodies in Industries

**Unit V**

07 Hours

- a. Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring.
- b. Large scale production fermenter design and its various controls.
- c. Study of the production of - penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin,
- d. Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substitutes.

**Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Appreciate the use of microorganisms in fermentation technology

**Recommended Books (Latest edition):**

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.
2. RA Goldshy et. al., : Kuby Immunology.
3. J.W. Goding: Monoclonal Antibodies.
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.
5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

## **BP606T PHARMACEUTICAL QUALITY ASSURANCE (Theory)**

### **Course Objectives:**

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It deals with the important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.

### **Course content:**

#### UNIT – I

10 Hours

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

Total Quality Management (TQM): Definition, elements, philosophies

ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines

Quality by design (QbD): Definition, overview, elements of QbD program, tools ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration NABL accreditation : Principles and procedures

### **Learning Outcomes:**

Upon completion of the course student shall be able to:

- Understand the cGMP aspects in a pharmaceutical industry
- Appreciate the importance of documentation
- Understand the scope of quality certifications applicable to pharmaceutical industries
- Understand the responsibilities of QA & QC departments

#### UNIT - II

10 Hours

Organization and personnel: Personnel responsibilities, training, hygiene and personal records. Premises: Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

Equipments and raw materials: Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

### **Learning Outcomes:**

Upon completion of the course student shall be able to:

- Understand the cGMP aspects in a pharmaceutical industry
- Appreciate the importance of documentation
- Understand the scope of quality certifications applicable to pharmaceutical industries
- Understand the responsibilities of QA & QC departments

#### UNIT – III

10 Hours

Quality Control: Quality control test for containers, rubber closures and secondary packing materials.

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

### **Learning Outcomes:**

Upon completion of the course student shall be able to:

- Understand the cGMP aspects in a pharmaceutical industry
- Appreciate the importance of documentation

- Understand the scope of quality certifications applicable to pharmaceutical industries
- Understand the responsibilities of QA & QC departments

#### UNIT – IV

08 Hours

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

Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

#### **Learning Outcomes:**

Upon completion of the course student shall be able to:

- Understand the cGMP aspects in a pharmaceutical industry
- Appreciate the importance of documentation
- Understand the scope of quality certifications applicable to pharmaceutical industries
- Understand the responsibilities of QA & QC departments

#### UNIT – V

07 Hours

Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation.

Warehousing: Good warehousing practice, materials management

#### **Learning Outcomes:**

Upon completion of the course student shall be able to:

- Understand the cGMP aspects in a pharmaceutical industry
- Appreciate the importance of documentation
- Understand the scope of quality certifications applicable to pharmaceutical industries
- Understand the responsibilities of QA & QC departments

#### **Recommended Books: (Latest Edition)**

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.
4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP's – P P Sharma.
6. ISO 9000 and Total Quality Management – Sadhank G Ghosh
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices – Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines

## SEMESTER - VII

### BP701T. INSTRUMENTAL METHODS OF ANALYSIS (Theory)

#### Course Objectives:

This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart a fundamental knowledge on the principles and instrumentation of spectroscopic and chromatographic technique. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

#### Course Content:

UNIT –I 10 Hours

UV Visible spectroscopy

Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations.

Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors- Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode.

Applications - Spectrophotometric titrations, Single component and multi component analysis  
Fluorimetry

Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications

#### Learning Outcomes:

Upon completion of the course the student shall be able to

- Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis
- Perform quantitative & qualitative analysis of drugs using various analytical instruments.

UNIT –II 10 Hours

IR spectroscopy

Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations

Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications

Flame Photometry-Principle, interferences, instrumentation and applications

Atomic absorption spectroscopy- Principle, interferences, instrumentation and applications

Nepheloturbidometry- Principle, instrumentation and applications

#### Learning Outcomes:

Upon completion of the course the student shall be able to

- Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis
- Perform quantitative & qualitative analysis of drugs using various analytical instruments.

UNIT –III 10 Hours

Introduction to chromatography

Adsorption and partition column chromatography-Methodology, advantages, disadvantages and applications.

Thin layer chromatography- Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications.

Paper chromatography-Introduction, methodology, development techniques, advantages, disadvantages and applications

Electrophoresis– Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications

**Learning Outcomes:**

Upon completion of the course the student shall be able to

- Understand the chromatographic separation and analysis of drugs.
- Perform quantitative & qualitative analysis of drugs using various analytical instruments.

UNIT –IV

08 Hours

Gas chromatography - Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications

High performance liquid chromatography (HPLC)-Introduction, theory, instrumentation, advantages and applications.

**Learning Outcomes:**

Upon completion of the course the student shall be able to

- =
- Understand the chromatographic separation and analysis of drugs.
- Perform quantitative & qualitative analysis of drugs using various analytical instruments.

UNIT –V

07 Hours

Ion exchange chromatography- Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications

Gel chromatography- Introduction, theory, instrumentation and applications

Affinity chromatography- Introduction, theory, instrumentation and applications

**Learning Outcomes:**

Upon completion of the course the student shall be able to

- Understand the chromatographic separation and analysis of drugs.
- Perform quantitative & qualitative analysis of drugs using various analytical instruments.

**BP705P. INSTRUMENTAL METHODS OF ANALYSIS (Practical)**

4 Hours/Week

- 1 Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
- 2 Estimation of dextrose by colorimetry
- 3 Estimation of sulfanilamide by colorimetry
- 4 Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy
- 5 Assay of paracetamol by UV- Spectrophotometry
- 6 Estimation of quinine sulfate by fluorimetry
- 7 Study of quenching of fluorescence
- 8 Determination of sodium by flame photometry
- 9 Determination of potassium by flame photometry
- 10 Determination of chlorides and sulphates by nephelo turbidometry
- 11 Separation of amino acids by paper chromatography
- 12 Separation of sugars by thin layer chromatography
- 13 Separation of plant pigments by column chromatography
- 14 Demonstration experiment on HPLC
- 15 Demonstration experiment on Gas Chromatography

**Recommended Books (Latest Editions)**

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

## **BP 702 T. INDUSTRIAL PHARMACY-II (Theory)**

### **Course Objectives:**

This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market

### **Course Content:**

UNIT-I 10 Hours

Pilot plant scale up techniques: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology

### **Learning Outcomes:**

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

- Know the process of pilot plant and scale up of pharmaceutical dosage forms
- Understand the process of technology transfer from lab scale to commercial batch

UNIT-II 10 Hours

Technology development and transfer: WHO guidelines for Technology Transfer(TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues

### **Learning Outcomes:**

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

- Know different Laws and Acts that regulate pharmaceutical industry
- Understand the approval process and regulatory requirements for drug products

UNIT-III 10 Hours

Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals

Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.

### **Learning Outcomes:**

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

- Know different Laws and Acts that regulate pharmaceutical industry
- Understand the approval process and regulatory requirements for drug products

UNIT-IV 08 Hours

Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP

**Learning Outcomes:**

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

- Know different Laws and Acts that regulate pharmaceutical industry
- Understand the approval process and regulatory requirements for drug products

UNIT-V

07 Hours

Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

**Learning Outcomes:**

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

- Know different Laws and Acts that regulate pharmaceutical industry
- Understand the approval process and regulatory requirements for drug products

**Recommended Books: (Latest Editions)**

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at [http://en.wikipedia.org/wiki/Regulatory\\_Affairs](http://en.wikipedia.org/wiki/Regulatory_Affairs).
2. International Regulatory Affairs Updates, 2005. available at <http://www.iraup.com/about.php>
3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
4. Regulatory Affairs brought by learning plus, inc. available at <http://www.cgmp.com/ra.htm>.



## **BP 703 T. PHARMACY PRACTICE (Theory)**

### **Course Objectives:**

In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. In community pharmacy, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling for improved patient care in the community set up.

Unit I:

10 Hours

a) Hospital and its organization

Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non-clinical basis, Organization Structure of a Hospital, and Medical staffs involved in the hospital and their functions.

b) Hospital pharmacy and its organization

Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists.

c) Adverse drug reaction

Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management.

d) Community Pharmacy

Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale drug store.

### **Learning Outcomes:**

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

- Know various drug distribution methods in a hospital
- Appreciate the pharmacy stores management and inventory control
- Monitor drug therapy of patient through medication chart review and clinical review
- Obtain medication history interview and counsel the patients
- Identify drug related problems
- Detect and assess adverse drug reactions
- Interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states
- Know pharmaceutical care services
- Do patient counselling in community pharmacy;
- Appreciate the concept of rational drug therapy

Unit II:

10 Hours

a) Drug distribution system in a hospital

Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, Dispensing of drugs to ambulatory patients, and Dispensing of controlled drugs.

b) Hospital formulary

Definition, contents of hospital formulary, Differentiation of hospital formulary and Drug list, preparation and revision, and addition and deletion of drug from hospital formulary.

c) Therapeutic drug monitoring

Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring.

d) Medication adherence

Causes of medication non-adherence, pharmacist role in the medication adherence, and monitoring of patient medication adherence.

e) Patient medication history interview

Need for the patient medication history interview, medication interview forms.

f) Community pharmacy management

Financial, materials, staff, and infrastructure requirements.

### **Learning Outcomes:**

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

- Know various drug distribution methods in a hospital
- Appreciate the pharmacy stores management and inventory control
- Monitor drug therapy of patient through medication chart review and clinical review
- Obtain medication history interview and counsel the patients
- Identify drug related problems
- Detect and assess adverse drug reactions
- Interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states
- Know pharmaceutical care services
- Do patient counselling in community pharmacy;
- Appreciate the concept of rational drug therapy

Unit III:

10 Hours

a) Pharmacy and therapeutic committee

Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation.

b) Drug information services

Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.

c) Patient counseling

Definition of patient counseling; steps involved in patient counseling, and Special cases that require the pharmacist

d) Education and training program in the hospital

Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education.

e) Prescribed medication order and communication skills

Prescribed medication order- interpretation and legal requirements, and Communication skills-communication with prescribers and patients.

### **Learning Outcomes:**

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

- Know various drug distribution methods in a hospital
- Appreciate the pharmacy stores management and inventory control
- Monitor drug therapy of patient through medication chart review and clinical review
- Obtain medication history interview and counsel the patients
- Identify drug related problems
- Detect and assess adverse drug reactions
- Appreciate the concept of rational drug therapy

### **Unit IV**

8 Hours

#### a) Budget preparation and implementation

Budget preparation and implementation

#### b) Clinical Pharmacy

Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care. Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern.

#### c) Over the counter (OTC) sales

Introduction and sale of over the counter, and rational use of common over the counter medications.

### **Learning Outcomes:**

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

- Know various drug distribution methods in a hospital
- Appreciate the pharmacy stores management and inventory control
- Monitor drug therapy of patient through medication chart review and clinical review
- Obtain medication history interview and counsel the patients
- Identify drug related problems
- Detect and assess adverse drug reactions
- Appreciate the concept of rational drug therapy

### **Unit V**

7 Hours

#### a) Drug store management and inventory control

Organisation of drug store, types of materials stocked and storage conditions, Purchase and inventory control: principles, purchase procedure, purchase order, procurement and stocking, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure

#### b) Investigational use of drugs

Description, principles involved, classification, control, identification, role of hospital pharmacist, advisory committee.

#### c) Interpretation of Clinical Laboratory Tests

Blood chemistry, hematology, and urinalysis

### **Learning Outcomes:**

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

- Know various drug distribution methods in a hospital
- Appreciate the pharmacy stores management and inventory control

- Monitor drug therapy of patient through medication chart review and clinical review
- Obtain medication history interview and counsel the patients
- Identify drug related problems
- Detect and assess adverse drug reactions
- Interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states
- Know pharmaceutical care services
- Do patient counselling in community pharmacy;
- Appreciate the concept of rational drug therapy

**Recommended Books (Latest Edition):**

1. Merchant S.H. and Dr. J.S.Quadry. A textbook of hospital pharmacy, 4th ed. Ahmadabad: B.S. Shah Prakakshan; 2001.
2. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. A textbook of Clinical Pharmacy Practice- essential concepts and skills, 1st ed. Chennai: Orient Longman Private Limited; 2004.
3. William E. Hassan. Hospital pharmacy, 5th ed. Philadelphia: Lea & Febiger; 1986.
4. Tipnis Bajaj. Hospital Pharmacy, 1st ed. Maharashtra: Career Publications; 2008.
5. Scott LT. Basic skills in interpreting laboratory data, 4thed. American Society of Health System Pharmacists Inc; 2009.
6. Parmar N.S. Health Education and Community Pharmacy, 18th ed. India: CBS Publishers & Distributers; 2008.

**Journals:**

1. Therapeutic drug monitoring. ISSN: 0163-4356
2. Journal of pharmacy practice. ISSN : 0974-8326
3. American journal of health system pharmacy. ISSN: 1535-2900 (online)
4. Pharmacy times (Monthly magazine)

## **BP 704 T. NOVEL DRUG DELIVERY SYSTEMS (Theory)**

### **Course Objectives:**

This subject is designed to impart basic knowledge on the area of novel drug delivery systems.

### **Course content:**

#### Unit-I

10 Hours

Controlled drug delivery systems: Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates. Approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations

Polymers: Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems.

### **Learning Outcomes:**

Upon completion of the course student shall be able

- To understand various approaches for development of novel drug delivery systems.
- To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation

#### Unit-II

10 Hours

Microencapsulation: Definition, advantages and disadvantages, microspheres /microcapsules, microparticles, methods of microencapsulation, applications

Mucosal Drug Delivery system: Introduction, Principles of bioadhesion / mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems

Implantable Drug Delivery Systems: Introduction, advantages and disadvantages, concept of implants and osmotic pump

### **Learning Outcomes:**

Upon completion of the course student shall be able

- To understand various approaches for development of novel drug delivery systems.
- To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation

#### Unit-III

10 Hours

Transdermal Drug Delivery Systems: Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches

Gastroretentive drug delivery systems: Introduction, advantages, disadvantages, approaches for GRDDS – Floating, high density systems, inflatable and gastroadhesive systems and their applications

Nasopulmonary drug delivery system: Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers

### **Learning Outcomes:**

Upon completion of the course student shall be able

- To understand various approaches for development of novel drug delivery systems.
- To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation

#### Unit-IV

08 Hours

Targeted drug Delivery: Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications

Unit-V

07 Hours

Ocular Drug Delivery Systems: Introduction, intra ocular barriers and methods to overcome – Preliminary study, ocular formulations and ocuserts

Intrauterine Drug Delivery Systems: Introduction, advantages and disadvantages, development of intra uterine devices (IUDs) and applications

### **Learning Outcomes:**

Upon completion of the course student shall be able

- To understand various approaches for development of novel drug delivery systems.
- To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation

### **Recommended Books: (Latest Editions)**

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

### **Journals**

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian Drugs (IDMA)
3. Journal of Controlled Release (Elsevier Sciences)
4. Drug Development and Industrial Pharmacy (Marcel & Decker)
5. International Journal of Pharmaceutics (Elsevier Sciences)

## SEMESTER - VIII

### BP801T. BIOSTATISTICS AND RESEARCH METHODOLOGY (Theory)

#### Course Objectives:

To understand the applications of Biostatistics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel.

#### Course content:

##### Unit-I

10 Hours

Introduction: Statistics, Biostatistics, Frequency distribution

Measures of central tendency: Mean, Median, Mode- Pharmaceutical examples Measures of dispersion: Dispersion, Range, standard deviation, Pharmaceutical problems

Correlation: Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticals examples

#### Learning Outcomes:

Upon completion of the course the student shall be able to

- Know the various statistical techniques to solve statistical problems
- Appreciate statistical techniques in solving the problems.

##### Unit-II

10 Hours

Regression: Curve fitting by the method of least squares, fitting the lines  $y = a + bx$  and  $x = a + by$ , Multiple regression, standard error of regression- Pharmaceutical Examples  
Probability: Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties - problems

Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples

Parametric test: t-test(Sample, Pooled or Unpaired and Paired) , ANOVA, (One way and Two way), Least Significance difference

#### Learning Outcomes:

Upon completion of the course the student shall be able to

- Know the various statistical techniques to solve statistical problems
- Appreciate statistical techniques in solving the problems.

##### Unit-III

10 Hours

Non Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test

Introduction to Research: Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism

Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph Designing the methodology: Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

#### Learning Outcomes:

Upon completion of the course the student shall be able to

- Know the various statistical techniques to solve statistical problems
- Appreciate statistical techniques in solving the problems.

#### Unit-IV

8 Hours

Blocking and confounding system for Two-level factorials

Regression modeling: Hypothesis testing in Simple and Multiple regression models Introduction to Practical components of Industrial and Clinical Trials Problems: Statistical Analysis Using Excel, SPSS, MINITAB®, DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach

#### **Learning Outcomes:**

Upon completion of the course the student shall be able to

- Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment)
- Appreciate statistical techniques in solving the problems.

#### Unit-V

7 Hours

Design and Analysis of experiments:

Factorial Design: Definition, design. Advantage of factorial design Response Surface methodology: Central composite design, Historical design, Optimization Techniques

#### **Learning Outcomes:**

Upon completion of the course the student shall be able to

- Know the various statistical techniques to solve statistical problems
- Appreciate statistical techniques in solving the problems.

#### **Recommended Books (Latest edition):**

1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. New York.
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



## **BP 802T SOCIAL AND PREVENTIVE PHARMACY**

The purpose of this course is to introduce to students a number of health issues and their challenges. This course also introduced a number of national health programmes. The roles of the pharmacist in these contexts are also discussed.

### **Course content:**

Unit I: 10 Hours

Concept of health and disease: Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick.

Social and health education: Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention.

Sociology and health: Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health

Hygiene and health: personal hygiene and health care; avoidable habits

### **Learning Outcomes:**

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

- Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide.
- Have a critical way of thinking based on current healthcare development.
- Evaluate alternative ways of solving problems related to health and pharmaceutical issues

Unit II: 10 Hours

Preventive medicine: General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse

### **Learning Outcomes:**

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

- Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide.
- Have a critical way of thinking based on current healthcare development.
- Evaluate alternative ways of solving problems related to health and pharmaceutical issues

Unit III: 10 Hours

National health programs, its objectives, functioning and outcome of the following: HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.

### **Learning Outcomes:**

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

- Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide.

- Have a critical way of thinking based on current healthcare development.
- Evaluate alternative ways of solving problems related to health and pharmaceutical issues

Unit IV:

08 Hours

National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program

**Learning Outcomes:**

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

- Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide.
- Have a critical way of thinking based on current healthcare development.
- Evaluate alternative ways of solving problems related to health and pharmaceutical issues

Unit V:

07 Hours

Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school.

**Learning Outcomes:**

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

- Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide.
- Have a critical way of thinking based on current healthcare development.
- Evaluate alternative ways of solving problems related to health and pharmaceutical issues

**Recommended Books (Latest edition):**

1. Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2nd Edition, 2010, ISBN: 9789380704104, JAYPEE Publications
2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications
3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, 2014, ISBN: 9789351522331, JAYPEE Publications
4. Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications
5. Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011, ISBN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS.
6. Community Pharmacy Practice, Ramesh Adep, BSP publishers, Hyderabad

**Recommended Journals:**

1. Research in Social and Administrative Pharmacy, Elsevier, Ireland

## **BP803ET. PHARMA MARKETING MANAGEMENT (Theory)**

### **Course Objectives:**

The pharmaceutical industry not only needs highly qualified researchers, chemists and, technical people, but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry. The Knowledge and Know-how of marketing management groom the people for taking a challenging role in Sales and Product management.

#### Unit I

10 Hours

##### Marketing:

Definition, general concepts and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; analyzing consumer buying behavior; industrial buying behavior.

##### Pharmaceutical market:

Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation & targeting. Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist. Analyzing the Market; Role of market research.

### **Learning Outcomes:**

The course aims to provide an understanding of marketing concepts and techniques and their applications in the pharmaceutical industry.

#### Unit II

10 Hours

##### Product decision:

Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labelling decisions, Product management in pharmaceutical industry.

### **Learning Outcomes:**

The course aims to provide an understanding of marketing concepts and techniques and their applications in the pharmaceutical industry.

#### Unit III

10 Hours

##### Promotion:

Methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.

### **Learning Outcomes:**

The course aims to provide an understanding of marketing concepts and techniques and their applications in the pharmaceutical industry.

#### Unit IV

10 Hours

##### Pharmaceutical marketing channels:

Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management.

##### Professional sales representative (PSR):

Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.

**Learning Outcomes:**

The course aims to provide an understanding of marketing concepts and techniques and their applications in the pharmaceutical industry.

Unit V

10 Hours

Pricing:

Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority).

Emerging concepts in marketing:

Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.

**Learning Outcomes:**

The course aims to provide an understanding of marketing concepts and techniques and their applications in the pharmaceutical industry.

**Recommended Books: (Latest Editions)**

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S & Nanakamari, S: Marketing Managemnt:Global Perspective, IndianContext,Macmilan India, New Delhi.
7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.

## **BP804 ET PHARMACEUTICAL REGULATORY SCIENCE (Theory)**

### **Course Objectives:**

This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India & other countries like US, EU, Japan, Australia, UK etc. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.

### **Course content:**

#### Unit I

10Hours

#### New Drug Discovery and development

Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

### **Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Know about the process of drug discovery and development

#### Unit II

10Hours

#### Regulatory Approval Process

Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA.

#### Regulatory authorities and agencies

Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)

### **Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
- Know the regulatory approval process and their registration in Indian and international markets

#### Unit III

10Hours

#### Registration of Indian drug product in overseas market

Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD) research.

### **Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
- Know the regulatory approval process and their registration in Indian and international markets

#### Unit IV

08Hours

#### Clinical trials

Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safety monitoring in clinical trials

**Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Know the regulatory approval process and their registration in Indian and international markets

Unit V

07Hours

Regulatory Concepts

Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book

**Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
- Know the regulatory approval process and their registration in Indian and international markets

**Recommended books (Latest edition):**

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185. Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
8. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
9. Drugs: From Discovery to Approval, Second Edition By Rick Ng

## **BP 805T PHARMACOVIGILANCE (Theory)**

### **Course Objectives:**

This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions.

### **Course Content**

#### Unit I

10 Hours

##### Introduction to Pharmacovigilance

- History and development of Pharmacovigilance
- Importance of safety monitoring of Medicine
- WHO international drug monitoring programme
- Pharmacovigilance Program of India(PvPI)

##### Introduction to adverse drug reactions

- Definitions and classification of ADRs
- Detection and reporting
- Methods in Causality assessment
- Severity and seriousness assessment
- Predictability and preventability assessment
- Management of adverse drug reactions

##### Basic terminologies used in pharmacovigilance

- Terminologies of adverse medication related events
- Regulatory terminologies

### **Learning Outcomes:**

At completion of this paper it is expected that students will be able to (know, do, and appreciate):

- History and development of pharmacovigilance
- Dictionaries, coding and terminologies used in pharmacovigilance
- Detection of new adverse drug reactions and their assessment
- Adverse drug reaction reporting systems and communication in pharmacovigilance.

#### Unit II

10 hours

##### Drug and disease classification

- Anatomical, therapeutic and chemical classification of drugs
- International classification of diseases
- Daily defined doses
- International Non proprietary Names for drugs

##### Drug dictionaries and coding in pharmacovigilance

- WHO adverse reaction terminologies
- MedDRA and Standardised MedDRA queries
- WHO drug dictionary
- Eudravigilance medicinal product dictionary

##### Information resources in pharmacovigilance

- Basic drug information resources
- Specialised resources for ADRs

##### Establishing pharmacovigilance programme

- Establishing in a hospital
- Establishment & operation of drug safety department in industry
- Contract Research Organisations (CROs)
- Establishing a national programme

**Learning Outcomes:**

At completion of this paper it is expected that students will be able to (know, do, and appreciate):

- International standards for classification of diseases and drugs

Unit III

10 Hours

Vaccine safety surveillance

- Vaccine Pharmacovigilance
- Vaccination failure
- Adverse events following immunization

Pharmacovigilance methods

- Passive surveillance – Spontaneous reports and case series
- Stimulated reporting
- Active surveillance – Sentinel sites, drug event monitoring and registries
- Comparative observational studies – Cross sectional study, case control study and cohort study
- Targeted clinical investigations
- Communication in pharmacovigilance
- Effective communication in Pharmacovigilance
- Communication in Drug Safety Crisis management
- Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media

**Learning Outcomes:**

At completion of this paper it is expected that students will be able to (know, do, and appreciate):

- Detection of new adverse drug reactions and their assessment
- International standards for classification of diseases and drugs
- Adverse drug reaction reporting systems and communication in pharmacovigilance
- Methods to generate safety data during pre clinical, clinical and post approval phases of drugs' life cycle
- Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
- Writing case narratives of adverse events and their quality.

Unit IV

8 Hours

Safety data generation

- Pre clinical phase
- Clinical phase
- Post approval phase (PMS)

ICH Guidelines for Pharmacovigilance

- Organization and objectives of ICH
- Expedited reporting
- Individual case safety reports
- Periodic safety update reports
- Post approval expedited reporting
- Pharmacovigilance planning



- Good clinical practice in pharmacovigilance studies

**Learning Outcomes:**

At completion of this paper it is expected that students will be able to (know, do, and appreciate):

- Detection of new adverse drug reactions and their assessment
- International standards for classification of diseases and drugs
- Adverse drug reaction reporting systems and communication in pharmacovigilance
- Methods to generate safety data during pre clinical, clinical and post approval phases of drugs' life cycle
- Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation.

Unit V

7 hours

Pharmacogenomics of adverse drug reactions

- Genetics related ADR with example focusing PK parameters.
- Drug safety evaluation in special population
- Paediatrics
- Pregnancy and lactation
- Geriatrics

CIOMS

- CIOMS Working Groups
- CIOMS Form

CDSCO (India) and Pharmacovigilance

- D&C Act and Schedule Y
- Differences in Indian and global pharmacovigilance requirements

**Learning Outcomes:**

At completion of this paper it is expected that students will be able to (know, do, and appreciate):

- Why drug safety monitoring is important?
- History and development of pharmacovigilance
- Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India
- ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning
- CIOMS requirements for ADR reporting
- Writing case narratives of adverse events and their quality.

**Recommended Books (Latest edition):**

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert, Jones & Bartlett Publishers.
7. Textbook of Pharmacoepidemiology edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills: G. Parthasarathi, Karin Nyfort Hansen, Milap C. Nahata
9. National Formulary of India

10. Text Book of Medicine by Yashpal Munjal
11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna
12. <http://www.who.int/dynpage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297>
13. <http://www.ich.org/>
14. <http://www.cioms.ch/>
15. <http://cdsco.nic.in/>
16. [http://www.who.int/vaccine\\_safety/en/](http://www.who.int/vaccine_safety/en/)
17. [http://www.ipc.gov.in/PvPI/pv\\_home.html](http://www.ipc.gov.in/PvPI/pv_home.html)

## **BP 806 ET. QUALITY CONTROL AND STANDARDIZATION OF HERBALS**

**(Theory)**

### **Course Objectives:**

In this subject the student learns about the various methods and guidelines for evaluation and standardization of herbs and herbal drugs. The subject also provides an opportunity for the student to learn cGMP, GAP and GLP in traditional system of medicines.

Unit I

10 hours

Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms  
WHO guidelines for quality control of herbal drugs. Evaluation of commercial crude drugs intended for use

### **Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Know WHO guidelines for quality control of herbal drugs
- Know Quality assurance in herbal drug industry

Unit II

10 hours

Quality assurance in herbal drug industry of cGMP, GAP, GMP and GLP in traditional system of medicine.

WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines  
WHO Guidelines on GACP for Medicinal Plants.

### **Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Know WHO guidelines for quality control of herbal drugs

Unit III

10 hours

EU and ICH guidelines for quality control of herbal drugs.  
Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

### **Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Appreciate EU and ICH guidelines for quality control of herbal drugs

Unit IV

08 hours

Stability testing of herbal medicines. Application of various chromatographic techniques in standardization of herbal products.

Preparation of documents for new drug application and export registration GMP requirements and Drugs & Cosmetics Act provisions.

### **Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Know Quality assurance in herbal drug industry
- Know the regulatory approval process and their registration in Indian and international markets

Unit V

07 hours

Regulatory requirements for herbal medicines.

WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems

Comparison of various Herbal Pharmacopoeias.

Role of chemical and biological markers in standardization of herbal products

**Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Know the regulatory approval process and their registration in Indian and international markets

**Recommended Books: (Latest Editions)**

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I , Carrier Pub., 2006.
4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8.
8. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
9. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981.
10. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
11. WHO. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.
12. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

## **BP 807 ET. COMPUTER AIDED DRUG DESIGN (Theory)**

### **Course Objectives:**

This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.

### **Course Content:**

UNIT-I 10 Hours

Introduction to Drug Discovery and Development

Stages of drug discovery and development

Lead discovery and Analog Based Drug Design

Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation.

Analog Based Drug Design: Bioisosterism, Classification, Bioisosteric replacement. Any three case studies

### **Learning Outcomes:**

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

- Design and discovery of lead molecules
- The role of drug design in drug discovery process

UNIT-II 10 Hours

Quantitative Structure Activity Relationship (QSAR)

SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammett's substituent constant and Taft's steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.

### **Learning Outcomes:**

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

- The concept of QSAR and docking

UNIT-III 10 Hours

Molecular Modeling and virtual screening techniques

Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

Molecular docking: Rigid docking, flexible docking, manual docking, Docking based screening.

De novo drug design.

### **Learning Outcomes:**

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

- Various strategies to develop new drug like molecules.
- The design of new drug molecules using molecular modeling software

UNIT-IV 08 Hours

Informatics & Methods in drug design

Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

### **Learning Outcomes:**

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

- The role of drug design in drug discovery process

UNIT-V

07 Hours

Molecular Modeling: Introduction to molecular mechanics and quantum mechanics. Energy Minimization methods and Conformational Analysis, global conformational minima determination.

**Learning Outcomes:**

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

- Design and discovery of lead molecules
- The role of drug design in drug discovery process

**Recommended Books (Latest Editions)**

1. Robert GCK, ed., "Drug Action at the Molecular Level" University Prak Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.
3. Delgado JN, Remers WA eds "Wilson & Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry 'Lea & Febiger.
5. Koro Ikovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.
7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
8. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.

## **BP808ET CELL AND MOLECULAR BIOLOGY (Elective subject)**

### **Course Objectives:**

- Cell biology is a branch of biology that studies cells – their physiological properties, their structure, the organelles they contain, interactions with their environment, their life cycle, division, death and cell function.
- This is done both on a microscopic and molecular level.
- Cell biology research encompasses both the great diversity of single-celled organisms like bacteria and protozoa, as well as the many specialized cells in multi-cellular organisms such as humans, plants, and sponges.

### **Course content:**

#### Unit I

10Hours

- a. Cell and Molecular Biology: Definitions theory and basics and Applications.
- b. Cell and Molecular Biology: History and Summation.
- c. Properties of cells and cell membrane.
- d. Prokaryotic versus Eukaryotic
- e. Cellular Reproduction
- f. Chemical Foundations – an Introduction and Reactions (Types)

### **Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Summarize cell and molecular biology history.
- Summarize cellular functioning and composition.
- Describe the chemical foundations of cell biology.

#### Unit II

10 Hours

- a. DNA and the Flow of Molecular Information
- b. DNA Functioning
- c. DNA and RNA
- d. Types of RNA
- e. Transcription and Translation

### **Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Summarize the DNA properties of cell biology.

#### Unit III

10 Hours

- a. Proteins: Defined and Amino Acids
- b. Protein Structure
- c. Regularities in Protein Pathways
- d. Cellular Processes
- e. Positive Control and significance of Protein Synthesis

### **Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Describe protein structure and function.

#### Unit IV

08 Hours

- a. Science of Genetics
- b. Transgenics and Genomic Analysis
- c. Cell Cycle analysis

- d. Mitosis and Meiosis
- e. Cellular Activities and Checkpoints

**Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Describe cellular membrane structure and function.
- Describe basic molecular genetic mechanisms.
- Summarize the Cell Cycle

Unit V

07 Hours

- a. Cell Signals: Introduction
- b. Receptors for Cell Signals
- c. Signaling Pathways: Overview
- d. Misregulation of Signaling Pathways
- e. Protein-Kinases: Functioning

**Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Describe basic molecular genetic mechanisms.
- Summarize the Cell Cycle

**Recommended Books (latest edition):**

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th 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. Peppler: Microbial Technology.
9. Edward: Fundamentals of Microbiology.
10. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
11. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
12. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
13. RA Goldshy et. al.,: Kuby Immunology.



**BP809ET. COSMETIC SCIENCE (Theory)**

45Hours

**UNIT I**

10Hours

Classification of cosmetic and cosmeceutical products

Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs

Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients, preservatives. Classification and application

Skin: Basic structure and function of skin.

Hair: Basic structure of hair. Hair growth cycle.

Oral Cavity: Common problem associated with teeth and gums.

**Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Understand the design and properties of Cosmetics.
- Understand the effect of cosmetics on human body

**UNIT II**

10 Hours

Principles of formulation and building blocks of skin care products:

Face wash,

Moisturizing cream, Cold Cream, Vanishing cream and their advantages and disadvantages. Application of these products in formulation of cosmeceuticals. Antiperspirants & deodorants- Actives & mechanism of action.

Principles of formulation and building blocks of Hair care products:

Conditioning shampoo, Hair conditioner, anti-dandruff shampoo. Hair oils.

Chemistry and formulation of Para-phenylene diamine based hair dye. Principles of formulation and building blocks of oral care products: Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.

**Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Understand the design and properties of Cosmetics.
- Understand the effect of cosmetics on human body

**UNIT III**

10 Hours

Sun protection, Classification of Sunscreens and SPF.

Role of herbs in cosmetics:

Skin Care: Aloe and turmeric Hair care: Henna and amla.

Oral care: Neem and clove

Analytical cosmetics: BIS specification and analytical methods for shampoo, skin- cream and toothpaste.

**Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Understand the design and properties of Cosmetics.
- Understand the effect of cosmetics on human body

**UNIT IV**

08 Hours.

Principles of Cosmetic Evaluation: Principles of sebumeter, corneometer. Measurement of TEWL, Skin Color, Hair tensile strength, Hair combing properties  
Soaps, and syndet bars. Evolution and skin benefits.

**Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Understand the design and properties of Cosmetics.
- Understand the effect of cosmetics on human body

UNIT V

07 Hours

Oily and dry skin causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis.

Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and body odor.

Antiperspirants and Deodorants- Actives and mechanism of action

**Learning Outcomes:**

Upon completion of the subject student shall be able to;

- Understand the design and properties of Cosmetics.
- Understand the effect of cosmetics on human body

**References**

- 1 Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
- 2 Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th Edition, Vandana Publications Pvt. Ltd., Delhi.
- 3 Text book of cosmeticology by Sanju Nanda & Roop K. Khar, Tata Publishers.

## **BP810 ET. PHARMACOLOGICAL SCREENING METHODS**

### **Course Objectives:**

This subject is designed to impart the basic knowledge of preclinical studies in experimental animals including design, conduct and interpretations of results.

Unit –I

08 Hours

Laboratory Animals:

Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals.

Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia.

### **Learning Outcomes:**

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

- Appreciate the applications of various commonly used laboratory animals.
- Appreciate and demonstrate the various screening methods used in preclinical research

Unit –II            10 Hours

Preclinical screening models

- a. Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study.
- b. Study of screening animal models for

Diuretics, nootropics, anti-Parkinson's, antiasthmatics, Preclinical screening models: for CNS activity- analgesic, antipyretic, anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease

### **Learning Outcomes:**

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

- Appreciate and demonstrate the various screening methods used in preclinical research
- Appreciate and demonstrate the importance of biostatistics and research methodology
- Design and execute a research hypothesis independently

## **BP 811 ET. ADVANCED INSTRUMENTATION TECHNIQUES**

### **Course Objectives:**

This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart advanced knowledge on the principles and instrumentation of spectroscopic and chromatographic hyphenated techniques. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

### **Course Content:**

#### UNIT-I

10 Hours

Nuclear Magnetic Resonance spectroscopy

Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications

Mass Spectrometry- Principles, Fragmentation, Ionization techniques – Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications

### **Learning Outcomes:**

Upon completion of the course the student shall be able to

- Understand the advanced instruments used and its applications in drug analysis
- Know analysis of drugs using various analytical instruments

#### UNIT-II

10 Hours

Thermal Methods of Analysis: Principles, instrumentation and applications of Thermogravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC)

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.

### **Learning Outcomes:**

Upon completion of the course the student shall be able to

- Understand the advanced instruments used and its applications in drug analysis
- Know analysis of drugs using various analytical instruments

#### UNIT-III

10 Hours

Calibration and validation-as per ICH and USFDA guidelines

Calibration of following Instruments

Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer, Fluorimeter, Flame Photometer, HPLC and GC

### **Learning Outcomes:**

Upon completion of the course the student shall be able to

- Understand the calibration of various analytical instruments

#### UNIT-IV

08 Hours

Radio immune assay: Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay

Extraction techniques: General principle and procedure involved in the solid phase extraction and liquid-liquid extraction

**Learning Outcomes:**

Upon completion of the course the student shall be able to

- Understand the chromatographic separation and analysis of drugs.

UNIT-V

07 Hours

Hyphenated techniques-LC-MS/MS, GC-MS/MS, HPTLC-MS.

**Learning Outcomes:**

Upon completion of the course the student shall be able to

- Understand the advanced instruments used and its applications in drug analysis
- Understand the chromatographic separation and analysis of drugs.

**Recommended Books (Latest Editions)**

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

## **BP 812 ET. DIETARY SUPPLEMENTS AND NUTRACEUTICALS**

### **Course Objectives:**

This subject covers foundational topics that are important for understanding the need and requirements of dietary supplements among different groups in the population.

#### **UNIT I**

07 hours

- a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis, hypertension etc.
- b. Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community.
- c. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods: Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Ginkgo, Flaxseeds

### **Learning Outcomes:**

This module aims to provide an understanding of the concepts behind the theoretical applications of dietary supplements. By the end of the course, students should be able to:

- Understand the need of supplements by the different group of people to maintain healthy life.
- Appreciate the components in dietary supplements and the application.

#### **UNIT II**

15 hours

Phytochemicals as nutraceuticals: Occurrence and characteristic features(chemical nature medicinal benefits) of following

- a. Carotenoids-  $\alpha$  and  $\beta$ -Carotene, Lycopene, Xanthophylls, lutein
- b. Sulfides: Diallyl sulfides, Allyl trisulfide.
- c. Polyphenolics: Resveratrol
- d. Flavonoids- Rutin, Naringin, Quercetin, Anthocyanidins, catechins, Flavones
- e. Prebiotics / Probiotics.: Fructo oligosaccharides, Lacto bacillum
- f. Phyto estrogens : Isoflavones, daidzein, Genistein, lignans
- g. Tocopherols
- h. Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.

### **Learning Outcomes:**

This module aims to provide an understanding of the concepts behind the theoretical applications of dietary supplements. By the end of the course, students should be able to:

- Understand the need of supplements by the different group of people to maintain healthy life.
- Understand the outcome of deficiencies in dietary supplements.
- Appreciate the components in dietary supplements and the application.

#### **UNIT III**

07 hours

- a. Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.
- b. Dietary fibres and complex carbohydrates as functional food ingredients.

**Learning Outcomes:**

This module aims to provide an understanding of the concepts behind the theoretical applications of dietary supplements. By the end of the course, students should be able to:

- Understand the need of supplements by the different group of people to maintain healthy life.
- Understand the outcome of deficiencies in dietary supplements.
- Appreciate the components in dietary supplements and the application.

## UNIT IV

10 hours

- a. Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.
- b. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E,  $\alpha$ - Lipoic acid, melatonin Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole.
- c. Functional foods for chronic disease prevention

**Learning Outcomes:**

This module aims to provide an understanding of the concepts behind the theoretical applications of dietary supplements. By the end of the course, students should be able to:

- Understand the need of supplements by the different group of people to maintain healthy life.
- Understand the outcome of deficiencies in dietary supplements.
- Appreciate the components in dietary supplements and the application.

## UNIT V

06 hours

- a. Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals.
- b. Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.
- c. Pharmacopoeial Specifications for dietary supplements and nutraceuticals.

**Learning Outcomes:**

This module aims to provide an understanding of the concepts behind the theoretical applications of dietary supplements. By the end of the course, students should be able to:

- Appreciate the regulatory and commercial aspects of dietary supplements including health claims.

**References:**

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and nutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPublication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch 2nd Edn., Avery Publishing Group, NY (1997).

6. G. Gibson and C. Williams Editors 2000 Functional foods Woodhead Publ.Co.London.
7. Goldberg, I. Functional Foods. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in Essentials of Functional Foods M.K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 Modern Nutrition in Health and Disease. Eighth edition. Lea and Febiger



## **Semester VIII – Elective course on Pharmaceutical Product Development**

No of Hours: 3      Tutorial:1      Credit points:4

Unit-I 10 Hours

Introduction to pharmaceutical product development, objectives, and regulations related to preformulation, formulation development, stability assessment, manufacturing and quality control testing of different types of dosage forms

### **Learning Outcomes:**

Upon completion of the course the student shall be able to

- Understand the various product development techniques

Unit-II 10 Hours

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories

- Solvents and solubilizers
- Cyclodextrins and their applications
- Non - ionic surfactants and their applications
- Polyethylene glycols and sorbitols
- Suspending and emulsifying agents
- Semi solid excipients

### **Learning Outcomes:**

Upon completion of the course the student shall be able to

- Understand the various product development techniques

Unit-III 10 Hours

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories

- Tablet and capsule excipients
- Directly compressible vehicles
- Coat materials
- Excipients in parenteral and aerosols products
- Excipients for formulation of NDDS

Selection and application of excipients in pharmaceutical formulations with specific industrial applications

### **Learning Outcomes:**

Upon completion of the course the student shall be able to

- Understand the various product development techniques

Unit-IV 08 Hours

Optimization techniques in pharmaceutical product development. A study of various optimization techniques for pharmaceutical product development with specific examples. Optimization by factorial designs and their applications. A study of QbD and its application in pharmaceutical product development.

### **Learning Outcomes:**

Upon completion of the course the student shall be able to

- Understand the various product development techniques
- Understand the Optimization techniques in pharmaceutical product development

Selection and quality control testing of packaging materials for pharmaceutical product development- regulatory considerations.

**Learning Outcomes:**

Upon completion of the course the student shall be able to

- Understand the various product development techniques
- Understand the Quality control testing of packaging materials

**Recommended Books (Latest editions)**

1. Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, CharlesBon; Marcel Dekker Inc.
2. Encyclopedia of Pharmaceutical Technology, edited by James swarbrick, Third Edition, Informa Healthcare publishers.
3. Pharmaceutical Dosage Forms, Tablets, Volume II, edited by Herbert A. Lieberman and Leon Lachman; Marcel Dekker, Inc.
4. The Theory and Practice of Industrial Pharmacy, Fourth Edition, edited by Roop kKhar, S P Vyas, Farhan J Ahmad, Gaurav K Jain; CBS Publishers and Distributors Pvt.Ltd. 2013.
5. Martin's Physical Pharmacy and Pharmaceutical Sciences, Fifth Edition, edited by Patrick J. Sinko, BI Publications Pvt. Ltd.
6. Targeted and Controlled Drug Delivery, Novel Carrier Systems by S. P. Vyas and R. K.Khar, CBS Publishers and Distributors Pvt. Ltd, First Edition 2012.
7. Pharmaceutical Dosage Forms and Drug Delivery Systems, Loyd V. Allen Jr., Nicholas B.Popovich, Howard C. Ansel, 9th Ed. 40
8. Aulton's Pharmaceutics – The Design and Manufacture of Medicines, Michael E. Aulton, 3rd Ed.
9. Remington – The Science and Practice of Pharmacy, 20th Ed.
10. Pharmaceutical Dosage Forms – Tablets Vol 1 to 3, A. Liberman, Leon Lachman and Joseph B. Schwartz
11. Pharmaceutical Dosage Forms – Disperse Systems Vol 1 to 3, H.A. Liberman, Martin, M.R and Gilbert S. Banker.
12. Pharmaceutical Dosage Forms – Parenteral Medication Vol 1 & 2, Kenneth E. Avis and H.A. Libermann.
13. Advanced Review Articles related to the topics.