



# **NIRMALA COLLEGE OF PHARMACY MUVATTUPUZHA**

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## **FIRST CYCLE NAAC ACCREDITATION 2023**

### **CRITERION 1**



#### **CURRICULAR ASPECTS**

**1.3.1. Institution integrates crosscutting issues relevant to Professional Ethics, Gender, Human Values, Environment and Sustainability in transacting the Curriculum.**

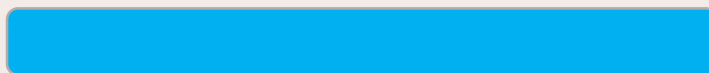
Submitted to



**THE NATIONAL ASSESSMENT AND ACCREDITATION COUNCIL**

## LIST OF B PHARM COURSES RELEVANT TO GENDER, HUMAN VALUES, ENVIRONMENT AND SUSTAINABILITY AND PROFESSIONAL ETHICS

❖ Gender Issues



❖ Human Values



❖ Environment And Sustainability



❖ Professional Ethics



**1.3.1. Institution Integrates Crosscutting Issues Relevant To Professional Ethics, Gender, Human Values, Environment And Sustainability In Transacting The Curriculum.**



## **SYLLABUS**

**For Courses affiliated to the  
KERALA UNIVERSITY OF HEALTH  
SCIENCES**

**Thrissur 680596**



**BACHELOR OF PHARMACY**

**Course Code: 009**

**BACHELOR OF PHARMACY (B. Pharm)  
(2017-18 Academic year onwards)**

**2017**



## 2.6. SYLLABUS

### Semester-I

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

**45 Hours**

**Scope:** *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.*

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

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

#### **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.*

##### **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*





### 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*

### 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.*

### 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 heartbeat, its regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of blood pressure, pulse, electrocardiogram and disorders of heart.*

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

4 Hours/week

*Practical physiology is complimentary to the theoretical discussions in physiology. Practical 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 Taylor. 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 Taylor. 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. Chatterje, Academic Publishers Kolkata

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

**45 Hours**

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

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

1. understand the principles of volumetric and electro chemical analysis
2. Carryout various volumetric and electrochemical titrations
3. develop analytical skills

### **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

#### **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

### 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
- **Basic Principles, methods and application of Diazotisation titration**

### 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

### 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

### 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)

45 Hours

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

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

1. Know the history of profession of pharmacy
2. Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations
3. Understand the professional way of handling the prescription
4. Preparation of various 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.

##### 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*

### UNIT – III

10 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.*

### 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.*

### UNIT– 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*

### BP109P. PHARMACEUTICS I (Practical)

3 Hours / week

- Syrups**                      a) Syrup IP'66                      b) Compound syrup of Ferrous phosphate BPC'68
- Elixirs**                      a) Piperazine citrate elixir                      b) Paracetamol pediatric elixir
- Linctus**                      a) Terpene hydrate Linctus IP'66                      b) Iodine Throat paint( Mandles Paint)
- Solutions**
  - Strong solution of ammonium acetate
  - Cresol with soap solution
  - Lugol's Solution
- Suspensions**
  - Calamine lotion                      b) Magnesium Hydroxide mixture                      c) Aluminium hydroxide gel
- Emulsions**
  - Turpentine Liniment                      b) Liquid paraffin emulsion
- Powders and Granules**
  - ORS powder (WHO)
  - Effervescent granules
  - Dusting powder



d) *Divided powders*

### 8. Suppositories

- a. *Glycero gelatin suppository*
- b. *Cocoa butter suppository*
- c. *Zinc oxide suppository*

### 9. Semisolids

- a. *Sulphur ointment*
- b. *Non staining iodine ointment with methyl salicylate*
- c. *Carbopol gel*

### 10. 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. *Francoise Nieloud and Gilberte Marti—Mestres: Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC, New York.*

### BP104T. PHARMACEUTICAL INORGANIC CHEMISTRY (Theory)

45 Hours

**Scope:** *This subject deals with the monographs of inorganic drugs and.*

**Objectives:** *Upon completion of course student shall be able to*

1. *know the sources of impurities and methods to determine the impurities in inorganic drugs and pharmaceuticals*
2. *understand the medicinal and pharmaceutical importance of inorganic compounds*



## 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*

### 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.*

### 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, Pharmaceutical Aid Kaolin and Bentonite*

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

### UNIT IV

08 Hours

- **Miscellaneous compounds**

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

**Poison and Antidote:** *Sodium thiosulphate\*, Activated charcoal, Sodium nitrite*

**Astringents:** *Zinc Sulphate, Potash Alum*

### 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  $I^{131}$ , Storage conditions, precautions & pharmaceutical application of radioactive substances.*



## **BP110P. PHARMACEUTICAL INORGANIC CHEMISTRY (Practical) 4Hours / 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 Potashalum 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, 4<sup>th</sup> edition.
2. A.I. Vogel, *Text Book of Quantitative Inorganic analysis*
3. P. Gundu Rao, *Inorganic Pharmaceutical Chemistry*, 3<sup>rd</sup> 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)**

**30 Hours**

**Scope:** *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.*

### **Objectives:**

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

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





**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*

**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*

**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*

**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*

**UNIT – V**

**04 Hours**

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

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

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

**30 Hours**

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

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

1. *know the classification and salient features of five kingdoms of life*
2. *understand the basic components of anatomy & physiology of plant*
3. *know understand the basic components of anatomy & physiology animal with special reference to human*

### **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.*

## **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*

## **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*

#### 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.*

#### 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.*

##### **Text Books**

- Text book of Biology by S. B. Gokhale*
- A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.*

##### **Reference Books**

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

#### **BP112RBP.REMEDIAL BIOLOGY (Practical)**

30 Hours

- Introduction to experiments in biology*
  - Study of Microscope*
  - Section cutting techniques*
  - Mounting and staining*
  - Permanent slide preparation*
- Study of cell and its inclusions*
- Study of Stem, Root, Leaf and its modifications*
- Detailed study of frog by using computer models*
- 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)

30 Hours

**Scope:** 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.

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

1. Know the theory and their application in Pharmacy
2. Solve the different types of problems by applying theory
3. Appreciate the important application of mathematics in Pharmacy

#### 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 ( -definition) ,

$$\lim_{x \rightarrow a} \frac{x^n - a^n}{x - a} = na^{n-1}, \lim_{\theta \rightarrow 0} \frac{\sin \theta}{\theta} = 1$$

#### 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*

### 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*

### 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*

### 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*

#### **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)**

**45 Hours**

**Scope:** *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.*

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

1. *Explain the gross morphology, structure and functions of various organs of the human body.*
2. *Describe the various homeostatic mechanisms and their imbalances.*
3. *Identify the various tissues and organs of different systems of human body.*
4. *Perform the hematological tests like blood cell counts, hemoglobin estimation, bleeding/clotting time etc. and also record blood pressure, heart rate, pulse and respiratory volume.*
5. *Appreciate coordinated working pattern of different organs of each system*
6. *Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.*

### **Course Content:**

#### **Unit I**

**10 hours**

- **Nervous system**

*Organization of nervous system, neuron, neuroglia, classification and properties of nerve fiber, 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, and cerebellum), spinal cord (gross structure, functions of afferent and efferent nerve tracts, reflex activity)*

#### **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.*

#### **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.*

#### **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*

#### **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*

#### **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 Taylor. 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 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 Taylor. 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. Chatterje, Academic Publishers Kolkata

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

45 Hours

**Scope:** 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.

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

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

### 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*



## 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*

*E<sub>1</sub> and E<sub>2</sub> reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and evidences. E<sub>1</sub> versus E<sub>2</sub> reactions, Factors affecting E<sub>1</sub> and E<sub>2</sub> 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*

## UNIT-III

10 Hours

- **Alkyl halides\***

*SN<sub>1</sub> and SN<sub>2</sub> reactions – kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations.*

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

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

- **Alcohols\*-** *Qualitative tests, Distinguishing tests between 10 Structure and uses of Ethyl alcohol, Methyl alcohol, chlorobutanol, Cetosteryl alcohol, Benzyl alcohol, Glycerol, Propylene glycol*

## 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.*

## 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*



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

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

**BP203 T. BIOCHEMISTRY (Theory)****45 Hours**

**Scope:** Biochemistry deals with complete understanding of the molecular levels of the chemical process associated with living cells. The scope 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.

**Objectives:** Upon completion of course student shall able to

1. Understand the catalytic role of enzymes, importance of enzyme inhibitors in design of new drugs, therapeutic and diagnostic applications of enzymes.
2. Understand the metabolism of nutrient molecules in physiological and pathological conditions.
3. Understand the genetic organization of mammalian genome and functions of DNA in the synthesis of RNAs and proteins.



## Course Content:

### UNIT I

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.*

### UNIT II

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.*

### Unit III

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.*

- **Biological oxidation**

*Electron transport chain (ETC) and its mechanism. Oxidative phosphorylation & its mechanism and substrate level phosphorylation.*

*Inhibitors, ETC and oxidative phosphorylation/Uncouplers.*

### UNIT IV

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 hormones 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, alkaptonuria, tyrosinemia)*





Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline  
*Catabolism of heme; hyperbilirubinemia and jaundice*

## UNIT V

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 of protein synthesis.*

## 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. Satyanarayana 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)

45 Hours

**Scope:** *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.**

**Objectives:** Upon completion of the subject student shall be able to –

1. Describe the etiology and pathogenesis of the selected disease states;
2. Name the signs and symptoms of the diseases; and
3. Mention the complications of the diseases.

**Course content:**

**Unit I**

**10 Hours**

• **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*

**Unit II**

**10 Hours**

• **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*

**Unit III**

**10 Hours**

• **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*

**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*

**Unit V**

**7 Hours**

• **Infectious diseases:** *Meningitis, Typhoid, Leprosy, Tuberculosis Urinary tract infections*

• **Sexually transmitted diseases:** *AIDS, Syphilis, Gonorrhea*



### 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*; 6<sup>th</sup> edition; India; Jaypee Publications; 2010.  
Laurence B, Bruce C, Bjorn K. ; *Goodman Gilman's The Pharmacological Basis of Therapeutics*; 12<sup>th</sup> edition; New York; McGraw-Hill; 2011.
3. 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;
4. William and Wilkins, Baltimore; 1991 [1990 printing].
5. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston; *Davidson's Principles and Practice of Medicine*; 21<sup>st</sup> edition; London; ELBS/Churchill Livingstone; 2010.
6. Guyton A, John .E Hall; *Textbook of Medical Physiology*; 12<sup>th</sup> edition; WB Saunders Company; 2010.
7. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; *Pharmacotherapy: A Pathophysiological Approach*; 9<sup>th</sup> edition; London; McGraw- Hill Medical; 2014.
8. V. Kumar, R. S. Cotran and S. L. Robbins; *Basic Pathology*; 6<sup>th</sup> edition; Philadelphia; WB Saunders Company; 1997.
9. Roger Walker, Clive Edwards; *Clinical Pharmacy and Therapeutics*; 3<sup>rd</sup> edition; London; Churchill Livingstone publication; 2003.

### Recommended Journals

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

### BP205 T. COMPUTER APPLICATIONS IN PHARMACY (Theory) 30 Hrs (2 Hrs/Week)

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

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

1. know the various types of application of computers in pharmacy
2. know the various types of databases
3. know the various applications of databases in pharmacy

### 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

**Concept of Information Systems and Software:** Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project



## 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*

## 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*

## UNIT – IV

06 Hours

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

## 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)*

## BP210P. COMPUTER APPLICATIONS IN PHARMACY (Practical) (2 hours/week)

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 – Wiley-Interscience, A John Willey and Sons, INC., Publication, USA
3. Bioinformatics (Concept, Skills and Applications) – S.C.Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002(INDIA)





4. *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)**

**30 hours**

**Scope:** *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.*

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

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

**Course content:**

**Unit-I**

**10 hours**

*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.*

**Unit-II**

**10 hours**

- *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)*

**Unit- III**

**10 hours**

*Environmental Pollution: Air pollution; Water pollution; Soil pollution*

**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 Pu blishing Pvt. Ltd., Ahmedabad 013, India,*
4. *Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p*



5. *Clark R.S., Marine Pollution, Clanderson Press Oxford*  
*Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001,*
6. *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)**

**45 Hours**

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

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

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

#### **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, Friedel crafts alkylation reactivity, limitations, Friedel crafts acylation.
- C. Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction
- D. Structure and uses of DDT, Saccharin, BHC and Chloramine

#### **UNIT II**

**10 Hours**

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

#### **UNIT III**

**10 Hours**

- **Fats and Oils**

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

#### **UNIT IV**

**08 Hours**

Polynuclear hydrocarbons: Synthesis, Reactions and Structure of Naphthalene, Phenanthrene, Anthracene, Diphenyl methane, Triphenyl methane and medicinal uses of their derivatives.



## UNIT V

07 Hours

### Cyclo alkanes\*

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

## BP305P. PHARMACEUTICAL ORGANIC CHEMISTRY – II (Practical)

4 Hrs/week

### I. Experiments involving laboratory techniques

- Recrystallisation
- 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/parabromo acetanilide from aniline/acetanilide by halogenation (Bromination reaction)
- 5–nitro salicylic acid/meta dinitro benzene from salicylic acid/ Nitrobenzene by nitration reaction
- Benzoic acid from benzoyl chloride by oxidation reaction
- Benzoic acid/ Salicylic acid from alkyl benzoate/ Alkyl salicylate by hydrolyses reaction
- 1-phenyl-azo-2-naphtho aniline by diazotization and coupling reaction
- 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, Vol.I
3. Text book of organic chemistry by B.S.Bahl and 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.57
8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.





**BP302T. PHYSICAL PHARMACEUTICS-I (Theory)****45 Hours**

**Scope:** *The course deals with the various physical, physicochemical properties and principle involved in dosage forms, formulations. Theory and practical components of the subject help the student to get a better insight in to various areas of formulation research and development and stability studies of pharmaceuticals.*

*Objectives.: upon the completion of the course student shall be able to*

*Understand various physicochemical properties of drug molecules in the designing the dosage form*

- 1. Demonstrate use of physicochemical properties in evaluation of dosage forms.*
- 2. Appreciate physicochemical properties of drug molecules in formulation research and development*

**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*

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

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

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

**UNIT-III****10 Hours**

**Micromeritics:** *Particle size and distribution, average 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.*

**UNIT-IV****08 Hours**

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

**UNIT – V****07 Hours**

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



**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 Hassel Balch 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 particle size, particle size distribution using sieving method*
7. *Determination of particle size, particle size distribution using Microscopic method*
8. *Determination of bulk density, true density and porosity*
9. *Determine the angle of repose and influence of lubricant on angle of repose*
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. *Lieberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume–1 to 3, Marcel Dekkar Inc.*
6. *Lieberman 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*

**BP 303 T. PHARMACEUTICAL MICROBIOLOGY (Theory)****45Hours****Scope:**

*In the broadest sense, scope of microbiology is the study of all organisms that are invisible to the naked eye– that is the study of microorganisms. Microorganisms are necessary for the production of bread, cheese, beer, antibiotics, vaccines, vitamins, enzymes etc. Microbiology has an impact on medicine, agriculture, food science, ecology, genetics, biochemistry, immunology etc.*

**Objectives:** *Upon completion of the subject student shall be able to;*

1. *Understand methods of identification, cultivation and preservation of various microorganisms*
2. *Importance of sterilization in microbiology. and pharmaceutical industry*
3. *Learn sterility testing of pharmaceutical products.*
4. *Microbiological standardization of Pharmaceuticals.*
5. *Understand the cell culture technology and its applications in pharmaceutical industries.*



**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, and quantitative measurement of bacterial growth (total & viable count).*

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

**UNIT II****10 Hours**

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

*Study of principle, procedure, merits, demerits and applications of Physical, chemical and mechanical method of sterilization.*

*Evaluation of the efficiency of sterilization methods.*

**UNIT III****10 Hours**

*Study of morphology, classification, reproduction/replication and cultivation of Fungi and Virus.*

*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.*

**UNIT IV****08 Hours**

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

*Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids. Assessment of a new antibiotic .*

**UNIT V****07 Hours**

*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*

**BP 307P. PHARMACEUTICAL MICROBIOLOGY (Practical)****04 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 (IMViC reactions)
11. Revision Practical Class

#### 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*, 4<sup>th</sup> edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, *Microbiology*, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: *Pharmaceutical Microbiology*.
5. Rose: *Industrial Microbiology*.
6. Probisher, Hinsdill et al: *Fundamentals of Microbiology*, 9th ed. Japan
7. Cooper and Gunn's: *Tutorial Pharmacy*, CBS Publisher and Distribution.
8. Peppler: *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

#### BP304T. PHARMACEUTICAL ENGINEERING (Theory)

45 Hours

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

**Objectives:** Upon completion of the course student shall be able:

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

#### 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.
- **Mixing:** Objectives, applications & factors affecting mixing, Difference between solid and liquid mixing, mechanism of solid mixing, liquids mixing and semisolids mixing. Principles, Construction, Working, uses, Merits and Demerits of Double cone blender, twin shell blender, ribbon blender, Sigma blade mixer, planetary mixers, Propellers, Turbines, Paddles & Silverson Emulsifier.

## UNIT-II

10 Hours

- **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.
- **Heat Transfer:** Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers.

## UNIT- III

10 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.
- **Distillation:** Objectives, applications & types of distillation. principles, construction, working, uses, merits and demerits of (lab scale and industrial scale) Simple distillation, preparation of purified water and water for injection BP by distillation, flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation

## UNIT-IV

08 Hours

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

## UNIT- V

7 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.
- **Material handling systems:** Objectives & applications of Material handling systems, different types of conveyors such as belt, screw and pneumatic conveyors.



**Recommended Books: (Latest Editions)**

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

**BP308P - PHARMACEUTICAL ENGINEERING (Practical)****4 Hours/week**

- I. *Particle size determination by beaker decantation method.*
- II. *To determine the overall heat transfer coefficient by heat exchanger.*
- III. *Construction of drying curves (for calcium carbonate and starch).*
- IV. *Determination of moisture content and loss on drying.*
- V. *Determination of humidity of air –From wet and dry bulb temperatures (use of Dew point method).*
- VI. *Description of Construction, working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier.*
- VII. *Size analysis by sieving – To evaluate size distribution of tablet granulations – Construction of various size frequency curves including arithmetic and Logarithmic probability plots.*
- VIII. *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.*
- IX. *Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such other major equipment.*
- X. *Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration And Thickness/ viscosity)*
- XI. *To calculate the mixing index for given sample by using Double Cone Blender.*



## Semester-IV

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

**45 Hours**

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

**Objectives:** *At the end of the course, the student shall be able to*

- 1. understand the methods of preparation and properties of organic compounds*
- 2. explain the stereo chemical aspects of organic compounds and stereo chemical reaction*
- 3. know the medicinal uses and other applications of organic compounds*

#### **Course Content:**

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

#### **UNIT-I**

**10 Hours**

*Stereo isomerism*

**10 Hours**

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

#### **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 stereo selective 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, reactivity and Basicity of pyrrole*

#### **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*



## UNIT-V

7 Hours

*Reactions of synthetic importance*

*Metal hydride reduction ( $\text{NaBH}_4$  and  $\text{LiAlH}_4$ ),*

*Birch reduction,*

*Oppenauer oxidation*

*Beckmanns rearrangement*

*Claisen Schmidt condensation*

*Clemmensen reduction,*

*Wolff Kishner reduction.*

*Dakin reaction.*

*Schmidt rearrangement.*

### 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)

45 Hours

**Scope:** 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.

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

1. understand the chemistry of drugs with respect to their pharmacological activity
2. understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
3. know the Structural Activity Relationship (SAR) of different class of drugs
4. write the chemical synthesis of some 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 (\*)

## 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:

*Principles - Phase I and Phase II.*

*Factors affecting drug metabolism including stereo chemical aspects.*





## UNIT- II

10 hours

### Drugs acting on Autonomic Nervous System Sympathomimetic agents:

*SAR of Sympathomimetic agents*

*Direct acting: Nor-epinephrine, Epinephrine, Phenylephrine\*, Dopamine, Methyldopa, Clonidine, Isoproterenol, Terbutaline, Salbutamol\*, Naphazoline, Oxymetazoline and Xylometazoline.*

*Indirect acting agents: Hydroxyamphetamine, Pseudoephedrine,*

*Agents with mixed mechanism: Ephedrine.*

*Adrenergic Antagonists:*

- *Alpha adrenergic blockers: Tolazoline\*, Phentolamine, Prazosin.*
- *Beta adrenergic blockers: SAR of beta blockers, Propranolol\*, Atenolol, , Esmolol, Metoprolol, Labetolol, Carvedilol.*

## 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, Homatropine hydrobromide, Ipratropium bromide\*.*

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

## UNIT- IV

8 Hours

*Drugs acting on Central Nervous System*

### A.Sedative and Hypnotics

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

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

*Miscellaneous:*

*Amides & imides: Glutethimide.*

*Alcohol & their carbamate derivatives: Meprobamate.*



*Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.*

## **B. Antipsychotics**

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

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

Fluorobutyrophenones: Haloperidol, Droperidol, Risperidone.

Beta amino ketones: Molindone hydrochloride.

Benzamides: Sulpieride.

## **C. Anticonvulsants: SAR of Anticonvulsants, mechanism of anticonvulsant action**

Barbiturates: Phenobarbitone,

Hydantoins: Phenytoin\*.

Oxazolidine diones: Trimethadione, Paramethadione Succinimides: Phensuximide, Methsuximide, Ethosuximide\* Urea and monoacylureas: Carbamazepine\*

Benzodiazepines: Clonazepam

Miscellaneous: Primidone, Valproic acid, Gabapentin, Felbamate

## **UNIT – V**

**7 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.

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.

Narcotic antagonists: Nalorphine hydrochloride, Naloxone hydrochloride.

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

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

**4 Hours/Week**

### **I. Preparation of drugs/ intermediates**

- 1 1,3-pyrazole
- 2 1,3-oxazole
- 3 Benzimidazole
- 4 Benztriazole
- 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)

45Hours

**Scope:** The course deals with the various physical, physicochemical properties and principle involved in dosage forms, formulations. Theory and practical components of the subject help the student to get a better insight in to various areas of formulation research and development and stability studies of pharmaceuticals.

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

1. Understand various physicochemical properties of drug molecules in the designing the dosage form
2. Know the principles of chemical kinetics & to use them in assigning expiry date for Formulation
3. Demonstrate use of physicochemical properties in evaluation of dosage forms
4. Appreciate physicochemical properties of drug molecules in formulation research and Development

### Course Content:

#### UNIT-I

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

#### UNIT-II

10 hours

**Rheology:** Newtonian systems, law of flow, kinematic viscosity, effect of temperature, non-Newtonian systems, pseudoplastic, dilatants, 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

### UNIT-III

10 hours

**Coarse dispersion:** Suspension, interfacial properties of suspended particles, settling in suspensions, formulation of suspensions. Emulsions and theories of emulsification, microemulsion and multiple emulsions; Physical stability of emulsions, preservation of emulsions, rheological properties of emulsions.

### UNIT-IV

8 hours

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

### UNIT-V

7 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.

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

4 Hrs/week

1. Determination of surface tension of given liquids by drop count and drop weight method
2. Determination of HLB number of a surfactant by saponification method
3. Determination of Freundlich and Langmuir constants using activated char coal
4. Determination of critical micellar concentration of surfactants
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)****45 Hours**

**Scope:** *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.*

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

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

**Course Content:****UNIT-I****5 Hours****General Pharmacology**

- 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.*
- Pharmacokinetics– Membrane transport, absorption, distribution, metabolism and excretion of drugs .Enzyme induction, enzyme inhibition, kinetics of elimination*

**UNIT-II****15 Hours****General Pharmacology**

- 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.*
- Adverse drug reactions.*
- Drug interactions (pharmacokinetic and pharmacodynamic)*
- Drug discovery and clinical evaluation of new drugs –Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.*
- Principles of toxicology - Definition and basic knowledge of acute, subacute and chronic toxicity. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity General principles of treatment of poisoning.*
- Chronopharmacology - Definition of rhythm and cycles. Biological clock and their significance leading to chronotherapy.*



### UNIT-III

10 Hours

#### Pharmacology of peripheral nervous system

- a. Organization and function of ANS.
- b. Neurohumoral transmission, co-transmission and classification of neurotransmitters.
- c. Parasympathomimetics; Clinical symptoms and management of organophosphorus poisoning; Parasympatholytics, Sympathomimetics, sympatholytics.
- d. Neuromuscular blocking agents and skeletal muscle relaxants (peripheral).
- e. Local anesthetic agents.
- f. Drugs used in myasthenia gravis and glaucoma

### UNIT-IV

8 Hours

#### Pharmacology of 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. Clinical symptoms and management of barbiturates poisoning
- f. Alcohols and disulfiram

### UNIT-V

07 Hours

#### Pharmacology of central nervous system

- a. Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, antimanics and hallucinogens.
- b. Drugs used in Parkinsons disease and Alzheimer's disease.
- c. CNS stimulants and nootropics.
- d. Opioid analgesics and antagonists; Clinical symptoms and management of morphine poisoning
- e. Drug addiction, drug abuse, tolerance and dependence.

### BP 408 P.PHARMACOLOGY-I (Practical)

4Hrs/Week

1. Introduction to experimental pharmacology.
  - a. Commonly used instruments in experimental pharmacology.
  - b. Study of common laboratory animals.
  - c. Maintenance of laboratory animals as per CPCSEA guidelines.
  - d. Common laboratory techniques. Blood withdrawal, serum and plasma separation, anesthetics and euthanasia used for animal studies.
2. Dose calculation in pharmacological experiments
3. Study of different routes of drugs administration in mice/rats.
4. Introduction to in-vitro pharmacology and physiological salt solutions.
5. DRC of acetylcholine using isolated chicken ileum.
6. Effect of spasmogens and spasmolytics using isolated chicken ileum (eg- physostigmine, atropine)
7. Determination of PA<sub>2</sub> value of Atropine using isolated chicken ileum (by Schilds plot method).
8. Study of effect of drugs on gastrointestinal motility



9. Determination of acute oral toxicity (LD50) of a drug from a given data
10. Determination of acute skin irritation / corrosion of a test substance
11. Determination of acute eye irritation / corrosion of a test substance
12. Calculation of pharmacokinetic parameters from a given data

*Note: Wherever wet laboratory experiments are not feasible, simulated experiments by software /videos may be used.*

#### **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 McGraw-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)**

**45 Hours**

**Scope:** The subject involves the fundamentals of Pharmacognosy like scope, classification of crude drugs, their identification and evaluation, phytochemicals present in them and their medicinal properties. To study production of plants and phytochemicals through plant tissue culture.

**Objectives:** Upon completion of the course, the student shall be able

1. To know the techniques in the cultivation and production of crude drugs
2. To know the crude drugs, their uses and chemical nature
3. To know the evaluation techniques for the herbal drugs
4. To carry out the microscopic and morphological evaluation of crude drugs

#### **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, ( seed, leaf, bark, wood, root, rhizome, flower, fruit and entire drug) unorganized drugs, (dried latex, dried juices, dried extracts, gums, mucilages, oleoresins and oleo- gum -resins).

##### **Classification of drugs:**

Alphabetical, morphological, taxonomical, chemical, pharmacological, chemo and serotaxonomical 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.*

*Quantitative microscopy of crude drugs including lycopodium spore method, leaf constants, Camera Lucida, and calibration of eye piece micrometer using stage micrometer.*

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

*Cultivation, Collection, Processing and storage of drugs of natural origin: **General aspects on cultivation and collection, processing and storage 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:** *In situ and ex situ conservation of medicinal plants.*

**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*

**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 general tests for identification of Alkaloids, Glycosides, Flavonoids, Tannins, Volatile oil and Resins.*

**UNIT V****08 Hours**

*Study of biological source, chemical constituents and uses of drugs of natural origin containing following Plant drugs /Products:*

*Fibers - Cotton, Jute, Hemp*

*Hallucinogen- Cannabis,*

*Teratogens- Tobacco, Colchicum, Veratrum*

*Natural allergens-Classification, Preparation and standardization of allergenic extract.*

**Primary metabolites:**

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

**Carbohydrates:** *Acacia, Agar, Starch, 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: Antiviral, Antimicrobial, Anticancer and Cardiovascular agents.*

**BP409 P. PHARMACOGNOSY AND PHYTOCHEMISTRY I (Practical)****4 Hours/week**

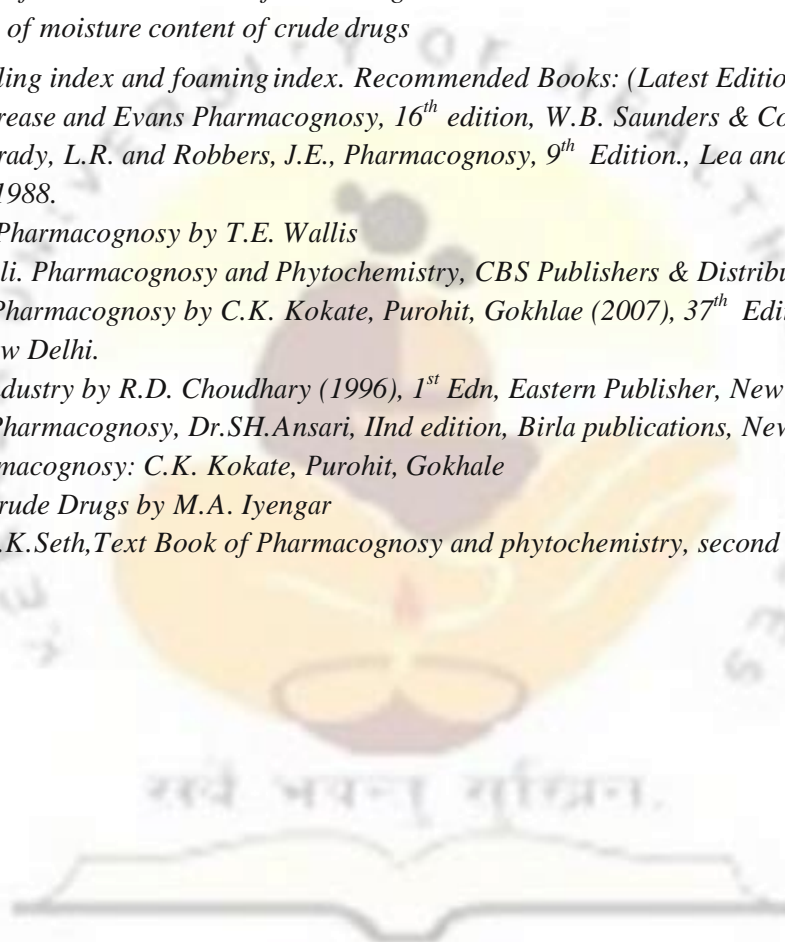
1. *Analysis of crude drugs by chemical tests:*

(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 termination number and palisade ratio.*
  4. *Determination of size of starch grains, calcium oxalate crystals by eye piece micrometer*
  5. *Determination of Fiber length and width by eye piece micrometer.*
  6. *Determination of number of starch grains by Lycopodium spore method*
  7. *Determination of Ash values.*
  8. *Determination of Extractive values of crude drugs.*
  9. *Determination of moisture content of crude drugs*
10. *Determination of swelling index and foaming index. Recommended Books: (Latest Editions)*
1. *W.C.Evans, Trease and Evans Pharmacognosy, 16<sup>th</sup> edition, W.B. Saunders & Co., London, 2009.*
  2. *Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9<sup>th</sup> Edition., 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, Gokhale (2007), 37<sup>th</sup> Edition, Nirali Prakashan, New Delhi.*
  6. *Herbal drug industry by R.D. Choudhary (1996), 1<sup>st</sup> Edn, Eastern Publisher, New Delhi.*
  7. *Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007*
  8. *Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhale*
  9. *Anatomy of Crude Drugs by M.A. Iyengar*
  10. *Biren Shah ,A.K.Seth,Text Book of Pharmacognosy and phytochemistry, second edition ,Elsevier publications.*



## Semester-V

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

**45 Hours**

**Scope:** 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.

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

1. Understand the chemistry of drugs with respect to their pharmacological activity
2. Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
3. Know the Structure Activity Relationship of different class of drugs
4. Study the chemical synthesis of selected 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 (\*)

### **UNIT- I**

**10 Hours**

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

**H<sub>1</sub>-antagonists:** Diphenhydramine hydrochloride\*, Dimenhydrinate, Tripeleminamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride\*, Promethazine hydrochloride\*, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Cromolyn sodium

**H<sub>2</sub>-antagonists:** Cimetidine\*, Famotidine, Ranitidine.

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

**Anti-neoplastic agents:**

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

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

**Antibiotics:** Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin

**Plant products:** Etoposide, Vinblastin sulphate, Vincristin sulphate

**Miscellaneous:** Cisplatin, Mitotane.

### **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,*

*Thiazides: Chlorthiazide\*, Hydrochlorothiazide,*

*Loop diuretics: Furosemide\*, Bumetanide, Ethacrynic acid.*

*Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride.*

*Osmotic Diuretics: Mannitol*

**Anti-hypertensive Agents:** Timolol, Captopril, Lisinopril, Enalapril, Benazepril hydrochloride, Clonidine hydrochloride, Sodium nitroprusside, Diazoxide, Minoxidil, Hydralazine hydrochloride.

**UNIT- III****10 Hours**

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

**Anti-hyperlipidemic agents:** Clofibrate, Lovastatin, Cholestamine and Cholestipol

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

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

**UNIT- IV****08 Hours**

**Drugs acting on Endocrine system**

Nomenclature, **Stereochemistry and metabolism of steroids**

**Sex hormones:** **Testosterone**, Nandrolone, **Progestones**, **Oestriol**, **Oestradiol**, Oestrione, Diethyl stilbestrol.

**Drugs for erectile dysfunction:** **Sildenafil**, **Tadalafil**.

**Oral contraceptives:** Mifepristone, Norgestrel, Levonorgestrel

**Corticosteroids :** Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone

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

**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, Cyclomethycaine, Piperocaine.

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

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

**Miscellaneous:** Phenacaine, Dibucaine.\*

**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. Organic Chemistry by I.L. Finar, Vol. II.
7. The Organic Chemistry of Drug Synthesis by Lednicher, Vol. 1 to 5.
8. Indian Pharmacopoeia.
9. Text book of practical organic chemistry – A.I. Vogel.

## BP 502 T. FORMULATIVE PHARMACY (Theory)

45 Hours

**Scope:** 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.

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

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

**Course content:**

3 hours/ week

### 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

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

### UNIT-III

08 Hours

**Capsules:**

**a. Hard gelatin capsules:** Introduction, Extraction of gelatin and production of hard gelatin capsule shells. size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules. 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 minimum/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules

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

#### 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.
- c. Formulation of injections, sterile powders, emulsions, suspensions, large volume parenterals and lyophilized products, Sterilization.
- d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests.

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

#### 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.

#### BP 506 P. FORMULATIVE PHARMACY (Practical)

4Hours/week

1. Preformulation study for prepared granules
2. Preparation and evaluation of Paracetamol tablets
3. Preparation and evaluation of Aspirin tablets
4. Coating of tablets
5. Preparation and evaluation of Tetracycline capsules
6. Preparation of Calcium Gluconate injection
7. Preparation of Ascorbic Acid injection
8. Preparation of Paracetamol Syrup
9. Preparation of Eye drops
10. Preparation of Pellets by extrusion spheronization technique
11. Preparation of Creams (cold / vanishing cream)
12. Evaluation of Glass containers



**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 Remington: *The Science and Practice of Pharmacy*, 20th edition Pharmaceutical Science (RPS)
5. *Theory and Practice of Industrial Pharmacy* by Liberman & Lachman
6. *Pharmaceutics– The science of dosage form design* by M.E.Aulton, Churchill livingstone, Latest edition
7. *Introduction to Pharmaceutical Dosage Forms* by H. C. Ansel, Lea & Febiger, Philadelphia, 5<sup>th</sup> edition, 2005
8. *Drug stability – Principles and practice* by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.

**BP503.T. PHARMACOLOGY-II (Theory)****45 Hours**

**Scope:** 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.

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

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

**Course content****UNIT-I****10 Hours****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.

**UNIT-II****10 Hours****Pharmacology of drugs acting on blood and blood forming organs.**

- a) Drug used in the therapy of shock.
- b) Hematinics, coagulants and anticoagulants.
- c) Fibrinolytics and anti-platelet drugs
- d) Plasma volume expanders



### Pharmacology of drugs acting on urinary system

- e) *Diuretics*
- f) *Anti-diuretics.*

### UNIT-III

10 Hours

#### 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, Clinical symptoms and management of Aspirin poisoning, Paracetamol poisoning.*
- f. *Anti-gout drugs*
- g. *Antiheumatic drugs*

### UNIT-IV

08 Hours

#### 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.*

### UNIT-V

07hours

#### Pharmacology of drugs acting on endocrine system

- a. *Androgens and Anabolic steroids.*
- b. *Estrogens, progesterone and oral contraceptives.*
- c. *Drugs acting on the uterus*

#### Bioassay

- a) *Principles and applications of bioassay.*
- b) *Types of bioassay*
- c) *Bioassay of insulin, oxytocin, vasopressin, ACTH, d-tubocurarine, digitalis, histamine, Heparin sodium, Antirabies vaccine, Diphtheria antitoxin*

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

4Hrs/Week

1. *Effect of drugs on ciliary motility of frog oesophagus*
2. *Effect of drugs on rabbit eye.*
3. *Study of local anesthetics by different methods .*
4. *Effect of saline purgative on frog intestine*
5. *Insulin hypoglycemic effect in rabbit*
6. *Test for pyrogens ( Rabbit method)*



7. Study of effect of hepatic microsomal enzyme inducers on the phenobarbitone sleeping time in mice.
8. Effect of drugs on isolated frog heart.
9. Effect of drugs on blood pressure and heart rate of dog.
10. Study of diuretic activity of drugs using rats/mice.
11. Bioassay of agonist, eg .Acetyl choline on chicken ileum by matching method.
12. Bioassay of agonist, eg.Acetyl choline on chicken ileum by Bracketing method
13. Bioassay of agonist, eg.Acetyl choline on chicken ileum by interpolation method.
14. Bioassay of agonist, eg.Acetyl choline on chicken ileum by three point bioassay.
15. Bioassay of agonist, eg.Acetyl choline on chicken ileum by four point bioassay. (Demonstration only)

Note: **Wherever wet laboratory experiments are not feasible**, simulated experiments by software /videos may be used.

#### 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 Gilmans, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A.,<sup>89</sup> 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. Lippincotts 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)

45 Hours

**Scope:** 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.

**Objectives:** Upon completion of the course, the student shall be able

1. to know basic metabolic pathways and formation of different secondary metabolites
2. to know various medicinally important secondary metabolites
3. to know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents
4. to carryout isolation and identification of phytoconstituents

#### 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.





## UNIT-II

20 Hours

*Study of the biological source, cultivation (\*marked only), commercial varieties, chemical constituents, chemistry & chemical classes, substitutes, adulterants, Diagnostic, macroscopic and microscopic (# marked only) features, specific chemical tests, general methods of extraction & analysis, therapeutic uses and commercial applications of following secondary metabolites:*

**Alkaloids:** *Vinca, Rauwolfia\*#, Belladonna, Opium\*, Ephedra, Cinchona#*

**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*

## UNIT-III

10 Hours

*Industrial production, estimation and utilization of the following phytoconstituents:*

*Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine*

## UNIT IV

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.*

## BP 508 P. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)

4 Hours/Week

1. *Morphology, histology and powder characteristics : Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander*
2. *Exercise involving isolation & detection of active principles*
  - a. *Caffeine - from tea dust.*
  - b. *Starch from Potato*
  - c. *Calcium citrate from lemon juice*
  - d. *Pectin from lemon peel*
  - e. *Casein from milk*
  - f. *Lawsone from Henna*
  - g. *Curcumin from turmeric*
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, 16<sup>th</sup> 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, Gokhale (2007), 37<sup>th</sup> Edition, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), 1<sup>st</sup> 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, VETylor.
10. Louis Appell, The formulation and preparation of cosmetic, fragrances and flavours, Micelle Press 1994.
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)

45 Hours

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

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

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

### 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.

#### 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

### 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; its 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

### 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, Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties

- **National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO)2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

### UNIT-V

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)**

### 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-VI

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

**45 Hours**

**Scope:** 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.

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

1. Understand the importance of drug design and different techniques of drug design.
2. Understand the chemistry of drugs with respect to their biological activity.
3. Know the metabolism, adverse effects and therapeutic value of drugs.
4. Know the importance of SAR of 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, - Lactamase inhibitors, Monobactams

Aminoglycosides: Streptomycin, Neomycin, Kanamycin

Tetracyclines: Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

### **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, Atovaquone.



### UNIT – III

10 Hours

#### Anti-tubercular Agents

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

*Anti tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine, Streptomycin, Capreomycin sulphate.*

#### Urinary tract anti-infective agents

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

*Miscellaneous: Furazolidone, Nitrofurantoin\*, Methenamine.*

#### Antiviral agents:

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

### 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, Praziquantel, Ivermectin.*

#### Sulphonamides and Sulfones

*Historical development, chemistry, classification and SAR of Sulfonamides:*

*Sulphamethizole, Sulfisoxazole, Sulphamethazine, Sulfacetamide\*, Sulphapyridine, Sulfamethoxazole\*, Sulphadiazine, Mefenide acetate, Sulfasalazine.*

*Folate reductase inhibitors: Trimethoprim\*, Cotrimoxazole.*

*Sulfones: Dapsone\*.*

### 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, Tafts steric parameter and Hansch analysis. Pharmacophore modeling and docking techniques.*

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

### 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<sup>®</sup>

**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 (Lipinski's RO5)

### Recommended Books (Latest Editions)

1. Wilson and Gisvold'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)

45 Hours

**Scope:** 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, immuno-pharmacology and in addition, emphasis on the principles of toxicology and chronopharmacology.

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

1. understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
2. comprehend the principles of toxicology and treatment of various poisonings and
3. appreciate correlation of pharmacology with related medical sciences.

### 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 diarrhea
- c. Appetite stimulants and suppressants.
- d. Digestants and carminatives.
- e. Emetics and anti-emetics.
- f. Drugs on skin - melanising and demelanising agents, drugs used in psoriasis, acne

## UNIT-II

10hours

### 3. Chemotherapy

- a. General principles of chemotherapy. including classification of chemotherapeutic agents, microbial resistance, chemoprophylaxis
- b. Sulfonamides and cotrimoxazole. Urinary antiseptics
- c. Antibiotics- Penicillins, cephalosporins, monobactam, carbapenem chloramphenicol, macrolides Lincosamides, quinolones and fluoroquinolones, tetracycline and aminoglycosides, oxazolidinones

## UNIT-III

10 hours

### 3. Chemotherapy

- a. Antitubercular agents
- b. Antileprotic agents
- c. Antifungal agents
- d. Antiviral drugs including anti HIV drugs
- e. Anthelmintics
- f. Antimalarial drugs
- g. Antiamoebic agents

## UNIT-IV

08 hours

### 3. Chemotherapy

Drugs used in UTI and STDs.

Anticancer agents

### 4. Immunopharmacology

Immunostimulants, Immunosuppressant

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

## UNIT-V

07 hours

**Gene therapy-** concepts, approaches, gene transfer techniques and application Stem cell therapy -an overview

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

4Hrs/Week

- 1. Anti allergic activity by mast cell stabilization assay
- 2. Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.





3. Estimation of serum biochemical parameters .
  4. Effects of skeletal muscle relaxants using rota-rod apparatus.
  5. Effect of drugs on locomotor activity using actophotometer.
  6. Anticonvulsant effect of drugs by MES and PTZ method.
  7. Study of stereotype and anti-catatonic activity of drugs on rats/mice.
  8. Study of anxiolytic activity of drugs using rats/mice.
  9. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
  10. Analgesic activity of drug using central and peripheral methods
  11. Biostatistics methods in experimental pharmacology ( student s t test, ANOVA)
  12. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)
- Note: Wherever **wet laboratory experiments are not feasible**, simulated experiments by software /videos may be used.

### 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 McGraw-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. Lippincotts 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)

**45 hours**

**Scope:** 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, nutraceuticals etc. **The subject also emphasizes on Good Manufacturing Practices (GMP), patenting and regulatory issues of herbal drugs**

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

1. understand raw material as source of herbal drugs from cultivation to herbal drug product
2. know the WHO and ICH guidelines for evaluation of herbal drugs
3. know the herbal cosmetics, natural sweeteners, nutraceuticals
4. appreciate patenting of herbal drugs, GMP .
5. To understand the preparation and development of herbal formulation
6. To understand the herbal drug interactions.



## Course content:

### UNIT-I

06 Hours

#### Herbs as raw materials

*Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation. 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.*

### UNIT-II

05 Hours

- 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.*

### UNIT-III

07 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: Alfalfa, 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: Hypericum, Kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.*

### UNIT-IV

10 Hours

#### Herbal Cosmetics

*Sources and description of raw materials of herbal origin used in herbal cosmetics such as*

- a) *Fixed oils: Almond oil, Arachis oil, castor oil, olive oil, coconut oil*
- b) *Waxes: Bees wax, Carnauba wax, Paraffin wax, Spermaceti*
- c) *Gums: Guar gum, Sodium Alginate, Tragacanth*
- d) *Colours: Cochineal, Saffron, Indigo, Henna*
- e) *Perfumes: Rose oil, Jasmine oil, Lavender oil.*
- f) *Protective agents: Neem, Cucumber, Aloe*
- g) *Bleaching agents: Lemon, Turmeric*
- h) *Antioxidants: Green tea, Sesame oil in products such as skin care, hair care and oral hygiene products.*

#### 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*



## UNIT- V

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:**

- a) Definition of the terms: Patent, IPR, Farmers right, Breeders right, Bioprospecting and Biopiracy.
- b) 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.

## UNIT-VI

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.**

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

4 hours/ week

1. To perform preliminary phytochemical screening of crude drugs.
2. Determination of Ash values
3. Determination of moisture content of crude drugs
4. Determination of Extractive values of crude drugs
5. Determination of the alcohol content of Asava and Arista
6. Preparation of herbal cosmetics
7. Preparation and standardization of herbal formulation
8. Determination of swelling index and foaming index
9. Monograph analysis of herbal drugs from recent Pharmacopoeias
10. Analysis of fixed oils

### **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)****45 Hours**

**Scope:** *This subject is designed to impart knowledge and skills necessary for dose calculations, dose*

*Adjustments and to apply Biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of Biopharmaceutics and pharmacokinetics are provided to help the students to clarify the concepts.*

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

- 1. Understand the basic concepts in biopharmaceutics and pharmacokinetics.*
- 2. Use plasma data and derive the pharmacokinetic parameters to describe the process of drug absorption, distribution, metabolism and elimination.*
- 3. Critically evaluate biopharmaceutic studies involving drug product equivalency*
- 4. Design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.*
- 5. Detect potential clinical pharmacokinetic problems and apply basic pharmacokinetic principles to solve them*

**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 of drugs Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs*

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

**Biotransformation** *Phase I and Phase II reactions.*

**Drug Elimination:** *Renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs*

**Bioavailability and Bioequivalence:** *Objectives of bioavailability studies, absolute and relative bioavailability, measurement of bioavailability, in-vitro drug dissolution models, in- vitro, in-vivo correlations, bioequivalence studies, methods to enhance the bioavailability.*

**UNIT- III****10 Hours**

**Pharmacokinetics:** *Introduction to Pharmacokinetics models, Compartment models, Non compartment models, physiological models, One compartment open model. a. Intravenous Injection (Bolus) b. Intravenous infusion, extra vascular administrations, calculations of  $K_a$  and  $K_E$ . From plasma and urinary excretion data*

**UNIT- IV****08 Hours**

**Multicompartment models:** *Two compartment open model. IV bolus Multiple Dosage Regimens:*

- a). Repetitive Intravenous injections- One Compartment Open Model*
- b). Repetitive Extravascular dosing- One Compartment Open model*





## UNIT- V

07 Hours

**Nonlinear Pharmacokinetics:** *Introduction, Factors causing Non-linearity, Michaelis-menton method of estimating parameters,*

### 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 pharmaceutics and Pharmacokinetics-A Treatise*, By D. M. Brahmkar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi
5. *Pharmacokinetics*: By Milo Gibaldi Donald, R. Marcel 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 Robert F Notari Marcel Dekker Inc, New York and Basel, 1987.
12. *Remingtons Pharmaceutical Sciences*, By Mack Publishing Company, Pennsylvania

## BP 605 T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)

45 Hours

### Scope:

*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.*

**Objectives:** Upon completion of the subject student shall be able to;

1. Understanding the importance of Immobilized enzymes in Pharmaceutical Industries
2. Genetic engineering applications in relation to production of pharmaceuticals
3. Importance of Monoclonal antibodies in Industries
4. Appreciate the use of microorganisms in fermentation technology

## 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.  
Basic principles of genetic engineering.



## 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 products: i) Interferon ii) hepatitis- B vaccine iii) Insulin hormone.
- d) Brief introduction to PCR
- e) Types of immunity- humoral immunity, cellular immunity

## UNIT III

10 Hours

- 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 vaccines, antitoxins, serum-immuno blood derivatives and other products relative to immunity.
- e) Storage conditions and stability of official vaccines
- f) Hybridoma technology- Production, Purification and Applications

## UNIT IV

08 Hours

- a) Immuno blotting techniques- ELISA, Western blotting, Southern blotting.
- b) Microbial genetics including transformation, transduction, conjugation, plasmids and transposons.
- c) Introduction to Microbial biotransformation and applications.

## UNIT V

07 Hours

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

### Recommended Books (Latest edition):

1. B.R. Glick and J.J. Pasternak: *Molecular Biotechnology: Principles and Applications of Recombinant DNA*: 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, Degrand, Ohio.
6. S.B. Primrose: *Molecular Biotechnology (Second Edition)* Blackwell Scientific Publication.
7. Stanbury F., P., Whitaker A., and Hall J., S., *Principles of fermentation technology*, 2nd edition, Aditya books Ltd., New Delhi



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

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

1. understand the CGMP aspects in a pharmaceutical industry appreciate the importance of documentation
2. understand the scope of quality certifications applicable to pharmaceutical industries
3. understand the responsibilities of QA & QC departments

**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 & ISO 14000:** Overview, Benefits, Elements, steps for registration

**NABL accreditation :** Principles and procedures.

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

**Warehousing:** Good warehousing practice, materials management

### 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

### 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.

### UNIT V

07 Hours

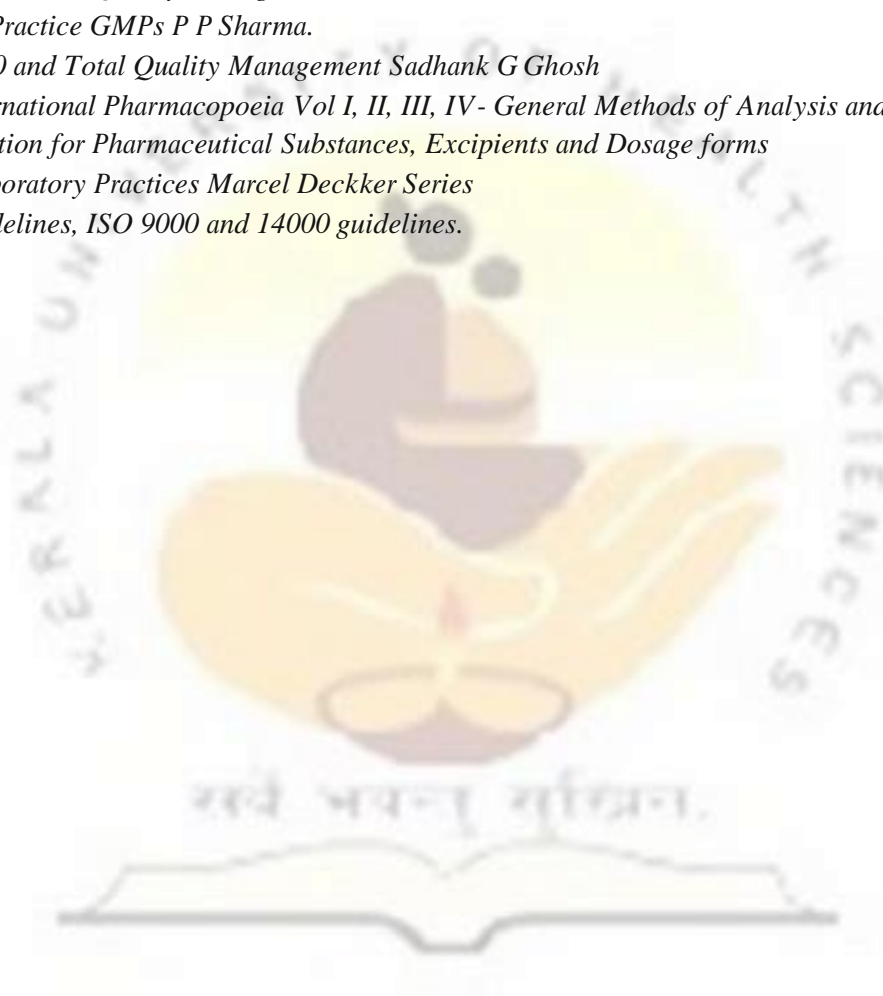
**Calibration and Validation:** Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan.



*Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation.*

**Recommended Books: (Latest Edition)**

1. *Quality Assurance Guide by organization of Pharmaceutical Products of India.*
2. *Good Laboratory Practice Regulations, 2<sup>nd</sup> 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 GMPs 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 Dekker Series*
9. *ICH guidelines, ISO 9000 and 14000 guidelines.*





## **Semester-VII**

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

**45 Hours**

**Scope:** *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.*

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

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

#### **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*

#### **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

#### **UNIT –III**

**10 Hours**

##### **Introduction to chromatography**

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



**Thin layer chromatography & High performance thin layer chromatography:** *Introduction, Principle, Methodology, R<sub>f</sub> 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*

#### **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.*

#### **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 filtration chromatography**– *Introduction, theory, instrumentation and applications*

**Affinity chromatography**– *Introduction, theory, instrumentation and applications*

#### **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*

## **BP702T. INDUSTRIAL PHARMACY(Theory)**

**45 Hours**

**Scope:** *This course is designed to impart fundamental knowledge on pharmaceutical product commercialization from laboratory to market*

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

1. *Know the process of pilot plant and scale up of pharmaceutical dosage forms*
2. *Understand the process of technology transfer from lab scale to commercial batch*
3. *Know different laws and acts that regulate pharmaceutical industry in India and US*
4. *Understand the approval process and regulatory requirements for drug products*

### **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*

#### **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, packing 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** - *APCTT, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT or Technology of Transfer (ToT) related documentation - confidentiality agreements, licensing, MoUs, legal issues*

#### **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, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application(NDA), Data Presentation for FDA Submissions.*

#### **UNIT-IV**

**08 Hours**

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

#### **UNIT-V**

**07 Hours**

**Industrial Safety:** *Plant Location & layout, utility services, Mechanical hazards, Chemical hazards, Electrical hazards, Fire Hazards, Pharmaceutical hazards and their safety. Accident records*



### Recommended Books: (Latest Editions)

1. *Regulatory Affairs* from Wikipedia, the free encyclopedia modified on 7<sup>th</sup> 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>
5. *A concise textbook of Drug Regulatory Affairs: N Uduppa, Krishnamurthy Bhat*
6. *Drug regulatory Affairs: Singh G*
7. *Drug Regulatory Affairs: Dr. N S Vyawahare*
8. *The pharmaceutical regulatory process, 2<sup>nd</sup> Edition: Bylra R Berry, Robert P Martin*

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

45 Hours

**Scope:** 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 counseling for improved patient care in the community set up.*

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

1. Know various drug distribution methods in a hospital.
2. Appreciate the pharmacy stores management and inventory control.
3. Monitor drug therapy of patient through medication chart review and clinical review.
4. Obtain medication history interview and counsel the patients.
5. Identify drug related problems.
6. Detect and assess adverse drug reactions.
7. Interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states.
8. Know pharmaceutical care services.
9. Do patient counseling in community pharmacy.
10. *Appreciate the concept of rational drug therapy.*

### 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 staff 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 ) 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.*

### **d) 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.*

### **Unit -II**

**8 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) Clinical Pharmacy**

*Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care.*

#### **c) Patient medication history interview**

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

#### **d) Therapeutic drug monitoring**

*Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring*

#### **e) Medication adherence**

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

### **Unit - III**

**8 Hours**

a) *Adverse drug reaction - Classification, reporting and management.*

b) *Drug interactions - Pharmacokinetic and Pharmacodynamic interactions with examples.*

c) *Drug information services*

*Drug and Poison information center, Sources of drug information, computerized services, and storage and retrieval of information.*

d) *Patient counseling*

*Definition of patient counseling; steps involved in patient counseling.*

e) *Communication skill , communication skill with prescribers and patients*

### **Unit - IV**

**12 Hours**

a) *Rational use of drugs- rational use of injections, antibiotics and over the counter drugs, sale of over the counter drugs.*

b) *Pharmacotherapeutics : Drug therapy and management aspect of following disorders*

*Diabetes, Hypertension, congestive cardiac failure, myocardial infarction, Asthma, Epilepsy, Peptic ulcer, rheumatoid arthritis and tuberculosis.*

c) *Interpretation of Clinical Laboratory Tests.*

*Hematology, liver function test, renal function test, pulmonary function test.*

### **Unit - V**

**07 Hours**

a) *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.*



*b) Drug store management and inventory control*

*Organization 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.*

**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*, 4th ed. American Society of Health System Pharmacists Inc; 2009.
6. Parmar N.S. *Health Education and Community Pharmacy*, 18th ed. India: CBS Publishers & Distributors; 2008. (can be deleted –health education not included in the syllabus)
7. *Clinical pharmacy and therapeutics* by Roger walker-clivie Edwards (Churchill livingstone) –to be included for therapeutics)

**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 704T: NOVEL DRUG DELIVERY SYSTEMS (Theory)**

**45 Hours**

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

**Objectives:** *Upon completion of the course student shall be able*

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

**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.*

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

**Unit-II 10 Hours**

**Microencapsulation:** *Definition, advantages and disadvantages, microspheres/microcapsules, micro particles, 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*

**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*

**Unit-IV**

**08 Hours**

**Nanotechnology and its Concepts:** *Concepts and approaches for targeted drug delivery systems, 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*

**Recommended Books: (Latest Editions)**

1. Y W. Chien, *Novel Drug Delivery Systems*, 2<sup>nd</sup> 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- RESEARCH METHODOLOGY AND BIOSTATISTICS**

**45 Hours**

**Scope:** *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.*

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

- 1. How to select a research topic in his/her areas of interest.*
- 2. The fundamentals of collecting, analyzing and interpreting the relevant data.*
- 3. Different computational methods and software's facilitating research*

#### **Course content:**

##### **Unit-I**

**10 Hours**

**An Introduction to Research:** *Definition and characteristics of Research, Types of Research, Criteria of good research, Research Process, Review of literature and Research gap, Formulating and defining the research problem. Research methods v/s methodology. Format for Research Protocol. Research ethics and importance of Institutional Review Boards. Significance of research in Pharmaceutical Sciences*

##### **Unit-II**

**6 Hours**

**Different types of data:** *Different methods for data collection. Experimental and observational studies. Questionnaires and rating scales. Primary and secondary data. Different types of data distribution. Coding and tabulation of data. Graphical representation of data.*

##### **Unit-III**

**8 Hours**

**Introduction to Epidemiological methods:** *Types of epidemiology studies. Standard measures in epidemiological studies. Measures of disease frequency, Measures of association. Study designs in epidemiology studies. Intervention studies, Controlled clinical trials. Errors in Epidemiological studies. Validity and Reliability. Bias and confounding.*

##### **Unit-IV**

**8 Hours**

**Biostatistics:** *Definition and application. Various terms in statistics, Descriptive statistics: Measures of central tendency. Measures of dispersion. Inferential statistics: Different areas of inferential statistics. Sampling Fundamentals: Need for sampling. Probability and nonprobability samplings. Sample size, criteria for inclusion and exclusion, dropouts.*

##### **Unit-V**

**13 Hours**

**Research question and Hypothesis:** *Characteristics of good Hypothesis, Testing of Hypothesis. Procedure for hypothesis testing, Tests for significance. P value, Type I and Type II errors, Different Parametric and Nonparametric tests and their applications. Interpretation of results. Computer software's in Bio statistical Analysis*





**Thesis writing:** *Components of Thesis. Paraphrasing and Plagiarism. References and Bibliography. Research publication, Impact factor, and Publication ethics.*

**Recommended Books:**

1. *Research Methodology; Methods and Techniques.* C.R.Kothari. New Age International (P)Limited
2. *Fundamentals of Statistics.* S.C. Gupta. Himalaya Publishing House
3. Mahajan's Methods in Biostatistics for Medical Students and Research workers. Jaypee Publishers

**BP 802T SOCIAL AND PREVENTIVE PHARMACY**

**45 Hours**

**Scope:** *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.*

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

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

**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*

**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*

**Unit III:**

**10 Hours**

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

**Unit IV:**

**08 Hours**

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



**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*

**Recommended Books (Latest edition):**

1. *Short Textbook of Preventive and Social Medicine*, Prabhakara GN, 2<sup>nd</sup> Edition, 2010, ISBN: 9789380704104, JAYPEE Publications
2. *Textbook of Preventive and Social Medicine (Mahajan and Gupta)*, Edited by Roy Rabindra Nath, Saha Indranil, 4<sup>th</sup> Edition, 2013, ISBN: 9789350901878, JAYPEE Publications
3. *Review of Preventive and Social Medicine (Including Biostatistics)*, Jain Vivek, 6<sup>th</sup> Edition, 2014, ISBN: 9789351522331, JAYPEE Publications
4. *Essentials of Community Medicine—A Practical Approach*, Hiremath Lalita D, Hiremath Dhananjaya A, 2<sup>nd</sup> Edition, 2012, ISBN: 9789350250440, JAYPEE Publications
5. *Park Textbook of Preventive and Social Medicine*, K Park, 21<sup>st</sup> Edition, 2011, ISBN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS.
6. *Community Pharmacy Practice*, Ramesh Adepu, BSP publishers, Hyderabad

**Recommended Journals:**

1. *Research in Social and Administrative Pharmacy*, Elsevier, Ireland

**BP803ET. PHARMACEUTICAL MARKETING (Theory)****45 Hours**

**Scope:** The pharmaceutical industry not only needs highly qualified researchers, chemist, 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. Sales & Marketing which grooms the people for taking a challenging role in Sales and Product management. The career in product management starts from having hands on experience in sales and marketing only.

**Objectives:** The course aim is to provide an understanding of marketing concepts and techniques and the application of the same in the pharmaceutical industry.

**Course content:****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.

**Unit II****10 Hours**

**Product decision:** Meaning, Classification, product line and product mix decisions, product life cycle,



product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.

### Unit III

07 Hours

**Promotion:** Meaning and 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.

### 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.

### Unit V

08 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.

### 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, Indian Context, Macmillan 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)

45 Hours

**Scope:** This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, drug products in regulated countries like US, EU, Japan, Australia and Canada. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products in regulated countries.

**Objectives:** Upon completion of the subject student shall be able to;

1. Know about the process of drug discovery and development
2. Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
3. Know the regulatory approval process and their registration in Indian and international markets



## 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.*

### Unit II

10Hours

**Regulatory Approval Process:** *Approval processes and time lines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA) in US. Changes to an approved NDA / ANDA.*

**Regulatory authorities and agencies:** *Overview of regulatory authorities of United States, European Union, Australia, Japan, Canada (Organization structure and types of applications only)*

### Unit III

10 Hours

#### **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.*

### Unit IV

08 Hours

#### **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*

### Unit V

07 Hours

#### **Regulatory Concepts**

*Basic terminologies, guidance, guidelines, regulations, laws and acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book*

#### **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, 5<sup>th</sup> 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)**

**45 hours**

**Scope:** 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.

#### **Objectives:**

1. Why drug safety monitoring is important?
2. History and development of pharmacovigilance.
3. National and international scenario of pharmacovigilance.
4. Dictionaries, coding and terminologies used in pharmacovigilance.
5. Detection of new adverse drug reactions and their assessment.
6. International standards for classification of diseases and drugs.
7. Adverse drug reaction reporting systems and communication in pharmacovigilance.
8. **Methods to generate safety data during pre clinical, clinical and post approval phases of drugs' life cycle.**
9. Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation.
10. Pharmacovigilance Program of India (PvPI).
11. ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning.
12. CIOMS requirements for ADR reporting.
13. Writing case narratives of adverse events and their quality.

#### **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.



## 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*

## 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*

## Unit IV

8 Hours

### Statistical methods for evaluating medication safety data

**Safety data generation** - *Pre clinical phase, Clinical phase, Post approval phase.*

### 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.*

## Unit V

7 hours

### Pharmacogenomics of adverse drug reactions

**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.*



**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.whoumc.org/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)****45 Hours**

**Scope:** 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.

**Objectives:** Upon completion of the subject student shall be able to;

1. know WHO guidelines for quality control of herbal drugs
2. know Quality assurance in herbal drug industry
3. know the regulatory approval process and their registration in Indian and international markets
4. appreciate EU and ICH guidelines for quality control of herbal drugs



**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.

**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.

**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

**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.

**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

**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)**

**45 Hours**

**Scope:** This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.

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

1. Design and discovery of lead molecules
2. The role of drug design in drug discovery process
3. The concept of QSAR and docking
4. Various strategies to develop new drug like molecules.
5. The design of new drug molecules using molecular modeling software

#### **Course Content:**

##### **UNIT-I**

**08 Hours**

##### **Introduction to Drug Discovery and Development**

- A) History of drug discovery and development
- B) Rational Drug Discovery- Different stages involved in rational drug discovery process, methods involved in lead discovery and lead optimization. Role of computer applications in lead discovery and lead optimization. Introduction to ligand and structure based drug design.

##### **UNIT-II**

**10 Hours**

##### **Quantitative Structure Activity Relationship (QSAR)**

Qualitative versus Quantitative SAR, Types of physicochemical parameters, Lipophilicity effects: Hansch equation, Electronic effects: Hammett equation, Steric effects: Taft equation. QSAR Methods: Hansch analysis and Free Wilson analysis. 3D-QSAR approaches like COMFA and COMSIA.

##### **UNIT-III**

**5 Hours**

##### **Pharmacophore modeling**

Concept of pharmacophore, pharmacophore mapping and pharmacophore based screening. Analog based drug design: Bioisosterism-classification and bioisosteric replacement.



## UNIT-IV

17Hours

### **Molecular Modeling:** *Introduction to molecular modeling*

- A)** *Molecular mechanics- Introduction, force field, potential free energy surface, energy minimization methods, global and local energy minimum conformations. Molecular docking-Rigid, semi-flexible and flexible docking, Docking components: Binding site identification, search algorithms, scoring functions and binding free energy. Case study on the design of HIV protease inhibitors using docking. Introduction to Molecular dynamic simulations.*
- B)** *Quantum mechanics-Introduction, Methods-ab initio and semi empirical methods, Applications of quantum mechanics in drug design.*
- c)** *Introduction to de novo drug design and homology modeling of proteins.*

## UNIT – V

05 Hours

### **Informatics methods in drug design**

*Introduction to bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.*

### **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. Cohen C., “Molecular Modelling in Drug Design” Academic Press, New York.
4. Wolf ME., ed “The Basis of Medicinal Chemistry, Burger’s Medicinal Chemistry” John Wiley & Sons, New York.
5. Goodman JM., “Chemical Applications of Molecular modeling”, Royal Society of Chemistry, Cambridge, UK.
6. Smith HJ., Williams H, eds, “Introduction to the principles of Drug Design” CRC Press, Boston.
7. Patrick Graham, L., *An Introduction to Medicinal Chemistry*, Oxford University Press.
8. Silverman RB., “The organic Chemistry of Drug Design and Drug Action” Academic Press, New York.
9. Foye WO., “Principles of Medicinal chemistry” Williams&Wilkins, Philadelphia, PA.
10. Koro Ikovas A, Burckhalter JH. “Essentials of Medicinal Chemistry” Wiley, New York.

## **BP808ET: CELL AND MOLECULAR BIOLOGY (Elective subject)**

45 Hours

### **Scope:**

*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. The course content will equip the students with adequate knowledge of the molecular process occurring within the cell and possibly pharmacological interventions into those processes*

### **Objectives:** *Upon completion of the subject student shall be able to;*

1. *Summarize cell and molecular biology history.*
2. *Summarize cellular functioning and composition.*
3. *Describe the chemical foundations of cell biology.*
4. *Summarize the DNA properties of cell biology.*
5. *Describe protein structure and function.*
6. *Describe cellular membrane structure and function.*



7. *Describe basic molecular genetic mechanisms.*
8. *Summarize the Cell Cycle*

**Course content:**

**Unit I**

**10 Hours**

- a) *Cell and Molecular Biology: Definitions theory and basics and Applications.*
- b) *Cell and Molecular Biology: History and Summation.*
- c) *Theory of the Cell. Properties of cells and cell membrane.*
- d) *Prokaryotic versus Eukaryotic*
- e) *Cellular Reproduction*
- f) *Chemical Foundations – An Introduction and Reactions (Types)*

**Unit II**

**10 Hours**

- a) *DNA and the Flow of Molecular Structure*
- b) *DNA Functioning*
- c) *DNA and RNA*
- d) *Types of RNA*
- e) *Transcription and Translation*

**Unit III**

**08 Hours**

- a) *Proteins*
- b) *Protein Structure*
- c) *Regularities in Protein Pathways*
- d) *Cellular Processes*
- e) *Positive Control and significance of Protein Synthesis*

**Unit IV**

**10 Hours**

- a) *Science of Genetics*
- b) *Transgenics and Genomic Analysis*
- c) *Cell Cycle analysis:*
- d) *Mitosis and Meiosis*

**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*

**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, 4<sup>th</sup> edition, CBS Publishers & Distributors, Delhi.*
3. *Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.*
4. *Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.*
5. *Rose: Industrial Microbiology.*



6. *Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan*
7. *Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.*
8. *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.*
14. *Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.*
15. *Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.*
16. *Rose: Industrial Microbiology.*
17. *Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan*
18. *Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.*
19. *Peppler: Microbial Technology.*
20. *Edward: Fundamentals of Microbiology.*
21. *N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi*
22. *Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company*
23. *B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.*
24. *RA Goldshy et. al., : Kuby Immunology.*

#### **BP809ET. COSMETIC SCIENCE (Theory)**

**45 Hours**

**Scope:** *Cosmetic Science is an exciting new applied science that deals with knowledge and understanding of the various disciplines within Cosmetic Science, Cosmetic Formulation Science and the organization and function of the Cosmetic, Toiletry and Perfumery industries. It not only provide knowledge on cosmetics, and related sciences, cosmeceuticals and personal care and hygiene products but also afford multidisciplinary scientific knowledge to gain expertise in the field and to respond the industry challenges effectively.*

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

1. *Know the cosmetic principles to address the needs of cosmetic industry.*
2. *Understand formulation science and analytical techniques required to scientifically design and develop cosmetic products.*
3. *Explain the scientific and technical aspects, high standards of practice and professional ethics within the cosmetic and toiletries industry.*

#### **UNIT I**

**10 Hours**

*Definition of cosmetics as per Indian regulations Classification of cosmetic and cosmeceutical products*

**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.*





## UNIT II

10 Hours

**Principles of formulation and building blocks of skin care products:** Face wash, Moisturizing cream, Cold Cream, Vanishing cream their relative sensory, advantages and disadvantages. Application of these products in formulation of cosmeceuticals.

**Principles of formulation and building blocks of Hair care products:** Conditioning shampoo, Hair conditioners, anti-dandruff shampoo. Hair oils. Hair dyes

**Principles of formulation and building blocks of oral care products:** Tooth paste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.

## 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

**Analysis of cosmetics:** BIS specification and analytical methods for shampoo, skin cream and toothpaste.

## UNIT IV

07 Hours

**Principles of Cosmetic Evaluation:** Principles of sebumeter, corneometer. Measurement of TEWL, Skin Color, Hair tensile strength

## UNIT V

08 Hours

Oily and dry skin, causes leading to dry skin, skin moisturisation.

**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

## References

- 1) Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
- 2) Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4<sup>th</sup> Edition, Vandana Publications Pvt. Ltd., Delhi.
- 3)

## BP 810 ET.EXPERIMENTAL PHARMACOLOGY

### (PHARMACOLOGICAL SCREENING METHODS)

45 Hours

**Scope:** This subject is designed to impart the basic knowledge of preclinical studies in experimental animals including design, conduct and interpretations of results.

### Objectives

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

1. Appreciate the applications of various commonly used laboratory animals.
2. Appreciate and demonstrate the various screening methods used in preclinical research
3. Appreciate and demonstrate the importance of biostatistics and research methodology
4. Design and execute a research hypothesis independently



**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.*

**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*

**Unit –III****10 Hours**

**Preclinical screening models:** *for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics*

**Unit –IV****12 Hours**

**Preclinical screening models:** *for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslipidemic, anti aggregatory, coagulants, and anticoagulants*  
*Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.*

**Unit –V****05 Hours****Research methodology and Bio-statistics**

*Selection of research topic, review of literature, research hypothesis and study Design. Pre-clinical data analysis and interpretation using Students 't' test and One-way ANOVA. Graphical representation of data*

**Recommended Books (latest edition):**

1. *Fundamentals of experimental Pharmacology-by M.N.Ghosh*
2. *Hand book of Experimental Pharmacology-S.K.Kulakarni*
3. *CPCSEA guidelines for laboratory animal facility.*
4. *Drug discovery and Evaluation by Vogel H.G.*
5. *Drug Screening Methods by Suresh Kumar Gupta and S. K. Gupta*
6. *Introduction to biostatistics and research methods by PSS Sundar Rao and J Richard*

**BP 811 ET. ADVANCED INSTRUMENTATION TECHNIQUES****45 Hours**

**Scope:** *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.*



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

1. understand the advanced instruments used and its applications in drug analysis
2. understand the chromatographic separation and analysis of drugs.
3. understand the calibration of various analytical instruments know analysis of drugs using various analytical instruments.

**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.

**UNIT-II**

**10 Hours**

**Thermal Methods of Analysis:** Principles, instrumentation and applications of Thermo gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetric (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.

**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*

**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

**UNIT-V**

**07Hours**

**Hyphenated techniques-LC-MS/MS, GC-MS/MS, HPTLC-MS**

**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



## 2.7. Total number of hours

*As given under course of study 2.4.3*

## 2.8 Branches if any with definition

*Not applicable*

## 2.9 Teaching learning methods

*As given under the syllabus*

## 2.10 Content of each subject in each year

*As given under the syllabus*

## 2.11 Number of hours per subject

*As given under the syllabus*

## 2.12 Practical training

*As given under the course content*

## 2.13 Records

*The students are expected to perform the number of experiments listed in the respective syllabus. Students are required to maintain practical records for each of the practical subjects and should be certified by the faculty in-charge before registering for end semester examination. It should be produced at the time of practical examination and to be certified by both internal and external examiners.*

## 2.14 Dissertation

*Not Applicable*

## 2.15 Special Training if any

*Not Applicable*

## 2.16 Project work to be done if any

*As given under the syllabus*

## 2.17 Any other requirements (CME, Paper publishing etc..)

*Not Applicable*

## 2.18 Prescribed/ recommended text books for each subject

*As given under the syllabus*

## 2.19 Reference books

*As given under the syllabus*

## 2.20 Journals

*As given under the course content*

## 2.21 Log book

*Not Applicable*

## 2.22 Program Committee

1. The B. Pharm program shall have a **Program Committee** constituted by the **Head of the institution** in consultation with all the Heads of the Departments.

2. The composition of the Program Committee shall be as follows:

(i) A **senior teacher** shall be the **Chairperson**

(ii) **One teacher** from each department handling B. Pharm courses;

(iii) **Four student** representatives of the program (one from each academic year), nominated by the Head of the institution.





### 3. Duties of the Program Committee:

- i. Periodically reviewing the progress of the classes.
- ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
- (iii) Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
- (iv) Communicating its recommendation to the Head of the institution on academic matters.
- (v) **The Program Committee shall** meet at least thrice in a semester preferably at the end of each sessional examination (Internal assessment) and before the end semester exam.

## 3. EXAMINATIONS

### 3.1 Eligibility to appear for exams

- A candidate is eligible for registering for the examinations only if he/she secures a minimum of 50% marks in internal assessment in theory and practical separately.
- Partial appearance for the examinations : A candidate is allowed partial appearance for the University examinations, including practical examinations, provided he/ she has 80% attendance in all subjects, in theory and practical separately.

**3.2 Eligibility for appearance for supplementary examinations:** A candidate can register for supplementary examinations if he/she has 80 % attendance in theory and practical separately for that subject/s and has minimum 50% Internal Assessment marks in theory and practical separately in that subject/s.

#### 3.2.1 Schedule of regular/ Supplementary examinations

*As given under the course content*

### 3.3 Scheme of examination showing maximum marks and minimum marks

*As given under the course content*

### 3.4 Papers in each year

*As given under the course content*

### 3.5 Details of theory exams

*As given under the course content*

### 3.6 Model question paper for each subject

*As given under Annexure 5.1.*

#### 3.6.1 Question paper pattern

*As given under the course content*



### 3.7 Internal assessment component

*As given under the course content*

### 3.8 Details of practical/ clinical practical exams

*As given under the course content*

### 3.9 Number of examiners (Internal & External) and the qualifications for theory and practical evaluation

*One internal and one external examiner for practical and viva voce examinations. Post Graduation in the relevant subject with minimum three years teaching experience after acquiring M.Pharm qualification in a PCI recognized institution*

### 3.10 Details of Viva

*As given under the course content.*

## 4. INTERNSHIP

*Not Applicable*

## 5. ANNEXURES

### 5.1 Model question paper for each subject with Question paper pattern

### 5.2 Check lists for monitoring: Log book, Seminar Assessment etc.

*To be formulated by the curriculum committee of the concerned institution*

