



छत्रपति शाहू जी महाराज विश्वविद्यालय, कानपुर

CHHATRAPATI SHAHU JI MAHARAJ UNIVERSITY, KANPUR

(पूर्ववर्ती कानपुर विश्वविद्यालय कानपुर)

Formerly Kanpur University, Kanpur – 208024

A Documentary Support

*For*

*Metric No. – 1.1.1*

**Programme Outcomes & Course Outcomes**

*Under the*

**Criteria - I**

**(Curriculum Design and Development)**

**Key Indicator - 1.1**

*In*

**Metric No. – 1.1.1**

**Bachelor of Pharmacy**

  
Co-ordinator  
Internal Quality Assurance Cell  
CSJM University, Kanpur

  
(Registrar)  
C.S.J.M. University  
Kanpur  
REGISTRAR  
C.S.J.M. UNIVERSITY  
KANPUR

## B.PHARM. SYLLABUS

### Matrix 1.1.1.

#### Relevance to Local, National regional and global development

#### SEMESTER 1<sup>st</sup>

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP101T	Human Anatomy and Physiology I Theory	3	1	4
BP102T	Pharmaceutical Analysis I– Theory	3	1	4
BP103T	PharmaceuticsI–Theory	3	1	4
BP104T	Pharmaceutical Inorganic Chemistry Theory	3	1	4
BP105T	Communication skills Theory*	2	-	2
BP106RBT	Remedial Biology*	2	-	2
BP106RMT	Remedial Mathematics Theory*	2	-	2
BP107P	Human Anatomy and Physiology Practical	4	-	2
BP108P	Pharmaceutical Analysis I Practical	4	-	2
BP109P	PharmaceuticsI Practical	4	-	2
BP110P	Pharmaceutical Inorganic Chemistry Practical	4	-	2
BP111P	Communication skills Practical*	2	-	1
BP112P	Remedial Biology Practical*	2	-	1
		32/34/36	4	27/29/30

#### **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

## **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 signalling pathway activation by extracellular signal molecule, Forms of intracellular signalling:

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 Integumentary system**

**10 Hours**

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

**BP 107P. HUMAN ANATOMY AND PHYSIOLOGY (Practical) 4 Hours/week**

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

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

**Recommended Books (Latest Editions)**

1. Sembulingam K. & Sembulingam P. Essentials of Medical Physiology. **8<sup>th</sup> ed.** New Delhi: Jaypee brothers medical publishers; **2019.**
2. Waugh A. & Grant A. Ross and Wilson Anatomy & Physiology in Health and Illness. **12<sup>th</sup> ed.** New York: Churchill Livingstone; **2014.**
3. Best C.H. & Taylor N.B. Physiological basis of Medical Practice. **5<sup>th</sup> ed.** Baltimore USA: Williams & Wilkins Company; **1950.**
4. Guyton C. & Hall J. E. Guyton and Hall Text book of Medical Physiology. **13<sup>th</sup> ed.** Miamisburg, OH, U.S.A. **2020.**

5. Tortora G. J. & Grabowski S. R. Principles of Anatomy and Physiology. **10<sup>th</sup> ed.** Palmetto, GA, U.S.A.: John Willey and Sons Inc.; **2003**.
6. Singh I. Textbook of Human Histology with color atlas and practical guide. **9<sup>th</sup> ed.** New Delhi: , Jaypee brother's medical publishers; **2019**.
7. Ghai C.L. Textbook of Practical Physiology. **8<sup>th</sup> ed.** New Delhi: Jaypee brother's medical publishers; **2013**.
8. Srinageswari k. & Sharma J. Practical workbook of Human Physiology. **2<sup>nd</sup> ed.** New Delhi: Jaypee brother's medical publishers; **2018**.
9. Chatterrje C.C. Human Physiology Vol. I & II, **12<sup>th</sup> ed.** Kolkata: Academic Publishers; **2018**.

#### **Reference Books (Latest Editions)**

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

### **BP 102T. 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

- understand the principles of volumetric and electrochemical analysis
- carryout various volumetric and electrochemical titrations
- 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.

**Diazotisation titration:** 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 Preparation and standardization of

(1) Sodium hydroxide (2) Sulphuric acid (3) Sodium thiosulfate (4) Potassium permanganate (5) Ceric ammonium sulphate

### II 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

### **III 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.

## **BP 103T. 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:

- Know the history of profession of pharmacy
- Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations
- Understand the professional way of handling the prescription
- Preparation of various conventional dosage forms

### **Course Content: UNIT– I**

**10 Hours**

**Historical back ground 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, bodyweight 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**

**08 Hours**

**Monophasic liquids:** Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions.

**Biphasic liquids: Suspensions:** Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome.

**Emulsions:** Definition, classification, emulsifying agent, test for the identification of type of Emulsion, Methods of preparation & stability problems and methods to overcome.

## **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.

## **BP 109 P. PHARMACEUTICS I (Practical)**

**4 hours a week**

**1 . Syrups** a) Syrup IP'66



b) Compound syrup of Ferrous Phosphate BPC' 68

**2. Elixirs** a) Piperazine citrate elixir b) Paracetamol pediatric elixir

**3. Linctus** a) Terpin Hydrate Linctus IP'66

**4. Solutions** b) Iodine Throat Paint (Mandle's Paint)

a) Strong solution of ammonium acetate

b) Cresol with soap solution

c) Lugol's solution

**5. Suspensions**

a) Calamine lotion b) Magnesium Hydroxide mixture c) Aluminium Hydroxide gel

**6. Emulsions** a) Turpentine Liniment b) Liquid paraffin emulsion

**7. Powders and Granules**

a) ORS powder (WHO)

b) Effervescent granules c) Dusting powder

d) Divided powders

**8. Suppositories**

a) Glycero gelatin suppository

b) Cocoa butter suppository

c) Zinc Oxide suppository

**8. Semisolids**

a) Sulphur ointment

b) Non staining-iodine ointment with methyl salicylate

c) Carbopol gel

**9. Gargles and Mouthwashes**

a) Iodine gargle

b) Chlorhexidine mouthwash

**Recommended Books : (Latest Editions)**

1. Ansel H.C et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and Walkins, New Delhi.

2. Aulton M.E Pharmaceuticals, The Science & Dosage form Design, Churchill Livingstone, Edinburgh.

3. Alfonso R. Gennaro Remington., The Science and Practice of Pharmacy, Lippincott Williams, New Delhi.

4. British Pharmacopoeia Commission , British Pharmacopoeia 2016. London: TSO; 2016.

5. Carter S.J., Cooper and Gunn's –Dispensing for Pharmaceutical Students, CBS Publishers, New Delhi.
6. Carter S.J. Cooper and Gunn's. Tutorial Pharmacy, CBS Publications New Delhi.
7. Dilip M Parikh :Handbook of Pharmaceutical Granulation Technology, Marcel Dekker, INC , New York.
8. E.A Rawlins, Bentley's Text Book of Pharmaceutics ,English Language Book Society, Elsevier Health Sciences, USA.
9. Francoise Nieloud and Gilberte Marti-Mestress: Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC, New York.
10. Indian Pharmacopoeia, Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Government of India.
11. Lachmann. Theory and Practice of Industrial Pharmacy, Lea & Febiger Publisher, The university of Michigan.

#### **BP104T. PHARMACEUTICAL INORGANIC CHEMISTRY (Theory) 45 Hours**

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

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

- to know the sources of impurities and methods to determine the impurities in inorganic drugs and pharmaceuticals
- 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, 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\*, Sodium 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 radioisotopes - Sodium iodide I131, Storage conditions, precautions & pharmaceutical application of radioactive substances.

## **BP 110 P. PHARMACEUTICAL INORGANIC CHEMISTRY (Practical)**

**4 Hours /Week**

**I Limit tests for following ions** Limit test for Chlorides and Sulphates Modified limit test for Chlorides and Sulphates Limit test for Iron Limit test for Heavy metals Limit test for Lead Limit test for Arsenic

**II Identification test** Magnesium hydroxide Ferrous sulphate Sodium bicarbonate Calcium gluconate Copper sulphate

**III Test for purity** Swelling power of Bentonite

Neutralizing capacity of aluminum hydroxide gel Determination of potassium iodate and iodine in potassium Iodide

#### **IV Preparation of inorganic pharmaceuticals** Boric acid Potash alum Ferrous sulphate

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

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London, 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

#### **BP 105T. COMMUNICATION SKILLS (Theory)**

**30 Hours**

**Scope:** This course will prepare the young pharmacy student to interact effectively with doctors, nurses, dentists, physiotherapists and other healthworkers. 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 words worth 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. Rutherford, Edition, Pearson Education, 2011

2. Communication skills, Sanjay Kumar, Pushpalata, 1<sup>st</sup> Edition, Oxford Press,
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, Konarnira, 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, McGraw 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

#### **BP106 RBT. 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

- know the classification and salient features of five kingdoms of life
- understand the basic components of anatomy & physiology of plant
- 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 aneuron

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**

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

### **Reference Books**

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

## **BP 112 RBP. REMEDIAL BIOLOGY (Practical)**

**30 Hours**

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

### **Reference Books**

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





**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 ( $\epsilon - \delta$  definition)

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

### **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, Minor and co-Factors, Adjoint or adjugate of a square matrix, Singular and non-singular matrices, Inverse of a matrix, Solution of system of linear 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:** Introduction, 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 2<sup>nd</sup>

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP201T	Human Anatomy and Physiology II – Theory	3	1	4
BP202T	Pharmaceutical Organic Chemistry I – Theory	3	1	4
BP203T	Biochemistry – Theory	3	1	4
BP204T	Pathophysiology – Theory	3	1	4
BP205T	Computer Applications in Pharmacy – Theory *	3	-	3
BP206T	Environmental sciences – Theory *	3	-	3
BP207P	Human Anatomy and Physiology II – Practical	4	-	2
BP208P	Pharmaceutical Organic Chemistry I– Practical	4	-	2
BP209P	Biochemistry – Practical	4	-	2
BP210P	Computer Applications in Pharmacy – Practical*	2	-	1
		32	4	29

### 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, haemoglobin 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:

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

## **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, cerebellum), spinal cord (gross structure, functions of afferent and efferent nerve tracts, reflex activity)

## **Unit II**

**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 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**

**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**

### **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.

1. Sembulingam K. & Sembulingam P. Essentials of Medical Physiology. **8<sup>th</sup> ed.** New Delhi: Jaypee brothers medical publishers; **2019**.
2. Waugh A. & Grant A. Ross and Wilson Anatomy & Physiology in Health and Illness. **12<sup>th</sup> ed.** New York: Churchill Livingstone; **2014**.
3. Best C.H. & Taylor N.B. Physiological basis of Medical Practice. **5<sup>th</sup> ed.** Baltimore USA: Williams & Wilkins Company; **1950**.
4. Guyton C. & Hall J. E. Guyton and Hall Text book of Medical Physiology. **13<sup>th</sup> ed.** Miamisburg, OH, U.S.A. **2020**.
5. Tortora G. J. & Grabowski S. R. Principles of Anatomy and Physiology. **10<sup>th</sup> ed.** Palmetto, GA, U.S.A.: John Willey and Sons Inc.; **2003**.
6. Singh I. Textbook of Human Histology with color atlas and practical guide. **9<sup>th</sup> ed.** New Delhi: , Jaypee brother's medical publishers; **2019**.

7. Ghai C.L. Textbook of Practical Physiology. **8<sup>th</sup> ed.** New Delhi: Jaypee brother's medical publishers; **2013**.
8. Srinageswari k. & Sharma J. Practical workbook of Human Physiology. **2<sup>nd</sup> ed.** New Delhi: Jaypee brother's medical publishers; **2018**.
9. Chatterrje C.C. Human Physiology Vol. I & II, **12<sup>th</sup> ed.** Kolkata: Academic Publishers; **2018**.

### **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 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**

**Alkanes\*, Alkenes\* and Conjugated dienes\*** SP<sup>3</sup> hybridization in alkanes, Halogenation of alkanes, uses of paraffins. Stabilities of alkenes, SP<sup>2</sup> hybridization in alkenes E1 and E2 reactions– kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and evidences. E and E1 versus E2 reactions, Factors affecting E 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**

**Alkyl halides**\*-SN1 and SN2 reactions- kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations. SN1 versus SN2 reactions, Factors affecting SN1 and SN2 reactions Structure and uses of ethylchloride, Chloroform, trichloroethylene, tetrachloroethylene, dichloromethane, tetrachloromethane and iodoform.

**Alcohols**\*-Qualitative tests, Structure and uses of Ethyl alcohol, Methyl alcohol, chlorobutanol, Ceto steryl alcohol, Benzyl alcohol, Glycerol, Propyleneglycol **UNIT-IV**

### **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**

#### **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, Ethylene diamine, Amphetamine

### **BP 208P. PHARMACEUTICAL ORGANIC CHEMISTRY-I (Practical) 4 Hours /week**

1. Systematic qualitative analysis of unknown organic compounds like
  1. Preliminary test: Color, odour, aliphatic/aromatic compounds, saturation and unsaturation, etc.
  2. Detection of elements like Nitrogen, Sulphur and Halogen by Lassaigne's test
  3. Solubility test
  4. Functional group test like Phenols, Amides/ Urea, Carbohydrates, Amines, Carboxylic acids, Aldehydes and Ketones, Alcohols, Esters, Aromatic and Halogenated Hydrocarbons, Nitro compounds and Anilides.



5. Melting point /Boiling point of organic compounds
6. Identification of the unknown compound from the literature using Melting point / boiling point.
7. Preparation of the derivatives and confirmation of the unknown Compound by melting point / boilingpoint.
8. Minimum 5 unknown organic compounds to be analysed systematically.
2. Preparation of suitable solid derivatives from organic compounds
3. 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, Lampmanand Kriz.
9. Reaction and reaction mechanism by Ahluwaliah /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 students shall be 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 enome and functions of DNA in the synthesis of RNAs and proteins.

## Course Content:

### BP203 T. BIOCHEMISTRY (Theory)

#### UNIT I

**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 II

**Carbohydrate metabolism** Glycolysis–Pathway, energetics and significance

Citric acid cycle-Pathway, energetic sand 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 phosphorylation

Inhibitors ETC and oxidative phosphorylation/Uncouplers

#### UNIT III

**Lipid metabolism**  $\beta$ -Oxidation of saturated fatty acid (Palmitic acid) Level

Formation and utilization of ketone bodies; ketoacidosis Denovo synthesis of fatty acids ( Palmitic acid) Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, Fatty liver and obesity.

**Amino acid metabolism** General reactions of amino acid metabolism: Transamination, deamination & decarboxylation, urea cycle and its disorders Catabolism of phenyl alanine and tyrosine and their metabolic disorders

(Phenyketonuria, Albinism, alkeptonuria, tyrosinemia) Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline Catabolism of heme; hyper bilirubinemia and jaundice

#### UNIT IV

**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 (semiconservative model) Transcription or RNA synthesis Genetic code, Translation or Protein synthesis and inhibitors

## **UNIT V**

**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

### **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. Nelson, D. L. & Cox, M. M. (2004). *Lehninger Principles of Biochemistry. Third edition.* , W.H. Freeman and Company (New York), ISBN: 13:978-1-4641-0962-1 / ISBN: 10:1-4641-0962-1.
2. Robert K. Murry, Daryl K. Granner and Victor W. Rodwell. (2021). *Harper's Biochemistry.* Lange.
3. Stryer, L., Berg M. J. & Tymoczko J. L. (2006) *Biochemistry. Sixth edition.* W. H. Freeman and Company and Sumanas, Inc.
4. Satyanarayan, U. & Chakrapani, U. (2021). *Biochemistry. Sixth edition.* Books and Allied (P) Ltd.
5. Donald, V. and Judith G.V. (2011). *Biochemistry 4th ed.*, John Wiley & Sons Asia Pvt.Ltd. (New Jersey), ISBN: 978-1180-25024.

6. Nicholas, C.P. and Lewis, S. (1999). *Fundamentals of Enzymology 3rd ed.*, Oxford University Press Inc. (New York), ISBN:0 19 850229 X
7. Devlin, T.M., John. (2011). *Textbook of Biochemistry with Clinical Correlations 7th ed.*, Wiley & Sons, Inc. (New Jersey), ISBN: 978-0-470-28173-4.
8. Voet, D.J., Voet, J.G. and Pratt, C.W. (2008). *Principles of Biochemistry 3rd ed.*, John Wiley & Sons, Inc. (New York), ISBN:13: 978-0470-23396-2

<b>BP 204T.</b>	<b>PATHOPHYSIOLOGY (THEORY)</b>	<b>45 Hours</b>
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**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**

**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, Intracellular 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**

**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 II**

**Haematological Diseases:** Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalassemia, 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**

Inflammatory bowel diseases, jaundice, hepatitis (A,B,C,D,E,F) alcoholic liver disease.

**Disease of bones and joints:** Rheumatoid arthritis, osteoporosis and gout

**Principles of cancer:** classification, etiology and pathogenesis of cancer

**Diseases of bones and joints:** Rheumatoid Arthritis, Osteoporosis, Gout

**Principles of Cancer:** Classification, etiology and pathogenesis of Cancer

## **Unit V**

**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; 10<sup>th</sup> edition; India; Elsevier; 2017.
2. Harsh Mohan; Text book of Pathology; 8<sup>th</sup> edition; India; Jaypee Publications; 2018.
3. Laurence B, Bruce C, Bjorn K.; Goodman Gilman 's The Pharmacological Basis of Therapeutics; 14<sup>th</sup> edition; New York; McGraw-Hill; 2022.
4. Best, Charles Herbert 1899-1978; Taylor, Norman Burke 1885-1972; West, John B(John Burnard); Best and Taylor's Physiological basis of medical practice; 12th ed; united states;
5. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston; Davidson's Principles and Practice of Medicine; 21st edition; London; ELBS/Churchill Livingstone; 2010.
6. Guyton A, John. E Hall; Textbook of Medical Physiology; 14<sup>th</sup> edition; WB Saunders Company; 2020.

7. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; 10<sup>th</sup> edition; London; McGraw-Hill Medical; 2017.

8. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 10<sup>th</sup> edition; Philadelphia; WB Saunders Company; 2017.

9. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 6<sup>th</sup> edition; London; Churchill Livingstone publication; 2018.

#### **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:**

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

##### **Course content: UNIT– I**

**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 lifecycle, 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, MSACCESS, 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)

#### **BP 210P. COMPUTER APPLICATIONS IN PHARMACY (Practical)**

1. Design a questionnaire using a word processing package to gather information about a particular disease.
2. Create a HTML webpage 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 Wiley 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 Dream tech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi-110002

**BP206 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:**

**BP206 T. ENVIRONMENTAL SCIENCES (Theory)**

**30 Hours**

**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 Publishing Pvt. Ltd., Ahmedabad– 380 013, India,
4. Brunner R.C., 1989, Hazardous Waste Incineration, Mc Graw Hill Inc. 480p
5. Clark R.S., Marine Pollution, Clanderson Press Oxford
6. Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p
7. De A.K., Environmental Chemistry, Wiley Eastern Ltd.
8. Down of Earth, Centre for Science and Environment

**SEMESTER 3<sup>rd</sup>**

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP301T	Pharmaceutical Organic Chemistry II– Theory	3	1	4
BP302T	Physical Pharmaceutics I– Theory	3	1	4
BP303T	Pharmaceutical Microbiology– Theory	3	1	4
BP304T	Pharmaceutical Engineering– Theory	3	1	4
BP305P	Pharmaceutical Organic Chemistry II– Practical	4	-	2
BP306P	Physical Pharmaceutics I– Practical	4	-	2
BP307P	Pharmaceutical Microbiology– Practical	4	-	2
BP308P	Pharmaceutical Engineering– Practical	4	-	2
		28		24

**BP 301T. 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 are 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

**Aromatic Acids\***-Acidity, effect of substituents on acidity and important reactions of benzoic acid.

**UNIT III**

**10 Hours**

**Fats and Oils** a. Fatty acids-reactions.

b. Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils.

c. Analytical constants -Acid value, Saponification value, Ester value, Iodine value, Acetyl value, Reichert Meissl (RM) value-significance and principle involved in their determination.

**UNIT IV**

**08 Hours**

**Polynuclear hydrocarbons :**

a. Synthesis, reactions

b. Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene, Diphenylmethane, Triphenyl methane and their derivatives

**UNIT V**

**07 Hours**

**Cyclo alkanes\***Stabilities-Baeyer's strain theory, limitation of Baeyer's strain theory,

Coulson and Moffitt's modification, Sachse Mohr's theory (Theory of strainless rings), reactions of cyclopropane and cyclobutene only.

### **BP 305P. PHARMACEUTICAL ORGANIC CHEMISTRY-II (Practical) 4 Hrs/week**

I Experiments involving laboratory techniques : Recrystallization, Steam distillation

II Determination of following oil values (including standardization of reagents) Acid value, Saponification value, Iodine value

#### **III Preparation of compounds**

- Benzanilide/Phenyl benzoate/Acetanilide from Aniline/ Phenol /Aniline by acylation reaction.
- 2,4,6-Tribromoaniline/Parabromo acetanilide from Aniline/Acetanilide by halogenation (Bromination)reaction.
- 5-Nitro salicylic acid/Meta di nitrobenzene from Salicylic acid/Nitro benzene by nitration reaction.
- Benzoic acid from Benzyl chloride by oxidation reaction.
- Benzoic acid/Salicylic acid from alkyl benzoate/alkyl salicylate by Hydrolysis reaction.
- 1-Phenyl azo-2-naphthol from Aniline by diazotization and coupling reactions.
- Benzil from Benzoin by oxidation reaction.
- Dibenzal acetone from Benzaldehyde by Claisen Schmidt reaction
- Cinnamic acid from Benzaldehyde by Perkin reaction
- *P*-Iodo benzoic acid from *P*-amino benzoic acid

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

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

**BP 302T. PHYSICAL PHARMACEUTICS -I (Theory)****45Hours**

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

**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 forms
2. Know the principles of chemical kinetics & to use them for stability testing and Determination of expiry date of formulations
3. Demonstrate use of physicochemical properties in the formulation Development and evaluation of dosage forms.

**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****10Hours**

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

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

**UNIT-III****08 Hours**

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

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

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

#### **UNIT-V**

**07 Hours**

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

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

**4 Hrs/week**

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

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

- 1) Alfred N. Martin, Patrick J. Sinko, Physical Pharmacy and Pharmaceutical Sciences. Ed. Patrick J. Sinko. Lippincott Williams & Wilkins, 2011.
- 2) Herbert A. Lieberman, Leon Lachman, Joseph B. Schwartz. Pharmaceutical Dosage Forms: Tablets, Vol. 2, 2nd Edition, Marcel Dekker, New York, 1990.
- 3) Mitchell J. Stoklosa, Pharmaceutical calculations., Lea & Febiger edition 6th. 1974.
- 4) Herbert Lieberman, Martin Rieger, Gilbert S. Banker. Pharmaceutical Dosage Forms book. Disperse Systems. Edition 2nd Edition. 2019
- 5) Experimental Pharmaceutics by Eugene, Parott.
- 6) Tutorial Pharmacy by Cooper and Gunn.
- 7) Physical Pharmaceutics by Ramasamy C and Manavalan R.
- 8) Laboratory Manual of Physical Pharmaceutics, C.V.S. Subramanyam, J. Thimmasettee

9) Test book of Physical Pharmacy, by Gaurav Jain & Roop K.Khar

**BP303 T. PHARMACEUTICAL MICROBIOLOGY (Theory)**

**45Hours**

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

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

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

**Course content: Unit I**

**10 Hours**

Introduction, history of microbiology, its branches, scope and its importance. Introduction to Prokaryotes and Eukaryotes Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count). Study of different types of phase contrast microscopy, dark field microscopy and electron microscopy.

**Unit II**

**10 Hours**

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

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

Evaluation of the efficiency of sterilization methods. Equipments employed in large scale sterilization. Sterility indicators.

**Unit III**

**10 Hours**

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

Classification and mode of action of disinfectants Factors influencing disinfection, antiseptics and their evaluation. For Bacteriostatic and bactericidal actions Evaluation of bactericidal &

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

#### **Unit IV**

**08 Hours**

Designing of aseptic area, laminar flow equipments; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification. Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and aminoacids. 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) 4 Hrs/week**

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

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

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 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, Hinsdillet al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooperand 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

### **BP 304 T. 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 carryout various test to prevent environmental pollution.
5. To appreciate and comprehend significance of plant layout 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.

## **UNIT-II**

**10Hours**

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

**Evaporation:** Objectives, applications and factors influencing evaporation, differences between evaporation and other heat process. principles, construction, working, uses, merits and demerits of Steam jacketed kettle, horizontal tube evaporator, climbing film evaporator, forced circulation evaporator, multiple effect evaporator & Economy of multiple effect evaporator.

**Distillation:** Basic Principles and methodology of simple distillation, flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation

## **UNIT-III**

**08 Hours**

**Drying:** Objectives, applications & mechanism of drying process, measurements & applications of Equilibrium Moisture content, rate of drying curve. principles, construction, working, uses, merits and demerits of Tray dryer, drum dryer spray dryer, fluidized bed dryer, vacuum dryer, freeze dryer.

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

## **UNIT-IV**

**08 Hours**

**Filtration:** Objectives, applications, Theories & Factors influencing filtration, filter aids, filter medias. Principle, Construction, Working, Uses, Merits and demerits of plate & frame filter, filter leaf, rotary drum filter, Meta filter & Cartridge filter, membrane filters and Seidtz filter.

**Centrifugation:** Objectives, principle & applications of Centrifugation, principles, construction, working, uses, merits and demerits of Perforated basket centrifuge, Non-perforated basket centrifuge, semi continuous centrifuge & super centrifuge.

## **UNIT-V 07 Hours**

**Materials of pharmaceutical plant construction, Corrosion and its prevention:** Factors affecting during materials selected for Pharmaceutical plant construction, Theories of

corrosion, types of corrosion and their prevention. Ferrous and nonferrous metals, inorganic and organic non metals, basic of material handling systems.

**BP 308P- PHARMACEUTICAL ENGINEERING (Practical)**

**4 Hours/week**

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

**Recommended Books: (Latest Editions)**

1. Walter L Badger & Julius Banchero; Introduction to chemical engineering; McGraw Hill; 1955.
2. Nigel J.K. Simpson; Solid phase extraction, Principles, techniques and applications; Tylor & Francis; CRC Press; 1<sup>st</sup> edition; 2000.
3. McCabe Smith; Unit operation of chemical engineering; McGraw Hill; 2005.

4. C.V.S Subrahmanyam et al.; Pharmaceutical engineering principles and practices; Vallabh Prakashan; Delhi; 2018.
5. David B. Troy, Paul Beringer; Remington practice of pharmacy; Lippincott Williams & Wilkins; 23<sup>rd</sup> edition; 2020.
6. Lachmann; Theory and practice of industrial pharmacy; Lie & Febiger; 4<sup>th</sup> edition; 2020.
8. S.J. Carter; Cooper and Gunn's Tutorial pharmacy; CBS Publisher & Distributors; 12<sup>th</sup> edition; 2008.

#### SEMESTER 4<sup>th</sup>

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP401T	Pharmaceutical Organic Chemistry III– Theory	3	1	4
BP402T	Medicinal Chemistry I – Theory	3	1	4
BP403T	Physical Pharmaceutics II – Theory	3	1	4
BP404T	Pharmacology I – Theory	3	1	4
BP405T	Pharmacognosy and Phytochemistry I– Theory	3	1	4
BP406P	Medicinal Chemistry I – Practical	4	-	2
BP407P	Physical Pharmaceutics II – Practical	4	-	2
BP408P	Pharmacology I – Practical	4	-	2
BP409P	Pharmacognosy and Phytochemistry I – Practical	4	-	2
		31	5	28

#### **BP 401T. 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 stereochemical aspects of organic compounds and stereochemical Reactions
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**

Optical isomerism–Optical activity, enantiomerism, diastereoisomerism, mesocompounds  
Elements of symmetry, chiral and achiral molecules DL system of nomenclature of optical isomers, sequence rules, RS system of Nomenclature of optical isomers Reactions of chiral molecules Racemic modification and resolution of racemic mixture. Asymmetric synthesis: partial and absolute

## **UNIT-II**

**10 Hours**

### **Geometrical isomerism**

Nomenclature of geometrical isomers (Cis Trans, EZ, Syn Antisystems) Methods of determination of configuration of geometrical isomers.

Conformational isomerism in Ethane, n-Butane and Cyclohexane. Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity. Stereospecific and stereoselective reactions

## **UNIT-III**

**10 Hours**

### **Heterocyclic compounds: Nomenclature and classification**

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

Relative aromaticity and reactivity of Pyrrole, Furan and Thiophene

## **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**

**07 Hours**

### **Reactions of synthetic importance**

Metal hydride reduction ( $\text{NaBH}_4$  and  $\text{LiAlH}_4$ ), Clemmensen reduction, Birch reduction, Wolff Kishner reduction. Oppenauer-oxidation and Dakin reaction. Beckmanns rearrangement and Schmidt rearrangement. Claisen-Schmidt condensation

### **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** Drug metabolism principles-Phase I and Phase II.

Factors affecting drug metabolism including stereochemical aspects.

#### **UNIT-II**

**10 Hours**

##### **Drugs acting on Autonomic Nervous System Adrenergic Neurotransmitters:**

Biosynthesis and catabolism of catecholamine. Adrenergic receptors (Alpha & Beta) and their distribution.

**Sympathomimetic agents: SAR of Sympathomimetic agents** Direct acting: Nor-epinephrine, Epinephrine, Phenylephrine\*, Dopamine, Methyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline, Salbutamol\*, Bitolterol, Naphazoline, Oxymetazoline and Xylometazoline.

**Indirect acting agents:** Hydroxy amphetamine, Pseudoephedrine, Propylhexedrine.

**Agents with mixed mechanism:** Ephedrine, Metaraminol.

**Adrenergic Antagonists:**

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

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

### **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, Tacrinehydrochloride, Ambenoniumchloride, Isofluorophate, Echothiophateiodide, Parathione, Malathion.

**Cholinesterase activator:** Pralidoxime chloride.

**Cholinergic Blocking agents: SAR of cholinolytic agents**

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

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

### **UNIT-IV**

**08 Hours**

**Drugs acting on Central Nervous System**

**A. Sedatives and Hypnotics: Benzodiazepines:** SAR of Benzodiazepines, Chlordiazepoxide, Diazepam\*, Oxazepam, Chlorazepate, Lorazepam, Alprazolam, Zolpidem

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

**Miscellaneous:**

Amides & imides: Glutethimide.

Alcohol & their carbamate derivatives: Meprobamate, Ethchlorvynol.

Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

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

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

**Flurobuterophenones:** Haloperidol, Droperidol, Risperidone.

**Betaaminoketones:** Molindone hydrochloride.

**Benzamides:** Sulpieride.

**D. Anticonvulsants:** SAR of Anticonvulsants, mechanism of anticonvulsant action

**Barbiturates:** Phenobarbitone, Methabarbital.

**Hydantoins:** Phenytoin\*, Mephenytoin, Ethotoin

**Oxazolidinediones:** Trimethadione, Paramethadione

**Succinimides:** Phensuximide, Methsuximide, Ethosuximide

**\*Urea and monoacylureas:** Phenacemide, Carbamazepine\*

**Benzodiazepines:** Clonazepam

**Miscellaneous:** Primidone, Valproic acid, Gabapentin, Felbamate

## UNIT– V

07 Hours

**Drugs acting on Central Nervous System General anesthetics: Inhalation anesthetics:**

Halothane\*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane.

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

**Dissociative anesthetics:** Ketamine hydrochloride.\*

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

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

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

## BP 406P. 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.

### **BP403 T. PHYSICALPHARMACEUTICS-II (Theory)**

**45Hours**

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

**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 forms
2. Know the principles of chemical kinetics & to use them for stability testing and Determination of expiry date of formulations
2. Demonstrate use of physicochemical properties in the formulation Development and evaluation of dosage forms.

### **Course Content:**

#### **UNIT-I**

**07 Hours**

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

#### **UNIT-II**

**10 Hours**

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

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

#### **UNIT-III**

**10 Hours**

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

#### **UNIT-IV**

**10Hours**

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

#### **UNIT-V**

**10 Hours**

**Drug stability:** Reaction kinetics: zero, pseudo-zero, first & second order, units of basic Rate constants, determination of reaction order. Physical and chemical factors influencing the chemical degradation of pharmaceutical product: temperature, solvent, ionic strength,

dielectric constant, specific & general acid base catalysis, Simple numerical problems. Stabilization of medicinal agents against common reactions like hydrolysis & oxidation. Accelerated stability testing in expiration dating of pharmaceutical dosage forms. Photolytic degradation and its prevention

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

**3**

**Hrs/week**

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

**Recommended Books: (Latest Editions)**

- 1) Alfred N. Martin, Patrick J. Sinko, Physical Pharmacy and Pharmaceutical Sciences. Ed. Patrick J. Sinko. Lippincott Williams & Wilkins, 2011.
- 2) Herbert A. Lieberman, Leon Lachman, Joseph B. Schwartz. Pharmaceutical Dosage Forms: Tablets, Vol. 2, 2nd Edition, Marcel Dekker, New York, 1990.
- 3) Mitchell J. Stoklosa, Pharmaceutical calculations., Lea & Febiger edition 6th. 1974.
- 4) Herbert Lieberman, Martin Rieger, Gilbert S. Banker. Pharmaceutical Dosage Forms book. Disperse Systems. Edition 2nd Edition. 2019.

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

**45 Hrs**

**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/subcellular/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**

**08 hours**

**1.General Pharmacologya.** Introduction to Pharmacology- Definition, historical landmarks and scope of pharmacology, nature and source of drugs, essential drugs concept and routes of drug administration, Agonists, antagonists (competitive and non competitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy.

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

#### **UNIT-II**

**12 Hours**

##### **General Pharmacology**

a. Pharmacodynamics-Principles and mechanisms of drug action. Receptor theories and classification of receptors, regulation of receptors. Drug receptors interactions signal transduction mechanisms, G-protein–coupled receptors, ion channel receptor, transmembrane enzyme linked receptors, transmembrane JAK-STAT binding receptor and receptors that regulate transcription factors, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action.

b. Adverse drug reactions.

c. Drug interactions (pharmacokinetic and pharmacodynamic)

d. Drug discovery and clinical evaluation of new drugs-Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.

#### **UNIT-III**

**10 Hours**

##### **2. Pharmacology of drugs acting on peripheral nervous system**

a. Organization and function of ANS.

b. Neurohumoral transmission, co-transmission and classification of neurotransmitters.

c. Parasympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics.

d. Neuromuscular blocking agents and skeletal muscle relaxants (peripheral).

e. Local anesthetic agents.

f. Drugs used in myasthenia gravis and glaucoma

#### **UNIT-IV**

**08 Hours**

#### **3.Pharmacology of drugs acting on central nervous system**

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

#### **UNIT-V**

**07 Hours**

#### **3. Pharmacology of drugs acting on central nervous system**

- a. Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens.
- b. Drugs used in Parkinsons disease and Alzheimer's disease.
- c. CNS stimulants and nootropics.
- d. Opioid analgesics and antagonistse. Drug addiction, drug abuse, tolerance and dependence.

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

**4Hrs/Week**

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

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

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

1. Rang H. P., Dale M. M., Ritter J. M., Flower R.J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S.B., Trevor A.J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G.B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology
6. K.D. Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, NewDelhi.
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,

### **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 the medicinal plants their medicinal properties.

**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. know the evaluation techniques for the herbal drugs
4. to carryout 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, unorganized drugs (dried latex, dried juices, dried extracts, gums and mucilages, oleoresins and oleo-gum-resins).

**Classification of drugs:** Alphabetical, morphological, taxonomical, chemical, pharmacological, chemo and 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 and properties.

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

## **UNIT-II**

**10 Hours**

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

Cultivation and Collection of drugs of natural origin

Factors influencing cultivation of medicinal plants.

Plant hormones and their applications. Polyploidy, mutation and hybridization with reference to medicinal plants

### **Conservation of medicinal plants**

## **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 test for identification of Alkaloids, Glycosides, Flavonoids, Tannins, Volatile oil and Resins

## **UNIT V**

**08 Hours**

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

**Plant Products:** Fibers- Cotton, Jute, Hemp Hallucinogens, Teratogens, Natural allergens

**Primary metabolites:** General introduction, detailed study with respect to chemistry, sources, preparation, evaluation, preservation, storage, therapeutic used and commercial utility as

Pharmaceutical Aids and /or Medicines for the following Primary metabolites:

**Carbohydrates:** Acacia, Agar, Tragacanth, Honey

**Proteins and Enzymes :** Gelatin, casein, proteolytic enzymes (Papain, bromelain, serratiopeptidase, urokinase, streptokinase, pepsin).

**Lipids (Waxes, fats, fixed oils):** Castor oil, Chaulmoogra oil, Wool Fat, Bees Wax

**Marine Drugs:** Novel medicinal agents from marine sources

### **BP 408 P. PHARMACOGNOSY AND PHYTOCHEMISTRY I (Practical)**

#### **4 Hours/Week**

1. Analysis of crude drugs by chemical tests:

(i) Tragacanth (ii) Acacia (iii) Agar (iv) Gelatin (v) starch (vi) Honey (vii) Castor oil

2. Determination of stomatal number and index

3. Determination of vein islet number, vein islet termination and palisade ratio.

4. Determination of size of starch grains, calcium oxalate crystals by eye piece micrometer

5. Determination of Fiber length and width

6. Determination of number of starch grains by Lycopodium spore method

7. Determination of Ash value

8. Determination of Extractive values of crude drugs

9. Determination of moisture content of crude drugs

10. Determination of swelling index and foaming

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

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

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

3. T.E. Wallis Text Book of Pharmacognosy, fifth edition, 2005, published by A. Churchill, Ltd., London

4. Mohammad Ali. Pharmacognosy and Phytochemistry, 2<sup>nd</sup> edition, 1991 CBS Publishers & Distribution, New Delhi.

5. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhale (2007), 37th Edition, Nirali Prakashan, New Delhi.

6. Herbal drug industry by R.D. Choudhary (1996), 1st Edn, Eastern Publisher, New Delhi.

7. Essentials of Pharmacognosy, Dr.SH.Ansari, 2<sup>nd</sup> edition, Birla publications, New Delhi, 2007

8. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae, 18<sup>th</sup> edition, 2017, Nirali Prakashan

#### SEMESTER 5<sup>th</sup>

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP501T	Medicinal Chemistry II–Theory	3	1	4
BP502T	Industrial Pharmacy I–Theory	3	1	4
BP503T	Pharmacology II–Theory	3	1	4
BP504T	Pharmacognosy and Phytochemistry II– Theory	3	1	4
BP505T	Pharmaceutical Jurisprudence – Theory	3	1	4
BP506P	Industrial Pharmacy I– Practical	4	-	2
BP507P	Pharmacology II– Practical	4	-	2
BP508P	Pharmacognosy and Phytochemistry II– Practical	4	-	2
		27	5	26

#### **BP 501T. 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 Structural 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 Humanbody **H-antagonists:** Diphenhydramine hydrochloride\*, Dimenhydrinate, Doxylamine succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride\*, Phenidamine tartarate, Promethazine hydrochloride\*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium

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

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

**Anti-neoplastic agents: Alkylating agents:** Mecllorethamine\*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa

**Antimetabolites:** Mercaptopurine\*, Thioguanine, Fluorouracil, Floxuridine, 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\*, Penta erythritol tetranitrate, Isosorbide dinitrite\*, Dipyridamole.

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

**Diuretics:** Carbonic anhydrase inhibitors: Acetazolamide\*, Methazolamide, Dichlorphenamide. Thiazides: Chlorthiazide\*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide,

Loop diuretics: Furosemide\*, Bumetanide, Ethacrynicacid. Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride.

Osmotic Diuretics: Mannitol

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

## **UNIT-III 10 Hours**

**Anti-arrhythmic Drugs:** Quinidine sulphate, Procainamide hydrochloride,

Disopyramide phosphate\*, Phenytoin sodium, Lidocaine hydrochloride, Tocainide hydrochloride, Mexiletine hydrochloride, Lorcainide hydrochloride, Amiodarone, Sotalol.

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

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

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

#### **UNIT-IV**

**08 Hours**

##### **Drugs acting on Endocrine system**

Nomenclature, Stereochemistry and metabolism of steroids

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

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

**Oral contraceptives:** Mifepristone, Norgestrel, Levonorgestrol

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

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

#### **UNIT- V**

**07 Hours**

##### **Antidiabetic agents:**

Insulin and its preparations Sulfonyl ureas: Tolbutamide\*, Chlorpropamide, Glipizide, Glimepiride.

Biguanides: Metformin.

Thiazolidinediones: Pioglitazone, Rosiglitazone.

Meglitinides: Repaglinide, Nateglinide.

Glucosidase inhibitors: Acarbose, Voglibose.

**Local Anesthetics:** SAR of Local anesthetics

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

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

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

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

##### **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 Lednicher, Vol. 1 to 5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I. Vogel.

### **BP 502 T. Industrial Pharmacy I (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:**

#### **UNIT-I**

**07 Hours**

**Preformulation Studies:** Introduction to pre-formulation, goals and objectives, study of physicochemical characteristics of drug substances.

**a. Physical properties:** Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism

**b. Chemical Properties:** Hydrolysis, oxidation, reduction, racemisation, polymerization BCS classification of drugs & its significant Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.

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

##### **Tablets:**

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

c. Quality control tests: In process and finished product tests

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

### **UNIT-III**

**08 Hours**

#### **Capsules:**

a. **Hard gelatin capsules:** Introduction, Production of hard gelatin capsule shells. Size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules.

b. **Soft gelatin capsules:** Nature of shell and capsule content, size of capsules, importance of base adsorption and minim/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules and their applications.

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

### **UNIT-IV**

**10 Hours**

#### **Parenteral Products:**

a. Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity

b. Production procedure, production facilities and controls, aseptic processing

c. Formulation of injections, sterile powders, large volume parenterals and lyophilized products.

d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests of parenteral products.

**Ophthalmic Preparations:** Introduction, formulation considerations; formulation of eyedrops, 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.**

**Industrial Pharmacy I (Practical)**

**4 Hours/week**

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

**Recommended Books: (Latest Editions)**

1. The theory and Practice of Industrial Pharmacy, Leon Lachman; Herbert A. Liberman, Joseph L. Kanig; Fourth edition. 2020, Vergese publishing house
2. Ansel's Pharmaceutical Dosage forms and Drug delivery systems, Loyd V. Allen, Jr. Nicholas G., Popovich, Howard C. Ansel, Eight edition 2005, Wolters Kluwer Health Pvt Ltd, New Delhi
3. Remington, The Science and Practice of Pharmacy, Paul Beriniger, Araderi Marderosian, Linda Felton, Steven Gelone *et.al*, 21 edition 2007, Volume I, Wolters Kluwer Health Pvt Ltd, New Delhi
4. Modern Pharmaceutics Gilbert S. Banker & C.T. Rhodes 3rd Edition, Marcel Dekker 2008.
5. Drug stability: Principles and Practices, Jens T. Carstensen, C.T. Rhodes, Marcel Dekker 2008
6. Pharmaceutical dosage forms: Tablet vol 1-3, H.A. Liberman, Leon Lachman & J.B. Schwartz, Marcel Dekker 2008
7. Bentley's: Textbook of Pharmaceutics, E.A. Rawlins, Elsevier 2012.
8. Cooper and Gunns: Dispensing for Pharmaceutical students, S.J. Carter, twelfth edition, 2000, S.K. Jain for CBS Publishers and distributors

9. Pharmaceutical Dosage forms : Disperse system, vol 1-3, H.A. Liberman, M.M Rieger & G.S Banker, Marcel dekker 1996.

### **BP 503.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**

##### **1. Pharmacology of drugs acting on cardio vascular system**

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

##### **2. Pharmacology of drugs acting on urinary system**

- a. Diuretics b. Anti-diuretics.

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

**10 hours**

##### **3. Autocoids and related drugs**

- a. Introduction to autacoids and classification
- b. Histamine, 5-HT and their antagonists.
- c. Prostaglandins, Thromboxanes and Leukotrienes.
- d. Angiotensin, Bradykinin and Substance P.
- e. Non-steroidal anti-inflammatory agents
- f. Anti-gout drugs
- g. Antirheumatic drugs

#### **UNIT-IV**

**08 hours**

#### **5. 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.
- c. Insulin, Oral Hypoglycemic agents and glucagon.
- d. e. ACTH and corticosteroids.

#### **UNIT-V**

**07 hours**

#### **5. Pharmacology of drugs acting on endocrine system**

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

#### **6. Bioassay**

- a. Principles and applications of bioassay.
- b. Types of bioassay
- c. Bioassay of insulin, oxytocin, vasopressin, ACTH, d-tubocurarine, digitalis, histamine and 5-HT

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

**4Hrs/Week**

- 1. Introduction to *in-vitro* pharmacology and physiological salt solutions.
- 2. Effect of drugs on isolated frog heart.
- 3. Effect of drugs on blood pressure and heartrate of dog.
- 4. Study of diuretic activity of drugs using rats/mice.
- 5. DRC of acetylcholine using frog rectus abdominis muscle.
- 6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively.

7. Bioassay of histamine using guinea pig ileum by matching method.
8. Bioassay of oxytocin using rat uterine horn by interpolation method.
9. Bioassay of serotonin using rat fundus strip by three point bioassay.
10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
11. Determination of PA<sub>2</sub> value of prazosin using rat anococcygeus muscle (by Schilds plot method).
12. Determination of PD<sub>2</sub> value using guinea pig ileum.
13. Effect of spasmogens and spasmolytics using rabbit jejunum.
14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
15. Analgesic activity of drug using central and peripheral methods

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

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

1. Rang H. P., Dale M.M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S.B., Trevor A.J., Basic and clinical pharmacology, Tata Mc Graw-Hill.
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G.B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins.
5. Mycek M.J, Gelnet S. Band 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 M N. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.

### **BP 504 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. Also this subject involves the study of producing the plants and



phytochemicals through plant tissue culture, drug interactions and basic principles of traditional system of medicine

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

1. to know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents
2. to understand the preparation and development of herbal formulation.
3. to understand the herbal drug interactions
4. to carry out 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 the 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**

**14 Hours**

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

**Alkaloids:** Vinca, Rauwolfia, Belladonna, Opium,

**Phenyl propanoids 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**

**06 Hours**

Isolation, Identification and Analysis of Phytoconstituents

- a) Terpenoids: Menthol, Citral, Artemisin
- b) Glycosides :Glycyrrhetic acid & Rutin
- c) Alkaloids: Atropine, Quinine, Reserpine, Caffeine
- d) Resins: Podophyllotoxin, Curcumin

#### **UNIT-IV**

**10 Hours**

Industrial production, estimation and utilization of the following phytoconstituents:

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

## **UNIT V**

**8Hours**

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

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

1. W.C. Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Saunders & Co., London, 2009.
2. Mohammad Ali. Pharmacognosy and Phytochemistry, 2<sup>nd</sup> edition, 1991 CBS Publishers & Distribution, New Delhi.
3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhale (2007), 37th Edition, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), 1<sup>st</sup> edition, Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr. S.H. Ansari, 2<sup>nd</sup> edition, Birla publications, New Delhi, 2007

6. Herbal Cosmetics by H. Pande, 3<sup>rd</sup> revised edition 2015, Asia Pacific Business press, Inc, New Delhi.

7. A.N. Kalia, Textbook of Industrial Pharmacognosy, 2<sup>nd</sup> edition CBS Publishers, New Delhi, 2005.

### **BP505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)**

**45 Hours**

**Scope:** This course is designed to impart basic knowledge on 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 of pharmaceuticals.
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; 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, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties

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

**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. Text book of Forensic Pharmacy by B.M. Mithal

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

#### SEMESTER 6<sup>th</sup>

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP601T	Medicinal Chemistry III – Theory	3	1	4
BP602T	Pharmacology III – Theory	3	1	4
BP603T	Herbal Drug Technology – Theory	3	1	4
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	3	1	4
BP605T	Pharmaceutical Biotechnology – Theory	3	1	4
BP606T	Quality Assurance –Theory	4	1	4
BP607P	Medicinal chemistry III – Practical	4	-	2
BP608P	Pharmacology III – Practical	4	-	2
BP609P	Herbal Drug Technology – Practical	4	-	2
		30	6	30

#### **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.

**β-Lactam antibiotics:** Penicillin, Cephalosporins, β-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 dihydrotriazines :** 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:** Furazolidine, Nitrofurantoin\*, Methanamine.

**Antiviral agents:** Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir\*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirding, 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:** Diethyl carbamazine citrate\*, Thiabendazole, Mebendazole\*, Albendazole, Niclosamide, Oxamniquine, Praziquantel, Ivermectin.

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

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

**Sulfones:** Dapsone\*.

#### **UNIT– V**

**07 Hours**

**Introduction to Drug Design** Various approaches used in drug design.

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

Pharmacophore modelling and docking techniques.

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

#### **BP 607P. MEDICINAL CHEMISTRY-III (Practical)**

**4 Hours /week**

##### **I Preparation of drugs and intermediates**

1 Sulphanilamide

2 7-Hydroxy, 4-methylcoumarin

- 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 Benzylpenicillin

**III** Preparation of medicinally important compounds or intermediates by Microwave irradiation technique

**IV** Drawing structures and reactions using chem draw®

**V** Determination of physicochemical properties such as logP, clog P, M R, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug like lines sscreening (LipinskiesRO5)

## **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 602 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 chrono-pharmacology.



**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**

**10 hours**

### **1.Pharmacology of drugs acting on Respiratory system**

- a. Anti-asthmatic drugs
- b. Drugs used in the management of COPD
- c. Expectorants and antitussives
- d. Nasal decongestants
- e. Respiratory stimulants

### **2.Pharmacology of drugs acting on the Gastrointestinal Tract**

- a. Antiulcer agents.
- b. Drugs for constipation and diarrhoea.
- c. Appetite stimulants and suppressants.
- d. Digestants and carminatives.
- e. Emetics and anti-emetics.

## **UNIT-II**

**10 hours**

### **3. Chemotherapy**

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

## **UNIT-III**

**10 hours**

### **3. Chemotherapy**

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

## **UNIT-IV**

**08 hours**

### **3. Chemotherapy**

1. Urinary tract infections and sexually transmitted diseases .

Chemotherapy of malignancy.

### **4. Immunopharmacology**

a. Immunostimulants

b. Immunosuppressant Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

## **UNIT-V**

**07 hours**

### **5.Principles of toxicology**

a. Definition and basic knowledge of acute, subacute and chronic toxicity.

b. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity

c. General principles of treatment of poisoning

d. Clinical symptoms and management of barbiturates, morphine, organo phosphorus compound and lead, mercury and arsenic poisoning.

### **6. Chrono-pharmacology**

a. Definition of rhythm and cycles.

b. Biological clock and their significance leading to chronotherapy.

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

**4Hrs/Week**

1. Dose calculation in pharmacological experiments

2. Antiallergic activity by mast cell stabilization assay

3. Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.

4. Study of effect of drugs on gastrointestinal motility

5. Effect of agonist and antagonists on guinea pig ileum

6. Estimation of serum biochemical parameters by using semi- autoanalyzer

7. Effect of saline purgative on frog intestine

8. Insulin hypoglycemic effect in rabbit

9. Test for pyrogens (rabbit method)

10. Determination of acute oral toxicity (LD50) of a drug from a given data

11. Determination of acute skin irritation / corrosion of a test substance

12. Determination of acute eye irritation /corrosion of a test substance

13. Calculation of pharmacokinetic parameters from a given data

14. Biostatistics methods in experimental pharmacology (Student's t test, ANOVA)

15. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon

Signed Rank test)

*\*Experiments are demonstrated by simulated experiments/videos*

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

1. Rang H. P., Dale M. M., Ritter J. M., Flower R.J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier

2. Katzung B. G., Masters S.B., Trevor A.J., Basic and clinical pharmacology, Tata Mc Graw-Hill

3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics

4. Marry Anne K. K., Lloyd Yee Y., Brian K.A., Robbin L.C., Joseph G.B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams & Wilkins

5. Mycek M. J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology

6. K.D. Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.

7. Sharma H.L., Sharma K.K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R. Craig & Robert

8. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,

9. Kulkarni S K. Handbook of experimental pharmacology. Vallabh Prakashan

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, nutraceutical 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.

**Course content:**

## UNIT-I

11 Hours

### Herbs as raw materials

Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation Source of Herbs Selection, identification and authentication of herbal materials Processing of herbal raw material

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

### Indian Systems of Medicine

a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy

b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika, Churna, Lehya and Bhasma.

## UNIT-II

7 Hours

### Nutraceuticals

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

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

**Herbal-Drug and Herb-Food Interactions:** General introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.

## UNIT-III

10 Hours

### Herbal Cosmetics

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

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

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

## UNIT-IV

10 Hours

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

**Patenting and Regulatory requirements of natural products:**

a) Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy

b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.

**Regulatory Issues** -Regulations in India (ASUDTAB, ASUDCC), Regulation of manufacture of ASU drugs – Schedule Z of Drugs & Cosmetics Act for ASU drugs.

**UNIT-V**

**07 Hours**

**General Introduction to Herbal Industry** Herbal drugs industry: Present scope and future prospects.

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

**Schedule T– Good Manufacturing Practice of Indian systems of medicine** Components of GMP (Schedule–T) and its objectives

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

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

**4**

**hours/week**

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

**Recommended Books:(Latest Editions)**

1. Textbook of Pharmacognosy by Trease & Evans.
2. Textbook of Pharmacognosy by Tyler, Brady & Robber.

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

#### **BP604 T. BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory) 45 Hours**

**Scope:** This subject is designed to impart knowledge and skills of Biopharmaceutics

And pharmacokinetics and their applications in pharmaceutical development, design of dose and dosage regimen and in solving the problems arisen therein.

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

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

#### **Course Content:**

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

**10 Hours**

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

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

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

**10Hours**

**Elimination:** Drug metabolism and basic understanding metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs

**Bioavailability and Bioequivalence:** Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, *in-vitro* drug dissolution models,

*in-vitro-in-vivo* correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.

### **UNIT-III**

**10 Hours**

**Pharmacokinetics:** Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model.

(a). Intravenous Injection (Bolus)

(b). Intravenous infusion and

(c) Extra vascular administrations. Pharmacokinetics parameters- $KE$ ,  $t_{1/2}$ ,  $V_d$ ,  $AUC$ ,  $K_a$ ,  $Cl_t$  and  $CLR$  -definitions methods of eliminations, understanding of their significance and Application

### **UNIT-IV**

**08 Hours**

**Multi compartment models:** Two compartment open model. IV bolus Kinetics of multiple dosing, steady state drug levels, calculation of loading and Maintenance doses and their significance in clinical settings.

### **UNIT-V**

**07 Hours**

**Non linear Pharmacokinetics:**

A. Introduction,

b. Factors causing Non-linearity.

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

### **REFERENCE BOOKS:**

1. Bio Pharmaceutics and Pharmacokinetics, P.L Madan, second edition, Jaypee Brothers medical Publishers (p) Ltd 2014

2 Bio- Pharmaceutics and Clinical Pharmacokinetics, Milo Gibaldi, Fourth edition, Pharma book syndicate 2006

3. Bio-Pharmaceutics and Pharmacokinetics : A Treatise, D.M. Brahamankar, Sunil B. Jaiswal, Second edition, Vallabh Prakashan 2009

4. Bio Pharmaceutics and Pharmacokinetics, J.S kulkarni, A.P Pawar, V.P Shedbalkar, CBS Publishers and Distributors, 2018

5. Applied Biopharmaceutics and Pharmacokinetics, Leon Shargel , S.W Pong, Andrew B.C, Fifth edition Mc Graw hill, 2005

6 Bio Pharmaceutics and clinical Pharmacokinetics an introduction, Robert E. Notari, Fourth edition , Marcel Dekker.1987

**Scope:**

**BP605 T. PHARMACEUTICAL BIOTECHNOLOGY (Theory) 45 Hours**

- 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.
- f) 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 Rdna technology and genetic engineering in the production of:
  - i) Interferon ii) Vaccines-hepatitis-B iii) Hormones-Insulin
- d) Brief introduction to PCR

**Unit III**

**10 Hours**

Types of immunity-humoral immunity, cellular immunity



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

#### **Unit IV**

**08 Hours**

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

#### **Unit V**

**07**

#### **Hours**

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

#### **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. 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., Whitakar A., and Hall J., S., Principles of fermentation technology, 2<sup>nd</sup> edition, Aditya books Ltd., New Delhi

## **BP 606T PHARMACEUTICAL QUALITY ASSURANCE (Theory)**

**45**

### **Hours**

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

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

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

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

#### **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 Non clinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities

#### **UNIT– IV**

**08Hours**

**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.

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

#### **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 Guidelines and Related materials Vol I WHO Publications.
4. A guide to Total Quality Management -Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP's– PP Sharma.
6. ISO 9000 and Total Quality Management–Sadhan K Ghosh
7. The International Pharmacopoeia–Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices– Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines

## SEMESTER 7<sup>th</sup>

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP701T	Instrumental Methods of Analysis – Theory	3	1	4
BP702T	Industrial Pharmacy II–Theory	3	1	4
BP703T	Pharmacy Practice– Theory	3	1	4
BP704T	Novel Drug Delivery System– Theory	3	1	4
BP705P	Instrumental Methods of Analysis - Practical	4	-	2
BP706PS	Practice School	12	-	6
		28	5	24

### **BP 701T. 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

**Nephelo-turbidometry**-Principle, instrumentation and applications

## **UNIT-III**

**10 Hours**

### **Introduction to chromatography**

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

**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 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

## **BP702 T. INDUSTRIAL PHARMACY II (Theory)**

**45 Hours**

**Scope:** This course is designed to impart fundamental knowledge on pharmaceutical product development and translation 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
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, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization- practical aspects and problems (case studies), TT agencies in India-APCTD, NRDC, TIFAC, BCIL, TBSE/SIDBI; TT related documentation – confidentiality agreement, licensing, MoUs, legal issues

**UNIT-III 10 Hours Regulatory affairs:** Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals

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

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

**Quality management systems:** Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO9000 series of quality systems standards, ISO 14000, NABL, GLP

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

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

- Recommended Books: (Latest Editions)**
1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7 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 JP 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>.

### **BP703T. 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 counselling 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 counselling in community pharmacy;
10. appreciate the concept of Rational drug therapy.

### **Unit I:**

**10 Hours**

#### **a) Hospital and it's organization**

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



**b) Hospital pharmacy and its organization** Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists.

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

**d) Community Pharmacy** Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale drugstore.

## **Unit II:**

**10 Hours**

### **a) Drug distribution system in a hospital**

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

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

**c) Therapeutic drug monitoring** Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring.

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

**e) Patient medication history interview** Need for the patient medication history interview, medication interview forms.

**f) Community pharmacy management** Financial, materials, staff, and infrastructure requirements.

## **Unit III:**

**10 Hours**

### **a) Pharmacy and therapeutic committee**

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

**b) Drug information services**

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

**c) Patient counselling** Definition of patient counseling; steps involved inpatient counseling, and Special cases that require the pharmacist

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

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

**Unit IV**

**8 Hours**

**a) Budget preparation and implementation** Budget preparation and implementation

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

Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern.

**c) Over the counter (OTC) sales** Introduction and sale of over the counter, and Rational use of common over the counter medications.

**Unit V**

**7 Hours**

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

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

**b) Investigational use of drugs**

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

**c) Interpretation of Clinical Laboratory Tests** Blood chemistry, hematology, and urinalysis

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.

#### **BP704T: 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. Physicochemical and biological properties of drugs relevant to controlled release formulations

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

#### **Unit-II 10 Hours**

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

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

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

#### **Unit-III**

**10 Hours**

**Transdermal Drug Delivery Systems:** Introduction, Permeation through skin, factors

Affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches

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

**Naso pulmonary 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**

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

#### **Unit-V**

**07 Hours**

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

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

**Recommended Books:(Latest Editions)**1. YW. 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.

### **SEMESTER 8<sup>th</sup>**

<b>Course code</b>	<b>Name of the course</b>	<b>No. of hours</b>	<b>Tutorial</b>	<b>Credit points</b>
BP801T	Biostatistics and Research Methodology	3	1	4

BP802T	Social and Preventive Pharmacy	3	1	4
BP803ET	Pharma Marketing Management	3+3=6	1+1=2	4+4=8
BP804ET	Pharmaceutical Regulatory Science			
BP805ET	Pharmacovigilance			
BP806ET	Quality Control and Standardization of Herbals			
BP807ET	Computer Aided Drug Design			
BP808ET	Cell and Molecular Biology			
BP809ET	Cosmetic Science			
BP810ET	Experimental Pharmacology			
BP811ET	Advanced Instrumentation Techniques			
BP812ET	Dietary Supplements and Nutraceuticals			
BP813PW	Project Work	12	-	6
		24	4	22

## **BP 801 T. BIOSTATISTICS AND RESEARCH METHODOLOGY (Theory) 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 the course the student shall be able to

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

### **Course content:**

#### **Unit-I**

**10 Hours**

**Introduction:** Statistics, Biostatistics, Frequency distribution

**Measures of central tendency:** Mean, Median, Mode-Pharmaceutical examples

**Measures of dispersion:** Dispersion, Range, standard deviation, Pharmaceutical problems

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

## **Unit-II**

**10 Hours**

**Regression:** Curve fitting by the method of least squares, fitting the lines  $y=a+bx$  and  $x=a+by$ , Multiple regression, standard error of regression-Pharmaceutical Examples

**Probability:** Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties-problems Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM)-Pharmaceutical examples

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

## **Unit-III**

**10 Hours**

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

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

**Graphs:** Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plotgraph

**Designing the methodology:** Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

**Unit-IV 8 Hours** Blocking and confounding system for Two-level factorials

**Regression modeling:** Hypothesis testing in Simple and Multiple regression models

**Introduction to Practical components of Industrial and Clinical Trials Problems:**

Statistical Analysis Using Excel, SPSS, MINITAB®, DESIGN OF EXPERIMENTS, R-Online Statistical Software's to Industrial and Clinical trial approach

## **Unit-V**

**7Hours**

**Design and Analysis of experiments:**

**Factorial Design:** Definition,  $2^2$ ,  $2^3$  design. Advantage of factorial design

**Response Surface methodology:** Central composite design, Historical design, Optimization Techniques

**Recommended Books (Latest edition):**

1. Pharmaceutical statistics -Practical and clinical applications, Sanford Bolton,

Publisher Marcel Dekker Inc. New York.

2. Fundamental of Statistics– Himalaya Publishing House-S.C. Gupta

3. Design and Analysis of Experiments – PHI Learning Private Limited, R. Pannarselvam,

3. Design and Analysis of Experiments – Wiley Students Edition, Douglas and C. Montgomery

4. Sanford Bolton; Pharmaceutical statistics- Practical and clinical applications; Marcel Dekker Inc. New York; 5<sup>th</sup> edition; 2010.

5. S.C. Gupta; Fundamental of Statistics; Himalaya Publishing House; 7<sup>th</sup> edition; 2018.

6. R. Pannarselvam; Design and Analysis of Experiments; PHI Learning Private Limited; 2<sup>nd</sup> edition; 2014.

7. Douglas and C. Montgomery; Design and Analysis of Experiments; Wiley Students Edition; 8<sup>th</sup> edition; 2022.

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

**Hours: 45**

**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:

- Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide.
- Have a critical way of thinking based on current health care development.
- 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:** Sociocultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health

**Hygiene and health:** personal hygiene and healthcare; 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 programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National Programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.

**Unit IV:**

**08 Hours**

National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the healthcare for the elderly, Social health programme; 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, 2nd Edition, 2010, ISBN: 9789380704104, JAYPEE Publications
2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications.
3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, 2014, ISBN: 9789351522331, JAYPEE Publications.



4. Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications.

5. Park Textbook of Preventive and Social Medicine, K Park, 21 st Edition, 2011, ISBN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS.

**BP 803 ET. PHARMA MARKETING MANAGEMENT (Theory) 45 Hours**

**Scope:** The pharmaceutical industry not only needs highly qualified researchers, chemists and, technical people, but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry. The Knowledge and Know-how of marketing management groom the people for taking a challenging role in Sales and Product management.

**Course Objective:** The course aims to provide an understanding of marketing concepts and techniques and their applications in the pharmaceutical industry.

**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:**

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

**Unit III 10 Hours**

**Promotion:** Methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.

**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****10 Hours****Pricing:**

Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. **An overview of DPCO (Drug**

**Price Control Order) and NPPA (National Pharmaceutical Pricing Authority).**

**Emerging concepts in marketing:** Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.

**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 McGraw Hill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata McGraw Hill
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: Marketing Management; Tata McGraw-Hill (India Edition)
6. Ramaswamy, U.S & Nanakamari, S: Marketing Management: 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.

**BP 804 ET: PHARMACEUTICAL REGULATORY SCIENCE (Theory)****45Hours**

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

**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**

**10 Hours**

##### **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**

**10 Hours**

##### **Regulatory Approval Process**

Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA /ANDA.

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

#### **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 terminology, 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, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
8. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
10. 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:**

*At completion of this paper it is expected that students will be able to (know, do, and appreciate):*

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 preclinical, clinical and post approval phases of drugs' lifecycle
9. Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
10. Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India
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 prevent ability 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
- Eudra vigilance medicinal product dictionary

### **Information resources in pharmacovigilance**

- Basic drug information resources
- Specialised resources for ADRs

### **Establishing pharmacovigilance programme**

- Establishing in a hospital
- Establishment & operation of drug safety department in industry
- Contract Research Organisations (CROs)
- Establishing a national programme

## **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, Health care facilities & Media

## **Unit IV**

**8 Hours**

### **Safety data generation**

- Preclinical phase
- Clinical phase
- Post approval phase (PMS) ICH Guidelines for Pharmacovigilance
- Organization and objectives of ICH
- Expedited reporting
- Individual case safety reports
- Periodic safety update reports
- Post approval expedited reporting
- Pharmacovigilance planning
- Good clinical practice in pharmacovigilance studies

## **Unit V**

**7 hours**

### **Pharmacogenomics of adverse drug reactions**

- Genetics related ADR with example focusing PK parameters.

### **Drug safety evaluation in special population**

- Paediatrics
- Pregnancy and lactation
- Geriatrics

### **CIOMS**

- CIOMS Working Groups
- CIOMS Form

### **CDSCO (India) and Pharmacovigilance**

- D & C Act and Schedule Y
- Differences in Indian and global pharmacovigilance requirements

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

1. Textbook of Pharmacovigilance: SK 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](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>.
14. [http://www.who.int/vaccine\\_safety/en/](http://www.who.int/vaccine_safety/en/)
15. [http://www.ipc.gov.in/PvPI/pv\\_home.html](http://www.ipc.gov.in/PvPI/pv_home.html)

### **BP806 ET. QUALITY CONTROL AND STANDARDIZATION OF HERBALS** (Theory)

**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**

**10hours**

**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 (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, 3<sup>rd</sup> 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

- Design and discovery of lead molecules
- The role of drug design in drug discovery process
- The concept of QSAR and docking
- Various strategies to develop new drug like molecules.
- The design of new drug molecules using molecular modelling software

#### **Course Content:**

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

**10 Hours**

**Introduction to Drug Discovery and Development** Stages of drug discovery and development

**Lead discovery and Analog Based Drug Design** Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation.

**Analog Based Drug Design:** Bio-isosterism, Classification, Bioisosteric replacement. Any three case studies

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

**10 Hours**

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

SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammett's substituent constant and Tafts steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.

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

**10 Hours**

### **Molecular Modeling and virtual screening techniques**

**Virtual Screening techniques:** Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening

**Molecular docking:** Rigid docking, flexible docking, manual docking, Docking based screening. *Denovo* drug design.

#### **UNIT-IV**

**08 Hours**

#### **Informatics & Methods in drug design**

Introduction to Bioinformatics, chemo informatics. ADME databases, chemical, biochemical and pharmaceutical databases.

#### **UNIT-V**

**07 Hours**

**Molecular Modeling:** Introduction to molecular mechanics and quantum mechanics. Energy Minimization methods and Conformational Analysis, Global conformational minima determination.

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

1. Robert GCK, ed., "Drug Action at the Molecular Level" University Park Press Baltimore
2. Martin YC. "Quantitative Drug Design" Dekker, New York.
3. Delgado JN, Remers WA eds "Wilson & Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry 'Lea & Febiger.
5. Koro I kovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
6. Wolf ME, "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.
7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
8. Smith HJ, Williams H, "Introduction to the principles of Drug Design" Wright Boston.
9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.

### **BP 808 ET: 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 lifecycle, 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.

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

- Summarize cell and molecular biology history.
- Summarize cellular functioning and composition.
- Describe the chemical foundations of cell biology.
- Summarize the DNA properties of cell biology.
- Describe protein structure and function.
- Describe cellular membrane structure and function.
- Describe basic molecular genetic mechanisms.
- 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) 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 Information
- b) DNA Functioning
- c) DNA and RNA
- d) Types of RNA
- e) Transcription and Translation

### **Unit III**

**10 Hours**

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

**Unit IV****08 Hours**

- a) Science of Genetics
- b) Transgenics and Genomic Analysis
- c) Cell Cycle analysis d) Mitosis and Meiosis
- e) Cellular Activities and Checkpoints

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

**BP 809ET. COSMETIC SCIENCE (Theory)****45Hours****UNIT I****10 Hours**

Classification of cosmetic and cosmeceutical products Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs

**Cosmetic excipients:** Surfactants, rheology modifiers, humectants, emollients, preservatives. Classification and application

**Skin:** Basic structure and function of skin.

**Hair :** Basic structure of hair. Hair growth cycle.

**Oral Cavity:** Common problem associated with teeth and gums.

## **UNIT II**

**10 Hours**

### **Principles of formulation and building blocks of skincare products:**

Facewash, Moisturizing cream, Cold Cream, Vanishing cream and their advantages and disadvantages. Application of these products in formulation of cosmeceuticals.

**Antiperspirants & deodorants-** Actives & mechanism of action.

### **Principles of formulation and building blocks of Hair care products :**

Conditioning shampoo, Hair conditioner, anti-dandruff shampoo. Hair oils. Chemistry and formulation of Para-phenylenediamine based hairdye. Principles of formulation and building blocks of oral care products: Toothpaste 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 Haircare: Henna and amla.

Oral care: Neem and clove **Analytical cosmetics:** BIS specification and analytical methods for shampoo, skin-Cream and toothpaste.

## **UNIT IV**

**08 Hours.**

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

Soaps, and syndet bars. Evolution and skin benefits.

## **UNIT V**

**07 Hours**

Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis. Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and body odor. Antiperspirants and Deodorants-Actives and mechanism of action

## **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)Text book of cosmeticology by Sanju Nanda & Roop K. Khar, Tata Publishers.

## **BP810 ET. 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,

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

### **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**

#### **Preclinical screening models:**

for ANS activity, sympathomimetics, sympatholytics, para sympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics

#### **Unit-IV**

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

**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

- understand the advanced instruments used and its applications in drug analysis
- understand the chromatographic separation and analysis of drugs.
- 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 Thermogravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC)

**X-Ray Diffraction Methods:** Origin of X-rays, basic aspects of crystals, X-Ray Crystallography, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications.

## **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 immunoassay

**Extraction techniques:** General principle and procedure involved in the solid phase extraction and liquid-liquid extraction

## **UNIT-V**

**07 Hours**

**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

### **BP 812 ET. DIETARY SUPPLEMENTS AND NUTRACEUTICALS**

**No. of hours : 3 Tutorial: 1 Credit point: 4 Scope:** This subject covers foundational topic that are important for understanding the need and requirements of dietary supplements among different groups in the population.

**Objective:** This module aims to provide an understanding of the concepts behind the theoretical applications of dietary supplements. By the end of the course, students should be able to :

1. Understand the need of supplements by the different group of people to maintain Healthy life.
2. Understand the outcome of deficiencies in dietary supplements.
3. Appreciate the components in dietary supplements and the application.
4. Appreciate the regulatory and commercial aspects of dietary supplements including Health claims.

#### **UNIT I**

**07 hours**

- a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis, hypertension etc.
- b. Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community.
- c. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods: Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Ginkgo, Flaxseeds

#### **UNIT II**

**15 hours**

Phytochemicals as nutraceuticals: Occurrence and characteristic features (chemical nature medicinal benefits) of following

- a) Carotenoids-  $\alpha$  and  $\beta$ -Carotene, Lycopene, Xanthophylls, leutin
- b) Sulfides: Diallyl sulfides, Allyl trisulfide.
- c) Polyphenolics: Resveratrol
- d) Flavonoids- Rutin, Naringin, Quercetin, Anthocyanidins, catechins, Flavones

- e) Prebiotics/Probiotics.: Fructo oligosaccharides, Lacto bacillum
- f) Phytoestrogens : Isoflavones, daidzein, Geobactin, lignans
- g) Tocopherols
- h) Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, ricebran, seafoods, coffee, tea and the like.

### **UNIT III**

**07 hours**

- a) Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids. Dietary fibres and complex carbohydrates as functional food ingredients.

### **UNIT IV**

**10 hours**

- a) Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage .Free radicals involvement in other disorders. Free radicals theory of ageing.
- b) Antioxidants: Endogenous antioxidants – enzymatic and non enzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, a Lipoicacid, melatonin  
Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole.
- c) Functional foods for chronic disease prevention

### **UNIT V**

**06 hours**

- a) Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals.
- b) Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.
- c) Pharmacopoeial Specifications for dietary supplements and nutraceuticals.

### **References:**

1. Dietetics by SriLakshmi
2. Role of dietary fibres and neutraceuticals in preventing diseases by K. T Agusti and P.Faizal : BS Ppublication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F. Balchand Phyllis A. Balch 2

Edn., Avery Publishing Group, NY (1997).

6. G. Gibson and C. Williams Editors *2000 Functional foods* Woodhead Publ. Co. London.

7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.

8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M.K. Sachmidl and T.P. Labuza eds. Aspen Press.

9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)

10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

### **Pharmaceutical Product Development**

**No of Hours: 3 Tutorial: 1**

**Credit points: 4**

#### **Unit-I**

**10 Hours**

Introduction to pharmaceutical product development, objectives, regulations related to preformulation, formulation development, stability assessment, manufacturing and quality control testing of different types of dosage forms

#### **Unit-II**

**10 Hours**

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories

- i. Solvents and solubilizers
- ii. Cyclodextrins and their applications
- iii. Non-ionic surfactants and their applications
- iv. Polyethylene glycols and sorbitols
- v. Suspending and emulsifying agents
- vi. Semi solid excipients

#### **Unit-III**

**10 Hours**

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories

- i. Tablet and capsule excipients
- ii. Directly compressible vehicles
- iii. Coat materials
- iv. Excipients in parenteral and aerosols products

v.      Excipients for formulation of NDDS

Selection and application of excipients in pharmaceutical formulations with specific industrial applications

**Unit-IV**

**08 Hours**

Optimization techniques in pharmaceutical product development. A study of various optimization techniques for pharmaceutical product development with specific examples. Optimization by factorial designs and their applications. A study of QbD and its application in pharmaceutical product development.

**Unit-V**

**07**

**Hours**

Selection and quality control testing of packaging materials for pharmaceutical product development-regulatory considerations.

**Recommended Books (Latest editions)**

1. Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, Charles Bon; Marcel Dekker Inc.
2. Encyclopedia of Pharmaceutical Technology, edited by James Swarbrick, Third Edition, Informa Healthcare publishers.
3. Pharmaceutical Dosage Forms, Tablets, Volume II, edited by Herbert A. Lieberman And Leon Lachman; Marcel Dekker, Inc.
4. The Theory and Practice of Industrial Pharmacy, Fourth Edition, edited by Roop K Khar, S P Vyas, Farhan J Ahmad, Gaurav K Jain; CBS Publishers and Distributors Pvt. Ltd. 2013.
5. Martin's Physical Pharmacy and Pharmaceutical Sciences, Fifth Edition, edited by Patrick J. Sinko, BI Publications Pvt. Ltd.
6. Targeted and Controlled Drug Delivery, Novel Carrier Systems by S.P. Vyas and R. K. Khar, CBS Publishers and Distributors Pvt. Ltd, First Edition 2012.
7. Pharmaceutical Dosage Forms and Drug Delivery Systems, Loyd V. Allen Jr., Nicholas B. Popovich, Howard C. Ansel, 9th Ed. 40
8. Aulton's Pharmaceutics– The Design and Manufacture of Medicines, Michael E. Aulton, 3rd Ed.
9. Remington– The Science and Practice of Pharmacy, 20th Ed.
10. Pharmaceutical Dosage Forms– Tablets Vol 1 to 3, A. Liberman, Leon Lachman And Joseph B. Schwartz
11. Pharmaceutical Dosage Forms– Disperse Systems Vol 1 to 3, H.A. Liberman,

Martin, M. R and Gilbert S. Banker.

12. Pharmaceutical Dosage Forms—Parenteral Medication Vol 1 & 2, Kenneth E. Avis  
And H.A. Libermann.

13. Advanced Review Articles related to the topics.