


**Pharmacy Council of India**  
New Delhi

**Rules & Syllabus for the Bachelor  
of Pharmacy (B. Pharm) Course**

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[Framed under Regulation 6, 7 & 8 of the Bachelor of  
Pharmacy (B. Pharm) course regulations 2014]

  
PRINCIPAL  
NARASARAOPETA INSTITUTE OF  
PHARMACEUTICAL SCIENCES  
kotappakonda Road, YELLAMANDA (PO)  
NARASARAOPET - 522 601  
Guntur (Dt.), A.P.

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

**45 Hours**

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

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

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

### **Course Content:**

#### **Unit I**

**10 hours**

- **Introduction to human body**

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

- **Cellular level of organization**

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

- **Tissue level of organization**

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

#### **Unit II**

**10 hours**

- **Integumentary system**

Structure and functions of skin

- **Skeletal system**

Divisions of skeletal system, types of bone, salient features and functions of bones of axial and appendicular skeletal system  
Organization of skeletal muscle, physiology of muscle contraction, neuromuscular junction



- **Joints**

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

### Unit III

10 hours

- **Body fluids and blood**

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

- **Lymphatic system**

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

### Unit IV

08 hours

**Peripheral nervous system:**

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

Origin and functions of spinal and cranial nerves.

- **Special senses**

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

### Unit V

07 hours

- **Cardiovascular system**

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

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

**4 Hours/week**

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

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

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

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
4. Text book of Medical Physiology- Arthur C, Guyton and John E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.

6. Textbook of Human Histology by Inderbir Singh, Jaypee brother's medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother's medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

**Reference Books (Latest Editions)**

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

## BP102T. PHARMACEUTICAL ANALYSIS (Theory)

45 Hours

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

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

- understand the principles of volumetric and electro chemical 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

(c)Pharmacopoeia, Sources of impurities in medicinal agents,limit tests.

#### UNIT-II

10 Hours

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

#### UNIT-III

10 Hours

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



#### UNIT-IV

08 Hours

##### Redox titrations

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

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

#### UNIT-V

07 Hours

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

## BP108P. PHARMACEUTICAL ANALYSIS (Practical)

4 Hours / Week

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

### Recommended Books: (Latest Editions)

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

### BP103T. PHARMACEUTICS- I (Theory)

45 Hours

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

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

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

##### UNIT – II

10 Hours

- **Pharmaceutical calculations:** Weights and measures – Imperial & Metric system, Calculations involving percentage solutions, alligation, proof spirit and isotonic solutions based on freezing point and molecular weight.
- **Powders:** Definition, classification, advantages and disadvantages, Simple & compound powders – official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.
- **Liquid dosage forms:** Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques

### UNIT – III

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 dosage forms



## BP109P. PHARMACEUTICS I (Practical)

3 Hours / week

### 1. Syrups

- a) Syrup IP'66
- b) Compound syrup of Ferrous Phosphate BPC'68

### 2. Elixirs

- a) Piperazine citrate elixir
- b) Paracetamol pediatric elixir

### 3. Linctus

- a) Terpin Hydrate Linctus IP'66
- b) Iodine Throat Paint (Mandles Paint)

### 4. Solutions

- a) Strong solution of ammonium acetate
- b) Cresol with soap solution
- c) Lugol's solution

### 5. Suspensions

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

### 6. Emulsions

- a) Turpentine Liniment
- b) Liquid paraffin emulsion

### 7. Powders and Granules

- a) ORS powder (WHO)
- b) Effervescent granules
- c) Dusting powder
- d) Divided powders

### 8. Suppositories

- a) Glycero gelatin suppository
- b) Cocoa butter suppository
- c) Zinc Oxide suppository

### 8. Semisolids

- a) Sulphur ointment
- b) Non staining-iodine ointment with methyl salicylate
- c) Carbopal gel

### 9. Gargles and Mouthwashes

- a) Iodine gargle
- b) Chlorhexidine mouthwash

### Recommended Books: (Latest Editions)

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

## BP104T. PHARMACEUTICAL INORGANIC CHEMISTRY (Theory)

45 Hours

**Scope:** This subject deals with the monographs of inorganic drugs and 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 radio isotopes - Sodium iodide  $I^{131}$ , Storage conditions, precautions & pharmaceutical application of radioactive substances.



## BP110P. PHARMACEUTICAL INORGANIC CHEMISTRY (Practical)

4 Hours / Week

- I **Limit tests for following ions**
  - Limit test for Chlorides and Sulphates
  - Modified limit test for Chlorides and Sulphates
  - Limit test for Iron
  - Limit test for Heavy metals
  - Limit test for Lead
  - Limit test for Arsenic
- II **Identification test**
  - Magnesium hydroxide
  - Ferrous sulphate
  - Sodium bicarbonate
  - Calcium gluconate
  - Copper sulphate
- III **Test for purity**
  - Swelling power of Bentonite
  - Neutralizing capacity of aluminum hydroxide gel
  - Determination of potassium iodate and iodine in potassium Iodide
- IV **Preparation of inorganic pharmaceuticals**
  - Boric acid
  - Potash alum
  - Ferrous sulphate

### Recommended Books (Latest Editions)

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

## BP105T.COMMUNICATION SKILLS (Theory)

30 Hours

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

### Objectives:

Upon completion of the course the student shall be able to

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

### Course content:

#### UNIT – I

07 Hours

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

#### UNIT – II

07 Hours

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

### UNIT – III

07 Hours

- **Basic Listening Skills:** Introduction, Self-Awareness, Active Listening, Becoming an Active Listener, Listening in Difficult Situations
- **Effective Written Communication:** Introduction, When and When Not to Use Written Communication - Complexity of the Topic, Amount of Discussion' Required, Shades of Meaning, Formal Communication
- **Writing Effectively:** Subject Lines, Put the Main Point First, Know Your Audience, Organization of the Message

### UNIT – IV

05 Hours

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

### UNIT – V

04 Hours

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

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

**2 Hours / week**

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

### **Basic communication covering the following topics**

Meeting People

Asking Questions

Making Friends

What did you do?

Do's and Dont's

### **Pronunciations covering the following topics**

Pronunciation (Consonant Sounds)

Pronunciation and Nouns

Pronunciation (Vowel Sounds)

### **Advanced Learning**

Listening Comprehension / Direct and Indirect Speech

Figures of Speech

Effective Communication

Writing Skills

Effective Writing

Interview Handling Skills

E-Mail etiquette

Presentation Skills



**Recommended Books: (Latest Edition)**

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

## BP 106RBT.REMEDIAL BIOLOGY (Theory)

30 Hours

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

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

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

#### Chemical coordination and regulation

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

#### Human reproduction

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

### UNIT IV

05 Hours

#### Plants and mineral nutrition:

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

#### Photosynthesis

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

### UNIT V

04 Hours

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

#### Plant growth and development

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

#### Cell - The unit of life

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

#### Tissues

- Definition, types of tissues, location and functions.

**Text Books**

- 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



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

**30 Hours**

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

#### **Reference Books**

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

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## BP 106RMT.REMEDIAL MATHEMATICS (Theory)

30 Hours

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

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

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

### Course Content:

#### UNIT – I

06 Hours

- **Partial fraction**

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

- **Logarithms**

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

- **Function:**

Real Valued function, Classification of real valued functions,

- **Limits and continuity :**

Introduction, Limit of a function, Definition of limit of a function ( $\epsilon - \delta$  definition),  $\lim_{x \rightarrow a} \frac{x^n - a^n}{x - a} = na^{n-1}$ ,  $\lim_{\theta \rightarrow 0} \frac{\sin \theta}{\theta} = 1$ ,

#### UNIT –II

06 Hours

- **Matrices and Determinant:**

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

### UNIT – III

06 Hours

- **Calculus**

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

### UNIT – IV

06 Hours

- **Analytical Geometry**

**Introduction:** Signs of the Coordinates, Distance formula,

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

**Integration:**

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

### UNIT-V

06 Hours

- **Differential Equations** : Some basic definitions, Order and degree, Equations in separable form, Homogeneous equations, Linear Differential equations, Exact equations, **Application in solving Pharmacokinetic equations**
- **Laplace Transform** : Introduction, Definition, Properties of Laplace transform, Laplace Transforms of elementary functions, Inverse Laplace transforms, Laplace transform of derivatives, Application to solve Linear differential equations, **Application in solving Chemical kinetics and Pharmacokinetics equations**

### Recommended Books (Latest Edition)

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

## Semester II



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

45 Hours

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

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

1. Explain the gross morphology, structure and functions of various organs of the human body.
2. Describe the various homeostatic mechanisms and their imbalances.
3. Identify the various tissues and organs of different systems of human body.
4. Perform the hematological tests like blood cell counts, 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:

#### Unit I

10 hours

- **Nervous system**

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

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

#### Unit II

06 hours

- **Digestive system**

Anatomy of GI Tract with special reference to anatomy and functions of stomach, ( Acid production in the stomach, regulation of acid production through parasympathetic nervous system, pepsin role in protein digestion) small intestine

and large intestine, anatomy and functions of salivary glands, pancreas and liver, movements of GIT, digestion and absorption of nutrients and disorders of GIT.

- **Energetics**

Formation and role of ATP, Creatinine Phosphate and BMR.

### **Unit III**

- **Respiratory system**

**10 hours**

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

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

- **Urinary system**

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

### **Unit IV**

**10 hours**

- **Endocrine system**

Classification of hormones, mechanism of hormone action, structure and functions of pituitary gland, thyroid gland, parathyroid gland, adrenal gland, pancreas, pineal gland, thymus and their disorders.

### **Unit V**

**09 hours**

- **Reproductive system**

Anatomy of male and female reproductive system, Functions of male and female reproductive system, sex hormones, physiology of menstruation, fertilization, spermatogenesis, oogenesis, pregnancy and parturition

- **Introduction to genetics**

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

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

**4 Hours/week**

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

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

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

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA



4. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
6. Textbook of Human Histology by Inderbir Singh, Jaypee brothers medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brothers medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

**Reference Books:**

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



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

45 Hours

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

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

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

### Course Content:

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

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

### UNIT-I

07 Hours

- **Classification, nomenclature and isomerism**

Classification of Organic Compounds

Common and IUPAC systems of nomenclature of organic compounds

(up to 10 Carbons open chain and carbocyclic compounds)

Structural isomerisms in organic compounds

### UNIT-II 10 Hours

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

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

Stabilities of alkenes, SP<sup>2</sup> hybridization in alkenes

E<sub>1</sub> and E<sub>2</sub> reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeff's orientation and evidences. E<sub>1</sub> versus E<sub>2</sub> reactions, Factors affecting E<sub>1</sub> and E<sub>2</sub> reactions. Ozonolysis, electrophilic addition reactions of alkenes, Markownikoff's orientation, free radical addition reactions of alkenes, Anti Markownikoff's orientation.

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

### UNIT-III 10 Hours

- **Alkyl halides\***

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

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

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

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

#### UNIT-IV 10 Hours

- **Carbonyl compounds\* (Aldehydes and ketones)**

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

#### UNIT-V

**08 Hours**

- **Carboxylic acids\***

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

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

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

**BP208P. 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/ boiling point.
  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, Lampman and Kriz.
9. Reaction and reaction mechanism by Ahluwalia/Chatwal.

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## BP203 T. BIOCHEMISTRY (Theory)

45 Hours

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

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

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

### Course Content:

#### UNIT I

08 Hours

- **Biomolecules**

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

- **Bioenergetics**

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

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

#### UNIT II

10 Hours

- **Carbohydrate metabolism**

Glycolysis – Pathway, energetics and significance

Citric acid cycle- Pathway, energetics and significance

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

Glycogen metabolism Pathways and glycogen storage diseases (GSD)

Gluconeogenesis- Pathway and its significance

Hormonal regulation of blood glucose level and Diabetes mellitus

- **Biological oxidation**

Electron transport chain (ETC) and its mechanism.

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Oxidative phosphorylation & its mechanism and substrate level phosphorylation

Inhibitors ETC and oxidative phosphorylation/Uncouplers

### UNIT III

10 Hours

- **Lipid metabolism**

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

Formation and utilization of ketone bodies; ketoacidosis

De novo synthesis of fatty acids (Palmitic acid)

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

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

- **Amino acid metabolism**

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

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

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

Catabolism of heme; hyperbilirubinemia and jaundice

#### **UNIT IV**

**10 Hours**

- **Nucleic acid metabolism and genetic information transfer**

Biosynthesis of purine and pyrimidine nucleotides

Catabolism of purine nucleotides and Hyperuricemia and Gout disease

Organization of mammalian genome

Structure of DNA and RNA and their functions

DNA replication (semi conservative model)

Transcription or RNA synthesis

Genetic code, Translation or Protein synthesis and inhibitors

## UNIT V

07 Hours

- **Enzymes**

Introduction, properties, nomenclature and IUB classification of enzymes

Enzyme kinetics (Michaelis plot, Line Weaver Burke plot)

Enzyme inhibitors with examples

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

Therapeutic and diagnostic applications of enzymes and isoenzymes

Coenzymes –Structure and biochemical functions

### BP 209 P. BIOCHEMISTRY (Practical)

4 Hours / Week

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

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

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

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

**45Hours**

**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**

**10Hours**

- **Basic principles of Cell injury and Adaptation:**

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



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

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

## Unit II

10Hours

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

## Unit II

10Hours

- **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

8 Hours

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

## Unit V

7 Hours

- **Infectious diseases:** Meningitis, Typhoid, Leprosy, Tuberculosis

Urinary tract infections

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

## Recommended Books (Latest Editions)

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1. Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins & Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier; 2014.
2. Harsh Mohan; Text book of Pathology; 6<sup>th</sup> edition; India; Jaypee Publications; 2010.
3. Laurence B, Bruce C, Bjorn K. ; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12<sup>th</sup> edition; New York; McGraw-Hill; 2011.
4. Best, Charles Herbert 1899-1978; Taylor, Norman Burke 1885-1972; West, John B (John Burnard); Best and Taylor's Physiological basis of medical practice; 12th ed; united states;
5. William and Wilkins, Baltimore; 1991 [1990 printing].
6. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston; Davidson's Principles and Practice of Medicine; 21<sup>st</sup> edition; London; ELBS/Churchill Livingstone; 2010.
7. Guyton A, John .E Hall; Textbook of Medical Physiology; 12<sup>th</sup> edition; WB Saunders Company; 2010.
8. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; 9<sup>th</sup> edition; London; McGraw-Hill Medical; 2014.
9. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6<sup>th</sup> edition; Philadelphia; WB Saunders Company; 1997.
10. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3<sup>rd</sup> edition; London; Churchill Livingstone publication; 2003.

#### **Recommended Journals**

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

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

**30 Hrs (2 Hrs/Week)**

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

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

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

### **Course content:**

#### **UNIT – I**

**06 hours**

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

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

#### **UNIT –II**

**06 hours**

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

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

#### **UNIT – III**

**06 hours**

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

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

#### **UNIT – IV**

**06 hours**

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

#### **UNIT-V**

**06 hours**

**Computers as data analysis in Preclinical development:**

Chromatographic data analysis(CDS), Laboratory Information management System (LIMS) and Text Information Management System(TIMs)



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

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

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

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

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

**30 hours**

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

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

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

### **Course content:**

#### **Unit-I**

**10hours**

The Multidisciplinary nature of environmental studies

Natural Resources

Renewable and non-renewable resources:

Natural resources and associated problems

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

#### **Unit-II**

**10hours**

Ecosystems

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

#### **Unit- III**

**10hours**

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, McGraw 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 III**



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

45 Hours

**Scope:** This subject deals with general methods of preparation and reactions of some organic compounds. Reactivity of organic compounds 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, Friedelcrafts alkylation- reactivity, limitations, Friedelcrafts acylation.
- C. Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction
- D. Structure and uses of DDT, Saccharin, BHC and Chloramine

### UNIT II

10 Hours

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

### UNIT III

10 Hours

- **Fats and Oils**

- a. Fatty acids – reactions.

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

#### UNIT IV

08 Hours

- **Polynuclear hydrocarbons:**

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

#### UNIT V

07 Hours

- **Cyclo alkanes\***

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

**BP305P. PHARMACEUTICAL ORGANIC CHEMISTRY -II (Practical)**

**4 Hrs/week**

**I Experiments involving laboratory techniques**

- Recrystallization
- Steam distillation

**II Determination of following oil values (including standardization of reagents)**

- Acid value
- Saponification value
- Iodine value

**III Preparation of compounds**

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

**Recommended Books (Latest Editions)**

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



8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.

**BP302T. 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  $\text{CCl}_4$  and water
5. Determination of % composition of NaCl in a solution using phenol-water system by CST method
6. Determination of surface tension of given liquids by drop count and drop weight method
7. Determination of HLB number of a surfactant by saponification method
8. Determination of Freundlich and Langmuir constants using activated char coal
9. Determination of critical micellar concentration of surfactants
10. Determination of stability constant and donor acceptor ratio of PABA-Caffeine complex by solubility method
11. Determination of stability constant and donor acceptor ratio of Cupric-Glycine complex by pH titration method

**Recommended Books: (Latest Editions)**

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

## **BP 303 T. PHARMACEUTICAL MICROBIOLOGY (Theory)**

**45Hours**

### **Scope:**

- Study of all categories of microorganisms 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 amino acids.

Assessment of a new antibiotic.

### **Unit V**

**07Hours**

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

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

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

Application of cell cultures in pharmaceutical industry and research.



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

**4 Hrs/week**

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

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

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4<sup>th</sup> edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Pepler: Microbial Technology.
9. I.P., B.P., U.S.P.- latest editions.
10. Ananthnarayan : Text Book of Microbiology, Orient-Longman, Chennai
11. Edward: Fundamentals of Microbiology.
12. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
13. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company

## 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 carry out various test to prevent environmental pollution.
5. To appreciate and comprehend significance of plant lay out design for optimum use of resources.
6. To appreciate the various preventive methods used for corrosion control in Pharmaceutical industries.

### Course content:

#### UNIT-I

10 Hours

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

#### UNIT-II

10 Hours

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

- **Evaporation:** Objectives, applications and factors influencing evaporation, differences between evaporation and other heat process. principles, construction, working, uses, merits and demerits of Steam jacketed kettle, horizontal tube evaporator, climbing film evaporator, forced circulation evaporator, multiple effect evaporator & Economy of multiple effect evaporator.
- **Distillation:** Basic Principles and methodology of simple distillation, flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation

### UNIT- III

08 Hours

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

### UNIT-IV

08 Hours

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

### UNIT- V

07 Hours

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



**Recommended Books: (Latest Editions)**

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



### BP308P - PHARMACEUTICAL ENGINEERING (Practical)

4 Hours/week

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

## SEMESTER IV

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

**45 Hours**

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

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

1. understand the methods of preparation and properties of organic compounds
2. explain the stereo chemical aspects of organic compounds and stereo chemical 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, meso compounds

Elements of symmetry, chiral and achiral molecules

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

Reactions of chiral molecules

Racemic modification and resolution of racemic mixture.

Asymmetric synthesis: partial and absolute

#### **UNIT-II**

**10 Hours**

Geometrical isomerism

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

Methods of determination of configuration of geometrical isomers.

Conformational isomerism in Ethane, n-Butane and Cyclohexane.

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

Stereospecific and stereoselective reactions

#### **UNIT-III**

**10 Hours**

PRINCIPAL  
NARASARAOPETA INSTITUTE OF  
PHARMACEUTICAL SCIENCES  
kotappakonda Road, NE LAKANDA (PO)  
NARASARAOPETA - 522 601  
Guntur (Dt.), A.P.

**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 stereo chemical 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: Hydroxyamphetamine, Pseudoephedrine, Propylhexedrine.
- Agents with mixed mechanism: Ephedrine, Metaraminol.

#### **Adrenergic Antagonists:**

**Alpha adrenergic blockers:** Tolazoline\*, Phentolamine, Phenoxylbenzamine, 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, Tacrine hydrochloride, Ambenonium chloride, Isoflurophate, Echothiophate iodide, Parathion, Malathion.

**Cholinesterase reactivator:** Pralidoxime chloride.

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

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

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

### **UNIT- IV**

**08 Hours**

#### **Drugs acting on Central Nervous System**

### **A. Sedatives and Hypnotics:**

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

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

#### **Miscellaneous:**

Amides & imides: Glutethimide.

Alcohol & their carbamate derivatives: Meprobamate, Ethchlorvynol.

Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

### **B. Antipsychotics**

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

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

**Fluorobutyrophenones:** Haloperidol, Droperidol, Risperidone.

**Beta amino ketones:** Molindone hydrochloride.

**Benzamides:** Sulpieride.

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

**Barbiturates:** Phenobarbitone, Methobarbital. **Hydantoins:**

Phenytoin\*, Mephénytoin, Ethoin **Oxazolidine diones:**

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.



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

**4 Hours/Week**

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

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

### **II Assay of drugs**

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

### **III Determination of Partition coefficient for any two drugs**

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

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.

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

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

45Hours

**Scope:** The course deals with the various physical 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

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

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

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

**3 Hrs/week**

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

**Recommended Books: (Latest Editions)**

1. Physical Pharmacy by Alfred Martin, Sixth edition
2. Experimental pharmaceutics by Eugene, Parott.
3. Tutorial pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical calculations, Lea & Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, Marcel Dekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C, and Manavalan R.

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

45 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/sub cellular/ macromolecular levels.
3. Apply the basic pharmacological knowledge in the prevention and treatment of various diseases.
4. Observe the effect of drugs on animals by simulated experiments
5. Appreciate correlation of pharmacology with other bio medical sciences

### Course Content:

#### UNIT-I

08 hours

##### 1. General Pharmacology

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

#### 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 antagonists
- e. Drug addiction, drug abuse, tolerance and dependence.



### BP 408 P.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, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert,
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,

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

**45 Hours**

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

**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 carry out the microscopic and morphological evaluation of crude drugs

### **Course Content:**

#### **UNIT-I**

**10 Hours**

##### **Introduction to Pharmacognosy:**

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

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

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

##### **Quality control of Drugs of Natural Origin:**

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

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

#### **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





**BP408 P. PHARMACOGNOSY AND PHYTOCHEMISTRY I (Practical)**


**4 Hours/Week**

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

**Recommended Books: (Latest Editions)**

1. W.C. Evans, Trease and Evans Pharmacognosy, 16<sup>th</sup> edition, W.B. Saunders & Co., London, 2009.
2. Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9<sup>th</sup> Edn., Lea and Febiger, Philadelphia, 1988.
3. Text Book of Pharmacognosy by T.E. Wallis
4. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
5. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhale (2007), 37<sup>th</sup> Edition, Nirali Prakashan, New Delhi.
6. Herbal drug industry by R.D. Choudhary (1996), 1<sup>st</sup> Edn, Eastern Publisher, New Delhi.
7. Essentials of Pharmacognosy, Dr. S.H. Ansari, 1<sup>st</sup> edition, Birla publications, New Delhi, 2007
8. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhale
9. Anatomy of Crude Drugs by M.A. Iyengar

## SEMESTER V

  
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## BP501T. MEDICINAL CHEMISTRY – II (Theory)

45 Hours

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

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

1. Understand the chemistry of drugs with respect to their pharmacological activity
2. Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
3. Know the 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<sub>1</sub>-antagonists:** Diphenhydramine hydrochloride\*, Dimenhydrinate, Doxylamines succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride\*, Phenidamine tartarate, Promethazine hydrochloride\*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium

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

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

**Anti-neoplastic agents:**

**Alkylating agents:** Meclorethamine\*, 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\*, Pentaerythritol tetranitrate, Isosorbide dinitrite\*, Dipyridamole.

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

### Diuretics:

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

Thiazides: Chlorthiazide\*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide,

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

Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride.

Osmotic Diuretics: Mannitol

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

## 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, Cholestamine 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, Progesterones, Oestriol, Oestradiol, Oestrone, 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, Mepylcaine, Cyclomethycaine, Piperocaine.

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

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

**Miscellaneous:** Phenacaine, Dipreron, 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.

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## BP 502 T. Industrial PharmacyI (Theory)

**45 Hours**

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

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

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

### Course content:

**3 hours/ week**

#### UNIT-I

**07 Hours**

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

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

**b. Chemical Properties:** Hydrolysis, oxidation, reduction, racemisation, polymerization

BCS classification of drugs & 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 eye drops, eye ointments and eye lotions; methods of preparation; labeling, containers; evaluation of ophthalmic preparations

### UNIT-V

10 Hours

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

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

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



### **BP 506 P. Industrial PharmacyI (Practical)**

**4 Hours/week**

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

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

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

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

**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**

**10hours**

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

- a. Introduction to hemodynamic and electrophysiology of heart.
- b. Drugs used in congestive heart failure
- c. Anti-hypertensive drugs.
- d. Anti-anginal drugs.
- e. Anti-arrhythmic drugs.
- f. Anti-hyperlipidemic drugs.

#### **UNIT-II**

**10hours**

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

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

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


- a. Diuretics
- b. Anti-diuretics.

#### **UNIT-III**

**10hours**

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

- a. Introduction to autocoids 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

  
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**UNIT-IV****08hours****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.
- d. Insulin, Oral Hypoglycemic agents and glucagon.
- e. ACTH and corticosteroids.

**UNIT-V****07hours****5. Pharmacology of drugs acting on endocrine system**

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

**6. Bioassay**

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

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

4Hrs/Week

1. Introduction to *in-vitro* pharmacology and physiological salt solutions.
2. Effect of drugs on isolated frog heart.
3. Effect of drugs on blood pressure and heart rate of dog.
4. Study of diuretic activity of drugs using rats/mice.
5. DRC of acetylcholine using frog rectus abdominis muscle.
6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively.
7. Bioassay of histamine using guinea pig ileum by matching method.
8. Bioassay of oxytocin using rat uterine horn by interpolation method.
9. Bioassay of serotonin using rat fundus strip by three point bioassay.
10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
11. Determination of  $PA_2$  value of prazosin using rat anococcygeus muscle (by Schilds plot method).
12. Determination of  $PD_2$  value using guinea pig ileum.
13. Effect of spasmogens and spasmolytics using rabbit jejunum.
14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
15. Analgesic activity of drug using central and peripheral methods

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

### Recommended Books (Latest Editions)

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



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

**45Hours**

**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 carryout isolation and identification of phytoconstituents

### **Course Content:**

#### **UNIT-I**

**7 Hours**

##### **Metabolic pathways in higher plants and their determination**

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

#### **UNIT-II**

**14 Hours**

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

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

**Phenylpropanoids and Flavonoids:** Lignans, Tea, Ruta

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

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

**Tannins:** Catechu, Pterocarpus

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

**Glycosides:** Senna, Aloes, Bitter Almond

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

#### **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**

**8 Hours**

##### **Basics of Phytochemistry**

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

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

**4 Hours/Week**

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

  
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## **BP 505 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. Forensic Pharmacy by B. Suresh

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

**SEMESTER VI**



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

45 Hours

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

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

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

#### Course Content:

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

#### UNIT – I

10 Hours

##### Antibiotics

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

**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 dihydro triazines:** Cycloguanil pamoate, Proguanil.

**Miscellaneous:** Pyrimethamine, Artesunate, Artemether, Atovaquone.

### UNIT – III

10 Hours

#### Anti-tubercular Agents

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

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

#### Urinary tract anti-infective agents

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

**Miscellaneous:** Furazolidine, Nitrofurantoin\*, Methanamine.

#### Antiviral agents:

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

### UNIT – IV

08 Hours

#### Antifungal agents:

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

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

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

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

### **Sulphonamides and Sulfones**

Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, 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 modeling and docking techniques.

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



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

4 Hours / week

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

- 1 Sulphanilamide
- 2 7-Hydroxy, 4-methyl coumarin
- 3 Chlorobutanol
- 4 Triphenyl imidazole
- 5 Tolbutamide
- 6 Hexamine

#### **II Assay of drugs**

- 1 Isonicotinic acid hydrazide
- 2 Chloroquine
- 3 Metronidazole
- 4 Dapsone
- 5 Chlorpheniramine maleate
- 6 Benzyl penicillin

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

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

#### **V Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinskies RO5)**

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

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.



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

## BP602 T. PHARMACOLOGY-III (Theory)

45 Hours

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

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

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

### Course Content:

#### UNIT-I

10hours

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

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

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

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

#### UNIT-II

10hours

##### 3. Chemotherapy

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

#### UNIT-III

10hours

##### 3. Chemotherapy

- a. Antitubercular agents
- b. Antileprotic agents

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

#### **UNIT-IV**

**08hours**

#### **3. Chemotherapy**

- l. Urinary tract infections and sexually transmitted diseases.
- m. Chemotherapy of malignancy.

#### **4. Immunopharmacology**

- a. Immunostimulants
- b. Immunosuppressant

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

#### **UNIT-V**

**07hours**

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

- a. Definition and basic knowledge of acute, subacute and chronic toxicity.
- b. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity
- c. General principles of treatment of poisoning
- d. Clinical symptoms and management of barbiturates, morphine, organophosphorus compound and lead, mercury and arsenic poisoning.

#### **6. Chronopharmacology**

- a. Definition of rhythm and cycles.
- b. Biological clock and their significance leading to chronotherapy.

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

4Hrs/Week

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

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

#### Recommended Books (Latest Editions)

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



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

**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 Gastro intestinal diseases.

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

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

#### **UNIT-III**

##### **Herbal Cosmetics**

**10 Hours**

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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 (ASU DTAB, ASU DCC), 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 609 P. HERBAL DRUG TECHNOLOGY (Practical)**

**4 hours/ week**

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

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

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



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

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 arising 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  
Hours**

**10**

**Introduction to  
Biopharmaceutics**

**Absorption;** Mechanisms of drug absorption through GIT, factors influencing drug absorption through GIT, absorption of drug from Non per oral extra-vascular routes, **Distribution** Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs

**UNIT- II  
Hours**

**10**

**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 -  $K_E$ ,  $t_{1/2}$ ,  $AD$ ,  $AB$ ,  $AB$ ,  $CL$  and  $CL_R$ - definitions methods of eliminations, understanding of their significance and application

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

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

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

**Nonlinear Pharmacokinetics:** a. Introduction, b. Factors causing Non-linearity.  
c. Michaelis-menton method of estimating parameters, Explanation with example of drugs.

**Recommended Books: (Latest Editions)**

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition, Prentice-Hall International edition. USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmanekar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: By Milo Gibaldi Donald, R. Marcel Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick
8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febiger, Philadelphia, 1995.
10. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
11. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Robert F Notari Marcel Dekker Inc, New York and Basel, 1987.
12. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania

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

**45 Hours**

### **Scope:**

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

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

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

### **Unit I**

**10 Hours**

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

08Hours

- 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. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal

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Society of Chemistry.

5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

  
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## **BP606TPHARMACEUTICAL 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 & ISO14000:** 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 Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities

#### UNIT – IV

08 Hours

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

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

#### UNIT – V

07 Hours

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

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

## SEMESTER VII

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

**45 Hours**

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

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

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

### **Course Content:**

#### **UNIT –I**

**10 Hours**

##### **UV Visible spectroscopy**

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

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

Applications - Spectrophotometric titrations, Single component and multi component analysis

##### **Fluorimetry**

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

#### **UNIT –II**

**10 Hours**

##### **IR spectroscopy**

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

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

**Flame Photometry**-Principle, interferences, instrumentation and applications

**Atomic absorption spectroscopy-** Principle, interferences, instrumentation and applications

**Nepheloturbidometry-** Principle, instrumentation and applications

### **UNIT –III**

**10 Hours**

#### **Introduction to chromatography**

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

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

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

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

### **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

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

**4 Hours/Week**

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

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

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



## BP 702 T. INDUSTRIAL PHARMACYII (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 ISO 9000 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<sup>th</sup> April available at [http://en.wikipedia.org/wiki/Regulatory\\_Affairs](http://en.wikipedia.org/wiki/Regulatory_Affairs).
2. International Regulatory Affairs Updates, 2005. available at <http://www.iraup.com/about.php>
3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
4. Regulatory Affairs brought by learning plus, inc. available at <http://www.cgmp.com/ra.htm>.

## BP 703T. PHARMACY PRACTICE (Theory)

45 Hours

**Scope:** In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. In community pharmacy, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient 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 counseling in community pharmacy;
10. appreciate the concept of Rational drug therapy.

### Unit I:

10 Hours

#### a) Hospital and its organization

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

#### b) Hospital pharmacy and its organization

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

#### c) Adverse drug reaction

Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting

drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management.

**d) Community Pharmacy**

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

**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) information services**

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

**c) Patient**

**counseling**

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

**d) Education and training program in the hospital**

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

**e) Prescribed medication order and communication skills**

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

**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

**Recommended Books (Latest Edition):**

1. Merchant S.H. and Dr. J.S.Quadry. *A textbook of hospital pharmacy*, 4th ed. Ahmadabad: B.S. Shah Prakakshan; 2001.
2. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. *A textbook of Clinical Pharmacy Practice- essential concepts and skills*, 1<sup>st</sup> ed. Chennai: Orient Longman Private Limited; 2004.
3. William E. Hassan. *Hospital pharmacy*, 5th ed. Philadelphia: Lea & Febiger; 1986.
4. Tipnis Bajaj. *Hospital Pharmacy*, 1<sup>st</sup> 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 & Distributers; 2008.

**Journals:**

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

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## BP 704T: NOVEL DRUG DELIVERY SYSTEMS (Theory)

45 Hours

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

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

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

### Course content:

#### Unit-I

10 Hours

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

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

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

#### Unit-IV

08 Hours

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

**Unit-V**

**07 Hours**

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

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

**Recommended Books: (Latest Editions)**

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

**Journals**

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

## SEMESTER VIII



## **BP801T. 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, (One way 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 Plot graph

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

#### **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<sup>®</sup>, 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. NewYork.
2. Fundamental of Statistics – Himalaya Publishing House- S.C.Guptha
3. Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam,
4. Design and Analysis of Experiments – Wiley Students Edition, Douglas and C. Montgomery

## 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 healthcare 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:** Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health

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

#### Unit II:

10 Hours

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

#### Unit III:

10 Hours

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

**Recommended Journals:**

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



## **BP803ET. 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 life cycle, 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 MC GrawHill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S & Nanakamari, S: Marketing Managemnt:Global Perspective, IndianContext,Macmilan India, New Delhi.
7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.

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## **BP804 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**

**10Hours**

##### **New Drug Discovery and development**

Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

#### **Unit II**

**10Hours**

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

Approval processes and 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**

**10Hours**

##### **Registration of Indian drug product in overseas market**

Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical



Document (eCTD), ASEAN Common Technical Document (ACTD) research.

#### **Unit IV**

**08Hours**

##### **Clinical trials**

Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safety monitoring in clinical trials

#### **Unit V**

**07Hours**

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

## BP 805T: PHARMACOVIGILANCE (Theory)

45 hours

**Scope:** This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions.

### Objectives:

*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 pre clinical, clinical and post approval phases of drugs' life cycle
9. Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
10. Pharmacovigilance Program of India (PvPI) 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 preventability assessment
- Management of adverse drug reactions

#### Basic terminologies used in pharmacovigilance

- Terminologies of adverse medication related events
- Regulatory terminologies

## **Unit II**

**10 hours**

### **Drug and disease classification**

- Anatomical, therapeutic and chemical classification of drugs
- International classification of diseases
- Daily defined doses
- International Non proprietary Names for drugs

### **Drug dictionaries and coding in pharmacovigilance**

- WHO adverse reaction terminologies
- MedDRA and Standardised MedDRA queries
- WHO drug dictionary
- Eudravigilance medicinal product dictionary

### **Information resources in pharmacovigilance**

- Basic drug information resources
- Specialised resources for ADRs

### **Establishing pharmacovigilance programme**

- Establishing in a hospital
- Establishment & operation of drug safety department in industry
- Contract 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, Healthcare facilities & Media



## Unit IV

8 Hours

### Safety data generation

- Pre clinical phase
- Clinical phase
- Post approval phase (PMS)

### ICH Guidelines for Pharmacovigilance

- Organization and objectives of ICH
- Expedited reporting
- Individual case safety reports
- Periodic safety update reports
- Post approval expedited reporting
- Pharmacovigilance planning
- Good clinical practice in pharmacovigilance studies

## 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: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert, Jones & Bartlett Publishers.
7. Textbook of Pharmacoepidemiology edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills: G. Parthasarathi, Karin Nyfort Hansen, Milap C. Nahata
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal

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11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna

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12. <http://www.who.unc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297>
13. <http://www.ich.org/>
14. <http://www.cioms.ch/>
15. <http://cdsco.nic.in/>
16. [http://www.who.int/vaccine\\_safety/en/](http://www.who.int/vaccine_safety/en/)
17. [http://www.ipc.gov.in/PvPI/pv\\_home.html](http://www.ipc.gov.in/PvPI/pv_home.html)

## **BP 806 ET. QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Theory)**

**Scope:** In this subject the student learns about the various methods and guidelines for evaluation and standardization of herbs and herbal drugs. The subject also provides an opportunity for the student to learn cGMP, GAP and GLP in traditional system of medicines.

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

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

### **Unit I**

**10 hours**

Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms

WHO guidelines for quality control of herbal drugs.

Evaluation of commercial crude drugs intended for use

### **Unit II**

**10 hours**

**Quality assurance in herbal drug industry** of cGMP, GAP, GMP and GLP in traditional system of medicine.

WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines

WHO Guidelines on GACP for Medicinal Plants.

### **Unit III**

**10 hours**

EU and ICH guidelines for quality control of herbal drugs.

Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

### **Unit IV**

**08 hours**

Stability testing of herbal medicines. Application of various chromatographic techniques in standardization of herbal products.

Preparation of documents for new drug application and export registration

GMP requirements and Drugs & Cosmetics Act provisions.

## Unit V

07 hours

Regulatory requirements for herbal medicines.

WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems

Comparison of various Herbal Pharmacopoeias.

Role of chemical and biological markers in standardization of herbal products

### Recommended Books: (Latest Editions)

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I, Carrier Pub., 2006.
4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8.
8. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
9. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981.
10. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
11. WHO. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.
12. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.



## BP 807 ET. COMPUTER AIDED DRUG DESIGN (Theory)

45 Hours

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

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

- 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 modeling 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:** Bioisosterism, 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 Taft's 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. *De novo* drug design.

#### UNIT-IV

08 Hours

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

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

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

**45 Hours**

**Scope:**

- Cell biology is a branch of biology that studies cells – their physiological properties, their structure, the organelles they contain, interactions with their environment, their life cycle, division, death and cell function.
- This is done both on a microscopic and molecular level.
- Cell biology research encompasses both the great diversity of single-celled organisms like bacteria and protozoa, as well as the many specialized cells in multi-cellular organisms such as humans, plants, and sponges.

**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**

**10Hours**

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

**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, 4<sup>th</sup> edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. Edward: Fundamentals of Microbiology.
10. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
11. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
12. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
13. RA Goldshy et. al., : Kuby Immunology.



## BP809ET. COSMETIC SCIENCE(Theory)

45Hours

### UNIT I

10Hours

Classification of cosmetic and cosmeceutical products

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

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

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

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

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

### UNIT II

10 Hours

**Principles of formulation and building blocks of skin care products:**

Face wash,

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

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

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

Conditioning shampoo, Hair conditioner, anti-dandruff shampoo.

Hair oils.

Chemistry and formulation of Para-phenylene diamine based hair dye.

Principles of formulation and building blocks of oral care products:

Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.

### UNIT III

10 Hours

Sun protection, Classification of Sunscreens and SPF.

**Role of herbs in cosmetics:**

Skin Care: Aloe and turmeric

Hair care: Henna and amla.

Oral care: Neem and clove

**Analytical cosmetics:** BIS specification and analytical methods for shampoo, skin-cream and toothpaste.

### 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.

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## 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

<b>Unit –I</b>	<b>08 Hours</b>
<b>Laboratory Animals:</b> 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.	
<b>Unit –II</b>	<b>10 Hours</b>
<b>Preclinical screening models</b> 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. <b>Study of screening animal models for</b> Diuretics, nootropics, anti-Parkinson's, antiasthmatics, <b>Preclinical screening models:</b> for CNS activity- analgesic, antipyretic, anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease	

<b>Unit –III</b>  <b>Preclinical screening models:</b> for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics	
<b>Unit –IV</b>  <b>Preclinical screening models:</b> for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslipidemic, anti aggregatory, coagulants, and anticoagulants Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.	
<b>Research methodology and Bio-statistics</b> 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	<b>05 Hours</b>

**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 immuno assay

**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, Gingko, 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) Phyto estrogens : Isoflavones, daidzein, Geestustin, lignans
- g) Tocopherols
- h) Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.

### 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.

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- b) 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 nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E,  $\alpha$ - Lipoic acid, melatonin  
Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole.
- c) Functional foods for chronic disease prevention

#### 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 Sri Lakshmi
2. Role of dietary fibres and nutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPublication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch 2<sup>nd</sup> 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

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**Semester VIII – Elective course on Pharmaceutical Product Development**

**No of Hours: 3**

**Tutorial:1**

**Credit points:4**

**Unit-I**

**10 Hours**

Introduction to pharmaceutical product development, objectives, 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.

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### **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 R. 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.



# 2016

## THE MASTER OF PHARMACY (M. PHARM.) COURSE REGULATION 2014

(BASED ON NOTIFICATION IN THE GAZETTE OF INDIA No. 362, DATED DECEMBER 11, 2014)

## SCHEME AND SYLLABUS



**PHARMACY COUNCIL OF INDIA**

Combined Council's Building, Kotla Road,  
Aiwan-E-Ghalib Marg, New Delhi-110 002.  
Website : [www.pci.nic](http://www.pci.nic).

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## PHARMACEUTICS (MPH)

### SEMESTER - I

#### MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)

##### Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

##### Objectives

After completion of course student is able to know,

- 1 Chemicals and Excipients
- 1 The analysis of various drugs in single and combination dosage forms
- 1 Theoretical and practical skills of the instruments

##### THEORY

60 HOURS

- |    |   |        |
|----|---|--------|
| 1. | a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.   | 11 Hrs |
|    | b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy  |        |
|    | c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.   |        |
|    | d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.  |        |
| 2  | NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and <sup>13</sup> C NMR. Applications of NMR spectroscopy. | 11 Hrs |

- |   |  |           |
|---|--|-----------|
| 3 | Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Metastable ions, Isotopic peaks and Applications of Mass spectroscopy  | 11<br>Hrs |
| 4 | Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:<br>a) Paper chromatography<br>b) Thin Layer chromatography<br>c) Ion exchange chromatography<br>d) Column chromatography<br>e) Gas chromatography<br>f) High Performance Liquid chromatography<br>g) Affinity chromatography  | 11<br>Hrs |
| 5 | a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:<br>a) Paper electrophoresis                      b) Gel electrophoresis<br>c) Capillary electrophoresis                d) Zone electrophoresis<br>e) Moving boundary electrophoresis      f) Iso electric focusing<br>b. X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction. | 11<br>Hrs |
| 6 | Immunological assays : RIA (Radio immuno assay), ELISA, Bioluminescence assays.  | 5 Hrs     |

## REFERENCES

1. Spectrometric Identification of Organic compounds –Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5<sup>th</sup> edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7<sup>th</sup> edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation – PD Sethi, 3<sup>rd</sup> Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis –Modern methods –Part B- JW Munson, Volume 11, Marcel Dekker Series



## DRUG DELIVERY SYSTEMS

(MPH 102T)

### SCOPE

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

### OBJECTIVES

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

- ▮ The various approaches for development of novel drug delivery systems.
- ▮ The criteria for selection of drugs and polymers for the development of delivering system.
- ▮ The formulation and evaluation of Novel drug delivery systems.

### THEORY

60 Hrs

1. Sustained Release (SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy. 10 Hrs
2. Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals. 10 Hrs
3. Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of mucoadhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations. 10 Hrs
4. Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers. 06 Hrs

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|---|--|--------|
| 5 | Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation. | 10 Hrs |
| 6 | Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.        | 08 Hrs |
| 7 | Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.                              | 06 Hrs |

#### REFERENCES

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

#### JOURNALS

1. Indian Journal of Pharmaceutical Sciences
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable



## MODERN PHARMACEUTICS (MPH 103T)

### Scope

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

### Objectives

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

- 1 The elements of preformulation studies.
- 1 The Active Pharmaceutical Ingredients and Generic drug Product development
- 1 Industrial Management and GMP Considerations.
- 1 Optimization Techniques & Pilot Plant Scale Up Techniques
- 1 Stability Testing, sterilization process & packaging of dosage forms.

### THEORY

60HRS

1. a. Preformation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation. 10 Hrs
- b. Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation 10 Hrs
- 2 Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ& P.Q. of facilities. 10 Hrs
- 3 cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management. 10 Hrs

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|---|---|--------|
| 4 | Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.   | 10 Hrs |
| 5 | Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation, Chi square test, students T-test, ANOVA test. | 10 Hrs |

## REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol.1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S.Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred Martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H. Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P. Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I-III.



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|---|---|-----------|
| 2 | CMC, post approval regulatory affairs. Regulation for combination products and medical devices. CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.   | 12<br>Hrs |
| 3 | Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).   | 12<br>Hrs |
| 4 | Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials. | 12<br>Hrs |

#### REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by IraR. Berryand Robert P.Martin, Drugs and the Pharmaceutical Sciences, Vol. 185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5<sup>th</sup> edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4. Guide book 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. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
7. [www.ich.org/](http://www.ich.org/)
8. [www.fda.gov/](http://www.fda.gov/)
9. [europa.eu/index\\_en.htm](http://europa.eu/index_en.htm)
10. <https://www.tga.gov.au/tga-basics>

## PHARMACEUTICS PRACTICAL - I

### (MPH 105PA)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. To carry out preformulation studies of tablets.
8. To study the effect of compressional force on tablets disintegration time.
9. To study Micromeritic properties of powders and granulation.

## PHARMACEUTICS PRACTICAL - II

### (MPH 105PB)

1. To study the effect of particle size on dissolution of a tablet.
2. To study the effect of binders on dissolution of a tablet.
3. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.
4. To perform In-vitro dissolution profile of CR/ SR marketed formulation
5. Formulation and evaluation of sustained release matrix tablets
6. Formulation and evaluation osmotically controlled DDS
7. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
8. Formulation and evaluation of Muco adhesive tablets.
9. Formulation and evaluation of trans dermal patches.



SEMESTER - II  
MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY &  
TARGETED DDS) (NTDS)  
(MPH 201T)

**Scope**

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

**Objectives**

Upon completion of the course student shall be able to understand

- 1 The various approaches for development of novel drug delivery systems.
- 1 The criteria for selection of drugs and polymers for the development of NTDS
- 1 The formulation and evaluation of novel drug delivery systems.

**THEORY**

60 Hrs

1. Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery. 12 Hrs
- 2 Targeting Methods: introduction preparation and evaluation. NanoParticles & Liposomes: Types, preparation and evaluation. 12 Hrs
- 3 Micro Capsules / Micro Spheres: Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes. 12 Hrs
- 4 Pulmonary Drug Delivery Systems: Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation. 12 Hrs
- 5 Nucleic acid based therapeutic delivery system: Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral genettransfer). Liposomal gene delivery systems. Bio distribution and Pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of future. 12 Hrs

**REFERENCES**

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.
3. N.K.Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001)

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## ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 202T)

### Scope

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students to clarify the concepts.

### Objectives

Upon completion of this course it is expected that students will be able understand,

- 1 The basic concepts in Biopharmaceutics and pharmacokinetics.
- 1 The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- 1 The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- 1 The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- 1 The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

### THEORY

60Hrs

1. Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH- partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of invivo data with invitro dissolution data. Transport model: Permeability - Solubility - Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.

12 Hrs

2. Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. Invitro-invivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.

12 Hrs



3. Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model –IV bolus, IV infusion, extra- vascular. Multicompartment model: two compartment- model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis–Menten equation, estimation of  $k_{max}$  and  $v_{max}$ . Drug interactions: introduction, the effect of protein-binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters. 12 Hrs
4. Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability, methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutical classification system, methods. Permeability: In- vitro, in-situ and In-vivo methods. generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution. 12 Hrs
5. Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Genetherapies. 12 Hrs



## REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmanekar and Sunil B. Jaiswal, Vallab Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land Yu ABC, 2<sup>nd</sup> edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thomas N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pamarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics, 1<sup>st</sup> edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009.
13. Absorption and Drug Development- Solubility, Permeability and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.

## COMPUTER AIDED DRUG DEVELOPMENT (MPH 203T)

### Scope

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

### Objectives

Upon completion of this course it is expected that students will be able to understand,

- 1 History of Computers in Pharmaceutical Research and Development
- 1 Computational Modeling of Drug Disposition
- 1 Computers in Preclinical Development
- 1 Optimization Techniques in Pharmaceutical Formulation
- 1 Computers in Market Analysis
- 1 Computers in Clinical Development
- 1 Artificial Intelligence (AI) and Robotics
- 1 Computational fluid dynamics (CFD)

### THEORY

60 Hrs

1. a. Computers in Pharmaceutical Research and Development: 12 Hrs  
A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling  
  
b. Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.
- 2 Computational Modeling Of Drug Disposition: Introduction, Modeling 12 Hrs  
Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution, Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.



- 3 Computer-aided formulation development: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis 12 Hrs
- 4
  - a. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fedvs.fasted state, In vitro dissolution and in vitro- in vivo correlation, Biowaiver considerations 12 Hrs
  - b. Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.
  - c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems
- 5 Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions. 12 Hrs

#### REFERENCES

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1<sup>st</sup> Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.



## FORMULATION DEVELOPMENT OF PHARMACEUTICAL AND COSMETIC PRODUCTS (MPH204T)

### Scope

This course is designed to impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D.

### Objectives

On completion of this course it is expected that students will be able to understand-  
The scheduled activities in a Pharmaceutical firm.

The pre formulation studies of pilot batches of pharmaceutical industry. The significance of dissolution and product stability

### THEORY

60 Hrs

1. Preformulation Studies: 12 Hrs  
Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.
2. Formulation Additives: 12 Hrs  
Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. Design of experiments – factorial design for product and process development.
3. Solubility & Dissolution: 12 Hrs  
Importance, experimental determination, phase- solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy. Theories and mechanisms of dissolution, in-vitro dissolution testing models – sink and non-sink. Factor influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Biorelevant media, in-vitro and in- vivo correlations, levels of correlations.
4. Product Stability: 12 Hrs  
Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf life assignment. Stability protocols, reports and ICH guidelines.
5. Cosmetics: 12 Hrs  
Formulation, Evaluation and packaging of the following cosmetic products: Dentrifices like tooth powders, pastes and gels. Manicure preparations like nail polish, lipsticks, eye lashes, Baby care products, Moisturizing cream, vanishing cream, cold cream, shampoo, Soaps and syndetbars

## REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy, 3<sup>rd</sup> ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2<sup>nd</sup> ed., CBS Publishers & distributors, New Delhi, 2005.
4. Conners KA. A Text book of pharmaceutical analysis Wells JL. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
5. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. Marcel Dekker Inc., New York, 1981
6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi, 2005.
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3<sup>rd</sup>ed., CBS publications, New Delhi, 2008.
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3<sup>rd</sup>ed., CBS Publishers & distributors, New Delhi, 2005.
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4<sup>th</sup> ed., Marcel Dekker Inc, New York, 2005.
11. W. Grimm - Stability testing of drug products.
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999.
13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I & II, 4<sup>th</sup>ed., CBS Publishers & distributors, New Delhi, 2004.
14. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
15. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
16. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
17. Encyclopaedia of Pharm. Technology, Vol I – III.
18. Wells J. I. Pharmaceutical Preformulation: The physicochemical properties of drug substances, Ellis Horwood Ltd. England, 1988.
19. Harry's Cosmeticology. 8<sup>th</sup> edition.
20. Poucher's perfume cosmetics and Soaps, 10<sup>th</sup> edition.
21. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma, 4<sup>th</sup> edition
22. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3<sup>rd</sup> edition.



### PHARMACEUTICS PRACTICAL - III (MPH 205PA)

1. To study the effect of temperature change, non solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by Winnoline<sup>R</sup> software
11. In vitro cell studies for permeability and metabolism

### PHARMACEUTICS PRACTICAL - IV (MPH 205PB)

1. DoE Using Design Expert<sup>®</sup> Software
2. Formulation data analysis Using Design Expert<sup>®</sup> Software
3. Quality-by-Design in Pharmaceutical Development
4. Computer Simulations in Pharmacokinetics and Pharmacodynamics
5. Computational Modeling Of Drug Disposition
6. To develop Clinical Data Collection manual
7. To carry out Sensitivity Analysis, and Population Modeling.
8. Development and evaluation of Creams
9. Development and evaluation of Shampoo and Toothpaste base
10. Formulation Development of Multi Vitamin Syrup
11. Use of Optimization techniques in Formulation Development of Tablets



## INDUSTRIALPHARMACY (MIP)

### SEMESTER - I

#### MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MIP 101T)

##### Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

##### Objectives

After completion of course student is able to know,

- 1 The analysis of various drugs in single and combination dosage forms
- 1 Theoretical and practical skills of the instruments

##### THEORY

60 Hrs

1. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.

11 Hrs

IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy

Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

- 2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and <sup>13</sup>C NMR. Applications of NMR spectroscopy.

11 Hrs

- 3 Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Metastable ions, Isotopic peaks and Applications of Mass spectroscopy.

11 Hrs

- 4 Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: 11 Hrs
- a) Paper chromatography                      b) Thin Layer chromatography
  - c) Ion exchange chromatography      d) Column chromatography
  - e) Gas chromatography
  - f) High Performance Liquid chromatography
  - g) Affinity chromatography
- 5 Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: 11 Hrs
- a) Paper electrophoresis                      b) Gel electrophoresis
  - c) Capillary electrophoresis              d) Zone electrophoresis
  - e) Moving boundary electrophoresis f) Isoelectric focusing

X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

6. Immunological Assays: Radioimmunity assay (RIA), ELISA (Theory & practical) and knowledge on Bioluminescence assays. 5 Hrs

#### REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6<sup>th</sup> edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis- Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5<sup>th</sup> edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis-Willards, 7<sup>th</sup> edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4<sup>th</sup> edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3<sup>rd</sup> edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation- PD Sethi, 3<sup>rd</sup> Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods– Part B-JW Munson, Vol 11, Marcel Dekker Series.



## PHARMACEUTICAL FORMULATION DEVELOPMENT (MIP 102T)

### Scope

This course is designed to impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D.

### Objectives

On completion of this course it is expected that students will be able to understand-

- 1 The scheduled activities in a Pharmaceutical firm.
- 1 The pre formulation studies of pilot batches of pharmaceutical industry.
- 1 The significance of dissolution and product stability

### THEORY

60Hrs

1. Preformulation Studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination. 12 Hrs
- 2 Formulation Additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipients science. Design of experiments–factorial design for product and process development. 12 Hrs
- 3 Solubility: Importance, experimental determination, phase- solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy. 12 Hrs
- 4 Dissolution: Theories, mechanisms of dissolution, in-vitro dissolution testing models – sink and non-sink. Factors influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Biorelevant media, in-vitro and in-vivo correlations, levels of correlations. 12 Hrs
- 5 Product Stability: Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf life assignment. Stability protocols, reports and ICH guidelines. 12 Hrs



## REFERENCES

- 1 Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy, 3<sup>rd</sup> ed., Varghese Publishers, Mumbai, 1991.
- 2 Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5<sup>th</sup> ed., B.I. Publications Pvt. Ltd, Noida, 2006.
- 3 Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms and tablets Vol. I-III, 2 ed., CBS Publishers & distributors, New Delhi, 2005.
- 4 Connors KA. A Text book of pharmaceutical analysis Wells JL. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
- 5 Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. Marcel Dekker Inc., New York, 1981
- 6 Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi, 2005.
- 7 Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3<sup>rd</sup> ed., CBS publications, New Delhi, 2008.
- 8 Carstensen JT, Rhodes CT. Drug stability principles and practices, 3<sup>rd</sup> ed., CBS Publishers & distributors, New Delhi, 2005.
- 9 Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4<sup>th</sup> ed., Marcel Dekkar, Inc, ew York, 2005.
11. W.Grimm- Stability testing of drug products.
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999.
13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, 4<sup>th</sup> ed., Part I & II, 2004.
14. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
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16. United States Pharmacopoeia. United States Pharmacopoeial Convention, Inc, USA, 2003.
17. Encyclopaedia of Pharm. Technology, Vol I-III.
18. Wells J. I. Pharmaceutical Preformulation: The physicochemical properties of drug substances, Ellis Horwood Ltd. England, 1988.

## NOVEL DRUG DELIVERY SYSTEMS (MIP 103T)

### Scope

This course is designed to impart knowledge and skills necessary to train the students in the area of novel drug delivery systems.

### Objective

On completion of this course it is expected that students will be able to understand,

- 1 The need, concept, design and evaluation of various customized, sustained and controlled release dosage forms.
- 1 To formulate and evaluate various novel drug delivery systems.

### THEORY

60 Hrs

1. Concept & Models for NDDS: Classification of rate controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS—intermittent, zero order & first order release.  
Carriers for Drug Delivery: Polymers / co-polymers- introduction, classification, characterization, polymerization techniques, application in CDDS/NDDS, biodegradable & natural polymers. 12 Hrs
- 2 Study of Various DDS: Concepts, design, formulation & evaluation of controlled release oral DDS, Mucoadhesive DDS (buccal, nasal, pulmonary) Pulsatile, colon specific, liquid sustained release systems, Ocular delivery systems. 12 Hrs
- 3 Transdermal Drug Delivery Systems: Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems. 08 Hrs
- 4 Sub Micron Cosmeceuticals: Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, eye etc and its regulatory aspects. 04 Hrs
- 5 Targeted Drug Delivery Systems: Importance, concept, biological process and events involved in drug targeting, design, formulation & evaluation, methods in drug targeting – nanoparticles, liposomes, niosomes, pharmacosomes, resealed erythrocytes, microspheres, magnetic microspheres. Specialized pharmaceutical emulsions – multiple emulsions, micro-emulsions. 06 Hrs



6. Protein/Peptide Drug Delivery Systems: Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stabilization methods. 06 Hrs
7. Biotechnology in Drug Delivery Systems: Brief review of major areas- recombinant DNA technology, monoclonal antibodies, genetherapy. 06 Hrs
8. New trends for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy. 06 Hrs

#### REFERENCES

1. Novel Drug Delivery System, Y.W. Chein, Vol 50, Marcel Dekker, NY.
2. Controlled Drug Delivery Systems, Robinson, Vol 29, Marcel Dekker, NY.
3. Transdermal Controlled Systemic Medications, YW Chein, Vol 31, Marcel Dekker, NY.
4. Bioadhesive DDS, E.Mathiowitz, Vol 98, Marcel Dekker, NY.
5. Nasal System Drug Delivery, K.S.E.Su, Vol 39, Marcel Dekker, NY.
6. Drug Delivery Devices, Vol 32, PTyle Marcel Dekker, NY.
7. Polymers for Controlled Drug Delivery, P.J.Tarcha, CRC Press.
8. Pharmaceutical Biotechnology, Vyas, CBS, Delhi.
9. Biotechnology of Industrial Antibiotics, E.J.Vandamme, Marcel Dekker, NY.
10. Protein Formulation & Delivery, E.J.McNally, Vol 99, Marcel Dekker, NY.
11. Drug Targeting, M.H.Rubinstein, John Wiley, NY.



## INTELLECTUAL PROPERTY RIGHTS (MIP 104T)

### Scope

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in drug regulatory affairs.

### Objectives

On completion of this course it is expected that students will be able to understand,

- 1 Assist in Regulatory Audit process.
- 1 Establish regulatory guidelines for drug and drug products
- 1 The Regulatory requirements for contract research organization

### THEORY

60Hrs

- |   |        |
|---|--------|
| 1. Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patents earch. Parts of patents. Filling of patents.The essential elements of patent; Guidelines for preparation of laboratory notebook, Non-obviousness in Patent. | 12 Hrs |
| 2. Role of GATT, TRIPS and WIPO   | 12 Hrs |
| 3. Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating Indian Pharmaceutical sector.   | 12 Hrs |
| 4. Brief introduction to CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA.   | 12 Hrs |
| 5. Regulatory requirements for contract research organization. Regulations for Biosimilars  | 12 Hrs |

### REFERENCES:

1. Pharmaceutical Process Validation: By FraR.Berry and Robert A.Nash, Vol 57, 2<sup>nd</sup> Edition
2. Applied Production and Operation Management By Evans, Anderson and Williams
3. GMP for pharmaceuticals Material Management by K.K.Ahuja Published by CBS publishers
4. ISO 9000-Norms and explanations
5. GMP for pharmaceuticals – Willing S.H.Marcel and Dekker

## INDUSTRIAL PHARMACY PRACTICAL - I (MIP 105PA)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC /GC
4. Estimation of riboflavin/quinine sulphate by fluorimetry
5. Estimation of sodium/potassium by flame photometry
6. Effect of surfactants on the solubility of drugs.
7. Effect of pH on the solubility of drugs.
8. Stability testing of solution and solid dosage forms for photodegradation..
9. Stability studies of drugs in dosage forms at 25°C, 60% RH and 40°C, 75%RH.

## INDUSTRIAL PHARMACY PRACTICAL - II (MIP 105PB)

1. Compatibility evaluation of drugs and excipients (DSC & FTIR).
2. Preparation and evaluation of different polymeric membranes.
3. Formulation and evaluation of sustained release oral matrix tablet/ oral reservoir system.
4. Formulation and evaluation of microspheres /microcapsules.
5. Formulation and evaluation of transdermal drug delivery systems.
6. Design and evaluation of face wash, body- wash, creams, lotions, shampoo, toothpaste, lipstick.
7. Electrophoresis of protein solution.
8. Preparation and evaluation of Liposome delivery system.



SEMESTER - II  
ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS  
(MIP 201T)

**Scope**

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply Biopharmaceutics theories in practical problem solving.

**Objectives**

On completion of this course it is expected that students will be able to understand,

- 1 The basic concepts in Biopharmaceutics and pharmacokinetics.
- 1 The use of raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- To critically evaluate Biopharmaceutics studies involving drug product equivalency.
- To design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

**THEORY**

60 Hrs

1. Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting, pH-partition theory, Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with invitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods. 12 Hrs
2. Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance: Introduction, Biopharmaceutic Factors Affecting Drug Bioavailability, Rate- Limiting Steps in Drug Absorption, Physicochemical Nature of the Drug Formulation Factors Affecting Drug Product Performance, In Vitro: Dissolution and Drug Release Testing, Compendial Methods of Dissolution, Alternative Methods of Dissolution Testing, Meeting Dissolution Requirements, Problems of Variable Control in Dissolution Testing Performance of Drug Products: In Vitro-In Vivo Correlation, Dissolution Profile Comparisons, Drug Product Stability, Considerations in the Design of a Drug Product. 12 Hrs
3. Pharmacokinetics: Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model- IV bolus, IV 12 Hrs



infusion, Extra-vascular; Multi Compartment model: Two compartment-model in brief, Non-Linear Pharmacokinetics: Cause of non-linearity, Michaelis–Menten equation, Estimation  $K_{max}$  and  $V_{max}$ . Drug interactions: Introduction, The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450- based drug interactions, Drug interactions linked to transporters.

4. Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability, , Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Evaluation of the Data, Bioequivalence Example, Study Submission and Drug Review Process, The Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution. 12 Hrs
  
5. Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Relationship between Pharmacokinetics including Pharmacodynamics: Generation of a pharmacokinetic– pharmacodynamic (PKPD) equation, Pharmacokinetic and pharmacodynamic, interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs: Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Genetherapies. 12 Hrs

## REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4<sup>th</sup> edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A.Treatise, D.M.Brahmankar and Sunil B.Jaiswal., Vallab Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2<sup>nd</sup> edition, Connecticut Appleton CenturyCrofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick.J, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expande by Robert.E.Notari, Marcel Dekker Inc, New York and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M.Pemarowski, 1<sup>st</sup> edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics, 1<sup>st</sup> edition, Sunil SJambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009.
13. Absorption and Drug Development- Solubility, Permeability and Charge State, AlexAvdeef, John Wiley & Sons, Inc, 2003.



## SCALE UP AND TECHNOLOGY TRANSFER (MIP 202T)

### Scope

This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

### Objectives:

On completion of this course it is expected that students will be able to understand,

- 1. Manage the scale up process in pharmaceutical industry.
- 1. Assist in technology transfer.
- 1. To establish safety guidelines, which prevent industrial hazards.

### THEORY

- |  |        |
|--|--------|
|  | 60 Hrs |
| 1. Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parenteral and semisolid preparations.<br>Scale up: Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parenteral, NDDS products—stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology. | 12 Hrs |
| 2. Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vender qualification.  | 12 Hrs |
| 3. Equipment Qualification: Importance, IQ, OQ, PQ for equipments – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine. Aseptic room validation.   | 12 Hrs |
| 4. Process validation: Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.  | 12 Hrs |
| 5. Industrial safety: Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution.   | 12 Hrs |



## REFERENCES

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T.Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L.Lachman, H.A.Lieberman, Varghese Publ. Bombay.
5. Tablet machine instruments in pharmaceuticals, PRWatt, JohnWiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parenteral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1,2,3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan, Dehli.

## PHARMACEUTICAL PRODUCTION TECHNOLOGY (MIP 203T)

### Scope

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in Production

### Objectives

On completion of this course it is expected that students will be able to understand,

Handle the scheduled activities in a Pharmaceutical firm.

Manage the production of large batches of pharmaceutical formulations.

### THEORY

- |  |        |
|--|--------|
|  | 60 Hrs |
| 1. Improved Tablet Production: Tablet production process, unit operation improvements, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.<br>Coating Technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.   | 12 Hrs |
| 2 Parenteral Production: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.   | 12 Hrs |
| 3 Lyophilization & Spray drying Technology: Principles, process, freeze-drying and spray drying equipments.  | 12 Hrs |
| 4 Capsule Production: Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered.<br>Disperse Systems Production: Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion, problems encountered.<br>Packaging Technology: Types of packaging materials, machinery, labeling, package printing for different dosage forms. | 12 Hrs |
| 5. Air Handling Systems: Study of AHUs, humidity & temperature control, air filtration systems, dust collectors. Water Treatment Process: Techniques and maintenance – RO, DM, ultra – filtration, WFI.  | 12 Hrs |

## REFERENCES

1. The Theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publ, Bombay.
2. Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.
3. Pharmaceutical Dosage Forms, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
4. Pharmaceutical Dosage Forms, Parenteral medications, Vol 1, 2 by K.E.Avis, Marcel Dekker, NY.
5. Pharmaceutical Production Facilities, design and applications, by G.C.Cole, Taylor and Francis.
6. Dispersed System Vol 1,2,3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Product design and testing of polymeric materials by N.P.Chezerisionoff.
8. Pharmaceutical Project Management, T.Kennedy, Vol 86, Marcel Dekker, NY.
9. Packaging Pharmaceutical and Health Care, H.Lockhard.
10. Quality Control of Packaging Materials in Pharmaceutical Industry, Kharburn, Marcel Dekker, NY.
11. Freeze drying/ Lyophilization of Pharmaceuticals & Biological Products, L.Ray, Vol 96, Marcel Dekker, NY.
12. Tablet Machine Instrumentation InPharmaceutials, PR Watt, Ellis Horwoods, UK.



## ENTREPRENEURSHIP MANAGEMENT (MIP 204T)

### Scope

This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

### Objectives:

On completion of this course it is expected that students will be able to understand,

- 1 The Role of enterprise in national and global economy
- 1 Dynamics of motivation and concepts of entrepreneurship Demands
- 1 and challenges of Growth Strategies and Networking

### THEORY

60 Hrs

- |   |        |
|---|--------|
| 1. Conceptual Frame Work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management.   | 12 Hrs |
| 2. Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency –Concepts. Developing Entrepreneurial competencies-requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.                                      | 12 Hrs |
| 3. Launching and Organising an Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilisation - finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation. | 12 Hrs |
| 4. Growth Strategies And Networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth– Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study.  | 12 Hrs |
| 5. Preparing Project Proposal to start on New Enterprise Project work–Feasibility report; Planning, resource mobilization and implementation.   | 12 Hrs |

### REFERENCES

1. Akhauri, M.M.P. (1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R.D & Brush, C.G. (1996) The Women Entrepreneurs, D.C. Health & Co., Toronto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Irwin, INC, USA.
4. Meredith, G.G.etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C. (1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad ED II.

### INDUSTRIAL PHARMACY PRACTICAL - III (MIP 205PA)

1. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
2. Comparison of dissolution of two different marketed products /brands
3. Protein binding studies of a highly protein bound drug & poorly protein bound drug
4. Bioavailability studies of Paracetamol (Animal).
5. Pharmacokinetic and IVIVC data analysis by Winnoline R software
6. In vitro cell studies for permeability and metabolism

### INDUSTRIAL PHARMACY PRACTICAL - IV (MIP 205PB)

1. Formulation and evaluation of tablets
2. Formulation and evaluation of capsules
3. Formulation and evaluation of injections
4. Formulation and evaluation of emulsion
5. Formulation and evaluation of suspension.
6. Formulation and evaluation of enteric coating tablets.
7. Preparation and evaluation of a freeze dried formulation.
8. Preparation and evaluation of a spray dried formulation.



## PHARMACEUTICAL ANALYSIS (MPA)

### SEMESTER - I

#### MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA 101T)

##### Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

##### Objectives

After completion of course student is able to know about chemicals and excipients

- 1 The analysis of various drugs in single and combination dosage forms
- 1 Theoretical and practical skills of the instruments

##### THEORY

60 Hrs

1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. 10 Hrs
- b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.
- c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
- d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.
- 2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors, Influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and <sup>13</sup>C NMR. Applications of NMR spectroscopy. 10 Hrs
- 3 Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Metastable ions, Isotopic peaks and Applications of Mass spectroscopy. 10 Hrs



- 4 Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: 10 Hrs
- Thin Layer chromatography
  - High Performance Thin Layer Chromatography
  - Ion exchange chromatography
  - Column chromatography
  - Gas chromatography
  - High Performance Liquid chromatography
  - Ultra High Performance Liquid chromatography
  - Affinity chromatography
  - Gel Chromatography
5. a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: 10 Hrs
- a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Isoelectric focusing
  - b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction
6. a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. 10 Hrs
- b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

## REFERENCES

1. Spectrometric Identification of Organic compounds- Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5<sup>th</sup> edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis- Willards, 7<sup>th</sup> edition, CBS publishers.
4. Practical Pharmaceutical Chemistry- Beckett and Stenlake, Vol II, 4<sup>th</sup> edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3<sup>rd</sup> edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation- PD Sethi, 3<sup>rd</sup> Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern Methods- Part B- JW Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2<sup>nd</sup> edn., P.S Kalsi, Wileyestern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, K.A. Connors, 3<sup>rd</sup> Edition, John Wiley & Sons, 1982.



## ADVANCED PHARMACEUTICAL ANALYSIS (MPA 102T)

### Scope

This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradants, Stability testing of phytopharmaceuticals and their protocol preparation. It also covers the biological testing of various vaccines and their principle and procedure.

### Objective

After completion of the course students shall able to know,

- 1 Appropriate analytical skills required for the analytical method development.
- 1 Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.
- 1 Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products

### THEORY

60 Hrs

#### 1. Impurity and stability studies:

10 Hrs

Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines

Impurities in new drug products:

Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products

Impurities in residual solvents:

General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents.

#### 2 Elemental impurities:

10 Hrs

Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis

Stability testing protocols:

Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates. With practical considerations.

#### 3 Impurity profiling and degradant characterization: Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations.

10 Hrs



profiling and degradant characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products

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|---|--|--------|
| 4 | Stability testing of phytopharmaceuticals:<br>Regulatory requirements, protocols, HPTLC /HPLC finger printing, interactions and complexity.  | 10 Hrs |
| 5 | Biological tests and assays of the following:<br>a. Adsorbed Tetanus vaccine<br>c. Human anti haemophilic vaccine<br>e. Tetanus Anti toxin<br>g. Oxytocin<br>i. Antivenom. PCR, PCR studies for gene regulation, instrumentation<br>(Principle and Procedures) | 10 Hrs |
| 6 | Immunoassays (IA)<br>Basic principles, Production of antibodies, Separation of bound and unbound drug, Radio immunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.  | 10 Hrs |

## REFERENCES

1. Vogel's textbook of quantitative chemical analysis- Jeffery J Bassett, J. Mendham, R. C. Denney, 5<sup>th</sup> edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry- Beckett and Stenlake, Vol II, 4<sup>th</sup> Edition, CBS publishers, NewDelhi, 1997.
3. Textbook of Pharmaceutical Analysis- KA Connors, 3<sup>rd</sup> Edition, John Wiley & Sons, 1982.
4. Pharmaceutical Analysis-Higuchi, Brochmman and Hassen, 2<sup>nd</sup> Edition, Wiley – Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation– PD Sethi, 3<sup>rd</sup> Edition, CBS Publishers, New Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods- JW Munson– Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, NewDelhi, 1964.
8. Indian Pharmacopoeia, Vol I, II & III 2007, 2010, 2014.
9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005
12. Analytical Profiles of drug substances and Excipients– Harry G Brittan, Volume 21 – 30, Elsevier, 2005.
13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2<sup>nd</sup> edition, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

## PHARMACEUTICAL VALIDATION (MPA 103T)

### Scope

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

### Objectives

Upon completion of the subject student shall be able to

- 1 Explain the aspect of validation
- 1 Carry out validation of manufacturing processes
- 1 Apply the knowledge of validation to instruments and equipments
- 1 Validate the manufacturing facilities

### THEORY

60 Hrs

1. Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan. 12 Hrs  
Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT) Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re-Qualification (Maintaining status- Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments.
- 2 Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette. 12 Hrs
- 3 Validation of Utility systems: Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen. Cleaning Validation: Cleaning Validation- Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP). 12 Hrs
- 4 Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP. Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP5. 12 Hrs



- 5      General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices. 12 Hrs

#### REFERENCES

1. B.T.Loftus & R.A.Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol.129, 3<sup>rd</sup> Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3<sup>rd</sup> edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by TerveeksorDeeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2<sup>nd</sup> Edition, by Carleton & Agalloco, (MarcelDekker).
5. Michael Levin, Pharmaceutical Process Scale-Up, Drugs and Pharm.Sci. Series, Vol. 157, 2<sup>nd</sup> Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed ImtiazHaider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, PhillipA.Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and JamesAgalloco(Ed.), Marcel Dekker, 2<sup>nd</sup> Ed.
9. Analytical Method validation and Instrument Performance Verification by ChurgChan, HeimanLam, Y.C.Lee,Yue. Zhang, WileyInter Science.

## FOOD ANALYSIS

(MPA 104T)

### Scope

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products.

### Objectives

At completion of this course student shall be able to understand various analytical techniques in the determination of

- 1 Food constituents
- 1 Food additives
- 1 Finished food products
- 1 Pesticides in food
- 1 And also student shall have the knowledge on food regulations and legislations

### THEORY

60 Hrs

1. Carbohydrates: classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, Crude fibre and application of food carbohydrates  
Proteins: Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins. 12 Hrs
- 2 Lipids: Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fats and fatty foods.  
Vitamins: classification of vitamins, methods of analysis of vitamins, Principles of microbial assay of vitamins of B-series. 12 Hrs
- 3 Food additives: Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents.  
Pigments and synthetic dyes: Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes. 12 Hrs



- 4 General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including 12 Hrs adulterants and contaminants of milk.  
Analysis of fermentation products like wine, spirits, beer and vinegar.
- 5 Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products. 12 Hrs  
Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA.

#### REFERENCES

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Analysis of Food constituents– Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International, 18<sup>th</sup> edition, 2005.



## PHARMACEUTICAL ANALYSIS PRACTICAL - I (MPA 105PA)

- 1 Calibration of glass wares
- 2 Calibration of pH meter
- 3 Calibration of UV-Visible spectrophotometer
- 4 Calibration of FTIR spectrophotometer
- 5 Calibration of GC instrument
- 6 Calibration of HPLC instrument
- 7 Cleaning validation of any one equipment
- 8 Impurity profiling of drugs
- 9 Assay of official compounds by different titrations
- 10 Assay of official compounds by instrumental techniques.
- 11 Estimation of riboflavin/quinine sulphate by fluorimetry
- 12 Estimation of sodium/potassium by flame photometry
- 13 Quantitative determination of hydroxyl group.
- 14 Quantitative determination of aminogroup
- 15 Colorimetric determination of drugs by using different reagents

## PHARMACEUTICAL ANALYSIS PRACTICAL - II (MPA 105PB)

- 1 Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
- 2 Simultaneous estimation of multi component containing formulations by UV spectrophotometry
- 3 Experiments based on HPLC
- 4 Experiments based on Gas Chromatography
- 5 Determination of total reducing sugar
- 6 Determination of proteins
- 7 Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
- 8 Determination of fat content and rancidity in food products
- 9 Analysis of natural and synthetic colors in food
- 10 Determination of preservatives in food
- 11 Determination of pesticide residue in food products
- 12 Analysis of vitamin content in food products
- 13 Determination of density and specific gravity of foods
- 14 Determination of food additives

SEMESTER - II  
ADVANCED INSTRUMENTAL ANALYSIS  
(MPA 201T)

**Scope**

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, and hyphenated techniques.

**Objectives**

After completion of course student is able to know,

- 1 interpretation of the NMR, Mass and IR spectra of various organic compounds
- 1 theoretical and practical skills of the hyphenated instruments
- 1 identification of organic compounds

**THEORY**

60 Hrs

1. HPLC: Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC- role and principles of ultra, nano liquid chromatography in pharmaceutical analysis. Immobilized polysaccharide CSP's: Advancement in enantiomeric separations, revised phase Chiral method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC. 12 Hrs
- 2 Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases. 12 Hrs  
Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification. High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications.
- 3 Supercritical fluid chromatography: Principles, instrumentation, pharmaceutical applications. 12 Hrs  
Capillary electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method development in CE, Crown ethers as buffer additives in capillary electrophoresis. CE-MS hyphenation



- 4 Mass spectrometry: Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, metastable ions, isotopic peaks and applications of mass spectrometry. LC- MS hyphenation and DART MS analysis. Mass analysers (Quadrupole, Time of flight, FT-ICR, iontrap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF; Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap). 12 Hrs
- 5 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR with reference to <sup>13</sup>CNMR: Spin spin and spin lattice relaxation phenomenon. <sup>13</sup>CNMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations. 12 Hrs

#### REFERENCES

1. Spectrometric Identification of Organic compounds- Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis- Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5<sup>th</sup> edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis- Willards, 7<sup>th</sup> edition, CBS publishers.
4. Organic Spectroscopy- William Kemp, 3<sup>rd</sup> edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC-PD Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation- PD Sethi, 3<sup>rd</sup> Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods –Part B- JW Munson, Volume 11, Marcel Dekker Series.
8. Organic Spectroscopy by Donald L. Pavia, 5<sup>th</sup> Edition.



## MODERN BIO-ANALYTICAL TECHNIQUES (MPA 202T)

### Scope

This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

### Objectives

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

- 1 Extraction of drugs from biological samples
- 1 Separation of drugs from biological samples using different techniques
- 1 Guidelines for BABE studies.

### THEORY

60 Hrs

1. Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid-Liquid extraction and Solid phase extraction and other novel sample preparation approach. Bioanalytical method validation: USFDA and EMEA guidelines. 12 Hrs
- 2 Biopharmaceutical Consideration: Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods. 12 Hrs
- 3 Pharmacokinetics and Toxicokinetics: Basic consideration, Drug interaction (PK-PD interactions), The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics-Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC- MS in bioactivity screening and proteomics. 12 Hrs
- 4 Cell culture techniques Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry. 12 Hrs

5 Metabolite identification:

In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met-ID. Regulatory perspectives.

12 Hrs

In-vitro assay of drug metabolites & drug metabolizing enzymes.

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies.

REFERENCES

- 1 Analysis of drugs in Biological fluids- Joseph Chamberlain, 2<sup>nd</sup> Edition. CRC Press, New York. 1995.
- 2 Principles of Instrumental Analysis- Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5<sup>th</sup> edition, Eastern Press, Bangalore, 1998.
- 3 Pharmaceutical Analysis- Higuchi, Brochman and Hassen, 2<sup>nd</sup> Edition, Wiley – Interscience Publications, 1961.
- 4 Pharmaceutical Analysis- Modern methods– Part B- JW Munson, Volume 11, Marcel Dekker Series
- 5 Practical HPLC method Development – Snyder, Kirkland, Glajch, 2<sup>nd</sup> Edition, John Wiley & Sons, New Jersey, USA.
- 6 Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2<sup>nd</sup> Edition, Marcel Dekker, New York, USA. 1997.
- 7 Chromatographic methods in clinical chemistry & Toxicology– Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jersey, USA. 2007.
- 8 Good Laboratory Practice Regulations, 2<sup>nd</sup> Edition, Sandy Weinberg, Vol. 69, Marcel Dekker Series, 1995.
- 9 Good Laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
- 10 ICH, USFDA & CDSCO Guidelines.
- 11 Palmer



## QUALITY CONTROL AND QUALITY ASSURANCE (MPA 203T)

### Scope

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

### Objectives

At the completion of this subject it is expected that the student shall be able to know

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

### THEORY

60 hrs

1. Concept and Evolution of Quality Control and Quality Assurance 12 Hrs

Good Laboratory Practice, GMP, Overview of ICH Guidelines-QSEM, with special emphasis on Q-series guidelines.

Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation.

2. cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guidelines. 12 Hrs

3. Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3) 12 Hrs

Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials.



4. Documentation in pharmaceutical industry: Three tier documentation, 12 Hrs  
Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data.
5. Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging. 12 Hrs

#### REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3<sup>rd</sup> revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2<sup>nd</sup> Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compendium of Guidelines and Related materials, Vol I & II, 2<sup>nd</sup> edition, WHO Publications, 1999.
4. How to Practice GMP's – PP Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3<sup>rd</sup> edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F.Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4<sup>th</sup> edition, Susmit Publishers, 2006.
10. QA Manual–D.H.Shah, 1<sup>st</sup> edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol.52, 3<sup>rd</sup> edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Health care Manufacturers and Their Suppliers, Sixth Edition, (Volume1-With Check lists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.

## HERBAL AND COSMETIC ANALYSIS (MPA 204T)

### Scope

This course is designed to impart knowledge on analysis of herbal products. Regulatory requirements, herbal drug interaction with monographs. Performance evaluation of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.

### Objectives

At completion of this course student shall be able to understand

- 1 Determination of herbal remedies and regulations
- 1 Analysis of natural products and monographs
- 1 Determination of Herbal drug-drug interaction
- 1 Principles of performance evaluation of cosmetic products.

### THEORY

60 Hrs

1. Herbal remedies- Toxicity and Regulations: Herbals vs Conventional drugs, 12 Hrs  
Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines.
2. Adulteration and Deterioration: Introduction, types of adulteration/substitution 12 Hrs  
of herbal drugs, Causes and Measure of adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations. Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patent law as applicable herbal drugs and natural products and its protocol.
3. Testing of natural products and drugs: Effect of herbal medicine on clinical 12 Hrs  
laboratory testing, Adulterant screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products, protocol.  
Monographs of Herbal drugs: Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.



- 4 Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for biodrug adverse reactions, biodrug-drug and biodrug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines. 12 Hrs
- 5 Evaluation of cosmetic products: Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS. 12 Hrs
- Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skincare products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards.

#### REFERENCES

- a. Pharmacognosy by Trease and Evans
- b. Pharmacognosy by Kokate, Purohit and Gokhale
- c. Quality Control Methods for Medicinal Plant, WHO, Geneva
- d. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar
- e. Essential of Pharmacognosy by Dr.S.H.Ansari
- f. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4<sup>th</sup> edition, Vandana Publications Pvt.Ltd., Delhi
- g. Indian Standard specification, for raw materials, BIS, New Delhi.
- h. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
- i. Harry's Cosmeticology, 8<sup>th</sup> edition
- j. Suppliers catalogue on specialized cosmetic excipients
- k. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
- l. Hilda Butler, 10<sup>th</sup> Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3<sup>rd</sup> Edition,



### PHARMACEUTICAL ANALYSIS PRACTICAL - III (MPA 205PA)

1. Comparison of absorption spectra by UV and Wood ward – Fiesure rule
2. Interpretation of organic compounds by FT-IR
3. Interpretation of organic compounds by NMR
4. Interpretation of organic compounds by MS
5. Determination of purity by DSC in pharmaceuticals
6. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
7. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis.
8. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques.
9. Isolation of analgesics from biological fluids (Blood serum and urine).
10. Protocol preparation and performance of analytical / Bioanalytical method validation.
11. Protocol preparation for the conduct of BA/BE studies according to guidelines.

### PHARMACEUTICAL ANALYSIS PRACTICAL - IV (MPA 205PB)

1. In process and finished product quality control tests for tablets, capsules, parenterals and creams
2. Quality control tests for Primary and secondary packing materials
3. Assay of raw materials as per official monographs
4. Testing of related and foreign substances in drugs and raw materials
5. Preparation of Master Formula Record.
6. Preparation of Batch Manufacturing Record.
7. Quantitative analysis of rancidity in lipsticks and hairoil
8. Determination of aryl amine content and Developer in hair dye
9. Determination of foam height and SLS content of Shampoo.
10. Determination of total fatty matter in creams (Soap, skin and hair creams)
11. Determination of acid value and saponification value.
12. Determination of calcium thioglycolate in depilatories





# भारत का राजपत्र The Gazette of India

साप्ताहिक/WEEKLY

प्राधिकार से प्रकाशित  
PUBLISHED BY AUTHORITY

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इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।  
(Separate paging is given to this Part in order that it may be filed as a separate compilation)

भाग III—खण्ड 4

[PART III—SECTION 4]

[सांविधिक निकायों द्वारा जारी की गई विविध अधिसूचनाएं जिसमें कि आदेश, विज्ञापन और सूचनाएं सम्मिलित हैं]  
[Miscellaneous Notifications including Notifications, Orders, Advertisements and Notices issued by  
Statutory Bodies]

भारतीय रिज़र्व बैंक

मुंबई-400001, दिनांक 9 अप्रैल 2008

संदर्भ : बैंपविवि. सं. आईबीडी.-14241/23.13.048/2007-08--भारतीय रिज़र्व बैंक अधिनियम, 1934 (1934 का 2) की धारा 42 की उप-धारा (6) के खण्ड (ग) के अनुसरण में भारतीय रिज़र्व बैंक इसके द्वारा निदेश देता है कि उक्त अधिनियम की दूसरी अनुसूची में निम्नलिखित परिवर्तन किये जाएं :--

“अरब बांग्लादेश बैंक लिमिटेड” शब्दों के स्थान पर “एबी बैंक लिमिटेड” शब्द होंगे।

आनन्द सिन्हा

प्रिन्सिपल निदेशक  
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# APPENDIX-A

(See regulation 8)

## PHARM.D. SYLLABUS

### First Year

#### 1.1 HUMAN ANATOMY & PHYSIOLOGY (THEORY)

**Theory : 3 Hrs. /Week**

- 1. Scope and Objectives:** This course is designed to impart a fundamental knowledge on the structure and functions of the human body. It also helps in understanding both homeostasis mechanisms and homeostatic imbalances of various body systems. Since a medicament, which is produced by pharmacist, is used to correct the deviations in human body, it enhances the understanding of how the drugs act on the various body systems in correcting the disease state of the organs.
- 2. Upon completion of the course the student shall be able to:**
  - a. describe the structure (gross and histology) and functions of various organs of the human body;
  - b. describe the various homeostatic mechanisms and the imbalances of various systems;
  - c. identify the various tissues and organs of the different systems of the human body;
  - d. perform the hematological tests and also record blood pressure, heart rate, pulse and Respiratory volumes;
  - e. appreciate coordinated working pattern of different organs of each system; and
  - f. appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body


#### 3. Course materials:

##### Text books

- a. Tortora Gerard J. and Nicholas, P. Principles of anatomy and physiology  
Publisher Harpercollins college New York.
- b. Wilson, K.J.W. Ross and Wilson's foundations of anatomy and physiology.  
Publisher: Churchill Livingstone, Edinburg.

##### Reference books

- a. Guyton arthur, C. *Physiology of human body*. Publisher: Holtsaunders.
- b. Chatterjee, C.C. *Human physiology*. Volume 1&11. Publisher: medical allied agency, Calcutta.
- c. Peter L. Williams, Roger Warwick, Mary Dyson and Lawrence, H.
- d. *Gray's anatomy*. Publisher: Churchill Livingstone, London.

  
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#### 4. Lecture wise program :

##### Topics

- 1 Scope of anatomy and physiology, basic terminologies used in this subject  
(Description of the body as such planes and terminologies)
- 2 Structure of cell - its components and their functions.
- 3 Elementary tissues of the human body: epithelial, connective, Muscular and nervous tissues-their sub-types and characteristics
- 4 a) Osseous system - structure, composition and functions of the Skeleton. (done in practical classes - 6hrs)  
b) Classification of joints, Types of movements of joints and disorders of joints  
(Definitions only)
- 5 Haemopoetic System  
a) Composition and functions of blood  
b) Haemopoiesis and disorders of blood components (definition of disorder)  
c) Blood groups  
d) Clotting factors and mechanism  
e) Platelets and disorders of coagulation
- 6 Lymph  
a) Lymph and lymphatic system, composition, formation and circulation.  
b) Spleen: structure and functions, Disorders  
c) Disorders of lymphatic system (definition only)
- 7 Cardiovascular system  
a) Anatomy and functions of heart  
b) Blood vessels and circulation (Pulmonary, coronary and systemic circulation)  
c) Electrocardiogram (ECG)  
d) Cardiac cycle and heart sounds  
e) Blood pressure - its maintenance and regulation  
f) Definition of the following disorders  
Hypertension, Hypotension, Arteriosclerosis, Atherosclerosis, Angina, Myocardial infarction, Congestive heart failure, Cardiac arrhythmias
- 8 Respiratory system  
a) Anatomy of respiratory organs and functions  
b) Mechanism / physiology of respiration and regulation of respiration  
c) Transport of respiratory gases  
d) Respiratory volumes and capacities, and Definition of: Hypoxia, Asphyxia, Dybarism, Oxygen therapy and resuscitation.
- 9 Digestive system  
a) Anatomy and physiology of GIT  
b) Anatomy and functions of accessory glands of GIT  
c) Digestion and absorption  
d) Disorders of GIT (definitions only)

- 10 Nervous system
  - a) Definition and classification of nervous system
  - b) Anatomy, physiology and functional areas of cerebrum
  - c) Anatomy and physiology of cerebellum
  - d) Anatomy and physiology of mid brain
  - e) Thalamus, hypothalamus and Basal Ganglia
  - f) Spinal cord: Structure & reflexes - mono-poly-planter
  - g) Cranial nerves - names and functions
  - h) ANS - Anatomy & functions of sympathetic & parasympathetic N.S.
- 11 Urinary system
  - a) Anatomy and physiology of urinary system
  - b) Formation of urine
  - c) Renin Angiotensin system - Juxtaglomerular apparatus - acid base Balance
  - d) Clearance tests and micturition
- 12 Endocrine system
  - a) Pituitary gland
  - b) Adrenal gland
  - c) Thyroid and Parathyroid glands
  - d) Pancreas and gonads
- 13 Reproductive system
  - a) Male and female reproductive system
  - b) Their hormones - Physiology of menstruation
  - c) Spermatogenesis & Oogenesis
  - d) Sex determination (genetic basis)
  - e) Pregnancy and maintenance and parturition
  - f) Contraceptive devices
- 14 Sense organs
  - a) Eye
  - b) Ear
  - c) Skin
  - d) Tongue & Nose
- 15 Skeletal muscles
  - a) Histology
  - b) Physiology of Muscle contraction
  - c) Physiological properties of skeletal muscle and their disorders (definitions)
- 16 Sports physiology
  - a) Muscles in exercise, Effect of athletic training on muscles and muscle performance,
  - b) Respiration in exercise, CVS in exercise, Body heat in exercise, Body fluids and salts in exercise,
  - c) Drugs and athletics

## 1.1 HUMAN ANATOMY & PHYSIOLOGY (PRACTICAL)

**Practical : 3 Hrs./Week**

**General Requirements:** Dissection box, Laboratory Napkin, muslin cloth, record, Observation book(100pages), Stationary items, Blood lancet.

### Course materials:

#### Text books

Goyal, R. K, Natvar M.P, and Shah S.A, Practical anatomy, physiology and biochemistry, latest edition, Publisher: B.S Shah Prakashan, Ahmedabad.

#### Reference books

Ranade VG, Text book of practical physiology, Latest edition, Publisher: PVG, Pune  
Anderson Experimental Physiology, Latest edition, Publisher: NA

### List of Experiments:

1. Study of tissues of human body
  - (a) Epithelial tissue.
  - (b) Muscular tissue.
2. Study of tissues of human body
  - (a) Connective tissue.
  - (b) Nervous tissue.
3. Study of appliances used in hematological experiments.
4. Determination of W.B.C. count of blood.
5. Determination of R.B.C. count of blood.
6. Determination of differential count of blood.
7. Determination of
  - (a) Erythrocyte Sedimentation Rate.
  - (b) Hemoglobin content of Blood.
  - (c) Bleeding time & Clotting time.
8. Determination of
  - (a) Blood Pressure.
  - (b) Blood group.
9. Study of various systems with the help of charts, models & specimens
  - (a) Skeleton system part I-axial skeleton.
  - (b) Skeleton system part II- appendicular skeleton.
  - (c) Cardiovascular system.
  - (d) Respiratory system.

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- (e) Digestive system.
- (f) Urinary system.
- (g) Nervous system.
- (h) Special senses.
- (i) Reproductive system.

10. Study of different family planning appliances.
11. To perform pregnancy diagnosis test.
12. Study of appliances used in experimental physiology.
13. To record simple muscle curve using gastrocnemius sciatic nerve preparation.
14. To record simple summation curve using gastrocnemius sciatic nerve preparation.
15. To record simple effect of temperature using gastrocnemius sciatic nerve preparation.
16. To record simple effect of load & after load using gastrocnemius sciatic nerve preparation.
17. To record simple fatigue curve using gastrocnemius sciatic nerve preparation.

**Scheme of Practical Examination:**

	Sessionals	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

## 1.2 PHARMACEUTICS (THEORY)

**Theory : 2 Hrs. /Week**

1. **Scope and objectives:** This course is designed to impart a fundamental knowledge on the art and science of formulating different dosage forms. It prepares the students for most basics of the applied field of pharmacy.
2. **Upon the completion of the course the student s hould be able to:**
  - a. know the formulation aspects of different dosage forms;
  - b. do different pharmaceutical caluculation involved in formulation;
  - c. formulate different types of dosage forms; and
  - d. appreciate the importance of good formulation for effectiveness.

### 3. Course materials:

#### Text books

- a. Cooper and Gunns Dispensing for pharmacy students.
- b. A text book Professional Pharmacy by N.K.Jain and S.N.Sharma.

#### Reference books

- a. Introduction to Pharmaceutical dosage forms by Howard C. Ansel.
- b. Remington's Pharmaceutical Sciences.
- c. Register of General Pharmacy by Cooper and Gunn.
- d. General Pharmacy by M.L.Schroff.

### 4. Lecture wise programme:

#### Topics

- 1
  - a. Introduction to dosage forms - classification and definitions
  - b. Prescription: definition, parts and handling
  - c. Posology: Definition, Factors affecting dose selection. Calculation of children and infant doses.
- 2 Historical back ground and development of profession of pharmacy and pharmaceutical industry in brief.
- 3 Development of Indian Pharmacopoeia and introduction to o ther Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.
- 4 Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc.
- 5 Powders and Granules: Classification advantages and disadvantages, Preparation of simple, compound powders, Insufflations, Dusting powders, Eutectic and Explosive powders, Tooth powder and effervescent powders and granules.
- 6 Monophasic Dosage forms: Theoretical aspects of formulation including adjuvant like stabilizers, colorants, flavours with examples. Study of Monophasic liquids like gargles, mouth washes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions.

- 7 Biphasic dosage forms: Suspensions and emulsions, Definition, advantages and disadvantages, classification, test for the type of emulsion, formulation, stability and evaluation.
- 8 Suppositories and pessaries: Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation.
- 9 Galenicals: Definition, equipment for different extraction processes like infusion, Decoction, Maceration and Percolation, methods of preparation of spirits, tinctures and extracts.
- 10 Pharmaceutical calculations.
- 11 Surgical aids: Surgical dressings, absorbable gelatin sponge, sutures, ligatures and medicated bandages.
- 12 Incompatibilities: Introduction, classification and methods to overcome the incompatibilities.

## 1.2 PHARMACEUTICS (PRACTICAL)

**Practical : 3 Hrs./Week**

### **List of Experiments:**

#### **1. Syrups**

- a. Simple Syrup I.P
- b. Syrup of Ephedrine Hcl NF
- c. Syrup Vasaka IP
- d. Syrup of ferrous Phosphate IP
- e. Orange Syrup

#### **2. Elixir**

- a. Piperizine citrate elixir BP
- b. Cascara elixir BPC
- c. Paracetamol elixir BPC

#### **3. Linctus**

- a. Simple Linctus BPC
- b. Pediatric simple Linctus BPC

#### **4. Solutions**

- a. Solution of cresol with soap IP
- b. Strong solution of ferric chloride BPC
- c. Aqueous Iodine Solution IP
- d. Strong solution of Iodine IP
- e. Strong solution of ammonium acetate IP



**5. Liniments**

- a. Liniment of turpentine IP\*
- b. Liniment of camphor IP

**6. Suspensions\***

- a. Calamine lotion
- b. Magnesium Hydroxide mixture BP

**7. Emulsions\***

- a. Cod liver oil emulsion
- b. Liquid paraffin emulsion

**8. Powders**

- a. Eutectic powder
- b. Explosive powder
- c. Dusting powder
- d. Insufflations

**9. Suppositories**

- a. Boric acid suppositories
- b. Chloral suppositories

**10. Incompatibilities**

- a. Mixtures with Physical
- b. Chemical & Therapeutic incompatibilities

\* colourless bottles required for dispensing \* Paper envelope (white), butter paper and white paper required for dispensing.

**Scheme of Practical Examination:**

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

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### 1.3 MEDICINAL BIOCHEMISTRY (THEORY)

**Theory : 3 Hrs. /Week**

1. **Scope of the Subject:** Applied biochemistry deals with complete understanding of the molecular level of the chemical process associated with living cells. Clinical chemistry deals with the study of chemical aspects of human life in health and illness and the application of chemical laboratory methods to diagnosis, control of treatment, and prevention of diseases.
2. **Objectives of the Subject** (Know, do, appreciate) :  
The objective of the present course is providing biochemical facts and the principles to the students of pharmacy. Upon completion of the subject student shall be able to -
  - a. understand the catalytic activity of enzymes and importance of isoenzymes in diagnosis of diseases;
  - b. know the metabolic process of biomolecules in health and illness (metabolic disorders);
  - c. understand the genetic organization of mammalian genome; protein synthesis; replication; mutation and repair mechanism;
  - d. know the biochemical principles of organ function tests of kidney, liver and endocrine gland; and
  - e. do the qualitative analysis and determination of biomolecules in the body fluids.

#### **Text books (Theory)**

- a. Harpers review of biochemistry - Martin
- b. Text book of biochemistry - D.Satyanarayana
- c. Text book of clinical chemistry- Alex kaplan & Laverne L.Szabo

#### **Reference books (Theory)**

- a. Principles of biochemistry -- Lehninger
- b. Text book of biochemistry -- Ramarao
- c. Practical Biochemistry-David T.Plummer.
- d. Practical Biochemistry-Pattabhiraman.

### 3. **Lecture wise programme:**

#### **Topics**

- 1 **Introduction to biochemistry:** Cell and its biochemical organization, transport process across the cell membranes. Energy rich compounds; ATP, Cyclic AMP and their biological significance.
- 2 **Enzymes:** Definition; Nomenclature; IUB classification; Factor affecting enzyme activity; Enzyme action; enzyme inhibition. Isoenzymes and their therapeutic and diagnostic applications; Coenzymes and their biochemical role and deficiency diseases.
- 3 **Carbohydrate metabolism:** Glycolysis, Citric acid cycle (TCA cycle), HMP shunt, Glycogenolysis, gluconeogenesis, glycogenesis. Metabolic disorders of carbohydrate metabolism (diabetes mellitus and glycogen storage diseases); Glucose, Galactose tolerance test and their significance; hormonal regulation of carbohydrate metabolism.



- 4 **Lipid metabolism:** Oxidation of saturated ( $\beta$ -oxidation); Ketogenesis and ketolysis; biosynthesis of fatty acids, lipids; metabolism of cholesterol; Hormonal regulation of lipid metabolism. Defective metabolism of lipids (Atherosclerosis, fatty liver, hypercholesterolemia).
- 5 **Biological oxidation:** Coenzyme system involved in Biological oxidation. Electron transport chain (its mechanism in energy capture; regulation and inhibition); Uncouplers of ETC; Oxidative phosphorylation;
- 6 **Protein and amino acid metabolism:** protein turn over; nitrogen balance; Catabolism of Amino acids (Transamination, deamination & decarboxylation). Urea cycle and its metabolic disorders; production of bile pigments; hyperbilirubinemia, porphoria, jaundice. Metabolic disorder of Amino acids.
- 7 **Nucleic acid metabolism:** Metabolism of purine and pyrimidine nucleotides; Protein synthesis; Genetic code; inhibition of protein synthesis; mutation and repair mechanism; DNA replication (semiconservative /onion peel models) and DNA repair mechanism.
- 8 **Introduction to clinical chemistry: Cell;** composition; malfunction; Roll of the clinical chemistry laboratory.
- 9 **The kidney function tests:** Role of kidney; Laboratory tests for normal function includes-
  - a) Urine analysis (macroscopic and physical examination, quantitative and semiquantitative tests.)
  - b) Test for NPN constituents. (Creatinine /urea clearance, determination of blood and urine creatinine, urea and uric acid)
  - c) Urine concentration test
  - d) Urinary tract calculi. (stones)
- 10 **Liver function tests:** Physiological role of liver, metabolic, storage, excretory, protective, circulatory functions and function in blood coagulation.
  - a) Test for hepatic dysfunction-Bile pigments metabolism.
  - b) Test for hepatic function test- Serum bilirubin, urine bilirubin, and urine urobilinogen.
  - c) Dye tests of excretory function.
  - d) Tests based upon abnormalities of serum proteins.
 Selected enzyme tests.
- 11 **Lipid profile tests:** Lipoproteins, composition, functions. Determination of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides.
- 12 **Immunochemical techniques** for determination of hormone levels and protein levels in serum for endocrine diseases and infectious diseases.

Radio immuno assay (RIA) and Enzyme Linked Immuno Sorbent Assay (ELISA) 13

**Electrolytes:** Body water, compartments, water balance, and electrolyte distribution. Determination of sodium, calcium potassium, chlorides, bicarbonates in the body fluids.



### 1.3 MEDICINAL BIOCHEMISTRY (PRACTICAL)

**Practical : 3 Hrs./Week**

**Title of the Experiment:**

- 1 Qualitative analysis of normal constituents of urine.\*
  - 2 Qualitative analysis of abnormal constituents of urine.\*
  - 3 Quantitative estimation of urine sugar by Benedict's reagent method.\*\*
  - 4 Quantitative estimation of urine chlorides by Volhard's method.\*\*
  - 5 Quantitative estimation of urine creatinine by Jaffe's method.\*\*
  - 6 Quantitative estimation of urine calcium by precipitation method.\*\*
  - 7 Quantitative estimation of serum cholesterol by Libermann Burchard's method.\*\*
  - 8 Preparation of Folin Wu filtrate from blood.\*
  - 9 Quantitative estimation of blood creatinine.\*\*
  - 10 Quantitative estimation of blood sugar Folin- Wu tube method.\*\*
  - 11 Estimation of SGOT in serum.\*\*
  - 12 Estimation of SGPT in serum.\*\*
  - 13 Estimation of Urea in Serum.\*\*
  - 14 Estimation of Proteins in Serum.\*\*
  - 15 Determination of serum bilirubin\*\*
  - 16 Determination of Glucose by means of Glucoseoxidase.\*\*
  - 17 Enzymatic hydrolysis of Glycogen/Starch by Amylases.\*\*
  - 18 Study of factors affecting Enzyme activity. (pH & Temp.)\*\*
  - 19 Preparation of standard buffer solutions and its pH measurements (any two)\*
  - 20 Experiment on lipid profile tests\*\*
  - 21 Determination of sodium,calcium and potassium in serum.\*\*
- \*\* indicate major experiments & \* indicate minor experiments

**Assignments:**

Format of the assignment

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

**Scheme of Practical Examination:**

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

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## 1.4 PHARMACEUTICAL ORGANIC CHEMISTRY (THEORY)

**Theory : 3 Hrs. /Week**

1. **Scope and objectives:** This course is designed to impart a very good knowledge about
  - a. IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds;
  - b. Some important physical properties of organic compounds;
  - c. Free radical/ nucleophilic [alkyl/ acyl/ aryl] /electrophilic substitution, free radical/ nucleophilic / electrophilic addition, elimination, oxidation and reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability of compounds;
  - d. Some named organic reactions with mechanisms; and
  - e. Methods of preparation, test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.

### 2. Course materials:

#### Text books

- a. T.R.Morrison and R. Boyd - Organic chemistry,
- b. Bentley and Driver-Text book of Pharmaceutical chemistry
- c. I.L.Finer- Organic chemistry, the fundamentals of chemistry

#### Reference books

- a. Organic chemistry - J.M.Cram and D.J.Cram
- b. Organic chemistry- Brown
- c. Advanced organic chemistry- Jerry March, Wiley
- d. Organic chemistry- Cram and Hammond, Pine Hendrickson

### 3. Lecture wise programme :

#### Topics

- 1 Structures and Physical properties:
  - a. Polarity of bonds, polarity of molecules, M.P, Inter molecular forces, B.P, Solubility, non ionic solutes and ionic solutes, protic and aprotic Solvents, ion pairs,
  - b. Acids and bases, Lowry bronsted and Lewis theories
  - c. Isomerism
- 2 Nomenclature of organic compound belonging to the following classes Alkanes, Alkenes, Dienes, Alkynes, Alcohols, Aldehydes, Ketones, Amides, Amines, Phenols, Alkyl Halides, Carboxylic Acid, Esters, Acid Chlorides And Cycloalkanes.
- 3 Free radicals chain reactions of alkane : Mechanism, relative reactivity and stability
- 4 Alicyclic compounds : Preparations of cyclo alkanes, Bayer strain theory and orbital picture of angle strain.
- 5 Nucleophilic aliphatic substitution mechanism: Nucleophiles and leaving groups, kinetics of second and first order reaction, mechanism and kinetics of  $SN_2$  reactions. Stereochemistry and steric hindrance, role of solvents, phase transfer catalysis, mechanism and kinetics of  $SN_1$  reactions, stereochemistry, carbocation and their stability, rearrangement of carbocation, role of solvents in  $SN_1$  reaction, Ion dipole bonds,  $SN_2$  versus  $SN_1$  solvolyses, nucleophilic assistance by the solvents.

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- 6 Dehydro halogenation of alkyl halides: 1,2 elimination, kinetics, E2 and E1 mechanism, elimination via carbocation, evidence for E2 mechanism, absence of rearrangement isotope effect, absence hydrogen exchange, the element effect, orientation and reactivity, E2 versus E1, elimination versus substitution, dehydration of alcohol, ease of dehydration, acid catalysis, reversibility, orientation.
- 7 Electrophillic and free radicals addition: Reactions at carbon-carbon, double bond, electrophile, hydrogenation, heat of hydrogenation and stability of alkenes, markownikoff rule, addition of hydrogen halides, addition of hydrogen bromides, peroxide effect, electrophillic addition, mechanism, rearrangement, absence of hydrogen exchange, orientation and reactivity, addition of halogen, mechanism, halohydrin formation, mechanism of free radicals additon, mechanism of peroxide initiated addition of hydrogen bromide, orientation of free addition, additions of carbene to alkene, cyclo addition reactions.
- 8 Carbon-carbon double bond as substituents: Free radical halogenations of alkenes, comparision of free radical substitution with free radical addition, free radical substitution in alkenes, orientation and reactivity, allylic rearrangements.
- 9 Theory of resonance: Allyl radical as a resonance hybrid, stability, orbital picture, resonance stabilisation of allyl radicals, hyper conjugation, allyl cation as a resonance hybrid, nucleophyllic substitution in allylic substrate, SN1 reactivity, allylic rearrangement, resonance stabilisation of allyl cation, hyper conjugation, nucleophilic substitution in allylic substrate, SN2 nucleophilic substitiuon in vinylic substrate, vinylic cation, stability of conjugated dienes, resonance in alkenes, hyper conjugation, ease of formation of conjugated dienes, orientation of elimination, electrophilic addition to conjugated dienes, 1,4- addition, 1,2-versus 1,4-addition, rate versus equilibrium, orientation and reactivity of free radical addition to conjugated dienes.
- 10 Electrophilic aromatic substitution: Effect of substituent groups, determination of orientation, determination of relative reactivity, classification of substituent group, mechanism of nitration, sulphonation, halogenation, friedel craft alkylation, friedel craft acylation, reactivity and orientation, activating and deactivating O,P,M directing groups, electron release via resonance, effect of halogen on electrophilic aromatic substitution in alkyl benzene, side chain halogination of alkyl benzene, resonance stabilization of benzyl radical.
- 11 Nucleophilic addition reaction: Mechanism, ionisation of carboxylic acids, acidity constants, acidity of acids, structure of carboxylate ions, effect of substituent on acidity, nucleophilic acyl substitution reaction, conversion of acid to acid chloride, esters, amide and anhydride. Role of caboxyl group, comparison of alkyl nucleophilic substitution with acyl nucleophilic substitution.



- 12 Mechanism of aldol condensation, claisen condensation, cannizzaro reaction, crossed aldol condensation, crossed cannizzaro reaction, benzoin condensation, perkin condensation. Knoevenagel, Reformatsky reaction, Wittig reaction, Michael addition.
- 13 Hoffman rearrangement: Migration to electron deficient nitrogen, Sandmeyer's reaction, basicity of amines, diazotisation and coupling, acidity of phenols, Williamson synthesis, Fries rearrangement, Kolbe reaction, Reimer tieman's reactions.
- 14 Nucleophilic aromatic substitution: Bimolecular displacement mechanisms, orientation, comparison of aliphatic nucleophilic substitution with that of aromatic.
- 15 Oxidation reduction reaction.
- 16 Study of the following official compounds- preparation, test for purity, assay and medicinal uses of Chlorbutol, Dimercaprol, Glyceryl trinitrate, Urea, Ethylene diamine dihydrate, Vanillin, Paraldehyde, Ethylene chloride, Lactic acid, Tartaric acid, citric acid, salicylic acid, aspirin, methyl salicylate, ethyl benzoate, benzyl benzoate, dimethyl phthalate, sodium lauryl sulphate, saccharin sodium, mephensin.

#### 1.4 PHARMACEUTICAL ORGANIC CHEMISTRY (PRACTICAL)

**Practical : 3 Hrs./Week**

**I. Introduction to the various laboratory techniques through demonstration involving synthesis of the following compounds (at least 8 compounds to be synthesised):**

1. Acetanilide / aspirin (Acetylation)
2. Benzanilide / Phenyl benzoate (Benzoylation)
3. P-bromo acetanilide / 2,4,6 - tribromo aniline (Bromination)
4. Dibenzylidene acetone (Condensation)
5. 1-Phenylazo-2-naphthol (Diazotisation and coupling)
6. Benzoic acid / salicylic acid (Hydrolysis of ester)
7. M-dinitro benzene (Nitration)
8. 9, 10 - Anthraquinone (Oxidation of anthracene) / preparation of benzoic acid from toluene or benzaldehyde
9. M-phenylene diamine (Reduction of M-dinitrobenzene) / Aniline from nitrobenzene
10. Benzophenone oxime
11. Nitration of salicylic acid
12. Preparation of picric acid
13. Preparation of O-chlorobenzoic acid from O-chlorotoluene
14. Preparation of cyclohexanone from cyclohexanol

  
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**II. Identification of organic compounds belonging to the following classes by :**

Systematic qualitative organic analysis including preparation of derivatives  
Phenols, amides, carbohydrates, amines, carboxylic acids, aldehyde and ketones,  
Alcohols, esters, hydrocarbons, anilides, nitrocompounds.

**III. Introduction to the use of stereo models:**

Methane, Ethane, Ethylene, Acetylene, Cis alkene, Trans alkene, inversion of configuration.

**Scheme of Practical Examination:**

	<b>Sessionals</b>	<b>Annual</b>
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

## 1.5 PHARMACEUTICAL INORGANIC CHEMISTRY (THEORY)

**Theory : 2 Hrs. /Week**

1. **Scope and objectives:** This course mainly deals with fundamentals of Analytical chemistry and also the study of inorganic pharmaceuticals regarding their monographs and also the course deals with basic knowledge of analysis of various pharmaceuticals.
2. **Upon completion of the course student shall be able to:**
  - a. understand the principles and procedures of analysis of drugs and also regarding the application of inorganic pharmaceuticals;
  - b. know the analysis of the inorganic pharmaceuticals their applications; and
  - c. appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.

### 3. Course materials:

#### Text books

- a. A text book Inorganic medicinal chemistry by Surendra N. Pandeya
- b. A. H. Beckett and J. B. Stanlake's Practical Pharmaceutical chemistry Vol-I & Vol-II
- c. Inorganic Pharmaceutical Chemistry III-Edition P.Gundu Rao


#### Reference books

- a. Inorganic Pharmaceutical Chemistry by Anand & Chetwal
- b. Pharmaceutical Inorganic chemistry by Dr.B.G.Nagavi
- c. Analytical chemistry principles by John H. Kennedy
- d. I.P.1985 and 1996, Govt. of India, Ministry of health

### 4. Lecture wise programme:

#### Topics

- 1 Errors
- 2 Volumetric analysis
- 3 Acid-base titrations
- 4 Redox titrations
- 5 Non aqueous titrations
- 6 Precipitation titrations
- 7 Complexometric titrations
- 8 Theory of indicators
- 9 Gravimetry
- 10 Limit tests
- 11 Medicinal gases
- 12 Acidifiers
- 13 Antacids
- 14 Cathartics
- 15 Electrolyte replenishers

  
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- 16 Essential Trace elements
- 17 Antimicrobials
- 18 Pharmaceutical aids
- 19 Dental Products
- 20 Miscellaneous compounds
- 21 Radio Pharmaceuticals

## 1.5 PHARMACEUTICAL INORGANIC CHEMISTRY (PRACTICAL)

**Practical : 3 Hrs./Week**

### 1. Limit test (6 exercises)

- a. Limit test for chlorides
- b. Limit test for sulphates
- c. Limit test for iron
- d. Limit test for heavy metals
- e. Limit test for arsenic
- f. Modified limit tests for chlorides and sulphates

### 2. Assays (10 exercises)

- a. Ammonium chloride- Acid-base titration
- b. Ferrous sulphate- Cerimetry
- c. Copper sulphate- Iodometry
- d. Calcium gluconate- Complexometry
- e. Hydrogen peroxide - Permanganometry
- f. Sodium benzoate - Nonaqueous titration
- g. Sodium chloride - Modified volhard's method
- h. Assay of KI -  $\text{KIO}_3$  titration
- i. Gravimetric estimation of barium as barium sulphate
- j. Sodium antimony gluconate or antimony potassium tartarate

### 3. Estimation of mixture (Any two exercises)

- a. Sodium hydroxide and sodium carbonate
- b. Boric acid and Borax
- c. Oxalic acid and sodium oxalate

### 4. Test for identity (Any three exercises)

- a. Sodium bicarbonate
- b. Barium sulphate
- c. Ferrous sulphate
- d. Potassium chloride

**5. Test for purity (Any two exercises)**

- Swelling power in Bentonite
- Acid neutralising capacity in aluminium hydroxide gel
- Ammonium salts in potash alum
- Adsorption power heavy Kaolin
- Presence of Iodates in KI

**6. Preparations (Any two exercises)**

- Boric acids
- Potash alum
- Calcium lactate
- Magnesium sulphate

**Scheme of Practical Examination :**

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment 1&2	03	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

## 1.6 REMEDIAL MATHEMATICS/BIOLOGY (THEORY)

**Theory : 3 Hrs. /Week**

### REMEDIAL MATHEMATICS :

1. **Scope and objectives:** This is an introductory course in mathematics. This subjects deals with the introduction to matrices, determinants, trigonometry, analytical geometry, differential calculus, integral calculus, differential equations, laplace transform.
2. **Upon completion of the course the student shall be able to : -**
  - a. Know Trigonometry, Analytical geometry, Matrices, Determinant, Integration, Differential equation, Laplace transform and their applications;
  - b. solve the problems of different types by applying theory; and
  - c. appreciate the important applications of mathematics in pharmacy.

### 3. Course materials:

#### Text books

- a. Differential calculus By Shantinakaran
- b. Text book of Mathematics for second year pre- university by Prof.B.M.Sreenivas

#### Reference books

- a. Integral calculus By Shanthinarayan
- b. Engineering mathematics By B.S.Grewal
- c. Trigonometry Part-I By S.L.Loney

### 4. Lecture wise programme :

#### Topics

- 1 **Algebra :** Determinants, Matrices
- 2 **Trigonometry :** Sides and angles of a triangle, solution of triangles
- 3 **Analytical Geometry :** Points, Straight line, circle, parabola
- 4 **Differential calculus:** Limit of a function, Differential calculus, Differentiation of a sum, Product, Quotient Composite, Parametric, exponential, trigonometric and Logarithmic function. Successive differentiation, Leibnitz's theorem, Partial differentiation, Euler's theorem on homogeneous functions of two variables
- 5 **Integral Calculus:** Definite integrals, integration by substitution and by parts, Properties of definite integrals.
- 6 **Differential equations:** Definition, order, degree, variable separable, homogeneous, Linear, heterogeneous, linear, differential equation with constant coefficient, simultaneous linear equation of second order.
- 7 **Laplace transform:** Definition, Laplace transform of elementary functions, Properties of linearity and shifting.



## BIOLOGY :

1. **Scope and objectives:** This is an introductory course in Biology, which gives detailed study of natural sources such as plant and animal origin. This subject has been introduced to the pharmacy course in order to make the student aware of various naturally occurring drugs and its history, sources, classification, distribution and the characters of the plants and animals. This subject gives basic foundation to Pharmacognosy.

### 2. Course materials:

#### 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.

### 3. Lecture wise programme :

#### Topic

#### PART - A

- 01 Introduction
- 02 General organization of plants and its inclusions
- 03 Plant tissues
- 04 Plant kingdom and its classification
- 05 Morphology of plants
- 06 Root, Stem, Leaf and Its modifications
- 07 Inflorescence and Pollination of flowers
- 08 Morphology of fruits and seeds
- 09 Plant physiology
- 10 Taxonomy of Leguminosae, umbelliferae, Solanaceae, Lilliacae, Zinziberaceae, Rubiaceae
- 11 Study of Fungi, Yeast, Penicillin and Bacteria

#### PART-B

- 01 Study of Animal cell
- 02 Study animal tissues
- 03 Detailed study of frog
- 04 Study of Pisces, Raptiles, Aves
- 05 General organization of mammals
- 06 Study of poisonous animals

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## 1.6 BIOLOG Y (PRACTICAL)

**Practical : 3 Hrs./Week**

**Title:**

1. Introduction of biology experiments
2. Study of cell wall constituents and cell inclusions
3. Study of Stem modifications
4. Study of Root modifications
5. Study of Leaf modifications
6. Identification of Fruits and seeds
7. Preparation of Permanent slides
8. T.S. of Senna, Cassia, Ephedra, Podophyllum.
9. Simple plant physiological experiments
10. Identification of animals
11. Detailed study of Frog
12. Computer based tutorials

**Scheme of Practical Examination :**

	Sessionals	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance.

## **Second year**

### **2.1 PATHOPHYSIOLOGY (THEORY)**

**Theory : 3 Hrs. /Week**

- 1. Scope of the Subject:** 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 of its application in other subject of pharmacy.
- 2. Objectives of the Subject :** Upon completion of the subject student shall be able to -
  - a. describe the etiology and pathogenesis of the selected disease states;
  - b. name the signs and symptoms of the diseases; and
  - c. mention the complications of the diseases.

**Text books (Theory)**

- a. Pathologic basis of disease by- Cotran, Kumar, Robbins
- b. Text book of Pathology- Harsh Mohan
- c. Text book of Pathology- Y.M. Bhide

**Reference books (Theory)**

- a. Clinical Pharmacy and Therapeutics; Second edition; Roger Walker; Churchill Livingstone publication

**3. Detailed syllabus and lecture wise schedule :**

**Chapter**

- 1 Basic principles of cell injury and Adaptation**
  - a) Causes, Pathogenesis and morphology of cell injury
  - b) Abnormalities in lipoproteinaemia, glycogen infiltration and glycogen infiltration and glycogen infiltration and glycogen storage diseases
- 2 Inflammation**
  - a) Pathogenesis of acute inflammation, Chemical mediators in inflammation, Types of chronic inflammation
  - b) Repairs of wounds in the skin, factors influencing healing of wounds
- 3 Diseases of Immunity**
  - a) Introduction to T and B cells
  - b) MHC proteins or transplantation antigens
  - c) Immune tolerance
    - Hypersensitivity
      - Hypersensitivity type I, II, III, IV, Biological significance, Allergy due to food, chemicals and drugs
    - Autoimmunity
      - Criteria for autoimmunity, Classifications of autoimmune diseases in man, mechanism of autoimmunity, Transplantation and immunologic tolerance, allograft rejections, transplantation antigens, mechanism of rejection of allograft.
    - Acquired immune deficiency syndrome (AIDS)



- Amyloidosis

- 4 **Cancer:** differences between benign and malignant tumors, Histological diagnosis of malignancy, invasions and metastasis, patterns of spread, disturbances of growth of cells, classification of tumors, general biology of tumors, spread of malignant tumors, etiology and pathogenesis of cancer.
- 5 Types of shock, mechanisms, stages and management
- 6 Biological effects of radiation
- 7 Environmental and nutritional diseases
  - i) Air pollution and smoking- SO<sub>2</sub>, NO, NO<sub>2</sub>, and CO
  - ii) Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation.
- 8 Pathophysiology of common diseases
  - a. Parkinsonism
  - b. Schizophrenia
  - c. Depression and mania
  - d. Hypertension,
  - e. Stroke (ischaemic and hemorrhage)
  - f. Angina, CCF, Atherosclerosis, Myocardial infarction
  - g. Diabetes Mellitus
  - h. Peptic ulcer and inflammatory bowel diseases
  - i. Cirrhosis and Alcoholic liver diseases
  - j. Acute and chronic renal failure
  - k. Asthma and chronic obstructive airway diseases
- 9 Infectious diseases :  
Sexually transmitted diseases (HIV, Syphilis, Gonorrhea), Urinary tract infections, Pneumonia, Typhoid, Tuberculosis, Leprosy, Malaria Dysentery (bacterial and amoebic ), Hepatitis- infective hepatitis.

#### 4. Assignments :

##### Title of the Experiment

- 1 Chemical Mediators of inflammation
- 2 Drug Hypersensitivity
- 3 Cigarette smoking & its ill effects
- 4 Biological Effects of Radiation
- 5 Etiology and hazards of obesity
- 6 Complications of diabetes
- 7 Diagnosis of cancer
- 8 Disorders of vitamins
- 9 Methods in Pathology-Laboratory values of clinical significance
- 10 Pathophysiology of Dengue Hemorrhagic Fever (DHF)

##### Format of the assignment

- 1 Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy.
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

  
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## 2.2 PHARMACEUTICAL MICROBIOLOGY (THEORY)

**Theory : 3 Hrs. /Week**

1. **Scope of the Subject:** Microbiology has always been an essential component of pharmacy curriculum. This is because of the relevance of microbiology to pharmaceutical sciences and more specifically to pharmaceutical industry. Pharmaceutical biotechnology is the logical extension of pharmaceutical microbiology, which is expected to change the complete drug product scenario in the future.

This course deals with the various aspects of microorganisms, its classification, morphology, laboratory cultivation identification and maintenance. It also discusses with sterilization of pharmaceutical products, equipment, media etc. The course further discusses the immunological preparations, diseases its transmission, diagnosis, control and immunological tests.

2. **Objectives of the Subject :**

Upon completion of the subject student shall be able to -

- a. know the anatomy, identification, growth factors and sterilization of microorganisms;
- b. know the mode of transmission of disease causing microorganism, symptoms of disease, and treatment aspect;
- c. do estimation of RNA and DNA and there by identifying the source ;
- d. do cultivation and identification of the microorganisms in the laboratory;
- e. do identification of diseases by performing the diagnostic tests; and
- f. appreciate the behavior of motility and behavioral characteristics of microorganisms.

**Text books (Theory)**

- a. Vanitha Kale and Kishor Bhusari — Applied Microbiology | Himalaya Publishing house Mumbai.
- b. Mary Louis Turgeon — Immunology and Serology in Laboratory Medicines| 2<sup>nd</sup> edition, 1996 Mosby- Year book inc St. Louis Missouri 63146.
- c. Harsh Mohan, — Text book of Pathology| 3<sup>rd</sup> edition, 1998, B-3 Ansari road Darya ganj N. Delhi.

**Reference books (Theory)**

- a. Prescott L.M., Jarley G.P Klein D.A —Microbiology| 2<sup>nd</sup>- edition Mc Graw Hill Company Inc
- b. Rawlins E.A.|Bentley's Text Book of Pharmaceutics| B ailliere Tindals 24-28 London 1988
- c. Forbisher — Fundamentals of Microbiology| Philadelphia W.B. Saunders.
- d. Prescott L.M. Jarley G.P., Klein.D.A. — Microbiology.|2<sup>nd</sup> edition WMC Brown Publishers, Oxford. 1993
- e. War Roitt, Jonathan Brostoff, David male, — Immunology|3<sup>rd</sup> edition 1996, Mosby-year book Europe Ltd, London.
- f. Pharmacopoeia of India, Govt of India, 1996.

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### 3. Detailed syllabus and lecture wise schedule :

#### Title of the topic

- 1 Introduction to the science of microbiology. Major divisions of microbial world and Relationship among them.
- 2 Different methods of classification of microbes and study of Bacteria, Fungi, virus, Rickettsiae, Spirochetes.
- 3 Nutritional requirements, growth and cultivation of bacteria and virus. Study of different important media required for the growth of aerobic and anaerobic bacteria & fungi. Different media, enriched media and selective media, maintenance of lab cultures.
- 4 Different methods used in isolation and identification of bacteria with emphasis to different staining techniques and biochemical reactions. Counting of bacteria -Total and Viable counting techniques.
- 5 Detailed study of different methods of sterilization including their merits and demerits. Sterilization methods for all pharmaceutical products. Detailed study of sterility testing of different pharmaceutical preparations . Brief information on Validation.
- 6 Disinfectants- Study of disinfectants, antiseptics, fungicidal and virucidal agents factors affecting their activation and mechanism of action. Evaluation of bactericidal, bacteristatic, , virucidal activities, evaluation of preservatives in pharmaceutical preparations.
- 7 Immunology- Immunity, Definition, Classification, General principles of natural immunity, Phagocytosis, acquired immunity( active and passive ) . Antigens, chemical nature of antigens structure and formation of Antibodies, Antigen-Antibody reactions. Bacterial exotoxins and endotoxins. Significance of toxoids in active immunity, Immunization programme, and importance of booster dose.
- 8 Diagnostic tests : Schick's Test, Elisa test, Western Blot test, Southern Blot PCR Widal, QBC, Mantoux Peripheral smear. Study of malarial parasite.
- 9 Microbial culture sensitivity Testing: Interpretation of results Principles and methods of different microbiological assays, microbiological assay of Penicillin, Streptomycin and vitamin B<sub>2</sub> and B<sub>12</sub>. Standardisation of vaccines and sera.
- 10 Study of infectious diseases: Typhoid, Tuberculosis, Malaria, Cholera, Hepatitis, Meningitis, Syphilis & Gonorrhea and HIV.

### 2.2 PHARMACEUTICAL MICROBIOLOGY (PRACTICAL)

**Practical : 3 Hrs./Week**

#### Title of the Experiment:

- 1 Study of apparatus used in experimental microbiology\*.
- 2 Sterilisation of glass ware's. Preparation of media and sterilisation.\*
- 3 Staining techniques - Simple staining ; Gram's staining ; Negative staining\*\*
- 4 Study of motility characters\*.
- 5 Enumeration of micro-organisms (Total and Viable)\*
- 6 Study of the methods of isolation of pure culture.\*
- 7 Bio chemical testing for the identification of micro\*-organisms.

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- 8 Cultural sensitivity testing for some micro-organisms.\*
- 9 Sterility testing for powders and liquids.\*
- 10 Determination of minimum inhibitory concentration.\*
- 11 Microbiological assay of antibiotics by cup plate method.\*
- 12 Microbiological assay of vitamins by Turbidometric method\*\*
- 13 Determination of RWC.\*\*
- 14 Diagnostic tests for some common diseases, Widal, malarial parasite.\*\*

\* Indicate minor experiment & \*\* indicate major experiment

#### Assignments:

- 1 Visit to some pathological laboratories & study the activities and equipment/instruments used and reporting the same.
2. Visit to milk dairies (Pasturization) and microbial laboratories (other sterilization methods) & study the activities and equipment/instruments used and reporting the same.
3. Library assignments
  - a. Report of recent microbial techniques developed in diagnosing some common diseases.
  - b. Latest advancement developed in identifying, cultivating & handling of microorganisms.

#### Format of the assignment:

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

#### Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

## 2.3 PHARMACOGNOSY & PHYTOPHARMACEUTICALS (THEORY)

**Theory : 3 Hrs. /Week**

1. **Scope and objectives:** This subject has been introduced for the pharmacy course in order to make the student aware of medicinal uses of various naturally occurring drugs its history, sources, distribution, method of cultivation, active constituents, medicinal uses, identification tests, preservation methods, substitutes and adulterants.
2. **Upon completion of the course student shall be able to:**
  - a. understand the basic principles of cultivation, collection and storage of crude drugs;
  - b. know the source, active constituents and uses of crude drugs; and
  - c. appreciate the applications of primary and secondary metabolites of the plant.

### 3. Course materials:

#### Text books

- a. Pharmacognosy by G.E. Trease & W.C.Evans.
- b. Pharmacognosy by C.K.Kokate, Gokhale & A.C.Purohit.

#### Reference books

- a. Pharmacognosy by Brady & Tyler.E.
- b. Pharmacognosy by T.E.Wallis.
- c. Pharmacognosy by C.S. Shah & Qadery.
- d. Pharmacognosy by M.A. Iyengar.

### 4. Lecture wise programme:

#### Topics

- 1 Introduction.
- 2 Definition, history and scope of Pharmacognosy.
- 3 Classification of crude drugs.
- 4 Cultivation, collection, processing and storage of crude drugs.
- 5 Detailed method of cultivation of crude drugs.
- 6 Study of cell wall constituents and cell inclusions.
- 7 Microscopical and powder Microscopical study of crude drugs.
- 8 Study of natural pesticides.
- 9 Detailed study of various cell constituents.
- 10 Carbohydrates and related products.
- 11 Detailed study carbohydrates containing drugs.(11 drugs)
- 12 Definition sources, method extraction, chemistry and method of analysis of lipids.
- 13 Detailed study of oils.
- 14 Definition, classification, chemistry and method of analysis of protein.
- 15 Study of plants fibers used in surgical dressings and related products.
- 16 Different methods of adulteration of crude drugs.



## 2.3 PHARMACOGNOSY & PHYTOPHARMACEUTICALS (PRACTICAL)

**Practical : 3 Hrs./Week**

**General Requirements:** Laboratory Napkin, Observation Book 150 pages Zero brush, Needle, Blade, Match box.


**List of experiments:**

- 1 Introduction of Pharmacognosy laboratory and experiments.
- 2 Study of cell wall constituents and cell inclusions.
- 3 Macro, powder and microscopic study of Datura.
- 4 Macro, powder and microscopic study of Senna.
- 5 Macro, powder and microscopic study of Cassia.cinnamom.
- 6 Macro, powder and microscopic study of Cinchona.
- 7 Macro, powder and microscopic study of Ephedra.
- 8 Macro, powder and microscopic study of Quassia.
- 9 Macro, powder and microscopic study of Clove
- 10 Macro, powder and microscopic study of Fennel.
- 11 Macro, powder and microscopic study of Coriander.
- 12 Macro, powder and microscopic study of Isapgol.
- 13 Macro, powder and microscopic study of Nux vomica.
- 14 Macro, powder and microscopic study of Rauwolfia.
- 15 Macro, powder and microscopic study of Liquorice.
- 16 Macro, powder and microscopic study of Ginger.
- 17 Macro, powder and microscopic study of Podophyllum.
- 18 Determination of Iodine value.
- 19 Determination of Saponification value and unsaponifiable matter.
- 20 Determination of ester value.
- 21 Determination of Acid value.
- 22 Chemical tests for Acacia.
- 23 Chemical tests for Tragacanth.
- 24 Chemical tests for Agar.
- 25 Chemical tests for Starch.
- 26 Chemical tests for Lipids.(castor oil,sesame oil, shark liver oil,bees wax)
- 27 Chemical tests for Gelatin.

**Scheme of Practical Examination:**

	Sessionals	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance.

  
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## 2.4 PHARMACOLOGY - I (THEORY)

**Theory : 3 Hrs. /Week**

1. **Scope of the Subject:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, apart from general pharmacology, drugs acting on autonomic nervous system, cardiovascular system, central nervous system, blood and blood forming agents and renal system will be taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.
2. **Objectives of the Subject :** Upon completion of the subject student shall be able to (Know, do, appreciate) -
  - a. understand the pharmacological aspects of drugs falling under the above mentioned chapters;
  - b. handle and carry out the animal experiments;
  - c. appreciate the importance of pharmacology subject as a basis of therapeutics; and
  - d. correlate and apply the knowledge therapeutically.

**Text books (Theory)** (Author, Title, Edition, Publication Place, Publisher, Year of Publication)

- a. Tripathi, K. D. Essentials of medical pharmacology. 4<sup>th</sup> Ed, 1999. Publisher: Jaypee, Delhi.
- b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16<sup>th</sup> edition (single volume), 1999. Publisher: Popular, Dubai.
- c. Rang, H.P. & Dale, M.M. Pharmacology. 4<sup>th</sup> edition, 1999. Publisher: Churchill Living stone.

**Reference books (Theory)**(Author, Title, Edition, Publication Place, Publisher, Publication Year)

- a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9<sup>th</sup> Ed, 1996. Publisher Mc Graw Hill, Pergamon press.
- b. Craig, C.R.&Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher : Little Brown.Co
- c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, Int.
- d. Shargel and Leon. Applied Biopharmaceutics and pharmacokinetics. Latest edition. Publisher: Prentice Hall, London.

**Text books (Practical) :**

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

**Reference books (Practical)**

- a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.

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- b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
- c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
- d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

### 3. Detailed syllabus and lecture wise schedule :

#### Title of the topic

#### 1. General Pharmacology

- a) Introduction, definitions and scope of pharmacology
- b) Routes of administration of drugs
- c) Pharmacokinetics (absorption, distribution, metabolism and excretion)
- d) Pharmacodynamics
- e) Factors modifying drug effects
- f) Drug toxicity - Acute, sub- acute and chronic toxicity.
- g) Pre-clinical evaluations
- h) Drug interactions

*Note:* The term Pharmacology used here refers to the classification, mechanism of action, pharmacokinetics, pharmacodynamics, adverse effects, contraindications, Therapeutic uses, interactions and dose and route of administration.

#### 2. Pharmacology of drugs acting on ANS

- a) Adrenergic and antiadrenergic drugs
- b) Cholinergic and anticholinergic drugs
- c) Neuromuscular blockers
- d) Mydriatics and miotics
- e) Drugs used in myasthenia gravis
- f) Drugs used in Parkinsonism

#### 3. Pharmacology of drugs acting on cardiovascular system

- a) Antihypertensives
- b) Anti-anginal drugs
- c) Anti-arrhythmic drugs
- d) Drugs used for therapy of Congestive Heart Failure
- e) Drugs used for hyperlipidaemias

4. **Pharmacology of drugs acting on Central Nervous System**

- a) General anesthetics
- b) Sedatives and hypnotics
- c) Anticonvulsants
- d) Analgesic and anti- inflammatory agents
- e) *Psychotropic drugs*
- f) Alcohol and methyl alcohol
- g) CNS stimulants and cognition enhancers
- h) Pharmacology of local anaesthetics

5. **Pharmacology of Drugs acting on Respiratory tract**

- a) Bronchodilators
- b) Mucolytics
- c) Expectorants
- d) Antitussives
- e) NasalDecongestants

6. **Pharmacology of Hormones and Hormone antagonists**

- a) Thyroid and Antithyroid drugs
- b) Insulin, Insulin analogues and oral hypoglycemic agents
- c) Sex hormones and oral contraceptives
- d) Oxytocin and other stimulants and relaxants

7. **Pharmacology of autocoids and their antagonists**

- a) Histamines and Antihistaminics
- b) 5-Hydroxytryptamine and its antagonists
- c) Lipid derived autocoids and platelet activating factor



## 2.5 COMMUNITY PHARMACY (THEORY)

**Theory : 2 Hrs. /Week**

- 1. Scope:** In the changing scenario of pharmacy practice in India, Community Pharmacists are expected to offer various pharmaceutical care services. In order to meet this demand, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling, health screening services for improved patient care in the community set up.
- 2. Objectives:** Upon completion of the course, the student shall be able to -
  - a. know pharmaceutical care services;
  - b. know the business and professional practice management skills in community pharmacies;
  - c. do patient counselling & provide health screening services to public in community pharmacy;
  - d. respond to minor ailments and provide appropriate medication;
  - e. show empathy and sympathy to patients; and
  - f. appreciate the concept of Rational drug therapy.

### **Text Books:**

- a. Health Education and Community Pharmacy by N.S.Parmar.
- b. WHO consultative group report.
- c. Drug store & Business management by Mohammed Ali & Jyoti.

### **Reference books:**

- a. Handbook of pharmacy - health care. Edt. Robin J Harman. The Pharmaceutical press.
- b. Comprehensive Pharmacy Review - Edt. Leon Shargel. Lippincott Williams & Wilkins.

### **Special require ments:**

1. Either the college is having model community pharmacy (meeting the schedule N requirement) or sign MoU with at least 4-5 community pharmacies nearby to the college for training the students on dispensing and counselling activities.
2. Special equipments like B.P apparatus, Glucometer, Peak flow meter, and apparatus for cholesterol estimation.

### **3. Scheme of evaluation (80 Marks)**

- |  |    |
|--|----|
| 1. Synopsis  | 10 |
| 2. Major Experiment  | 30 |
| (Counselling of patients with specific diseases - emphasis should be given on Counselling introduction, content, process and conclusion) |    |
| 3. Minor Experiment(Ability to measure B.P/ CBG / Lung function)   | 15 |
| 4. Prescription Analysis (Analyzing the prescriptions for probable drug interaction and ability to tell the management)                  | 15 |
| 5. Viva - Voce   | 10 |

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#### 4. Lecture wise programme :

##### Topics

- 1 **Definition, scope, of community pharmacy**  
**Roles and responsibilities of Community pharmacist**
- 2 **Community Pharmacy Management**
  - a) Selection of site, Space layout, and design
  - b) Staff, Materials- coding, stocking
  - c) Legal requirements
  - d) Maintenance of various registers
  - e) Use of Computers: Business and health care soft wares
- 3 **Prescriptions** - parts of prescription, legality & identification of medication related problems like drug interactions.
- 4 **Inventory control in community pharmacy**  
Definition, various methods of Inventory Control  
**ABC, VED, EOQ, Lead time, safety stock**
- 5 **Pharmaceutical care**  
Definition and Principles of Pharmaceutical care.
- 6 **Patient counselling**  
Definition, outcomes, various stages, barriers, Strategies to overcome barriers  
Patient information leaflets- content, design, & layouts, advisory labels
- 7 **Patient medication adherence**  
Definition, Factors affecting medication adherence, role of pharmacist in improving the adherence.
- 8 **Health screening services**  
Definition, importance, methods for screening  
Blood pressure/ blood sugar/ lung function and  
Cholesterol testing
- 9 **OTC Medication- Definition, OTC medication list & Counselling**
- 10 **Health Education**  
WHO Definition of health, and health promotion, care for children, pregnant & breast feeding women, and geriatric patients.  
Commonly occurring Communicable Diseases, causative agents,  
Clinical presentations and prevention of communicable diseases - Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy, Syphilis, Gonorrhea and AIDS  
Balance diet, and treatment & prevention of deficiency disorders  
Family planning - role of pharmacist
- 11 **Responding to symptoms of minor ailments**  
Relevant pathophysiology, common drug therapy to,  
Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Pyrexia, Ophthalmic symptoms, worms infestations.
- 12 **Essential Drugs concept and Rational Drug Therapy**  
**Role of community pharmacist**
- 13 **Code of ethics for community pharmacists**



## 2.6 PHARMACOTHERAPEUTICS - I (THEORY)

**Theory : 3 Hrs. /Week**

1. **Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives:** At completion of this subject it is expected that students will be able to understand -
  - a. the pathophysiology of selected disease states and the rationale for drug therapy;
  - b. the therapeutic approach to management of these diseases;
  - c. the controversies in drug therapy;
  - d. the importance of preparation of individualised therapeutic plans based on diagnosis;
  - e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
  - f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
  - g. summarise the therapeutic approach to management of these diseases including reference to the latest available evidence;
  - h. discuss the controversies in drug therapy;
  - i. discuss the preparation of individualised therapeutic plans based on diagnosis; and
  - j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

### Text Books

- a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.
- b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange.

### Reference Books

- a. Pathologic basis of disease - Robins SL, W.B.Saunders publication.
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication.
- c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication.
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
- e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature.



### 3. Detailed syllabus and lecture wise schedule :

**Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases**

**Title of the topic**

- 1 **Cardiovascular system:** Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, , Hyperlipidaemias , Electrophysiology of heart and Arrhythmias
- 2 **Respiratory system :** Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases  
**Endocrine system :** Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis
- 3 **General prescribing guidelines for**
  - a. Paediatric patients
  - b. Geriatric patients
  - c. Pregnancy and breast feeding
- 4 **Ophthalmology:** Glaucoma, Conjunctivitis- viral & bacterial
- 5 **Introduction to rational drug use**  
Definition, Role of pharmacist Essential drug concept Rational drug formulations

## 2.6 PHARMACOTHERAPEUTICS - I (PRACTICAL)

**Practical : 3 Hrs./Week**

**Practicals :**

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 20 cases should be presented and recorded covering most common diseases.

**Assignments :**

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 -2000 words] should be submitted for evaluation.

  
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**Format of the assignment:**

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

**Scheme of Practical Examination:**

	<b>Sessionals</b>	<b>Annual</b>
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

  
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## **Third Year**

### **3.1 PHARMACOLOGY - II (THEORY)**

**Theory : 3 Hrs. /Week**

1. **Scope of the Subject:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, drugs acting on autacoids, respiratory system, GIT, immune system and hormones, and pharmacology of autacoids and hormones will be concentrated. In addition, pharmacology of chemotherapeutic agents, vitamins, essential minerals and principles of toxicology are also taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.
2. **Objectives of the Subject Upon completion of the subject student shall be able to:**
  - a. understand the pharmacological aspects of drugs falling under the above mentioned chapters,
  - b. carry out the animal experiments confidently,
  - c. appreciate the importance of pharmacology subject as a basis of therapeutics, and
  - d. correlate and apply the knowledge therapeutically.

#### **Text books (Theory)**

- a. Tripathi, K. D. Essentials of medical pharmacology. 4<sup>th</sup> edition, 1999. Publisher: Jaypee, Delhi.
- b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16<sup>th</sup> edition (single volume), 1999. Publisher: Popular, Dubai.
- c. Rang, H.P. and Dale, M.M. Pharmacology. 4<sup>th</sup> edition, 1999. Publisher: Churchill Living stone.

#### **Reference books (Theory)**

- a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9<sup>th</sup> edition, 1996. Publisher: Mc Graw Hill, Pergamon press.
- b. Craig, C.R. and Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown and company.
- c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, International.
- d. Gupta, P.K. and Salunkhe, D.K. Modern Toxicology. Volume I, II and III. Latest edition. Publisher: B.V. Gupta, Metropolitan Book Co. (p) Ltd, New Delhi.

#### **Text books (Practical)**

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

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**Reference books (Practical) :**

- a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.
- b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
- c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
- d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

**3. Detailed syllabus and lecture wise schedule:****Title of the topic**

1. **Pharmacology of Drugs acting on Blood and blood forming agents**
  - a) Anticoagulants
  - b) Thrombolytics and antiplatelet agents
  - c) Haemopoietics and plasma expanders
2. **Pharmacology of drugs acting on Renal System**
  - a) Diuretics
  - b) Antidiuretics
3. **Chemotherapy**
  - a) Introduction
  - b) Sulfonamides and co-trimoxazole
  - c) Penicillins and Cephalosporins
  - d) Tetracyclins and Chloramphenicol
  - e) Macrolides, Aminoglycosides, Polyene & Polypeptide antibiotics
  - f) Quinolones and Fluroquinolones
  - g) Antifungal antibiotics
  - h) Antiviral agents
  - i) Chemotherapy of tuberculosis and leprosy
  - j) Chemotherapy of Malaria
  - k) Chemotherapy of protozoal infections (amoebiasis, Giardiasis)
  - l) Pharmacology of Anthelmintic drugs
  - m) Chemotherapy of cancer (Neoplasms)
4. **Immunopharmacology**  
Pharmacology of immunosuppressants and stimulants
5. **Principles of Animal toxicology**  
Acute, sub acute and chronic toxicity

  
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6. **The dynamic cell: The structures and functions of the components of the cell**

- a) Cell and macromolecules: Cellular classification, subcellular organelles, macromolecules, large macromolecular assemblies
- b) Chromosome structure: Pro and eukaryotic chromosome structures, chromatin structure, genome complexity, the flow of genetic information.
- c) DNA replication: General, bacterial and eukaryotic DNA replication.
- d) The cell cycle: Restriction point, cell cycle regulators and modifiers.
- e) Cell signaling: Communication between cells and their environment, ion-channels, signal transduction pathways (MAP kinase, P38 kinase, JNK, Ras and PI3-kinase pathways, biosensors.

**The Gene: Genome structure and function:**

- a) Gene structure: Organization and elucidation of genetic code.
- b) Gene expression: Expression systems (pro and eukaryotic), genetic elements that control gene expression (nucleosomes, histones, acetylation, HDACS, DNA binding protein families.
- c) Transcription and Transcription factors: Basic principles of transcription in pro and eukaryotes. Transcription factors that regulate transcription in pro and eukaryotes.

RNA processing: rRNA, tRNA and mRNA processing.

Protein synthesis: Mechanisms of protein synthesis, initiation in eukaryotes, translation control and post-translation events

Altered gene functions: Mutations, deletions, amplifications, LOH, traslocations, trinucleotide repeats and other genetic abnormalities.

Oncogenes and tumor suppressor genes.

The gene sequencing, mapping and cloning of human disease genes.

Introduction to gene therapy and targeting.

Recombinant DNA technology: principles. Processes (gene transfer technology) and applications

**Books:**

- 1 Molecular Biology of the Cell by Alberts B., Bray, D., Lewis, J., Raff M., Roberts, K and Watson, JD, 3<sup>rd</sup> edition.
- 2 Molecular Cell Biology By Lodish, H., Baltimore, D., Berk, A et al., 5<sup>th</sup> edition.
- 3 Molecular Biology by Turner, PC., McLennan, AG., Bates, AD and White MRH 2<sup>nd</sup> edition.
- 4 Genes VIII by Lewin, B., (2004)
- 5 Pharmaceutical Biotechnology, by Crommelin, DJA and Sindelar RD (1997)
- 6 Recombinant DNA by Watson, JD., Gilman, M., et al., (1996)
- 7 Biopharmaceutical: Biochemistry and Biotechnology by Walsh, G., (1998)

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### 3.1 PHARMACOLOG Y - II (PRACTICAL)

**Practical : 3 Hrs./Week**

**List of Experiments:**

1. Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea pigs, e. Rabbits).
2. Study of physiological salt solutions used in experimental pharmacology.
3. Study of laboratory appliances used in experimental pharmacology.
4. Study of use of anesthetics in laboratory animals.
5. To record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.
6. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.
7. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three point method.
8. To record the dose response curve of Histamine using isolated guinea-pig ileum preparation.
9. Study of agonistic and antagonistic effects of drugs using isolated guinea-pig ileum preparation.
10. To carry out bioassay of Histamine using isolated guinea-pig ileum preparation by interpolation method.
11. To carry out bioassay of Histamine using guinea-pig ileum preparation by three point method.
12. To study the routes of administration of drugs in animals (Rats, Mice, Rabbits).
13. Study of theory, principle, procedure involved and interpretation of given results for the following experiments:
  - a) Analgesic property of drug using analgesiometer.
  - b) Antiinflammatory effect of drugs using rat-paw edema method.
  - c) Anticonvulsant activity of drugs using maximal electroshock and pentylenetetrazole methods.
  - d) Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods.
  - e) Locomotor activity evaluation of drugs using actophotometer and rotorod.
  - f) Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.

**Scheme of Practical Examination:**

	Sessionals	Annual
Identification	02	10
Synopsis	04	10
Major Experiment (Bioassay)	08	30
Minor Experiment (Interpretation of given Graph or simulated experiment)	04	10
Viva	02	10
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>3hrs</b>	<b>4hrs</b>

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

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### 3.2 PHARMACEUTICAL ANALYSIS (THEORY)

**Theory : 3 Hrs. /Week**

**1. Quality Assurance:**

- a. Introduction, sources of quality variation, control of quality variation.
- b. Concept of statistical quality control.
- c. Validation methods- quality of equipment, validation of equipment and validation of analytical instruments and calibration.
- d. GLP, ISO 9000.
- e. Total quality management, quality review and documentation.
- f. ICH- international conference for harmonization-guidelines.
- g. Regulatory control.

**2. Chromatography:**

Introduction, history, classification, separation techniques, choice of methods. The following techniques be discussed with relevant examples of pharmaceutical products involving principles and techniques of separation of drugs from excipients.

- a. **Column Chromatography:** Adsorption column chromatography, Operational technique, frontal analysis and elution analysis. Factors affecting column efficiency, applications and partition chromatography.
- b. **TLC:** Introduction, principle, techniques,  $R_f$  value and applications.
- c. **PC:** Introduction, principle, types of paper chromatography, preparation techniques, development techniques, applications.
- d. **Ion-exchange chromatography:** Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications.
- e. **HPLC:** Introduction, theory, instrumentation, and applications.
- f. **HPTLC:** Introduction, theory, instrumentation, and applications.
- g. **Gas Chromatography:** Introduction, theory, instrumentation-carrier gases, types of columns, stationary phases in GLC & GSC. Detectors- Flame ionization detectors, electron capture detector, thermal conductivity detector. Typical gas chromatogram, derivatisation techniques, programmed temperature gas chromatography, applications.
- h. **Electrophoresis:** Principles of separation, equipment for paper and gel electrophoresis, and application.
- i. **Gel filtration and affinity chromatography:** Introduction, technique, applications.

### 3. Electrometric Methods:

Theoretical aspects, instrumentation, interpretation of data/spectra and analytical applications be discussed on the following topics.

- a. **Potentiometry:** Electrical potential, electrochemical cell, reference electrodes, indicator electrodes, measurement of potential and pH, construction and working of electrodes, Potentiometric titrations, methods of detecting end point, Karl Fischer titration.
- b. **Conductometry:** Introduction, conductivity cell, conductometric titrations and applications.
- c. **Polarography:** Instrumentation, DME, residual current, diffusion current and limiting current, polarographic wave, Ilkovic's equation, Effect of oxygen on polarographic wave, Polarographic maxima and suppressors and applications.
- d. **Amperometric Titrations:** Introduction, types of electrodes used, reference and indicator electrode, instrumentation, titration procedure, advantages and disadvantages of Amperometry over potentiometry. Pharma applications.

### 4. Spectroscopy:

Theoretical aspects, instrumentation, elements of interpretation of data/spectra and application of analytical techniques be discussed on:

#### a. Absorption Spectroscopy:

- Theory of electronic, atomic and molecular spectra. Fundamental laws of photometry, Beer-Lambert's Law, application and its deviation, limitation of Beer law, application of the law to single and multiple component analysis, measurement of equilibrium constant and rate constant by spectroscopy. Spectra of isolated chromophores, auxochromes, batho-chromic shift, hypsochromic shift, hyperchromic and hypochromic effect, effect of solvent on absorption spectra, molecular structure and infrared spectra.

**Instrumentation** - Photometer, U.V.-Visible spectrophotometer - sources of U.V.-Visible radiations, collimating systems, monochromators, samples cells and following detectors-Photocell, Barrier layer cell, Phototube, Diode array, applications of U.V.-Visible spectroscopy in pharmacy and spectrophotometric titrations.

- **Infrared Spectroscopy:** Vibrational transitions, frequency - structure correlations, Infrared absorption bands, Instrumentation-IR spectrometer - sources of IR, Collimating systems, monochromators, sample cells, sample handling in IR spectroscopy and detectors-Thermocouple, Golay Cells, Thermistor, Bolometer, Pyroelectric detector, Applications of IR in pharmacy.



- **Fluorimetric Analysis:** Theory, luminescence, factors affecting fluorescence, quenching. Instrumentation, Applications, fluorescent indicators, study of pharmaceutically important compounds estimated by fluorimetry.
- b. **Flame Photometry:** Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceutical applications.
- c. **Atomic Absorption Spectrometry:** Introduction, Theory, types of electrodes, instrumentation and applications.
- d. **Atomic Emission Spectroscopy:** Spectroscopic sources, atomic emission spectrometers, photographic and photoelectric detection.
- e. **NMR & ESR (introduction only):** Introduction, theoretical aspects and applications.
- f. **Mass Spectroscopy: (Introduction only)** - Fragmentation, types of ions produced mass spectrum and applications.
- g. **Polarimetry: (Introduction only)** - Introduction to optical rotatory dispersion, circular dichroism, polarimeter.
- h. **X-RAY Diffraction: (Introduction only)** - Theory, reciprocal lattice concept, diffraction patterns and applications.
- i. **Thermal Analysis:** Introduction, instrumentation, applications, and DSC and DTA.

### 3.2 PHARMACEUTICAL ANALYSIS (PRACTICAL)

**Practical : 3 Hrs./Week**

#### **List of Experiments:**

1. Separation and identification of Amino Acids by Paper Chromatography.
2. Separation and identification of Sulpha drugs by TLC technique.
3. Effect of pH and solvent on the UV spectrum of given compound.
4. Comparison of the UV spectrum of a compound with that of its derivatives.
5. Determination of dissociation constant of indicators using UV-Visible spectroscopy.
6. Conductometric titration of mixture of acids with a strong base.
7. Potentiometric titration of an acid with a strong base.
8. Estimation of drugs by Fluorimetric technique.
9. Study of quenching effect in fluorimetry.
10. Colourimetric estimation of Sulpha drugs using BMR reagent.

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11. Simultaneous estimation of two drugs present in given formulation.
12. Assay of Salicylic Acid by colourimetry.
13. Determination of Chlorides and Sulphates in Calcium gluconate by Nepheloturbidimetric Method.
14. Determination of Na/K by Flame Photometry.
15. Determination of pKa using pH meter.
16. Determination of specific rotation.
17. Comparison of the IR spectrum of a compound with that of its derivatives.
18. Demonstration of HPLC.
19. Demonstration of HPTLC.
20. Demonstration of GC-MS.
21. Demonstration of DSC.
22. Interpretation of NMR spectra of any one compound.

#### Reference Books:

1. Text Book of Pharm. Analysis by Higuchi. T and Hasen. E. B., New York Inter Science Publishers.
2. Quantitative Pharma. Analysis by Jenkins, The Blakiston division, New York.
3. Quantitative Drug Analysis, by Garrot. D, Chapman & Hall Ltd., London.
4. Undergraduate Instrumental Analysis by James. E., CBS Publishers.
5. Instrumental Analysis by Willard and Merritt, EWP, East West Press Ltd., Delhi/Madras.
6. Pharm Analysis by Skoog and West, Sounders Manipal College Publishing.
7. Text Book of Chemical Analysis, by A.I.Vogel, ELBS with Macmillan press, Hampshire.
8. Textbook of Pharm. Analysis by K.A.Connors, John Wiley & Sons, New York, Brisbane, Singapore.
9. Textbook of Pharm. Analysis (Practical) by Beckett & Stenlake, CBS Publishers, Delhi.
10. Textbook of Drug Analysis by P.D. Sethi., CBS Publishers, Delhi.
11. Spectroscopy by Silverstein, John & Wiley & Sons. Inc., Canada & Singapore.
12. How to practise GMP-A Plan for total quality control by P.P. Sharma, Vandana Publications, Agra.
13. The Science & Practice of Pharmacy by Remington Vol-I & II, Mack Publishing Co. Pennsylvania.
14. TLC by Stahl, Spring Verlay.
15. Text Book of Pharm. Chemistry by Chatten, CBS Publications.
16. Spectroscopy by William Kemp, ELBS with Macmillan Press, Hampshire.
17. I.P.-1996, The Controller of Publications, New Delhi.
18. BPC- Dept. of Health, U.K. for HMSO.
19. USP - Mack Publishing Co., Easton, PA.
20. The Extra Pharmacopoeia - The Pharm. Press, London.

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## Practicals

### Title of the Experiment:

- 1 Study of agonistic and antagonistic effects of drugs using Guinea-pig ileum preparation.\*\*
- 2 To study the effects of drugs on intestinal motility using frog's esophagus model\*
- 3 To study the effects of drugs using rat uterus preparation.\*\*
- 4 To study the anticonvulsant property of drugs (any one model).\*
- 5 To study antihistaminic property of drug using histamine induced anaphylactic reaction in guinea pigs.
- 6 To study the apomorphine- induced compulsive behaviour (stereotypy) in mice.\*
- 7 To study the muscle relaxant property of diazepam in mice using rotarod apparatus.\*
- 8 To study the antiinflammatory property of indomethacin against carrageenan- induced paw oedema.\*\*
- 9 To study the anxiolytic effect of diazepam in mice using mirrored-chamber apparatus.\*\*
- 10 To demonstrate the effect of various drugs on the blood pressure and respiration of anaesthetized dog.
- 11 To study the effect of anthelmintics on earthworms.
- 12 To study the taming effect of chlorpromazine.\*
- 13 To study the effects of drugs on vas deferense of the male rat.\*\*
- 14 To study the effect of drugs on pesticide toxicity using rats as model.
- 15 To study the effect of drugs on heavy metal toxicity.

\*\* indicate major experiment & \* indicate minor experiment

### Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

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### 3.3 PHARMACOTHERAPEUTICS - II (THEORY)

**Theory : 3 Hrs. /Week**

1. **Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives of the Subject Upon completion of the subject student shall be able to -**
  - a. know the pathophysiology of selected disease states and the rationale for drug therapy
  - b. know the therapeutic approach to management of these diseases;
  - c. know the controversies in drug therapy;
  - d. know the importance of preparation of individualised therapeutic plans based on diagnosis; and
  - e. appreciate the needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

**Text books (Theory)**

Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication

**Reference books (Theory)**

- a. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange
- b. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
- c. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA]

**3. Detailed syllabus and lecture wise schedule :**

**Etiopathogenesis and pharmacotherapy of diseases associated with following systems / diseases -**

**Title of the topic**

1. **Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhoea and Syphilis
- 2 **Musculoskeletal disorders**  
Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.
- 3 **Renal system**  
Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders

  
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- 4 **Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis
- 5 **Dermatology:** Psoriasis, Scabies, Eczema, Impetigo

### 3.3 PHARMACOTHERAPEUTICS - II (PRACTICAL)

**Practical : 3 Hrs./Week**

**Practicals :**

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.

The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.

A minimum of 20 cases should be presented and recorded covering most common diseases.

**Assignments :**

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 -2000 words] should be submitted for evaluation.

**Format of the assignment :**

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

**Scheme of Practical Examination :**

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

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### 3.4 PHARMACEUTICAL JURISPRUDENCE (THEORY)

**Theory : 2 Hrs. /Week**

1. **Scope of the Subject:** (4-6 lines): This course exposes the student to several important legislations related to the profession of pharmacy in India. The Drugs and Cosmetics Act, along with its amendments are the core of this course. Other acts, which are covered, include the Pharmacy Act, dangerous drugs, medicinal and toilet preparation Act etc. Besides this the new drug policy, professional ethics, DPCO, patent and design Act will be discussed.
2. **Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, and appreciate) -
  - a. practice the Professional ethics;
  - b. understand the various concepts of the pharmaceutical legislation in India;
  - c. know the various parameters in the Drug and Cosmetic Act and rules ;
  - d. know the Drug policy, DPCO, Patent and design act;
  - e. understand the labeling requirements and packaging guidelines for drugs and cosmetics;
  - f. be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and
  - g. other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

#### **Text books (Theory)**

Mithal , B M. Textbook of Forensic Pharmacy. Calcutta :National; 1988.

#### **Reference books (Theory)**

- a. Singh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad: Law Book House; 1984.
- b. Jain, NK. A Textbook of forensic pharmacy. Delhi: Vallabh prakashan ; 1995.
- c. Reports of the Pharmaceutical enquiry Committee
- d. I.D.M.A., Mumbai. DPCO 1995
- e. Various reports of Amendments.
- f. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
- g. Eastern Book Company .The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.

### 3. Detailed syllabus and lecture wise schedule:

#### **Title of the topic**

1. **Pharmaceutical Legislations** - A brief review.
2. Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI.
3. **Drugs and Cos metics Act, 1940,and its rules 1945.**  
Objectives, Legal definition, Study of Schedule's with reference to Schedule B, C&C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y.  
Sales, Import, labeling and packaging of Drugs And Cosmetics  
Provisions Relating to Indigenous Systems.  
Constitution and Functions of DTAB,DCC,CDL.  
Qualification and duties -Govt. analyst and Drugs Inspector.

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4. **Pharmacy Act -1948.**

Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER.

5. **Medicinal and Toilet Preparation Act -1955.**

Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations.

6. **Narcotic Drugs and Psychotropic substances Act-1985 and Rules.** Objectives, Legal Definitions, General Study, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and regulations, Schedules to the Act.

7. **Study of Salient Features of Drugs and magic remedies Act and its rules.**

8. **Study of essential Commodities Act Relevant to drugs price control Order.**

9. **Drug Price control Order & National Drug Policy (Current).**

10. **Prevention Of Cruelty to animals Act-1960.**

11. **Patents & design Act-1970.**

12. **Brief study of prescription and Non-prescription Products.**

4. **Assignments:**

**Format of the assignment**

1. Minimum & Maximum number of pages
2. It shall be a computer draft copy
3. Reference(s) shall be included at the end.
4. Name and signature of the student
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min

**Case studies relating to**

1. Drugs and Cosmetics Act and rules along with its amendments, Dangerous Drugs Act, Medicinal and Toilet preparation Act, New Drug Policy, Professional Ethics, Drugs (Price control) Order, Patent and Design Act.
2. Various prescription and non-prescription products.
3. Medical and surgical accessories.
4. Diagnostic aids and appliances available in the market.



### 3.5 MEDICINAL CHEMISTRY (THEORY)

**Theory : 3 Hrs. /Week**

1. Modern concept of rational drug design: A brief introduction to Quantitative Structure Activity Relationship (QSAR), prodrug, combinatorial chemistry and computer aided drug design (CADD) and concept of antisense molecules.

A study of the development of the following classes of drugs including SAR, mechanism of action, synthesis of important compounds, chemical nomenclature, brand names of important marketed products and their side effects.

2. Anti- infective agents
  - a) Local anti- infective agents
  - b) Preservatives
  - c) Antifungal agents
  - d) Urinary tract anti- infectives
  - e) Antitubercular agents
  - f) Antiviral agents and Anti AIDS agents
  - g) Antiprotozoal agents
  - h) Anthelmintics
  - i) Antiscabies and Antipedicular agents
3. Sulphonamides and sulphones
4. Antimalarials
5. Antibiotics
6. Antineoplastic agents
7. Cardiovascular agents
  - a) Antihypertensive agents
  - b) Antianginal agents and vasodilators
  - c) Antiarrhythmic agents
  - d) Antihyperlipidemic agents
  - e) Coagulants and Anticoagulants
  - f) Endocrine
8. Hypoglycemic agents
9. Thyroid and Antithyroid agents
10. Diuretics
11. Diagnostic agents
12. Steroidal Hormones and Adrenocorticoids

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### 3.5 MEDICINAL CHEMISTRY (PRACTICAL)

#### Practical : 3 Hrs./Week

1. Assays of important drugs from the course content.
2. Preparation of medicinally important compounds or intermediates required for synthesis of drugs.
3. Monograph analysis of important drugs.
4. Determination of partition coefficients, dissociation constants and molar refractivity of compounds for QSAR analysis.

#### Reference Books:

- a. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.
- b. William.O.Foye, Principles of Medicinal Chemistry, B.I. Waverly Pvt. Ltd., New Delhi.
- c. Burgers, Medicinal Chemistry, M.E., Welly Med.Chemistry M.E. Walffed Johnwiley and Sons, Wiley-interscience Publication, New York, Toranto.
- d. A Text Book of Medicinal Chemistry Vol. I and II by Surendra N. Pandeya, S.G. Publisher, 6, Dildayal Nagar, Varanasi -10.
- e. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi - 54.
- f. Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19.
- g. Organic Drug Synthesis-Ledniser Mitzsher Vol. I and II.
- h. Pharmaceutical Chemistry drug Synthesis Vol. I and II by H. J. Roth and A. Kleemann.
- i. The Science and Practice of Pharmacy Vol. 1 and 2, Remington, MACK Publishing Company, Easton, Pennsylvania.

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### 3.6 PHARMACEUTICAL FORMULATIONS (THEORY)

**Theory : 2 Hrs. /Week**

1. **Scope of the Subject:** Scope and objectives of the course: Subject deals with the formulation and evaluation of various pharmaceutical dosage forms.
2. **Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, appreciate) -
  - a. understand the principle involved in formulation of various pharmaceutical dosage forms;
  - b. prepare various pharmaceutical formulation;
  - c. perform evaluation of pharmaceutical dosage forms; and
  - d. understand and appreciate the concept of bioavailability and bioequivalence, their role in clinical situations.

**Text books (Theory)**

- a. Pharmaceutical dosage forms, Vol, I,II and III by lachman
- b. Rowlings Text book of Pharmaceutics
- c. Tutorial Pharmacy - Cooper & Gun

**Reference books (Theory)**

- a. Remington's Pharmaceutical Sciences
- b. USP/BP/IP

**3. Detailed syllabus and lecture wise schedule:**

**Title of the topic**

1. Pharmaceutical dosage form- concept and classification
2. **Tablets:** Formulation of different types of tablets, tablet excipients, granulation techniques quality control and evaluation of tablets. Tablet coating, Type of coating, quality control tests for coated tablet.
3. **Capsules:** Production and filling of hard gelatin capsules, Raw material for shell, finishing, quality control tests for capsules. Production and filling of soft gelatin capsules, quality control tests for soft gelatin capsules.
4. **Liquid orals:** Formulation and evaluation of suspensions, emulsions and solutions. Stability of these preparations
5. **Parenterals** Introduction Containers used for Parenterals (including official tests) Formulation of large and small volume Parenterals Sterilization
6. **Ophthalmic preparations (Semi - Solids):** Introduction and classification Factors affecting absorption and anatomy of skin Packaging storage and labeling, Ointments Types of Ointment Base Preparation of ointment, Jellies Types of jellies Formulation of jellies Suppositories, Method of preparation, Types Packaging
7. Definition and concept of **Controlled and novel Drug delivery systems** with available examples, viz. parenteral, trans dermal, buccal, rectal, nasal, implants, ocular

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### 3.6 PHARMACEUTICAL FORMULATIONS (PRACTICAL)

**Practical : 3 Hrs./Week**

**List of Experiments :**

1. **Manufacture of Tablets**
  - a. Ordinary compressed tablet-wet granulation
  - b. Tablets prepared by direct compression.
  - c. Soluble tablet.
  - d. Chewable tablet.
2. **Formulation and filling of hard gelatin capsules**
3. **Manufacture of parenterals**
  - a. Ascorbic acid injection
  - b. Calcium gluconate injection
  - c. Sodium chloride infusion.
  - d. Dextrose and Sodium chloride injection/ infusion.
4. **Evaluation of Pharmaceutical formulations (QC tests)**
  - a. Tablets
  - b. Capsules
  - c. Injections
5. **Formulation of two liquid oral preparations and evaluation by assay**
  - a. Solution: Paracetamol Syrup
  - b. Antacid suspensions- Aluminum hydroxide gel
6. **Formulation of semisolids and evaluation by assay**
  - a. Salicylic acid and benzoic acid ointment
  - b. Gel formulation Diclofenac gel
7. **Cosmetic preparations**
  - a. Lipsticks
  - b. Cold cream and vanishing cream
  - c. Clear liquid shampoo
  - d. Tooth paste and tooth powders.
8. **Tablet coating (demonstration)**

**Scheme of Practical Examination :**

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

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## **Fourth Year**

### **4.1 PHARMACOTHERAPEUTICS - III (THEORY)**

**Theory : 3 Hrs. /Week**


1. **Scope :** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives:** At completion of this subject it is expected that students will be able to understand -
  - a. the pathophysiology of selected disease states and the rationale for drug therapy;
  - b. the therapeutic approach to management of these diseases ;
  - c. the controversies in drug therapy;
  - d. the importance of preparation of individualised therapeutic plans based on diagnosis;
  - e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
  - f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
  - g. to summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
  - h. to discuss the controversies in drug therapy;
  - i. to discuss the preparation of individualised therapeutic plans based on diagnosis; and
  - j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

#### **Text Books**

- a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication
- b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange

#### **Reference Books**

- a. Pathologic basis of disease - Robins SL, W.B.Saunders publication
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication
- c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
- e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature.

  
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#### 4.1 PHARMACOTHERAPEUTICS - III (PRACTICAL)

**Practical : 3 Hrs./Week**

**Practicals:**

Hospital postings for a period of at least 50 hours is required to understand the principles and practice involved in ward round participation and clinical discussion on selection of drug therapy. Students are required to maintain a record of 15 cases observed in the ward and the same should be submitted at the end of the course for evaluation. Each student should present at least two medical cases they have observed and followed in the wards.

**Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases:**

**Title of the topic**

- 1 **Gastrointestinal system:** Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, Viral hepatitis including jaundice, and Drug induced liver disorders.
- 2 **Haematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.
- 3 **Nervous system:** Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,
- 4 **Psychiatry disorders:** Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders
- 5 Pain management including Pain pathways, neuralgias, headaches.
- 6 Evidence Based Medicine

**Assignments:**

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500- 2000 words] should be submitted for evaluation.

**Format of the assignment:**

1. Minimum & Maximum number of pages
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

**Scheme of Practical Examination :**

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

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## 4.2 HOSPITAL PHARMACY (THEORY)

**Theory : 2 Hrs. /Week**

1. **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 dispensing, manufacturing of parenteral preparations, drug information, patient counselling, and therapeutic drug monitoring for improved patient care.
2. **Objectives:** Upon completion of the course, the student shall be able to -
  - a. know various drug distribution methods;
  - b. know the professional practice management skills in hospital pharmacies;
  - c. provide unbiased drug information to the doctors;
  - d. know the manufacturing practices of various formulations in hospital set up;
  - e. appreciate the practice based research methods; and
  - f. appreciate the stores management and inventory control.

**Text books: (latest editions)**

- a. Hospital pharmacy by William .E. Hassan
- b. A text book of Hospital Pharmacy by S.H. Merchant & Dr. J.S. Qadry. Revised by R.K. Goyal & R.K. Parikh

**References:**

- a. WHO consultative group report.
- b. R.P.S. Vol.2. Part -B; Pharmacy Practice section.
- c. Handbook of pharmacy - health care. Edt. Robin J Harman. The Pharmaceutical press.

### 3. Lecture wise programme :

**Topics**

- 1 **Hospital - its Organisation and functions**
- 2 **Hospital pharmacy-Organisation and management**
  - a) Organizational structure-Staff, Infrastructure & work load statistics
  - b) Management of materials and finance
  - c) Roles & responsibilities of hospital pharmacist
- 3 **The Budget - Preparation and implementation**
- 4 **Hospital drug policy**
  - a) Pharmacy and Therapeutic committee (PTC)
  - b) Hospital formulary
  - c) Hospital committees
    - Infection committee
    - Research and ethical committee
  - d) developing therapeutic guidelines
  - e) Hospital pharmacy communication - Newsletter

**5 Hospital pharmacy services**

- a) Procurement & warehousing of drugs and Pharmaceuticals
- b) Inventory control  
Definition, various methods of Inventory Control  
ABC, VED, EOQ, Lead time, safety stock
- c) Drug distribution in the hospital
  - i) Individual prescription method
  - ii) Floor stock method
  - iii) Unit dose drug distribution method
- d) Distribution of Narcotic and other controlled substances
- e) Central sterile supply services - Role of pharmacist

**6 Manufacture of Pharmaceutical preparations**

- a) Sterile formulations - large and small volume parenterals
- b) Manufacture of Ointments, Liquids, and creams
- c) Manufacturing of Tablets, granules, capsules, and powders
- d) Total parenteral nutrition

**7 Continuing professional development programs**

Education and training

**8 Radio Pharmaceuticals - Handling and packaging****9 Professional Relations and practices of hospital pharmacist****4.2 HOSPITAL PHARMACY (PRACTICAL)****Practical : 3 Hrs./Week**

1. Assessment of drug interactions in the given prescriptions
2. Manufacture of parenteral formulations, powders.
3. Drug information queries.
4. Inventory control

**List of Assignments:**

1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.
2. Pharmacy and Therapeutics committee - Organization, functions, and limitations.
3. Development of a hospital formulary for 300 bedded teaching hospital
4. Preparation of ABC analysis of drugs sold in one month from the pharmacy.
5. Different phases of clinical trials with elements to be evaluated.
6. Various sources of drug information and systematic approach to provide unbiased drug information.
7. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.

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**Special require ments:**

1. Each college should sign MoU with nearby local hospital having minimum 150 beds for providing necessary training to the students' on hospital pharmacy activities.
2. Well equipped with various resources of drug information.

**Scheme of Practical Examination:**

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
<b>Max Marks</b>	<b>20</b>	<b>70</b>
<b>Duration</b>	<b>03hrs</b>	<b>04hrs</b>

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva- voce and record maintenance).

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### 4.3 CLINICAL PHARMACY (THEORY)

**Theory : 3 Hrs. /Week**

#### 1. Objectives of the Subject :

- Upon completion of the subject student shall be able to (Know, do, appreciate) -
- monitor drug therapy of patient through medication chart review and clinical review ;
  - obtain medication history interview and counsel the patients ;
  - identify and resolve drug related problems;
  - detect, assess and monitor adverse drug reaction;
  - interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and
  - retrieve, analyse, interpret and formulate drug or medicine information.

#### Text books (Theory)

- Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
- Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
- Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.
- A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi etal, Orient Orient Langram Pvt.Ltd. ISSN8125026

#### References

- Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
- Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
- Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

#### 2. Detailed syllabus and lecture wise schedule:

##### Title of the topic

- Definitions, development and scope of clinical pharmacy**
- Introduction to daily activities of a clinical pharmacist**
  - Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
  - Ward round participation
  - Adverse drug reaction management
  - Drug information and poisons information
  - Medication history
  - Patient counseling
  - Drug utilisation evaluation (DUE) and review (DUR)
  - Quality assurance of clinical pharmacy services

3. **Patient data analysis**  
The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.
4. **Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results**
  - a. Haematological, Liver function, Renal function, thyroid function tests
  - b. Tests associated with cardiac disorders
  - c. Fluid and electrolyte balance
  - d. Microbiological culture sensitivity tests
  - e. Pulmonary Function Tests
5. **Drug & Poison information**
  - a. Introduction to drug information resources available
  - b. Systematic approach in answering DI queries
  - c. Critical evaluation of drug information and literature
  - d. Preparation of written and verbal reports
  - e. Establishing a Drug Information Centre
  - f. Poisons information- organization & information resources
6. **Pharmacovigilance**
  - a. Scope, definition and aims of pharmacovigilance
  - b. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used]
  - c. Reporting, evaluation, monitoring, preventing & management of ADRs
  - d. Role of pharmacist in management of ADR.
7. Communication skills, including patient counselling techniques, medication history interview, presentation of cases.
8. Pharmaceutical care concepts
9. Critical evaluation of biomedical literature
10. Medication errors

### 4.3 CLINICAL PHARMACY (PRACTICAL)

#### Practical : 3 Hrs./Week

Students are expected to perform 15 practicals in the following areas covering the topics dealt in theory class.

- a. Answering drug information questions (4 Nos)
- b. Patient medication counselling (4 Nos)
- c. Case studies related to laboratory investigations (4 Nos)
- d. Patient medication history interview (3 Nos)

**Assignment:**

Students are expected to submit THREE written assignments (1500 - 2000 words) on the topics given to them covering the following areas dealt in theory class.

Drug information, Patient medication history interview, Patient medication counselling, Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

**Format of the assignment:**

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

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#### 4.4 BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY)

**Theory : 2 Hrs. /Week**

##### 1. Detailed syllabus and lecture wise schedule

###### 1 Research Methodology

- a) Types of clinical study designs:  
Case studies, observational studies, interventional studies,
- b) Designing the methodology
- c) Sample size determination and Power of a study  
Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study
- d) Report writing and presentation of data

###### 2 Biostatistics

###### 2.1 a) Introduction

- b) Types of data distribution
- c) Measures describing the central tendency distributions- average, median, mode
- d) Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean.

###### 2.2 Data graphics

Construction and labeling of graphs, histogram, piecharts, scatter plots, semilogarithmic plots

###### 2.3 Basics of testing hypothesis

- a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals.
- b) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way)
- c) Level of significance (Non-parametric data)- Sign test, Wilcoxon's signed rank test, Wilcoxon rank sum test, Mann Whitney U test, Kruskal-Wallis test (one way ANOVA)
- d) Linear regression and correlation- Introduction, Pearson's and Spearman's correlation and correlation co-efficient.
- e) Introduction to statistical software: SPSS, Epi Info, SAS.

## 2.4 Statistical methods in epidemiology

Incidence and prevalence, relative risk, attributable risk

## 3. Computer applications in pharmacy

Computer System in Hospital Pharmacy: Patterns of Computer use in Hospital Pharmacy - Patient record database management, Medication order entry - Drug labels and list - Intravenous solution and admixture, patient medication profiles, Inventory control, Management report & Statistics.

Computer In Community Pharmacy

Computerizing the Prescription Dispensing process

Use of Computers for Pharmaceutical Care in community pharmacy

Accounting and General ledger system

Drug Information Retrieval & Storage :

Introduction - Advantages of Computerized Literature Retrieval

Use of Computerized Retrieval

### Reference books:

- a. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3<sup>rd</sup> edition, publisher Marcel Dekker Inc. New York.
- b. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich, 3<sup>rd</sup> edition, McGraw Hill Publications 2006

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## 4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

**Theory : 3 Hrs. /Week**

### 1. Biopharmaceutics

1. Introduction to Biopharmaceutics
  - a. Absorption of drugs from gastrointestinal tract.
  - b. Drug Distribution.
  - c. Drug Elimination.

### 2. Pharmacokinetics

2. Introduction to Pharmacokinetics.
  - a. Mathematical model
  - b. Drug levels in blood.
  - c. Pharmacokinetic model
  - d. Compartment models
  - e. Pharmacokinetic study.
3. One compartment open model.
  - a. Intravenous Injection (Bolus)
  - b. Intravenous infusion.
4. Multicompartment models.
  - a. Two compartment open model.
  - b. IV bolus, IV infusion and oral administration
5. Multiple - Dosage Regimens.
  - a. Repetitive Intravenous injections - One Compartment Open Model
  - b. Repetitive Extravascular dosing - One Compartment Open model
  - c. Multiple Dose Regimen - Two Compartment Open Model
6. Nonlinear Pharmacokinetics.
  - a. Introduction
  - b. Factors causing Non-linearity.
  - c. Michaelis- menton method of estimating parameters.
7. Noncompartmental Pharmacokinetics.
  - a. Statistical Moment Theory.
  - b. MRT for various compartment models.
  - c. Physiological Pharmacokinetic model.
8. Bioavailability and Bioequivalence.
  - a. Introduction.
  - b. Bioavailability study protocol.
  - c. Methods of Assessment of Bioavailability



## 4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

### Practical : 3 Hrs./Week

1. Improvement of dissolution characteristics of slightly soluble drugs by some methods.
2. Comparison of dissolution studies of two different marketed products of same drug.
3. Influence of polymorphism on solubility and dissolution.
4. Protein binding studies of a highly protein bound drug and poorly protein bound drug.
5. Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.
6. Bioavailability studies of some commonly used drugs on animal/human model.
7. Calculation of  $K_a$ ,  $K_e$ ,  $t_{1/2}$ ,  $C_{max}$ , AUC, AUMC, MRT etc. from blood profile data.
8. Calculation of bioavailability from urinary excretion data for two drugs.
9. Calculation of AUC and bioequivalence from the given data for two drugs.
10. In vitro absorption studies.
11. Bioequivalency studies on the different drugs marketed.(eg) Tetracycline, Sulphamethoxazole, Trimethoprim, Aspirin etc., on animals and human volunteers.
12. Absorption studies in animal inverted intestine using various drugs.
13. Effect on contact time on the plasma protein binding of drugs.
14. Studying metabolic pathways for different drugs based on elimination kinetics data.
15. Calculation of elimination half- life for different drugs by using urinary elimination data and blood level data.
16. Determination of renal clearance.

### References:

- a. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
- b. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania.
- c. Pharmacokinetics: By Milo Gibaldi Donald, R. Mercel Dekker Inc.
- d. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
- e. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
- f. Biopharmaceutics; By Swarbrick
- g. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmanekar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
- h. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febiger, Philadelphia, 1995.
- i. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
- j. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4<sup>th</sup> edition Revised and expanded by Robert F Notari Marcel Dekker Inc, New York and Basel, 1987.
- k. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

## 4.6 CLINICAL TOXICOLOGY (THEORY)

**Theory : 2 Hrs. /Week**

1. General principles involved in the management of poisoning
2. Antidotes and the clinical applications.
3. Supportive care in clinical Toxicology.
4. Gut Decontamination.
5. Elimination Enhancement.
6. Toxicokinetics.
7. Clinical symptoms and management of acute poisoning with the following agents -
  - a) Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.
  - b) Opiates overdose.
  - c) Antidepressants
  - d) Barbiturates and benzodiazepines.
  - e) Alcohol: ethanol, methanol.
  - f) Paracetamol and salicylates.
  - g) Non-steroidal anti- inflammatory drugs.
  - h) Hydrocarbons: Petroleum products and PEG.
  - i) Caustics: inorganic acids and alkali.
  - j) Radiation poisoning
8. Clinical symptoms and management of chronic poisoning with the following agents -  
Heavy metals: Arsenic, lead, mercury, iron, copper
9. Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.
10. Plants poisoning. Mushrooms, Mycotoxins.
11. Food poisonings
12. Envenomations - Arthropod bites and stings.

### **Substance abuse:**

Signs and symptoms of substance abuse and treatment of dependence

- a) CNS stimulants :amphetamine
- b) Opioids
- c) CNS depressants
- d) Hallucinogens: LSD
- e) Cannabis group
- f) Tobacco

### **References:**

- a. Matthew J Ellenhorn. ELLENHORNS MEDICAL TOXICOLOGY - DIAGNOSIS AND TREATMENT OF POISONING. Second edition. Williams and Willkins publication, London
- b. V V Pillay. HANDBOOK OF FORENSIC MEDICINE AND TOXICOLOGY. Thirteenth edition 2003 Paras Publication, Hyderabad



## **Fifth year**

### **5.1 CLINICAL RESEARCH (THEORY)**

**Theory : 3 Hrs. /Week**

#### **1. Drug development process:**

Introduction

Various Approaches to drug discovery

1. Pharmacological
2. Toxicological
3. IND Application
4. Drug characterization
5. Dosage form

#### **2. Clinical development of drug:**

1. Introduction to Clinical trials
2. Various phases of clinical trial.
3. Methods of post marketing surveillance
4. Abbreviated New Drug Application submission.
5. Good Clinical Practice - ICH, GCP, Central drug standard control organisation (CDSCO) guidelines
6. Challenges in the implementation of guidelines
7. Ethical guidelines in Clinical Research
8. Composition, responsibilities, procedures of IRB / IEC
9. Overview of regulatory environment in USA, Europe and India.
10. Role and responsibilities of clinical trial personnel as per ICH GCP
  - a. Sponsor
  - b. Investigators
  - c. Clinical research associate
  - d. Auditors
  - e. Contract research coordinators
  - f. Regulatory authority
11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)
12. Informed consent Process
13. Data management and its components
14. Safety monitoring in clinical trials.



**References :**

- a. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
- b. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
- c. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
- d. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
- e. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
- f. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
- g. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

  
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## 5.2 PHARMACOEPIDEMIOL O G Y AND PHARMACOECONOMICS (THEORY)

**Theory : 3 Hrs. /Week**

### 1. Pharmacoepidemiology :

#### **Definition and scope:**

Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.

#### **Measure ment of outcomes in pharmacoepidemiology**

Outcome measure and drug use measures

Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement

#### **Concept of risk in pharmacoepidemiology**

Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

#### **Pharmacoepidemiological methods**

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods

Drug utilization review, case reports, case series, surveys of drug use, cross - sectional studies, cohort studies, case control studies, case -cohort studies, meta - analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

#### **Sources of data for pharmacoeptide miological studies**

Ad Hoc data sources and automated data systems.

#### **Selected special applications of pharmacoepidemiology**

Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

### 2. Phrmacoeconomics:

#### **Definition, history, needs of pharmacoeconomic evaluations**

Role in formulary management decisions

#### **Pharmacoeconomic evaluation**

Outcome assessment and types of evaluation

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods:

Cost - minimization, cost- benefit, cost - effectiveness, cost utility

### 3. Applications of Pharmacoeconomics

Software and case studies

### 5.3 CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING (THEORY)

**Theory : 2 Hrs. /Week**

**1. Introduction to Clinical pharmacokinetics.**

**2. Design of dosage regimens:**

Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.

**3. Pharmacokinetics of Drug Interaction:**

- a. Pharmacokinetic drug interactions
- b. Inhibition and Induction of Drug metabolism
- c. Inhibition of Biliary Excretion.

**4. Therapeutic Drug monitoring:**

- a. Introduction
- b. Individualization of drug dosage regimen (Variability - Genetic, Age and Weight, disease, Interacting drugs).
- c. Indications for TDM. Protocol for TDM.
- d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.
- e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.

**5. Dosage adjustment in Renal and hepatic Disease.**


- a. Renal impairment
- b. Pharmacokinetic considerations
- c. General approach for dosage adjustment in Renal disease.
- d. Measurement of Glomerular Filtration rate and creatinine clearance.
- e. Dosage adjustment for uremic patients.
- f. Extracorporeal removal of drugs.
- g. Effect of Hepatic disease on pharmacokinetics.

**6. Population Pharmacokinetics.**

- a. Introduction to Bayesian Theory.
- b. Adaptive method or Dosing with feed back.
- c. Analysis of Population pharmacokinetic Data.

**7. Pharmacogenetics**

- a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.
- b. Genetic Polymorphism in Drug Transport and Drug Targets.
- c. Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations

  
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