Revised Syllabus

Bachelor of Pharmacy (B. Pharm.) I\textsuperscript{st} - VIII\textsuperscript{th} SEMESTER

[Effective from session 2017-18]

[As per the Pharmacy Council of India B. Pharm. course regulations 2014]
## Schemes for internal assessments and end semester examinations semester wise

### Semester I

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*Applicable ONLY for the students studied Mathematics / Physics / Chemistry at Higher Secondary Certificate(HSC)/ XIIth and appearing for Remedial Biology (RB)course.

§Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM)course.

* Non University Examination (NUE)
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| Total       | 80                                              | 125             | 20 Hrs          | 205                | 520               | 30 Hrs      |

* The subject experts at college level shall conduct examinations
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* The subject experts at college level shall conduct examinations
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<td>Quality Control and Standardizations of Herbals – Theory</td>
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<td>BP807ET</td>
<td>Computer Aided Drug Design – Theory</td>
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<td>BP808ET</td>
<td>Cell and Molecular Biology – Theory</td>
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<td>BP809ET</td>
<td>Cosmetic Science – Theory</td>
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<td>BP810ET</td>
<td>Experimental Pharmacology – Theory</td>
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<td>BP811ET</td>
<td>Advanced Instrumentation Techniques – Theory</td>
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<td>Project Work</td>
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<td>40</td>
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Semester I
BP101T. HUMAN ANATOMY AND PHYSIOLOGY-I (Theory)

45 Hours

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

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

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

Course Content:

Unit I

- 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

- 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

• **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 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

• **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.
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. To study the integumentary and special senses using specimen, models, etc.,
7. To study the nervous system using specimen, models, etc.,
8. To study the endocrine system using specimen, models, etc
9. To demonstrate the general neurological examination
   10. To demonstrate the function of olfactory nerve
11. To examine the different types of taste.
12. To demonstrate the visual acuity
13. To demonstrate the reflex activity
14. Recording of body temperature
15. To demonstrate positive and negative feedback mechanism.

Recommended Books (Latest Editions)

3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,Riverview,MI USA

7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother’s medical publishers, New Delhi.

8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother’s medical publishers, New Delhi.

Reference Books (Latest Editions)

1. Physiological basis of Medical Practice- Best and Tailor. Williams & Wilkins Co, Riverview, MI USA


3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje, 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

(a) Pharmaceutical analysis- Definition and scope
   i) Different techniques of analysis
   ii) Methods of expressing concentration
   iii) Primary and secondary standards.
   iv) Preparation and standardization of various molar and normal solutions- Oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulphate, sulphuric acid, potassium permanganate and ceric ammonium sulphate

(b) Errors: Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures

UNIT-II

- 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

- 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.
UNIT-IV

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

- Electrochemical methods of analysis
  - Conductometry - Introduction, Conductivity cell, Conductometric titrations, applications.
  - Potentiometry - Electrochemical cell, construction and working of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine end point of potentiometric titration and applications.
  - Polarography - Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications
BP108P. PHARMACEUTICAL ANALYSIS (Practical)
4 Hours / Week

I Preparation and standardization of
(1) Sodium hydroxide
(2) Sulphuric acid
(3) Sodium thiosulfate
(4) Potassium permanganate
(5) Ceric ammonium sulphate

II Assay of the following compounds along with Standardization of Titrant
(1) Ammonium chloride by acid base titration
(2) Ferrous sulphate by Cerimetry
(3) Copper sulphate by Iodometry
(4) Calcium gluconate by complexometry
(5) Hydrogen peroxide by Permanganometry
(6) Sodium benzoate by non-aqueous titration
(7) Sodium Chloride by precipitation titration

III Determination of Normality by electro-analytical methods
(1) Conductometric titration of strong acid against strong base
(2) Conductometric titration of strong acid and weak acid against strong base
(3) Potentiometric titration of strong acid against strong base

Recommended Books: (Latest Editions)

2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
4. Bentley and Driver's Textbook of Pharmaceutical Chemistry
5. John H. Kennedy, Analytical chemistry principles
6. Indian Pharmacopoeia.
BP103T. PHARMACEUTICS- I (Theory)

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

- **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

- **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

• **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

• **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.

UNIV – V

• **Semisolid dosage forms:** Definitions, classification, mechanisms and factors influencing dermal penetration of drugs. Preparation of ointments, pastes, creams and gels. Excipients used in semi solid dosage forms. Evaluation of semi solid dosages forms
BP109P. PHARMACEUTICALS (Practical)

1. Syrups
   a) Syrup IP
   b) Paracetamol pediatric syrup

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

3. Linctus
   a) Simple Linctus BPC

4. Solutions
   a) Strong solution of ammonium acetate
   b) Cresol with soap solution

5. Suspensions
   a) Calamine lotion
   b) Magnesium Hydroxide mixture

5. Emulsions
   a) Turpentine Liniment
   b) Liquid paraffin emulsion

6. Powders and Granules
   a) ORS powder (WHO)
   b) Effervescent granules
   c) Dusting powder

7. Suppositories
   a) Glycerol gelatin suppository
   b) Soap glycerin suppository

8. Semisolids
   a) Sulphur ointment
   b) Non staining iodine ointment with methyl salicylate
   c) Bentonite gel

9. Gargles and Mouthwashes
   a) Potassium chlorate gargle
   b) Chlorhexidine mouthwash

Recommended Books: (Latest Editions)

2. Carter S.J., Cooper and Gunn’s-Dispensing for Pharmaceutical Students, CBS publishers, New Delhi.


4. Indian pharmacopoeia.

5. British pharmacopoeia.


9. E.A. Rawlins, Bentley’s Text Book of Pharmaceutics, English Language Book Society, Elsevier Health Sciences, USA.


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

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**UNIT IV**

- **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

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**UNIT V**

- **Radiopharmaceuticals:** Radio activity, Measurement of radioactivity, Properties of α, β, γ 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)

2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
4. M.L Schroff, Inorganic Pharmaceutical Chemistry
5. Bentley and Driver's Textbook of Pharmaceutical Chemistry
7. Indian Pharmacopoeia
BP105T.COMMUNICATION SKILLS (Theory)

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

- **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

- **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

- **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

- **Interview Skills:** Purpose of an interview, Do’s and Don’ts of an interview

- **Giving Presentations:** Dealing with Fears, Planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery

UNIT – V

- **Group Discussion:** Introduction, Communication skills in group discussion, Do’s and Don’ts 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 Don’t’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)

6. Developing your influencing skills, Deborah Dalley, Lois Burton, Margaret, Green hall, 1st Edition Universe of Learning LTD, 2010
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

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, Potista, 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 & Dicotylidones.

UNIT II

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

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

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

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 and its modifications
4. Detailed study of frog by using computer models
5. Microscopic study and identification of tissues
6. Identification of bones
7. Determination of blood group
8. Determination of blood pressure
9. Determination of tidal volume

Reference Books
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

- 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 (\( \varepsilon - \delta \) definition), \( \lim_{x \to a} \frac{x^n - a^n}{x - a} = na^{n-1} \), \( \lim_{\theta \to 0} \sin \theta = 1 \).

UNIT – II

- Matrices and Determinant:
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

- Body fluids and blood
  Body fluids, composition and functions of blood, hemopoeisis, 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 II

10 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.

Unit III

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.

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

**Unit IV**

- **Respiratory system**
  Lung Volumes and capacities, transport of respiratory gases, artificial respiration, and resuscitation methods.

- **Urinary system**

**Unit V**

- **Reproductive system**
  Anatomy of male and female reproductive system, functions of male and female reproductive system, sex hormones, physiology of menstruation, fertilization, spermatogenesis, oogenesis, pregnancy and parturition

- **Introduction to genetics**
  Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance
BP 207 P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

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

1. Introduction to hemocytometry.
2. Enumeration of white blood cell (WBC) count
3. Enumeration of total red blood corpuscles (RBC) count
4. Determination of bleeding time
5. Determination of clotting time
6. Estimation of hemoglobin content
7. Determination of blood group.
8. Determination of erythrocyte sedimentation rate (ESR).
10. Recording of blood pressure.
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.
15. Demonstration of total blood count by cell analyser
16. Permanent slides of vital organs and gonads.

Recommended Books (Latest Editions)

3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
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
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterjee, 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***
  - SP³ hybridization in alkanes, Halogenation of alkanes, uses of paraffins. Stabilities of alkenes, SP² hybridization in alkenes
  - E₁ and E₂ reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and evidences. E₁ verses E₂ reactions, Factors affecting E₁ and E₂ reactions. Ozonolysis, electrophilic addition reactions of alkenes, Markownikoff’s orientation, free radical addition reactions of alkenes, Anti Markownikoff’s orientation.
  - Stability of conjugated dienes, Diel-Alder, electrophilic addition, free radical addition reactions of conjugated dienes, allylic rearrangement

**UNIT-III 10 Hours**
- **Alkyl halides**
  SN\(_1\) and SN\(_2\) reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations.
  SN\(_1\) versus SN\(_2\) reactions, Factors affecting SN\(_1\) and SN\(_2\) reactions
  Structure and uses of ethylchloride, Chloroform, trichloroethylene, tetrachloroethylene, dichloromethane, tetrachloromethane and iodoform.

- **Alcohols** - Qualitative tests, Structure and uses of Ethyl 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
   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
4. Organic Chemistry by P.L.Soni
5. Practical Organic Chemistry by Mann and Saunders.
8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.
9. Reaction and reaction mechanism by Ahluwaliah/Chatwal.
BP203 T. BIOCHEMISTRY (Theory)

45 Hours

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

Objectives: Upon completion of course 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  
10 Hours

• Carbohydrate metabolism
  
  Glycolysis – Pathway, energetics and significance  
  Citric acid cycle- Pathway, energetics and significance  
  HMP shunt and its significance; Glucose-6-Phosphate dehydrogenase (G6PD) deficiency  
  Glycogen metabolism Pathways and glycogen storage diseases (GSD)  
  Gluconeogenesis- Pathway and its significance  
  Hormonal regulation of blood glucose level and Diabetes mellitus

• Biological oxidation
  
  Electron transport chain (ETC) and its mechanism.  
  Oxidative phosphorylation & its mechanism and substrate level phosphorylation  
  Inhibitors ETC and oxidative phosphorylation/Uncouplers

UNIT II  
10 Hours

• Lipid metabolism
  
  β-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 (Phenyketonuria, Albinism, alkeptonuria, tyrosinemia)
  Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline
  Catabolism of heme; hyperbilirubinemia and jaundice

**UNIT III**

- **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 IV**

- **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 V  

- **Enzymes**
  
  Introduction, properties, nomenclature and IUB classification of enzymes  
  Enzyme kinetics (Michaelis plot, Line Weaver Burke plot)  
  Enzyme inhibitors with examples  
  Regulation of enzymes: enzyme induction and repression, allosteric enzymes regulation  
  Therapeutic and diagnostic applications of enzymes and isoenzymes  

**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)**

7. Outlines of Biochemistry by Conn and Stumpf.
10. Practical Biochemistry for Medical students by Rajagopal and Ramakrishna.
11. Practical Biochemistry by Harold Varley.

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**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:**
  
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, thalasemia, hereditary acquired anemia, hemophilia

Endocrine system: Diabetes, thyroid diseases, disorders of sex hormones

Nervous system: Epilepsy, Parkinson’s disease, stroke, psychiatric disorders: depression, schizophrenia and Alzheimer’s disease.

Gastrointestinal system: Peptic Ulcer

Unit IV 8 Hours

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

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

Principles of cancer: classification, etiology and pathogenesis of cancer

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)
1. Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins & Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier; 2014.
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].
9. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia; WB Saunders Company; 1997.

**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

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

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

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  

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

UNIT-V  

**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.
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):

2. Computer Application in Pharmaceutical Research and Development –Sean Ekins –Wiley-Interscience, A John Willey and Sons, INC., Publication, USA
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.

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
5. Clark R.S., Marine Pollution, Clanderson Press Oxford
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

UNIT III

10 Hours

- Fats and Oils
  a. Fatty acids – reactions.

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

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

UNIT V

- 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-napthol from Aniline by diazotization and coupling reactions.
   - Benzil from Benzoin by oxidation reaction.
   - Dibenzal acetone from Benzaldehyde by Claison Schmidt reaction
   - Cinnammic 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
4. Organic Chemistry by P.L.Soni
5. Practical Organic Chemistry by Mann and Saunders.
8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.

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

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

**Objectives:** Upon the completion of the course student shall be able to
1. Understand various physicochemical properties of drug molecules in the designing the dosage form
2. Know the principles of chemical kinetics & to use them in assigning expiry date for formulation
3. Demonstrate use of physicochemical properties in evaluation of dosage forms.
4. Appreciate physicochemical properties of drug molecules in formulation research and development

**Course Content:**

**UNIT-I**

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

**UNIT-II**

**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**

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

UNIT-IV 08 Hours

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

UNIT-V 07 Hours

**pH, buffers and Isotonic solutions:** Sorensen’s pH scale, pH determination (electrometric and calorimetric), applications of buffers, buffer equation, buffer capacity, buffers in pharmaceutical and biological systems, buffered isotonic solutions.
1. Determination the solubility of drug at room temperature
2. Determination of pKa value by Half Neutralization/ Henderson Hassel Balch equation.
3. Determination of Partition co-efficient of benzoic acid in benzene and water
4. Determination of Partition co-efficient of Iodine in CCl₄ and water
5. Determination of % composition of NaCl in a solution using phenol-water system by CST method
6. Determination of particle size, particle size distribution using sieving method
7. Determination of particle size, particle size distribution using Microscopic method
8. Determination of bulk density, true density and porosity
9. Determine the angle of repose and influence of lubricant on angle of repose
10. Determination of stability constant and donor acceptor ratio of PABA-Caffeine complex by solubility method
11. Determination of stability constant and donor acceptor ratio of Cupric-Glycine complex by pH titration method

Recommended Books: (Latest Editions)

1. Physical pharmacy by Alfred Martin
2. Experimental pharmaceutics by Eugene, Parott.
3. Tutorial pharmacy by Cooper and Gunn.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, MarcelDekkar Inc.
7. Physical pharmaceutics by Ramasamy C and ManavalanR.
8. Laboratory manual of physical pharmaceutics, C.V.S. Subramanyam, J. Thimma settee
BP 303 T. PHARMACEUTICAL MICROBIOLOGY (Theory)

Scope:

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

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

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

Course content:

Unit I 10 Hours
Introduction, history of microbiology, its branches, scope and its importance.
Introduction to Prokaryotes and Eukaryotes
Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count).
Study of different types of phase contrast microscopy, dark field microscopy and electron microscopy.

Unit II 10 Hours
Identification of bacteria using staining techniques (simple, Gram’s & Acid fast staining) and biochemical tests (IMViC).
Study of principle, procedure, merits, demerits and applications of Physical, chemical and mechanical method of sterilization.
Evaluation of the efficiency of sterilization methods.
Equipments employed in large scale sterilization.
Sterility indicators.

**Unit III**  
10 Hours

Study of morphology, classification, reproduction/replication and cultivation of Fungi and Virus.
Classification and mode of action of disinfectants
Factors influencing disinfection, antiseptics and their evaluation. For bacteriostatic and bactericidal actions
Evaluation of bactericidal & Bacteriostatic.
Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, 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.
Assessment of a new antibiotic and testing of antimicrobial activity of a new substance.
General aspects-environmental cleanliness.

**Unit V**  
07 Hours

Types of spoilage, factors affecting the microbial spoilage of pharmaceutical products, sources and types of microbial contaminants, assessment of microbial contamination and spoilage.
Preservation of pharmaceutical products using antimicrobial agents, evaluation of microbial stability of formulations.
Growth of animal cells in culture, general procedure for cell culture, Primary, established and transformed cell cultures.
Application of cell cultures in pharmaceutical industry and research.
BP 307P: PHARMACEUTICAL MICROBIOLOGY (Practical)

4 Hrs/week

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

Recommended Books (Latest edition)

5. Rose: Industrial Microbiology.
7. Cooper and Gunn’s: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
10. Ananthnarayan : Text Book of Microbiology, Orient-Longman, Chennai
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

UNIT-II

10 Hours

- **Flow of fluids**: Types of manometers, Reynold’s 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.


• **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.


UNIT- III  

10 Hours

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

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

UNIT-IV  

08 Hours

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

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

UNIT- V  

07 Hours

• **Plant location, industrial hazards and plant safety:** Plant Layout, utilities and services, Mechanical hazards, Chemical hazards, Fire hazards, explosive hazards and their safety.

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

• **Material handling systems:** Objectives & applications of Material handling systems, different types of conveyors such as belt, screw and pneumatic conveyors.
**Recommended Books: (Latest Editions)**

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, dehumidifier.
VIII. Size analysis by sieving – To evaluate size distribution of tablet granulations – Construction of various size frequency curves including arithmetic and logarithmic probability plots.
IX. Size reduction: To verify the laws of size reduction using ball mill and determining Kicks, Rittinger’s, Bond’s coefficients, power requirement and critical speed of Ball Mill.
X. Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such other major equipment.
XI. Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration and Thickness/ viscosity
XII. To study the effect of time on the Rate of Crystallization.
XIII. To calculate the uniformity Index for given sample by using Double Cone Blender.
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
**Heterocyclic compounds:**  
Nomenclature and classification  
Synthesis, reactions and medicinal uses of following compounds/derivatives  
Pyrrole, Furan, and Thiophene - Relative aromaticity, reactivity and Basicity of pyrrole

**UNIT-IV**  
8 Hours

Synthesis, reactions and medicinal uses of following compounds/derivatives  
Pyrazole, Imidazole, Oxazole and Thiazole.  
Pyridine, Quinoline, Isoquinoline, Acridine and Indole. Basicity of pyridine
Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives

**UNIT-V**  
07 Hours

**Reactions of synthetic importance**  
Metal hydride reduction (NaBH$_4$ and 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.
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

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

Drugs acting on Autonomic Nervous System

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

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

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

**Adrenergic Antagonists:**

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

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

**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):**

**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

**Barbiturtes:** SAR of barbiturates, Barbital*, Phenobarbital, Mephobarbital, Amobarbital, Butabarbital, Pentobarbital, Secobarbital

**Miscellaneous:**
- Amides & imides: Glutethmide.
- Alcohol & their carbamate derivatives: Meprobamate, Ethchlorvynol.
- Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

B. Antipsychotics

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

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

**Fluro buterophenones:** Haloperidol, Droperidol, Risperidone.

**Beta amino ketones:** Molindone hydrochloride.

**Benzamides:** Sulpiride.

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

**Barbiturates:** Phenobarbitone, Methabarbital.

**Hydantoins:** Phenytoin*, Mephenytoin, Ethotoin.

**Oxazolidine diones:** Trimethadione, Paramethadione.

**Succinimides:** Phensuximide, Methsuximide, Ethosuximide*

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

**Benzodiazepines:** Clonazepam

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

UNIT – V

Drugs acting on Central Nervous System

07 Hours
General anesthetics:

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

**Ultra short acting barbiturates:** Methohexitol 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, Anilerdine 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)

2. Foye’s Principles of Medicinal Chemistry.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington’s Pharmaceutical Sciences.
6. Martindale’s extra pharmacopoeia.
9. Indian Pharmacopoeia.
Scope: The course deals with the various physical, physicochemical properties and principle involved in dosage forms, formulations. Theory and practical components of the subject help the student to get a better insight in to various areas of formulation research and development and stability studies of pharmaceuticals.

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

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

Course Content:

UNIT-I 10 Hours


UNIT-II 10 Hours

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

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

UNIT-III 10 Hours

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

UNIT-IV 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-V 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.
BP 407P. PHYSICAL PHARMACEUTICS- II (Practical)

3 Hrs/week

1. Determination of surface tension of given liquids by drop count and drop weight method
2. Determination of HLB number of a surfactant by saponification method
3. Determination of Freundlich and Langmuir constants using activated char coal
4. Determination of critical micellar concentration of surfactants
5. Determination of viscosity of liquid using Ostwald’s viscometer
6. Determination sedimentation volume with effect of different suspending agent
7. Determination sedimentation volume with effect of different concentration of single suspending agent
8. Determination of viscosity of semisolid by using Brookfield viscometer
9. Determination of reaction rate constant first order.
10. Determination of reaction rate constant second order
11. Accelerated stability studies

Recommended Books: (Latest Editions)
1. Physical Pharmacy by Alfred Martin, Sixth edition
2. Experimental pharmaceutics by Eugene, Parott.
3. Tutorial pharmacy by Cooper and Gunn.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C, and Manavalan R.
BP 404 T. PHARMACOLOGY-I (Theory)

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 the effect of drugs on animals by simulated experiments

Appreciate correlation of pharmacology with other biomedical sciences

Course Content:

UNIT-I

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

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 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 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 central nervous system
   b. Drugs used in Parkinson’s 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.
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.
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)

3. Goodman and Gilman’s, The Pharmacological Basis of Therapeutics
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott’s Illustrated Reviews-Pharmacology
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R. Craig & Robert,
10. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,
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
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, leafconstants, camera lucida and diagrams of microscopic objects to scale with camera lucida.

UNIT-II
Cultivation, Collection, Processing and storage of drugs of natural origin:
Cultivation andCollection of drugs of natural origin
Factors influencing cultivation of medicinal plants.
Plant hormones and their applications.
Polyplody, mutation and hybridization with reference to medicinal plants

Conservation of medicinal plants

UNIT-III
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 paliside 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)

3. Text Book of Pharmacognosy by T.E. Wallis
8. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae
SEMESTER V
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 human body

H₁-antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines cuscinate, Clemastine fumarate, Diphenylphryaline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclozine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetazine Cromolyn sodium

H₂-antagonists: Cimetidine*, Famotidine, Ranitidin.

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

Anti-neoplastic agents: Meclorethamine*, Cyclophosphamide, Melphalan,
Chlorambucil, Busulfan, Thiopeta

**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, Dichlorphenamid.
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, Lorcanide hydrochloride, Amiodarone, Sotalol.

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

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

**Drugs used in Congestive Heart Failure:** Digoxin, Digitoxin, Nesiritide, Bosentan, Tezosentan
UNIT- IV  
08 Hours

Drugs acting on Endocrine system

Nomenclature, Stereochemistry and metabolism of steroids

Sex hormones: Testosterone, Nandralone, Progestrones, 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


Thiazolidinediones: Pioglitazone, Rosiglitazone.

Meglitinides: Repaglinide, Nateglinide.

Glucosidase inhibitors: Acrabose, Voglibose.

Local Anesthetics: SAR of Local anesthetics

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

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

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

Miscellaneous: Phenacaine, Diperodon, Dibucaine.*

Recommended Books (Latest Editions)

2. Foye’s Principles of Medicinal Chemistry.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington’s Pharmaceutical Sciences.
6. Martindale’s extra pharmacopoeia.
9. Indian Pharmacopoeia.
Scope: Course enables the student to understand and appreciate the influence of pharmaceutical additives and various pharmaceutical dosage forms on the performance of the drug product.

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

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

Course content:

UNIT-I 07 Hours

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

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

b. Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization BCS classification of drugs

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

UNIT-II 10 Hours

Tablets:


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 solutions, suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia
UNIT-III

Capsules:


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

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

UNIT-IV

Parenteral Products:

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

b. Production procedure, production facilities and controls.

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

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

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

UNIT-V

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. FORMULATIVEPHARMACY (Practical)

4 Hours/week

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

Recommended Books: (Latest Editions)

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman & J.B. Schwartz
2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman
3. Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman
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
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 autacoids and classification
   b. Histamine, 5-HT and their antagonists.
   c. Prostaglandins, Thromboxanes and Leukotrienes.
   d. Angiotensin, Bradykinin and Substance P.
   e. Non-steroidal anti-inflammatory agents
   f. Anti-gout drugs
   g. Antirheumatic drugs
UNIT-IV

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

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
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.
10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
12. Determination of PD₂ value using guinea pig ileum.
13. Effect of spasmogens and spasmolytics using rabbit jejunum.
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)**

3. Goodman and Gilman’s, *The Pharmacological Basis of Therapeutics*
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 20 Hours
General introduction, composition, chemistry & chemical classes, general methods of extraction & analysis, 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, Áloes, Bitter Almond
Iridoids, Other terpenoids & Naphthaquinones: Gentian, Artemisia, taxus, carotenoids

UNIT-III 10 Hours
Industrial production, estimation and utilization of the following phytoconstituents: Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine

UNIT IV 8 Hours
Basics of Phytochemistry
Modern methods of extraction, application of latest techniques like Spectroscopy, chromatography and electrophoresis in the isolation, purification and identification of crude drugs.
BP 508 P. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)
4 Hours/Week

1. Morphology, histology and powder characteristics & 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 phytoconstitutents by TLC
6. Analysis of crude drugs by chemical tests: (i) Asafoetida (ii) Benzoin (iii) Colophony (iv) Aloes (v) Myrrh

Recommended Books: (Latest Editions)
5. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
10. The formulation and preparation of cosmetic, fragrances and flavours.
12. Text Book of Biotechnology by Vyas and Dixit.
BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)

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

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

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

Course Content:

UNIT-I

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

Drugs and Cosmetics Act, 1940 and its rules 1945.


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

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


- **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**

- **Study of Salient Features of Drugs and magic remedies Act and its rules**: Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties

- **Prevention of Cruelty to animals Act-1960**: Objectives, Definitions, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties

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

**UNIT-V**

- **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
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
SEMESTER VI
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

Antibiotics

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

β-Lactam antibiotics: Penicillin, Cepholosporins, β- Lactamase inhibitors, Monobactams

Aminoglycosides: Streptomycin, Neomycin, Kanamycin

Tetracyclines: Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

UNIT – II

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.

Antimalarians: Etiology of malaria.

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

Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil.

Miscellaneous: Pyrimethamine, Artesunate, Artemether, Atovoquone.

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 Streptomycine, Capreomycin sulphate.

Urinary tract anti-infective agents

Quinolones: SAR of quinolones, Nalidixic Acid, Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Loroxiloxacin, Sparfloxac, Gatiflloxacin, Moxifloxacin

Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine.

Antiviral agents:


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*.


**Sulphonamides and Sulfones**

Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulphisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxaole*, Sulphadiazine, Mefenide acetate, Sulfsalazine.

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

**Sulfones:** Dapsone*.

**UNIT – V**

**Introduction to Drug Design**

Various approaches used in drug design.

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

Pharmacophore modeling and docking techniques.

**Combinatorial Chemistry:** Concept and applications of combinatorial chemistry: solid phase and solution phase synthesis.
BP607P. MEDICINAL CHEMISTRY- III (Practical)

4 Hours / week

I Preparation of drugs and intermediates
1 Sulphanilamide
2 7-Hydroxy, 4-methyl coumarin
3 Chlorobutanol
4 Triphenyl imidazole
5 Tolbutamide
6 Hexamine

II Assay of drugs
1 Isonicotinic acid hydrazide
2 Chloroquine
3 Metronidazole
4 Dapsone
5 Chlorpheniramine maleate
6 Benzyl penicillin

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

IV Drawing structures and reactions using chem draw®

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

Recommended Books (Latest Editions)
2. Foye’s Principles of Medicinal Chemistry.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington’s Pharmaceutical Sciences.
6. Martindale’s extra pharmacopoeia.
9. Indian Pharmacopoeia.
BP602 T. PHARMACOLOGY-III (Theory)

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

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-ematics.

UNIT-II

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

UNIT-III

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

UNIT-IV
3. Chemotherapy
   a. Urinary tract infections and sexually transmitted diseases.
   b. Chemotherapy of malignancy.

4. Immunopharmacology
   a. Immunostimulants
   b. Immunosuppressant
      Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

UNIT-V
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.
1. Dose calculation in pharmacological experiments
2. Antiallergic activity by mast cell stabilization assay
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)**

3. Goodman and Gilman’s, The Pharmacological Basis of Therapeutics
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott’s Illustrated Reviews-Pharmacology
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
10. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,
BP 603 T. HERBAL DRUG TECHNOLOGY (Theory)

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 6 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.

UNIT-II 05 Hours
a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy
b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika, Churna, Lehya and Bhasma.

UNIT-III 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-IV 10 Hours
Herbal Cosmetics
Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums, colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products.

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

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

**UNIT- V**

**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-VI**

**General Introduction to Herbal Industry**
Herbal drugs industry: Present scope and future prospects.
A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.

**Schedule T – Good Manufacturing Practice of Indian systems of medicine**
Components of GMP (Schedule – T) and its objectives
Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.
BP 609 P. HERBAL DRUG TECHNOLOGY (Practical)
4 hours/ week

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

**Recommended Books: (Latest Editions)**

1. Textbook of Pharmacognosy by Trease & Evans.
2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
3. Pharmacognosy by Kokate, Purohit and Gokhale
4. Essential of Pharmacognosy by Dr.S.H.Ansari
5. Pharmacognosy & Phytochemistry by V.D.Rangari
6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
BP 604 T. BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

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

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

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

Course Content:

UNIT-I 10 Hours
Introduction to Biopharmaceutics

UNIT- II 10 Hours
Drug Elimination renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs

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

UNIT- III 10 Hours Pharmacokinetics: Introduction to Pharmacokinetics models, Compartment models, Non compartment models, physiological models, One compartment open model. a. Intravenous Injection (Bolus) b. Intravenous infusion, extra vascular administrations, calculations of Ka, Kₑ. From plasma and urinary excretion data

UNIT- IV 08 Hours
**Multicompartment models:** Two compartment open model. IV bolus

**Multiple – Dosage Regimens:**
- a). Repetitive Intravenous injections – One Compartment Open Model
- b). Repetitive Extravascular dosing – One Compartment Open model

**UNIT- V 07 Hours Nonlinear Pharmacokinetics:**
- c. Michaelis-menton method of estimating parameters, Biotransformation of drugs

**Recommended Books: (Latest Editions)**

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
5. Pharmacokinetics: By Milo Gibaldi Donald, R. MerceI Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick
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, Penicillínase.
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 products:
d) Interferon b) Vaccines- hepatitis- B c) Hormones- Insulin.
e) Brief introduction to PCR
Types of immunity- humoral immunity, cellular immunity

Unit III 10 Hours
a) Structure of Immunoglobulins  
b) Structure and Function of MHC  
c) Hypersensitivity reactions, Immune stimulation and Immune suppressions.  
d) General method of the preparation of bacterial vaccines, toxoids, viral 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

**Unit IV**  
08 Hours

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

**Unit V**  
07 Hours

a. Types of mutation/mutants  
b) Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring.  
c) Large scale production fermenter design and its various controls.  
d) Study of the production of - penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin,

**Recommended Books (Latest edition):**

2. RA Goldshy et. al., : Kuby Immunology.  
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 covers the important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.

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

**UNIT - II 10 Hours Organization and personnel:** Personnel responsibilities, training, hygiene and personal records. **Premises:** Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

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

**UNIT – III 10 Hours Quality Control:** Quality control test for containers, rubber closures and secondary packing
materials.


**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)**

4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP’s – P P Sharma.
6. ISO 9000 and Total Quality Management – Sadhank G Ghosh
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices – Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines
SEMESTER VII
BP701T. INSTRUMENTAL METHODS OF ANALYSIS (Theory)

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

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

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

**Course Content:**

**UNIT-I**

10 Hours

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

**UNIT-II**

10 Hours

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

**UNIT-III**

10 Hours

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

UNIT-IV 08 Hours

Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by design, 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, Common Technical Document (CTD), Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

Recommended Books: (Latest Editions)


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 it’s organization

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

b) Hospital pharmacy and its organization

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

c) Adverse drug reaction

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

d) Community Pharmacy

Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale 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) Drug information services
Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.

c) **Patient counseling**

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

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

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

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

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

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.

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):**


**Journals:**

1. Therapeutic drug monitoring. ISSN: 0163-4356
2. Journal of pharmacy practice. ISSN : 0974-8326
3. American journal of health system pharmacy. ISSN: 1535-2900 (online)
4. Pharmacy times (Monthly magazine)
BP 704T: NOVEL DRUG DELIVERY SYSTEMS (Theory)

45 Hours

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

Objectives: Upon completion of the course student shall be able

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

Course content:

Unit-I 10 Hours

Controlled drug delivery systems: Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates. Approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles. 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
**Nanotechnology and its Concepts:** Concepts and approaches for targeted drug delivery systems, advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications

**Unit-V**

**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)


**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
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

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®, DESIGN OF EXPERIMENTS, R - Online Statistical Software’s to Industrial and Clinical trial approach

**Unit-V**

7 Hours

**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):**

3. Design and Analysis of Experiments – PHI Learning Private Limited, R. Pannerselvam,
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):**

6. Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad

**Recommended Journals:**

1. Research in Social and Administrative Pharmacy, Elsevier, Ireland
Scope:
The pharmaceutical industry not only needs highly qualified researchers, chemist, technical people but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry. Sales & Marketing which grooms the people for taking a challenging role in Sales and Product management. The career in product management starts from having hands on experience in sales and marketing only.

Course Objective: The course aim is to provide an understanding of marketing concepts and techniques and the application of the same 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:
Meaning, Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.

Unit III 10 Hours Promotion:
Meaning and methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.
Unit IV 10 Hours Pharmaceutical marketing channels:

Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management.

Professional sales representative (PSR):

Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.

Unit V 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
BP804 ET: PHARMACEUTICAL REGULATORY SCIENCE (Theory)

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

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

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

Course content:

Unit I

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

Regulatory Approval Process

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

Regulatory authorities and agencies

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

Unit III

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

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

Regulatory Concepts


Recommended books (Latest edition):

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
9. Drugs: From Discovery to Approval, Second Edition By Rick Ng
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)
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

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

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

Statistical methods for evaluating medication safety data
Safety data generation

- Pre clinical phase
- Clinical phase
- Post approval phase

ICH Guidelines for Pharmacovigilance

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

Unit V

7 hours

Pharmacogenomics of adverse drug reactions

Drug safety evaluation in special population

- Paediatrics
- Pregnancy and lactation
- Geriatrics

CIOMS

- CIOMS Working Groups
- CIOMS Form

CDSCO (India) and Pharmacovigilance

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

Recommended Books (Latest edition):

2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal
11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna
15. http://cdsco.nic.in/
17. 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 II I 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
5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
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, Hammet’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)**

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  
10 Hours
a) Cell and Molecular Biology: Definitions theory and basics and Applications.
b) Cell and Molecular Biology: History and Summation.
d) Prokaryotic versus Eukaryotic
e) Cellular Reproduction  
f) Chemical Foundations – an Introduction and Reactions (Types)

Unit II  
10 Hours
a) DNA and the Flow of Molecular Structure
b) DNA Functioning
b) 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):**

5. Rose: Industrial Microbiology.
7. Cooper and Gunn’s: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
10. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
11. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
13. RA Goldshy et. al., : Kuby Immunology.
BP809ET. COSMETIC SCIENCE (Theory)

UNIT I
Classification of cosmetic and cosmeceutical products

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

**Skin:** Basic structure and function of skin. **Hair:** Basic structure of hair. Hair growth cycle.

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

UNIT II

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

**Principles of formulation and building blocks of Hair care products:**
Conditioning shampoo, Hair conditioners, antidandruff 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

**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

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

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

Objectives
Upon completion of the course the student shall be able to,
- Appreciate the applications of various commonly used laboratory animals.
- Appreciate and demonstrate the various screening methods used in preclinical research
- Appreciate and demonstrate the importance of biostatistics and research methodology
- Design and execute a research hypothesis independently

Unit –I

Laboratory Animals:  
Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals. Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia.

Unit –II

Preclinical screening models
a. Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study.

b. Study of screening animal models for
   - Diuretics, nootropics, anti-Parkinson’s, antiasthmatics,

Preclinical screening models: for CNS activity- analgesic, antipyretic, anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer’s disease

08 Hours

10 Hours
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<th><strong>Unit –III</strong></th>
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<tr>
<td><strong>Preclinical screening models:</strong> for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaethetics</td>
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<th><strong>Unit –IV</strong></th>
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| **Preclinical screening models:** for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslepidemic, anti aggregatory, coagulants, and anticoagulants  
Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics. |

| **Research methodology and Bio-statistics** |
| **05 Hours** |
| 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 |

<table>
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<tr>
<th><strong>Recommended Books (latest edition):</strong></th>
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| 1. Fundamentals of experimental Pharmacology-by M.N.Ghosh  
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

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

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

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**  
**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**  
**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
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

Unit-V 07 Hours
Selection and quality control testing of packaging materials for pharmaceutical product development - regulatory considerations.
**Recommended Books (Latest editions)**

1. Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, Charles Bon; Marcel Dekker Inc.
3. Pharmaceutical Dosage Forms, Tablets, Volume II, edited by Herbert A. Lieberman and Leon Lachman; Marcel Dekker, Inc.
8. Aulton’s Pharmaceutics – The Design and Manufacture of Medicines, Michael E. Aulton, 3rd Ed.
10. Pharmaceutical Dosage Forms – Tablets Vol 1 to 3, A. Liberman, Leon Lachman and Joseph B. Schwartz
13. Advanced Review Articles related to the topics.