SYLLABUS

I Year – I SEMESTER

T	P	C
3+1	0	3

ENGLISH

DETAILED TEXT-I : Recommended Topics :

1. **THE KNOWLEDGE SOCIETY- APJ KALAM (RAVINDRA PUBLISHERS)**

   OBJECTIVE : To make the learners rediscover India as a land of Knowledge.

   OUTCOME : The learners will achieve a higher quality of life, strength and sovereignty of a developed nation.

2. **MAN'S PERIL (RAVINDRA PUBLISHERS)**

   OBJECTIVE : To inform the learner that all men are in peril.

   OUTCOME : The learner will understand that all men can come together and avert the peril.

3. **IN LONDON : M.K. GANDHI (RAVINDRA PUBLISHERS)**

   OBJECTIVE : To apprise the learner how Gandhi spent a period of three years in London as a student.

   OUTCOME : The learner will understand how Gandhi grew in introspection and maturity.

4. **PRINCIPLES OF GOOD WRITING: L.A. HILL (RAVINDRA PUBLISHERS)**

   OBJECTIVE: To inform the learners how to write clearly and logically.

   OUTCOME: The learner will be able to think clearly and logically and write clearly and logically.

Text Book : 'Sure Outcomes' by Orient Blak Swan Pvt. Ltd Publishers

NON-DETAILED TEXT:

(From Modern Trailblazers of Orient Blackswan)

(Common single Text book for two semesters)

(Semester I (1 to 4 lessons)/ Semester II (5 to 8 lessons)

1. **G.D. Naidu**

OBJECTIVE: To inspire the learners by G.D. Naidu's example of inventions and contributions.

OUTCOME: The learner will be in a position to emulate G.D.Naidu and take to practical applications.

2. **G.R. Gopinath**

OBJECTIVE: To inspire the learners by his example of inventions.

OUTCOME: Like G.R.Gopinath, the learners will be able to achieve much at a low cost and help the common man.

3. **Sudhamurthy**

OBJECTIVE: To inspire the learners by the unique interests and contributions of Sudha Murthy.

OUTCOME: The learner will take interest in multiple fields of knowledge and make life worthwhile through social service.

4. **Vijay Bhatkar**

OBJECTIVE: To inspire the learner by his work and studies in different fields of engineering and science.

OUTCOME: The learner will emulate him and produce memorable things.

Text Book : 'Trail Blazers' by Orient Black Swan Pvt. Ltd. Publishers

I Year – I SEMESTER

T	P	C
3/2+1	0	3/2

Remedial Mathematics –I/ Remedial Biology – I
Remedial Mathematics –I (50 Hrs)
(For Biology stream students)

UNIT I

Algebra:

Arithmetic Progression-Geometric Progression- Permutations & combinations - Binomial theorem partial fractions - Matrices - Determinants - Application of determinants to solve simultaneous equations (Cramer's Rule).

10

UNIT II

Trigonometry: Trigonometric ratios and the relations between them Sin (A+B), Cos (A+B), Tan (A+B) formulae only. Trigonometric ratios of multiple angles-Heights and distances (simple 000 problems there on).

10

UNIT III

Co-ordinate Geometry: Distances between points-Area of a triangle, Co-ordinates of a point dividing a given segment in a given ratio - locus - equation to a straight line in different forms-Angle between straight lines-point of intersection. 10

UNIT IV

Differential Calculus: Continuity and limit: Differentiation, derivability and derivative, R.H. derivatives and L.H. derivatives, Differentiation, General theorems of derivation. 05

UNIT V

Integral Calculus: Integration as on inverse process of differentiation, definite integrals, integration by substitution, integration by parts, integration of algebraic function of E^x evolution of area in simple cases.

10

UNIT VI

Differential equations: Formation of a differential equation, order and degree, solution of first order differential equations, Laplace transformation.

05

TEXT BOOKS

1. Intermediate first Year mathematics
2. Intermediate Second year mathematics, printed and published by Telugu Academy, Himayatnagar, Hyderabad
3. Pharmaceutical Arithmetic's by Mohd. Ali CBS publishers and distributor, New Delhi.
4. Higher Engineering Mathematics by Grewal.

Remedial Biology – I (40Hrs)
(For Maths stream students)

UNIT I

Classification of plant kingdom: Methods of classification of plants.

05

Plant cell: It's detailed structure, mitosis, meiosis different types of plant tissues and their functions.

05

UNIT II

Morphology and histology of root, stem, bark, wood, leaf, flower, fruit and seed. 05

Modifications of root, stem and leaf.

05

UNIT III

General survey of animal kingdom: Non-chordates (Protozoa, Porifera, Cnidaria, Platyheliminthes, Nemathelminthes, Annelida, Arthropoda, Mollusca, Echinodermata). 05

UNIT IV

Chordates: Phylum Hemichordata
Phylum Chordata (Classes: Pisces, Amphibians, Reptiles, Aves, Mammals)

05

UNIT V

Structure and life history of parasites: Amoeba, Entamoeba, Trypanosoma, Plasmodium, Taenia, Ascaris.

05

UNIT VI

General structure and life history of insects: Cockroach, Mosquito, Housefly, Itch mite and Silkworm. Relationship of insects with medicinal crops diseases. 05

TEXT BOOKS

1. Intermediate First Year and Second Year Botany / Zoology Text Books printed and published by Telugu Academy, Himayatnagar, Hyderabad.
2. A.C. Dutta, Text Book of Botany
3. Botnay for Degree students Vol I & II by B.P. Pandey

I Year – I SEMESTER

T	P	C
3+1	0	3

HUMAN ANATOMY & PHYSIOLOGY - I

UNIT-I

Scope of anatomy and physiology: Structure of cell, its components and their function. **Elementary tissues of the human body**: Epithelial, connective, muscular and nervous tissues, their sub- types and properties.

08

Skeletal muscles: Gross anatomy, physiology of muscle contraction, physiological properties of skeletal muscles and their disorders.

04

Skeletal system: Structure, composition and functions of skeleton. Classification of joints, types of movements at joints, disorders of joints.

04

LO: To understand different tissues are involved in the formation of organs and perform different functions. For example skeletal muscle produce by way of its contraction and relaxation produce movement of the skeletal, nerves are involved in the transmission of electrical impulses, bones form body frame, muscles produce contraction and help in movement, circulation, digestion and excretion. Epithelial tissues protect and secretes juices.

UNIT-II

Haemopoietic system:

Composition and functions of blood, Genesis and regulation of red blood cells production, blood groups, transfusion of blood. Leukocytes, properties of white blood cells, reticulo endothelial system, blood coagulation and its mechanism, formation and circulation of lymph. Disorders of blood.

Formed elements of blood :

WBC, RBC and Platelets, Heamopoiesis and blood hormones, Blood groups and their significance, Coagulating factors, Pathways of coagulation and Mechanism of coagulation, Disorders of blood and its components disorders of coagulation.

08

LO : Blood is involved in oxygen and carbon dioxide transport, maintenance of B.P, defense immunity and excretion.

UNIT III

Cardiovascular system:

Basic anatomy, structure and functions of the heart and blood vessels. Excitatory and conductive system of the heart, action potential in cardiac cycle, nervous regulation of heart. Systemic coronary and hepatic blood circulation, cardiac output, blood pressure in different blood vessels, blood pressure regulations and measurements. ECG of heart. Brief outline of cardiovascular disorders like hypertension, hypotension, atherosclerosis, angina, myocardial infarction, congestive heart failure and cardiac arrhythmias.

08

Lymph and Lymphatic System: Composition, formation and circulation of lymph; disorders of lymph and lymphatic system. Basic physiology and functions of spleen. 03

LO: Heart and blood vessels maintain BP, transport gases, nutrients and waste products. Their function is essential to sustain life.

UNIT IV

Respiratory System: Anatomy of respiratory organs. Functions of respiration, mechanism and regulation of respiration, respiratory volumes and vital capacity. 07

LO : To know above external and internal respiration exchanging of gases, need for oxygen for metabolism of nutrients and generation of energy and is essential for life process.

UNIT V

Digestive System: Anatomy, structure and functions of different parts of gastrointestinal tract, motility of alimentary canal and its regulation. Gastrointestinal secretions, their compositions, function and regulations. Digestion of food in mouth, stomach and small intestine and its absorption.

LO : To understand digestion in various parts of GIT, enzymes and secretions involved – their functions.

UNIT VI

Urinary System: Structure and functions of Nephron, formation of urine, renal mechanism for concentrating and diluting the urine, regulation of acid-base balance, knowledge on release of renin from kidney and its functions. Regulations of blood volume and extracellular fluid volume. Disease related to kidney.

05

LO : To understand how urine is formed and various mechanisms involved in formation of urine.

TEXT BOOKS

1. Tortora, G.J and Anagnodokas, Principles of Anatomy and Physiology, N.P Harper & Row Publishers N.Y
2. C.C.Chatterjee, Human Physiology.
3. Ross & Wilson, Anatomy-Physiology in health and illness.
4. Donald.C Rizzo, Fundamental of Anatomy and Physiology.

REFERENCES

1. A.C.Guyton, Text Book of Medical Physiology.
2. Best & Taylor, The Living Body-A Text Book on Human Physiology.

I Year – I SEMESTER

T	P	C
3+1	0	3

DISPENSING PHARMACY & ETHICS

UNIT-I

Dispensing Pharmacy: Principles of dispensing, form of prescription, handling of prescription, source of errors for prescription, care required in dispensing procedures including labelling of dispensed products. Weights and Measures, introduction to Latin terms, Percentage calculations, alligation method, proof spirit calculations, displacement value and calculations of isotonicity adjustment. General dispensing procedure- posology calculations of doses.

LO : To understand dispensing principles, procedures, calculations involved, doses.

UNIT-II

Principles involved and procedures adopted in dispensing of the following classes of preparations.

(i) Mixtures
(ii) Solutions – A study of the following solutions – Cresol with soap solution IP, Aqueous Iodine solution IP, Strong solution of Iodine IP, weak iodine solution IP, strong solution of Ammonium acetate.
(ii) emulsions (iv) powders (v) lotions & liniments (vi) ointments

LO : To understand principles and procedures involved in the dispensing of various categories of products.

Unit-III

Dosage forms – Purpose, classification, definitions and general characteristics of the following dosage forms

Solids : Tablet and capsules.

Liquid orals : Elixirs, Syrups, Linctus, Suspensions and Emulsions.

Liquids for external use : Lotions & liniments applications.

Semi solids : Ointments, Creams, Gels, Suppositories and Pessaries.

LO : To understand dosage forms and their general characteristics.

UNIT-IV

Incompatibilities: Physical, chemical and therapeutic incompatibilities – methods of overcoming and handling of incompatible prescriptions.

LO : To understand incompatibility and methods of overcoming incompatibility.

UNIT-V

Extraction and galenical products: Principle and methods of extraction - preparation of infusions, tinctures, dry, soft and liquid extracts.
LO : To understand extraction and galenical products – Principles and procedures.

UNIT-VI

Pharmacy Ethics as prescribed by PCI.

LO: To understand Ethics related to Pharmacy profession as prescribed by PCI.

TEXT BOOKS

1. Cooper & Gunns Dispensing Pharmacy, CBS, Publ. and Distributors New Delhi.
2. R.M Metha, Dispensing Pharmacy.
3. NK Jain and GD Guptha, Modern Dispensing Pharmacy, Pharma Med Press.
4. Sanmathi BS and Anshu Guptha, Dispensing Pharmacy – A Practical Manual, Pharma Med Press.

REFERENCES

1. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences.
2. E.A. Rawlkins, Bentley's Text Book of Pharmaceutics, Elbs publ.
3. Hoover, Dispensing of Medication.

I Year – I SEMESTER

T	P	C
3+1	0	3

PHARMACEUTICAL ORGANIC CHEMISTRY-I

UNIT-I

Structure and reactivity of organic molecules: Polarity of bonds, electronic effects: electromeric effect, inductive effect, mesomeric effect and Hyperconjugation and their influence on the properties of organic molecules; charged species: carbocations and carbanions, their generation, stabilities, rearrangement in the case of carbocations; Free radicals: formation and stability.

LO : Understanding the basic concepts influencing the reactivity of organic molecules, understanding the mechanisms wherever applicable, applications of the above in the interpretation of various properties of organic molecules.

UNIT-II

Alkanes and cycloalkanes: Nomenclature, general methods of preparation, chain and conformational isomerism in the case of alkenes and their relative stabilities, Bayer's strain theory and Sachse-Mohr theory in the case of cycloalkanes and their limitations.

Alkenes: Nomenclature, general methods of preparation, characteristic electrophilic and free radical addition reactions, orientation of product formation as interpreted by Markonikov's rule and peroxide effect (Anti-Markonikov's rule), ozonolysis and allylic substitution.

Alkadienes: Nomenclature, stability of conjugated dienes, 1,2- and 1,4-reactions and their relative stabilities.

Alkynes: Nomenclature, general methods of preparation, characteristic reactions with emphasis on acidity of one alkynes, formation of metal acetylides, stereospecific reduction of alkynes and addition of water involving keto-enol tautomerism

LO : Structures, equations involved in the preparations, mechanism of formation or the reaction, rearrangements if any, discussion on stabilities and applications of the characteristic reactions in synthesis.

UNIT-III

Alkylhalides: Nomenclature, general methods of preparation, significance of nucleophilic subsititution of alkylhalides in organic synthesis, mechanisms and salient features of S_N1 and S_N2 reactions with examples including the proof in favor of these reactions, a comparison of S_N1 and S_N2, elimination

reactions (E1 and E2): mechanisms, salient features and orientation of product formation in terms of Saytzeff's rule and Hoffmann orientation.

LO : Structures, equations involving the methods of preparations and reactions, stabilities and applications of the reactions.

UNIT-IV

Alcohols: Nomenclature, classification, methods of preparation, industrial synthesis of ethanol and methanol, reactions of alcohols involving the replacement of hydroxyl or replacement of the hydrogen of the hydroxyl, iodoform reaction and Lucas test.

Ethers: Nomenclature, Williamson's synthesis, action of hydroiodic acid on ethers.

LO : Structures, general properties, equations involving the methods of preparation and reactions, mechanisms, reactivities.

UNIT-V

Stereochemistry: Isomerism and its comparison to stereoisomerism, stereoisomers, optical isomers (enantiomers), characteristics of enantiomers (chirality), racemic mixtures, methods of separation of racemic mixtures, optical activity, optical rotation, specific rotation, plane of symmetry and centre of symmetry, diastereomers, their properties and required characteristics with examples as given by Fischer projection formulae; mesoform and its characteristics; Configuration: relative configuration (D and L), absolute configuration (R and S); Geometric isomerism: cis-trans isomerism and E and Z nomenclature.

LO : Stereochemical structures, importance of stereochemistry with respect to drugs as interpreted in terms of reactivity and the properties of chiral drugs.

UNIT-VI

Grignard reagent: Preparation, characteristic nucleophilic addition and substitution reactions, applications in organic synthesis and limitations.

LO : Structure, mechanism and usefulness in synthesis.

TEXT BOOKS

1. T.R. Morrison and R.N. Boyd, Organic chemistry, pentice hall of India private limited, New Delhi.
2. Arun Bahl & Bahl, Advanced Pharmaceutical Organic Chemistry.

REFERENCES

1. R.L Madan, Organic Chemistry.
2. Lloyd N. Ferguson, Text book of Organic Chemistry, 2nd edition.
3. Raj K Bansal, A textbook of Organic Chemistry, 5th edition.

I Year – I SEMESTER

T	P	C
0	3	2

ENGLISH COMMUNICATIONS SKILLS LAB

Suggested Lab Manuals:

OBJECTIVE: To impart to the learner the skills of grammar as well as communication through listening, speaking, reading, and writing including soft, that is life skills.

ADVANCED COMMUNICATION SKILLS

UNIT 6	Body language
UNIT 7	Dialogues
UNIT 8	Interviews and Telephonic Interviews
UNIT 9	Group Discussions
UNIT 10	Presentation Skills
UNIT 11	Debates

Text Book:

'Strengthen your Communication Skills' Part-B by Maruthi Publications

Reference Books:

1. INFOTECH English (Maruthi Publications)
2. Personality Development and Soft Skills (Oxford University Press, New Delhi)

I Year – I SEMESTER

T	P	C
0	2	0/1

REMEDIAL BIOLOGY LAB

1. Study of Simple and compound microscopes used in biology.
2. Section cutting, staining and mounting of sections.
3. Histological studies of the leaf, stem and root with description of their stained sections.
4. Description and study of floral characters of the plants representing the families in theory.
5. Observation of permanent slides.

I Year – I SEMESTER

T	P	C
0	3	2

DISPENSING PHARMACY LAB

1. Dispensing of prescriptions falling under the categories; Mixtures, solutions, emulsions, creams, ointments, powders, pastes, lotions, liniments, inhalations, paints. etc.

2. Identification of various types of incompatibilities in a prescription, correlation thereof and dispensing of such prescriptions.

3. Dispensing procedures involving pharmaceutical calculations, pricing of prescriptions and dosage calculations for pediatric and geriatric patients.

4. Dispensing of prescriptions involving adjustment of tonicity.

A total 50 prescriptions are to be dispensed.

I Year – I SEMESTER

T	P	C
0	3	2

PHARMACEUTICAL ORGANIC CHEMISTRY LAB

Introduction to Equipment & Glassware
Recrystallization method, determinations of Melting point, Boiling Point and distillation

I. Preparation of organic compounds (each involving a specific organic reaction covered in theory)

1. N.Acetylation : Preparation of Acetanilide from Aniline
2. 0-Acetylation : Preparation of Aspirin from salicylic acid
3. Nuclear Nitration : Preparation of μ-Dinitrobenzene from nitrobenzene
4. Oxidation : Preparation of Benzoic acid from Benzyl chloride
5. Esterification : Preparation of n-Butyl acetate from n-Butyl alcohol
6. Etherification : Preparation of α-Naphthyl methyl ether from α–Naphthol
7. Halogenation : Preparation of lodoform from iodation of acetone
8. Extensive Nuclear Substitution : Preparation of Tribromophenol
9. Bromination of Tribromoaniline from Phenol or Aniline

II. Systematic qualitative Analysis (Identification) of Monofunctional Organic Compounds:

Avoid water-soluble compounds, and compounds containing more than one functional group; at least six individual compounds to be analyzed.

REFERENCES

1. Vogel's Text Book of Practical Organic Chemistry, 5" Edition.
2. R.K. Bansal, Laboratory Manual of Organic Chemistry.
3. O.P. Agarwal, Advanced Practical Organic Chemistry.
4. F.G.Mann & B.C. Saunders, Practical Organic Chemistry.

I Year – II SEMESTER

T	P	C
3+1	0	3

HUMAN ANATOMY & PHYSIOLOGY – II (50 Hrs)

UNIT –I 08

Central Nervous System: Anatomy and physiology of different parts of brain, spinal cord and cranial nerves.

LO : Brain involvement in sensory and motor functions including pain persumption, sleep wake cycle, cognitive skills, memory, behavior and governance.

UNIT – II

Neuron, axon conduction, Neurochemical transmission, reflex action, electroencephalogram, specialized functions of the brain, and their functions. 08

LO : Chemical Mediators like Acetyl choline, Serotinine, Dopamine, Noradrenaline, glutamic acid, gaba involvement in transmission of impulse and disorders due to their changes.

UNIT - III

Autonomic Nervous System: Physiology and functions of sympathetic and parasympathetic nervous system. Mechanism of neurohumoral transmission in the A.N.S. 08

LO : Cholinergic system is Essential for life process while adrenergic system is needed to meet emergency by flight or fight. ANS works without rest through life without rest unlike CNS.

UNIT - IV

Endocrine System: Basic anatomy and physiology of pituitary, thyroid, parathyroid, adrenals, testes, ovary and endocrine functions of hormones and functions. 08

LO : Growth, reproduction and metabolism depend on hormonal activity. Their imbalance leads to disorders and some of them cannot be rectified.

UNIT-V

Reproductive System: Male and female reproductive systems and the functions of their hormones. Physiology of menstruation, Spermatogenesis and Oogenesis. 08

LO : Concept of male & female hormones, Characters, sex cell maturity, reproductive period, copulation and pregnancy, parturition, concept of pregnancy, menopause and their care.

UNIT-VI

Sense organs: basic anatomy and physiology of Eye, Ear, Nose, Tongue and skin. 10

LO : Sensations are the combined activities of sensory organs and specified areas of the brain.

TEXT BOOKS

1. Tortora, G.J and Anagnodokas, Principles of Anatomy and Physiology, N.P Harper & Row Publishers N.Y
2. Ross & Wilson – Anatomy & Physiology in health and illness – Anne Waugh, Allison Grant.
3. T.S. Ranganathan, A Text book of Human Anatomy.
4. Human Anatomy and Physiology. C.C Chatterjee.

REFERENCES

1. Donald.C Rizzo, Fundamental of Anatomy and Physiology.
2. Subrhamanyam and Others, A textbook of Physiology.
3. A.C.Guyton, Text Book of Medical PhysiologyKeele& Neil, Samson Wrights Applied Physiology.
4. Best & Taylor, The Living Body-A Text Book on Human Physiology.
5. M.N. Ghosh, Human Physiology Julia F. Gui, Learning Human Anatomy: A Laboratory Text.
6. B.D. Chaurasia, Human Anatomy, Regional and Applied, Part-I,II and III, CBS Publishers and Distributors, New Delhi.

I Year – II SEMESTER

T	P	C
3+1	0	3

PHARMACEUTICAL INORGANIC CHEMISTRY

UNIT-I

1. Classification of inorganic pharmaceuticals based on their applications and therapeutic uses.
2. Sources of impurities, quality control and test for purity. Limit tests for chlorides, sulphates, iron, arsenic, lead and heavy metals and their pharmacopoeial standards.

LO : Pharmaceutical orientation to inorganic chemistry, definitions, principles, procedures, limits of detection, keeping the impurities in pharmaceutical substances to the minimal level.

UNIT-II

1. **Sodium, potassium and calcium replenishers:** sodium chloride, compound sodium chloride solution (Ringer solution), potassium chloride, ORS.
2. **Calcium replenishers:** Calcium chloride, calcium gluconate, dibasic calcium phosphate.
3. **Acid-base regulators:** sodium bicarbonate, sodium lactate, sodium citrate/potassium citrate, sodium acetate and ammonium chloride.
4. **Antacids:** Aluminium hydroxide gel, dried aluminium hydroxide gel, magnesium oxide, magnesium hydroxide mixture, magnesium trisilicate and calcium carbonate.
5. **Expectorants:** Ammonium chloride, potassium iodide.
6. **Emetics:** Potassium antimony tartrate and copper sulfate.
7. **Antidotes:** Sodium thiosulphate and sodium nitrite.

LO : Properties, classification, preparation, assay of ammonium chloride, sodium thiosulfate and sodium nitrite, uses.

UNIT-III

1. **Adsorbents:** Light kaolin, heavy kaolin and activated charcoal.
2. **Astringents:** Zinc oxide and Bismuth subcarbonate.
3. **Protectants:** Calamine, zinc oxide, zinc state, talc and titanium dioxide.
4. **Silicone polymers:** Activated Dimethicone.

5. **Anti-infectives:** Hydrogen peroxide solution, potassium permanganate, silver nitrate (Silver protein), iodine (Solutions of iodine, povidone-iodine) boric acid and yellow mercuric chloride.

LO: Properties, preparation wherever applicable, assay of hydrogen peroxide, potassium permanganate, boric acid, zinc oxide and uses.

UNIT-IV:

1. **Laxatives:** Magnesium sulphate and sodium phosphate.
2. **Haematinics:** Ferrous sulphate, Ferrous fumarate, Ferrous gluconate, Ferric ammonium citrate, Iron and dextrose injection.
3. **Suspending agents:** Bentonite and colloidal silica.
4. **Excipients:** Di and tricalcium phosphates, magnesium stearate, talc and calcium carbonate (precipitated chalk).
5. **Colorants:** Titanium oxide and ferric oxide.

LO : Properties, preparations wherever applicable, uses.

UNIT-V

Dental products:

1. **Fluorides:** Sodium fluoride and stannous fluoride.
2. **Oral antiseptics:** Hydrogen peroxide, Zinc peroxide and mouth washes.
3. **Dentifrices:** Dibasic calcium phosphate, strontium chloride and sodium metaphosphate.
4. **Cements and Fillers:** Zinc oxide.

LO : Properties, preparations wherever applicable, uses.

UNIT-VI

Miscellaneous medicinal agents of inorganic nature:

Cisplatin (Antineoplastic), lithium carbonate (Antipsychotic), barium sulfate (diagnostic agent), plaster of paris (surgical aid), sodium auorthiomalate (antirheumatic), sodium antimonygluconate (internal parasiticid) and potassium perchlorate (antithyroid).

LO : Structures, properties and uses.

TEXT BOOKS

1. A.H.Beckett and J.B.Stenlake, Practical pharmaceutical chemistry, Part-I. The Athtone press, University of London, London.
2. Advanced Inorganic Chemistry by Satya prakash, G.D.Tuli

3. Wal Ankita, Wal, Pranay, Rai, Awani Kumar, Inorganic Pharmaceutical Chemistry, New Age International Publishers.

REFERENCES

1. J.H Block, E.Roche, T.O Soine and C.O. Wilson, Inorganic Medical and pharmaceutical

   Chemistry Lea & Febiger, Philadelphia PA.

2. P. Gundu Rao, Inorganic pharmaceutical chemistry; Vallabh Prakashan, Delhi.

3. L.M. Atherden, Bentley and Driver's Textbook of Pharmaceutical Chemistry Oxford

   University Press, London.

4. G.R Chatwal, Pharmaceutical Chemistry Inorganic, Himalaya Publishers.

5. K Somasekhar Rao, C Venkata Suresh, Pharmaceutical Inorganic Chemistry, Pharma Med Press.

I Year – II SEMESTER

T	P	C
3+1	0	3

PHARMACEUTICAL ORGANIC CHEMISTRY-II

UNIT-I

Benzene: Kekule's structure, aromaticity, Huckle's rule, resonance energy, characteristic electrophilic substitution reactions: nitration, halogenations, sulfonation, Friedel-Craft's alkylation and acylation with limitations, orientation in monosubstituted benzenes.

Polynuclear aromatic hydrocarbons: Nomenclature, methods of preparation of naphthalene, anthracene and phenanthrene, their oxidation and reduction reactions, relative susceptibilities to oxidation as interpreted in terms of sacrifice of resonance energies, electrophilic substitution reactions.

Arylhalides: Nomenclature, comparison of reactivity with respect to alkylhalides, mechanism of nucleophilic substitution (Benzyne concept).

LO : Understanding the properties of aromatic compounds, mechanisms of reactions and their usefulness in organic synthesis, electronic factors influencing orientation.

UNIT-II

Carbonyl compounds: Nomenclature, important methods of preparation, characteristic nucleophilic addition reactions (addition of bisulphate, Grignard reagent, hydrogen cyanide, hydrazine derivatives and alcohols); Aldol condensation, Cannizzaro reaction and Perkin reaction.

LO : General properties, relative reactivities towards nucleophilic addition, mechanisms and applications.

UNIT-III

Carboxylic acids: Nomenclature, important methods of preparation, characteristic reactions (acidity, relative acidities, reduction, H-V-Z reaction, conversion into acid chlorides, amides and esters); methods of preparation of important esters (acetoacetic ester and malonic ester) and their applications in organic synthesis.

LO : General properties, measurement of relative acidities, equations involving the reactions and mechanisms, applications in synthesis.

UNIT-IV

Phenols: Nomenclature, general methods of preparation, industrial synthesis of phenol by Dow process, characteristic reactions (acidity and its

comparison to alcohols and carboxylic acids as interpreted by resonance, ether formation, ester formation, Kolbe reaction, Reimer-Tiemann Reaction, bromination and nitration).

LO : Structures, equations, mechanisms, importance of these reactions in pharmaceutical organic synthesis.

UNIT-V

Amines and Diazonium compounds: Nomenclature, methods of preparation, characteristic reactions (basicity and relative basicities, alkylation and exhaustive alkylation, nitration and orientation), separation of all three classes of amines by Hinsberg's method; formation of Diazonium compounds, characteristic reactions (replacement by hydrogen, Sandmeyer reaction, replacement by nitrile, and their applications in synthesis and coupling reactions).

LO : Properties, structures, equations, mechanisms, orientations and applications.

UNIT-VI

Name reactions: Beckmann rearrangement, Mannich reaction, Fries rearrangement, Michael addition, Schmidt reaction, Benzoin condensation.

LO : General reaction, structures and mechanism, applications in organic synthesis.

TEXT BOOKS

1. T.R.Morrison and R.N.Boyd, Organic chemistry, pentice hall of India private limited, New Delhi.
2. Arun Bahl & Bahl, Advanced Pharmaceutical Organic Chemistry.

REFERENCES

1. R.L Madan, Organic Chemistry.
2. Lloyd N. Ferguson, Text book of Organic Chemistry, 2nd edition,.
3. Raj K Bansal, A textbook of Organic Chemistry, 5th edition.

I Year – II SEMESTER

T	P	C
3+1	0	3

PHYSICAL PHARMACY – I (50 Hrs)

UNIT I

Intermolecular forces and states of matter: Binding forces between molecules, the states of matter, the gaseous state, the liquid state, solids and the crystalline state. Phase equilibria and the phase rule. 10

LO **:** To learn intermolecular forces and states of matter,Phase equilibria and Phase rule

UNIT - II

Thermodynamics: The first law of thermodynamics. Thermochemistry.The second law of thermodynamics.The third law of thermodynamics, Free energy functions and applications. 10

LO **:** To understand laws of Thermodynamics and their Applications

UNIT - III

Physical properties of Drug Molecules: Dielectric constant induced polarization, dipole moment, refractive index and molar refraction, optical rotatory dispersion.

LO **:** To understand the physical properties of drug molecules and their significance. 06

UNIT - IV

Solutions of Non electrolytes: Concentration expressions, ideal and real solutions, colligative properties, molecular weight determinations. 06

LO **:** To understand properties of Non electrolytes and their significance

UNIT - V

Solutions of Electrolytes: Properties of solutions of electrolytes. The Arrhenius theory of electrolyte dissociation.The modern theory of strong electrolytes and other coefficients for expressing colligative properties. 08

LO **:** To know theories of electrolytes and their dissolution and colligative properties

UNIT - VI

Buffers and buffered isotonic systems: The buffer equation, buffer capacity, buffers in pharmaceutical and biological systems, buffered isotonic solutions, methods of adjusting tonicity and pH (relevant numerical problems).

10

LO **:** To know about buffers ,buffer isotonic solutions, Methods of adjusting isotonicity and their significance.

TEXT BOOKS

1. Patrick J. Sinko, Martin's Physical Pharmacy and Pharmaceutical Sciences Fifth Edition.
2. C.V.S.Subramanyam, Essentials of Physical Pharmacy, Vallabh Prakashan.
3. E. Shotton and K. Ridgaway, Physical Pharmaceutics, Oxford University Press, London.
4. S. J Carter, Cooper and Gunn's Tutorial pharmacy.

REFERENCES

1. Pharmacopoeia, (I.P., B.P., U.S.P. and European.)
2. Derle Deeliprao, Essentials of Physical Pharmacy
3. B.S Bahl, ArunBahl and G.D Tuli, Essentials of Physical Chemistry.
4. Pharmacopoeia (I.P, B.P, U.S.P and European)
5. Martindale, the Extra Pharmacopoeia; Latest Edition the Royal Pharmaceutical Society
6. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences
7. Robin J. Haiwan, Hand Book of Pharmacy and Health Care Edition, ThePharma Press, U.K.
8. Bentley's Text Book of Pharmaceutics by E.A. Rawlins

I Year – II SEMESTER

T	P	C
3+1	0	3

COMPUTER APPLICATIONS AND BIOSTATISTICS

Unit-I

Overview of computer with general applications: components of computers, computer languages, usage of computers, introduction of operative system.

Introduction to MS-Office: MS- word: Basics, working with files, working with text, formatting paragraphs, styles, lists, tables, graphics, spelling and grammar, page formatting macros and table of contents.

MS-Excel: Basics, spreadsheets, data types, formulas, formatting charts and graphs.

MS-Power Point: Basics, views, slide controls, applied design, page setup, templates, background control, colour screens, traditions and animations, working with texts and working with graphics.

MS-Access: Data base concepts, screens layouts, creating tables, data sheet record, table relationships, shorting and filtering, query forms, form controls, sub forms, reports, importing, exporting and linking.

LO **:** The student should be familiar with overview of the computers and MS-office

Unit-II

Information Technology Today: Internet and World Wide Web (www), structure and organization of www, browsers, information searching in www, search engines, pharmaceutical resources in www types of indexing tools and search strategies, Hyper Text Manuscripts Languages (HTML) and e-mail.

LO **:** Familiarity with internet, WWW, browsing, HTML & e-mails.

Unit-III

Database Management: Concepts and objectives of Database Management systems, advantages of database management systems and examples of DBMS packs (like DBASE III).

LO **:** Familiarity with Database management

Unit-IV

Data collection and treatment: Significant digits and rounding of numbers, data collection, random and non-random sampling methods, sample size, data

organization, diagrammatic representation of data, bar, pie, 2-D and 3-D diagrams.

Measures of central tendency and variations: Mean, median, mode, properties and applications, range, standard deviations and standard error of means, coefficient of variation, kurtosis, skewness and confidance (fiducial) limits for mean and proportions.

LO **:** Fundamentals of date / Sample collection and diagrammatic presentation.Measures of central tendency and dispersion.

Unit-V

Regression: Correlation and regression analysis, method of least squares and non-linear regression.

Statistical Quality control: Statistical Quality control charts like mean and range charts, p-chart, np-chart and c-chart. Applications of Statistical Quality control in pharmaceutical sciences.

LO **:** Correlation and regression quality control charts in pharmacy.

Unit-VI

Statistical inference: t-test, chi square test and their applications in pharmacy.

Elements of ANOVA: One-way and two-way with examples.

LO**:** Application of t-test, Chi square test and approve in the testing the significance of difference or similarity.

TEXTBOOKS

1. Computer Fundamentals, Anita Goel, Pearson.
2. Information Technology Workshop, 3e, G Praveen Babu, M V Narayana BS Publications.
3. Khan & Khan, “Fundamentals of Biostatistics”.
4. Pranab Kumar Banerjee, “Introduction to Biostatistics”.

REFERENCE BOOK:

1. Essential Computer and IT Fundamentals for Engineering and Science Students, Dr. N.B. Venkateswarlu
2. Biostatistics for medical, nursing and pharmacy students by A.Indrayan, L Satyanarayana.
3. Introduction to Information Technology, ITL Education Solutions Ltd., 2nd Ed, PEARSON
4. Comdex Information Technology, Vikas Gupta, dreamtech.

I Year – II SEMESTER

T	P	C
0	3	2

HUMAN ANATOMY PHYSIOLOGY LAB

1. Study of compound microscope and precautions to be taken while handling it.
2. Microscopic study of structure of cell and different tissues.
3. To understand and learn Blood withdrawal techniques.
4. Determination of bleeding time, clotting time, blood grouping and Estimation of Hemoglobin in blood.
5. Study of Haemocytometry.
6. Estimation of W.B.C count.
7. Estimation of R.B.C. count.
8. Estimation of D.L.C.
9. Study of human skeleton.
10. Study of different systems with the help of charts and models.
11. Recording of body temperature, pulse rate and blood pressure.
12. Determination of vital capacity, experiments on spirometry.
13. Various devices used in family planning like Copper T, Lippe's loop, diaphragm, condom and oral pills.

I Year – II SEMESTER

T	P	C
0	3	2

PHYSICAL PHARMACY – I LAB

1. Percent composition – Capillary Flow method.
2. Percent composition – Polarimeter&Refractometer.
3. Molecular weight – Landsberger method.
4. Molecular weight – Rast camphor method.
5. Calibration of pH Meter.
6. pH Estimation – pH meter.
7. pH Estimation – Colourimetric method.
8. pH Estimation by Half Neutralization Method.
9. Refractive index of liquids.
10. Phenol water system – Upper Consolute Temperature.
11. Lower consulate temperature – Tea and Water.
12. Heat of neutralization.
13. Phase diagram -Phenol – Water, Effect of Impurities.
14. Ternary phase diagram.
15. Preparation of Buffers and Buffer capacity determination.

I Year – II SEMESTER

T	P	C
0	3	2

COMPUTER APPLICATIONS LAB

Identification of the peripherals of a computer.

To prepare a report containing the block diagram of the CPU along with the configuration of each peripheral and its functions. Description of various I/O Devices

A practice on disassemble the components of a PC and assembling them to working condition.

Examples of Operating systems-Dos, Windows, Installation of MS windows on a PC.

Introduction to Memory and Storage Devices , I/O Port, Device Drivers, Assemblers, Compilers, Interpreters , Linkers, Loaders.

Internet & World Wide Web : Importance of Networking, Transmission Media, Networking Devices- Gateway, Routers, Hub, Bridge, NIC ,Bluetooth Technology, Wireless Technology, Modem, DSL, Dialup Connection.

Orientation & Connectivity Boot Camp and surfing the Web using Web Browsers: Students should get connected to their Local Area Network and access the Internet. In the process they should configure the TCP/IP setting and demonstrate how to access the websites and email. Students customize their web browsers using bookmarks, search toolbars and pop up blockers.

Search Engines & Netiquette: Students should know what search engines are and how to use the search engines. A few topics would be given to the students for which they need to search on Google.

MS Office

Word Orientation: Word as word Processors.

Accessing, overview of toolbars, saving files, Using help and resources, rulers, formatting ,Drop Cap , Applying Text effects, Using Character Spacing, Borders and Colors, Inserting Header and Footer, Using Date and Time option

Creating project : Abstract Features to be covered:-Formatting Styles, Inserting table, Bullets and Numbering, Changing Text Direction, Cell alignment, Footnote, Hyperlink, Symbols, Spell Check , Track Changes,

Images from files and clipart, Drawing toolbar and Word Art, Formatting Images, Textboxes and Paragraphs.

MS Excel

Excel Orientation: The mentor needs to tell the importance of MS Excel as a Spreadsheet tool, give the details of the tasks and features that would be covered in each.

Using Excel Accessing, overview of toolbars, saving excel files, Using help and resources**.**

Creating a Scheduler - Features to be covered: Gridlines, Format Cells, Summation, auto fill, Formatting Text.

Performance Analysis - Features to be covered: Split cells, freeze panes, group and outline, Sorting, Boolean and logical operators, Conditional formatting.

Power Point

Students will be working on basic power point utilities and tools which help them create basic power point presentation. Topic covered during this week includes :- PPT Orientation, Slide Layouts, Inserting Text, Word Art, Formatting Text, Bullets and Numbering, Auto Shapes, Lines and Arrows, Hyperlinks, Inserting –Images, Clip Art, Tables and Charts in PowerPoint.

Concentrating on the in and out of Microsoft power point. Helps them learn best practices in designing and preparing power point presentation. Topic covered during this week includes: - Master Layouts (slide, template, and notes), Types of views (basic, presentation, slide slotter, notes etc), and Inserting – Background, textures, Design Templates, Hidden slides.

MS Access:

Students have to work on creating data bases, tables, storing and organizing data in the data base, querying, Creating Forms and Reports (take appropriate examples.)

TEXT BOOK:

1 Computer Fundamentals, Anita Goel, Pearson.

2 Information Technology Workshop,3e, G Praveen Babu, M V Narayana BS Publications.

3 Introduction to Information Technology, ITL Education Solutions Ltd., 2nd & 3rd Eds., PEARSON

4 Comdex Information Technology, Vikas Gupta, dreamtech.

REFERENCE BOOK:

1. Williams, Using Information Technology: Practical Introduction, TMH.
2. Essential Computer and IT Fundamentals for Engineering and Science Students, Dr. N.B. Venkateswarlu.

II Year – I SEMESTER

T	P	C
3+1	0	3

PHARMACEUTICAL UNIT OPERATIONS –I (50 Hrs)

UNIT-I 08

Fluid Flow: Types of flow, Reynold's number, viscosity, concept of boundary layer, basic equations of fluid flow, valves, flow meters, manometers and measurement of flow and pressure.

LO: To understand fluid flow concepts – Reynold's number, viscosity, flow meters and valves – measurements of flow and pressure.

UNIT-II

Material handling systems: 10

a. Liquid handling -different types of pumps.

b. Gas handling -various types of fans, blowers and compressors.

c. Solid handling -conveyors

LO : To understand material handling systems – liquid, gas and solid handling.

UNIT-III 10

Filtration and Centrifugation: Theory of filtration, filter aids, filter media, industrial filters including filter press, rotary filter, edge filter, etc. Factors affecting filtration, mathematical problems on filtration, optimum-cleaning cycle in batch filters. Principles of centrifugation, industrial centrifugal filters, centrifugal filters, and centrifugal sedimeters.

LO : To understand theory and equipment of filtration and centrifugation.

UNIT-IV 10

Crystalization: Characteristics of crystals like; purity, size, shape, geometry, habit, forms, size and factors affecting it. Solubility curves and calculation of yields. Material and heat balances around Swenson Walker Crystallizer. Supersaturation theory and its limitations. Nucleation mechanisms, crystal growth. Study of various types of crystallizers, tanks, agitated batch, single vacuum, circulating magma and crystal crystallizers. Caking of crystals and its prevention. Numerical problems on yields.

LO : To know the crystallization theory, crystallization equipment and their applications.

UNIT-V

Dehumidification and Humidity control

Basic concepts and definition, wet bulb and adiabatic saturation temperature. Psychrometric chart and measurement of humidity, application of humidity measurement in pharmacy, equipments for dehumidification operations.

03

LO : To know the theory of dehumidification and humidity control, measurement of humidity.

Refrigeration and Air Conditioning:

Principles and applications of refrigeration and air conditioning.

02

LO : To understand the principles and applications of refrigeration and air conditioning.

UNIT-VI

Materials of Construction: General study of composition, corrosion, resistance, properties and applications of the materials of construction with special reference to stainless steel and glass. 04

Industrial hazards and safety precautions: Mechanical, Chemical, Electrical, fire and dust hazards. Industrial dermatitis, accident records etc.

03

LO : To understand the materials of construction, their properties and applications. To know the mechanical, chemical, fire and dust hazards and their prevention.

TEXT BOOKS

1. Prof. K. Samba Murthy, Pharmaceutical Engineering.
2. Badzer & Banchero, Introduction to Chemical Engineering.
3. C.V.S. Subramanayam, Pharmaceutial Unit Operation, VallabhPrakashan
4. S.J. Carter, Cooper and Gunn's Tutorial Pharmacy 6ed CBS publisher, Delhi.

REFERENCES

1. Perry's Handbook of Chemical Engineering.
2. Unit Operations by McCabe& Smith.
3. McCabe& Smith, Elements of Chemical Engineering.
4. Lippincott Williams and Wilkins : Remington Pharmaceutical Sciences.
5. EA Rawlins, Bently's Text Book of Pharmaceutics, 8edition, ELBS
6. C.G. Brown, Unit Operations (Indian ed)Asia Publishing House, Bombay
7. Remington's Pharmaceutical Sciences

II Year – I SEMESTER

T	P	C
3+1	0	3

PHARMACOGNOSY – I(50 Hrs)

UNIT- I

Definition, history, scope and development of Pharmacognosy. General introduction to alternative systems of medicine like Ayurveda, Siddha, Unani and Homeopathy. 02

Brief introduction to natural sources of drugs with examples: Plant Source, Animal Source, Mineral Source, Marine Source and microorganisms. 04

LO : To make the students understand that drugs are obtained from different sources and crude drugs, are used in the indigenous systems of medicine.

UNIT-II

Classification of Crude Drugs: Alphabetical, morphological, pharmacological, chemical, taxonomical and chemotaxonomical methods of classification with suitable examples. 06

LO : To make the students understand that crude drugs can be classified based on several criteria.

UNIT-III

Cultivation, collection, processing, drying and storage of medicinal plants: 08

- Factors influencing cultivation of medicinal plants.
- Plant hormones and their applications.
- Definitions and examples for polyploidy, mutation and hybridization with reference to medicinal plants.

Good Agriculture Practices: Strategies of obtaining improved cultivation of medicinal plants.

LO : To understand improve agricultural conditions provide high yield and the methods be standardized to get consistent yields.

UNIT-IV

Adulteration &Evaluation of crude drugs: 06

Adulteration of crude drugs: Different methods of adulteration of crude drugs and general methods for detection of adulterants. For example

i) Organoleptic ii) Microscopic iii) Physical iv) Chemical and Biological methods of evaluation.

LO : To provide enough knowledge to identify adulterants from genuine products and to provide quality products.

UNIT-V 06

Systematic pharmacognostic study of the following carbohydrates and derived products: Acacia, tragacanth, agar, starch, guargum, pectin, isabgol and honey.

LO : To provide quality products of the above as exceipients.

UNIT-VI

Systematic Pharmacognostic study of the following Lipids: Castor oil, cod liver oil, shark liver oil, linseedoil, cocoa butter, kokum butter, bees wax, wool fat, hydrocarpus oil, spremaceti, lard and olive oil.

08

Systematic Pharmacognostic study of the following volatile oils: Mentha, coriander, cinnamon, lemon oil,nutmeg, eucalyptus, ginger, cardamom, tulsi, lemon grass, caraway, cumin, dill, clove, fennel and black pepper.

06

LO : To maintain quality in fixed and volatile oils.

TEXT BOOKS

1. Kokate C.K, Purohit AP &GokhalePharmacognosy S.B (Nirali)
2. Trease and Evans Pharmacognosy, Latest Edition.
3. Tyler, Brady & Robert, Pharmacognosy.
4. T.E.Wallis, Textbook of Pharmacognosy, Pub by CBS Publishers and distributors, New Delhi.

REFERENCES

1. Atal C.R & Kapur B.M, Cultivation & Utilization of Medicinal Plants.
2. Ayurvedic Pharmacopoeia of India, Pub by Govt. of India.
3. A.A. Farooqi& B.S. SreeRamu, Cultivation of Medicinal and Aromatic Crops, University Press.
4. CSIR Publications, Wealth of India.
5. Handa and Kapoor, Text Book of Pharmacognosy.
6. Gokhale, Pharmacognosy.
7. Heinrich, Fundamentals of Pharmacognosy and Phytotherapy.
8. Taylor and Evans, Text Book of Pharmacognosy.
9. Iyengar, Pharmacognosy of Powdered Crude Drugs.
10. R.N Chopra, S.L Nair and I.C Chopra, Glossary of Indian Medicinal Plants, CSIR, New Delhi.

II Year – I SEMESTER

T	P	C
3+1	0	3

PHYSICAL PHARMACY -II(50 Hrs)

UNIT-I 08

Solubility and Distribution Phenomena : Solvent-solute interaction, solubility of gases in liquids, liquids in liquids, solids in liquids, distribution of solutes in immiscible solvents.

Introduction to phenomena of diffusion : Ficks first law and second law.

LO : To understand the solubility and distribution phenomenon and laws of diffusion.

UNIT-II

Kinetics: Rates and orders of the reaction. Influence of temperature and other factors on reaction rates. Decomposition and stabilization of medicinal agents, kinetics in the solid state and accelerated stability analysis (relevant numerical problems). 10

LO : To understand kinetic rates, order of reaction, decomposition pathways and methods of stabilization, stability testing methods, accelerated stability analysis.

UNIT-III

Interfacial Phenomena: Liquid interfaces, measurement of surface and interfacial tensions, adsorption at liquid interfaces. Surface active agents and systems of hydrophilic-lipophillic classification. Adsorption at solid interfaces. Electrical properties of interfaces. 08

LO : To understand theory of interfacial phenomenon, absorption, surfactants and theoretical properties of interfaces.

UNIT-IV

Micromeritics: Particle size and size distribution, methods for determining surface area, methods for determining particle size, pore size, particle shape and surface area, derived properties of powders.

08

LO : To learn micromeritic characteristics and their applications and significance.

UNIT-V

Rheology: Newtonian system, non-Newtonian system, thixotrophy, measurement and applications in formulations. Determination of viscosity and its applications. 08

LO : To understand rheology, types of flow, thixotrophy, its applications and viscosity.

UNIT –VI

Colloids: Introduction, types of colloidal systems, solubilization, Stability of colloids, optical properties, kinetic properties, electrical properties and Donnan Membrane equilibraium. 08

LO : To know colloids – types – properties – stability considerations.

TEXT BOOKS

1. Patrick J. Sinko, Martin's Physical Pharmacy and Pharmaceutical Sciences 5 Edition.
2. CVS Subhramanyam, Physical Pharmacy, Vallabhprakashan.
3. DeelipRaoDerle&Sai hanuman SagarBoddu. Essentials of Physical Pharmacy.
4. B. S. Bahl, Arunbahl and G. D. Tuli. Essentials of Physical Chemistry.

REFERENCE

1. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences
2. M.E. Aulton, Pharmaceutics – The science of dosage form design, 2edition
3. Bentley’s text book of Pharmaceutics. E. A. Rawlins.
4. E. Shotton and K. Ridgaway, Physical Pharmaceutics, Oxford University Press, London.
5. Pharmacopoiea (IP, BP, USP and European).

II Year – I SEMESTER

T	P	C
3+1	0	3

PHARMACEUTICAL MICROBIOLOGY(50 Hrs)

UNIT – I 10

Introduction to Microbiology: Origin, scope and discovery of spontaneous generations theory, contributions of Antony Von Leuwenhock, Pasteur, Koch and Lister.

Diversity of Microorganisms: Prokaryotes versus eukaryotes – eukaryotic and Prokaryotic cell structure, three domains of life (bacteria, archea and eurkaryotics). Pharmaceutical significance of protozoa, algae, fungi, bacteria and viruses. Characterisation and identification of microorganisms.

LO : To understand diversity of microorganisms and their spontaneous generation and use and harmful nature.

UNIT – II 10

Nutrition and Growth of Microbes: Nutritional requirements, Types of Nutrient media and growth conditions and Nutritional types based on energy source.

Isolation, cultivation (aerobic & anaerobic) and preservation of microorganisms, physiology of growth, bacterial growth curve, methods for determing bacterial numbers, mass and cell constitutents. Exponential growth and generation time.Bacterial growth in batch and continuous culture (chemostat and turbidostat) synchronous growth.

Microorganisms and their Environment: Effects and microbial adaptations to environmental conditions – Temperature, oxygen desiccation, extreme cold ionic effect, electricity, osmotic pressure, radiant energy, hydrostatic pressure, mechanical impact, vibration.

LO : To understand that bacterial growth curve consist of rapid growth followed by stabilization and later decline due to exhaustion of nutrients and several parameters affects the above.

UNIT –III 08

Control of Microorganisms: General Concepts, Inhibition of growth and killing, sterilization and disinfection, antisepsis and sanitation, mode of action application & limitation of physical agents (moist and dry heat, radiation and filtration), chemical agents. Various types of disinfectants, factors affecting sterilization and disinfection, evaluation of antimicrobial

activity. Chemotherapeutic agents, mode of action and applications, drug resistance. Official methods of sterility testing of pharmaceuticals and biosafety measures.

LO : To understand that moist heat, dry heat,radiation,filtration,chemicals can be used for sterilization and disinfection to provide aseptic condition in the filling areas, operation theatres etc

UNIT –IV 10

Bacterial Genetics: Genetic recombination in bacteria, DNA replication, transcription and translation. Gene regulation (lac operon and tryptophan operon).Mutagenesis, chemical and physical mutagens.

LO : To understand the concept of bacterial resistance to antibiotics and other conditions.

UNIT – V 04

Epidemiology of Diseases: Study of etiology, diagnosis, source of infection, mode of transmission, immunization methods, prevention and control of the following diseases. Bacillary dysentery, diphtheria, tuberculosis, leprosy, cholera, typhoid, syphilis, gonorrhea, tetanus, food poisoning and infection hepatitis.

LO: To understand that microbes are responsible for causing certain diseases.

UNIT – VI 08

Application of Microbes in Pharmaceutical Industry

a. **Microbiological Assays:** Principles and Methods involved in Assay of Antibiotics,

   Vitamins, Amino acids & Bio-Sensors in Analysis.

b. **Microbial Source & applications of various pharma products** like Antibiotics,

   Vitamins, amino acids, solvents, enzymes & genetic engineered products etc.

LO : To understand that antibiotics/Vitamins can be standardized by microbial assays. And some useful products can be produced as a bacterial metabolites.

TEXT BOOKS

1. Pelczar and Reid, Text Book of Microbiology.
2. Anantha Narayan and Jayram Panikar, Text Book of Microbiology, Orient Longman, Delhi.
3. N.K. Jain, Pharmaceutical Microbiology.
4. Alcamo, Microbiology.

REFERENCES

1 Heritage. J, Introductory Microbiology.
2 Nester, Anderson, Roberts, Pearsall, Microbiology, McGraw-Hill.
3 Hugo,W B Pharmaceutical Microbiology.
4 Tortora A. Gerard, Text Book of Microbiology.

II Year – I SEMESTER

T	P	C
3+1	0	3

ENVIRONMENTAL SCIENCES

UNIT - I

Multidisciplinary Nature of Environmental Studies: Definition, Scope and Importance– Need for Public Awareness. 01

Natural Resources : Renewable and non-renewable resources – Natural resources and associated problems – Forest resources – Use and over – exploitation, deforestation, case studies – Timber extraction – Mining, dams and other effects on forest and tribal people – Water resources – Use and over utilization of surface and ground water – Floods, drought, conflicts over water, dams – benefits and problems - Mineral resources: Use and exploitation, environmental effects of extracting and using mineral resources, case studies. - Food resources: World food problems, changes caused by agriculture and overgrazing, effects of modern agriculture, fertilizer-pesticide problems, water logging, salinity, case studies. – Energy resources: Growing energy needs, renewable and non-renewable energy sources use of alternate energy sources. Case studies. Land resources: Land as a resource, land degradation, man induced landslides, soil erosion and desertification. Role of an individual in conservation of natural resources.Equitable use of resources for sustainable lifestyles. 09

LO : To know environment, Natural resource, Conservation of national resources

UNIT - II

Ecosystems : Concept of an ecosystem. - Structure and function of an ecosystem. - Producers, consumers and decomposers. - Energy flow in the ecosystem - Ecological succession. - Food chains, food webs and ecological pyramids. - Introduction, types, characteristic features, structure and function of the following ecosystem :

a. Forest ecosystem
b. Grassland ecosystem
c. Desert ecosystem
d. Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)

10

LO : To understand various Ecosystems Characteristic features, structural functions of each.

UNIT-III

Biodiversity and its conservation : Introduction - Definition: genetic, species andecosystem diversity. - Bio-geographical classification of India - Value of biodiversity: consumptive use, productive use, social, ethical, aesthetic and option values - . Biodiversity at global, National and local levels. -. India as a mega-diversity nation - Hot-spots of biodiversity - Threats to biodiversity: habitat loss, poaching of wildlife, man-wildlife conflicts. - Endangered and endemic species of India – Conservation of biodiversity: In-situ and Ex-situ conservation of biodiversity.

LO : To understand biodiversity-basic principles-Conservation of Biodiversity.

UNIT -IV

Environmental Pollution : Definition, Cause, effects and control measures of :

a. Air pollution
b. Water pollution
c. Soil pollution
d. Marine pollution
e. Noise pollution
f. Thermal pollution
g. Nuclear hazards

Solid waste Management: Causes, effects and control measures of urban and industrial wastes. - Role of an individual in prevention of pollution. - Pollution case studies. - Disaster management: floods, earthquake, cyclone and landslides. 10

LO : To know about environmental pollution, types of pollution-Causes-Measures to prevent and solid waste management-techniques/Methods.

UNIT - V

Social Issues and the Environment: Environmental ethics: Issues and possible solutions. Climate change, global warming, acid rain, ozone layer depletion, nuclear accidents and holocaust. Case Studies – Waste land reclamation, Consumerism and waste products. Environment Protection Act - Air (Prevention and Control of Pollution) Act, Water (Prevention and control of Pollution) Act, Wildlife Protection Act, Forest Conservation Act, Issues involved in enforcement of environmental legislation, Public awareness.

05

Human population & environment: Population growth, variation among nations, population explosion – family welfare programs. Environment and

human health. Human rights. Value education. Women and child welfare. Role of technology in environment and human health. 05

LO : To know about social issues in environment, ethics, Acts related to environmental protection and conservation. Human population and environment, Human health issues.

UNIT -VI

Human Population and the Environment: Population growth, variation among nations. Population explosion – Family Welfare Programme. -Environment and human health. -Human Rights. -Value Education. HIV/AIDS. -Women and Child Welfare. - Role of information Technology in Environment and human health.

LO : Different aspects of human population and environment and their importance.

Text Books :

1. An Introduction to Environmental Studies by B. Sudhakara Reddy, T. SivajiRao, U. Tataji& K. Purushottam Reddy, Maruti Publications.

Reference:

1. Text Book of Environmental Studies by Deeshita Dave & P. UdayaBhaskar, Cengage Learning.
2. Environmental Studies by K.V.S.G. Murali Krishna, VGS Publishers, Vijayawada.
3. Text Book of Environmental Sciences and Technology by M. Anji Reddy, BS Publications.

II Year – I SEMESTER

T	P	C
0	3	2

PHARMACOGNOSY LAB – I

1. Collection of natural herbs and preparation of herbariam/laminated photos for five drugs.
2. Macroscopy& Microscopy of the following:
   a. Any five carbohydrates mentioned in theory.
   b. any five lipids mentioned in theory.
   c. any five volatile oils mentioned in theory.
3. Chemical tests for the following:
   a. Any five carbohydrates mentioned in theory.
   b. any five lipids mentioned in theory.
   c. any five volatile oils mentioned in theory.
4. Cultivation of medicinal plants: Maintenance of one plant in Medicinal garden.

REFERENCES

1. Kandhelwal, Practical Pharmocognosy.
2. C.K. Kokate et.al, Practical Pharmocognosy.
3. Iyengar, Practial Pharmocognosy.

II Year – I SEMESTER

T	P	C
0	3	2

PHYSICAL PHARMACY-II LAB

1. Determination of bulk density, true density and percentage porosity.
2. Effect of particle size and effect of glidant on angle of repose.
3. Microscopic size analysis.
4. Determination of particle size by Andreason Pippette.
5. Determination of CMC of a surfactant.
6. Adsorption Isotherm.
7. Partition coefficient determination.
8. Determination of sedimentation volume and degree of flocculation.
9. Determination of Order of reaction – First order.
10. Determination of Second order reaction rate constant.
11. Effect of temperature on solubility of solid in liquid.
12. Effect of addition of Salt/pH/cosolvent on the solubility.
13. Surface tension using Stalagmometer.
14. HLB value estimation of surfactants.
15. Viscosity – by Ostwald Viscometer.
16. Preparation of Multiple emulsion - Demonstration.
17. Preparation of Micro emulsion- Demonstration.
18. Determination of Zeta potential - Demonstration.

II Year – I SEMESTER

T	P	C
0	3	2

PHARMACEUTICAL MICROBIOLOGY LAB

1. Study of apparatus used in experimental microbiology.
2. Sterilization techniques and their validations.
3. Preparation of various culture media.
4. Sterilization of glass ware and culture media.
5. Aseptic transfer of culture into different types of medias.
6. Staining methods - Simple staining, Gram's staining, Acid fast and negative staining.
7. Motility testing by hanging drop method.
8. Enumeration of bacteria by pour plate/spread plate technique.
9. Enumeration of bacteria by direct microscopic count.
10. Isolation of pure cultures by streak plate, spread plate, pour plate.
11. Evaluation of antiseptics and disinfectants, sterility of pharmaceutical products as per IP requirements.
12. Observation of colony characteristics.
13. Bio chemical reactions:
    - i) Indole test.
    - ii) Methyl red test.
    - iii) Vogesproskauer test.
    - iv) Starch hydrolysis test.
    - v) Fermentation of carbohydrates.
14. Morphology of molds, yeasts.
15. Preseravation of microrganisms (slant and stab cultures).

II Year – II SEMESTER

T	P	C
3+1	0	3

PHARMACEUTICAL UNIT OPERATIONS – II

UNIT-I

Heat Transfer: Source of heat, heat transfer, steam and electricity as heating media, determination of requirement of amount of steam/electrical energy, steam pressure, boiler capacity, mathematical problems on heat transfer.

LO : To understand principles and theory of Heat flow/ Conductions, Convection, Radiation-Heat exchangers.

UNIT-II

Evaporation: Basic concept of phase equilibria, factors affecting the evaporation, evaporators, film evaporators, single effect and multiple effect evaporators.

LO : To understand evaporation, Phase equilibrium, Theory of evaporation-Evaporators.

UNIT-III

Distillation: Raoult's law, phase diagrams, volatility, simple steam and flash distillations, principles of rectification, Azeotropic and extractive distillation.

LO : Theory of distillation types of rectifiers, their application.

UNIT-IV

Drying: Moisture content and mechanism of drying, rate of drying and time of drying calculations, classification and types of dryers, dryers used in pharmaceutical industries tray dryer, Fluid bed dryer, spray dryer, vacuum oven and freeze-dryer.

LO : Drying, Moisture content, rate of evaporation, types of dryers construction working and Applications.

UNIT-V

Size Reduction: Definition, objectives of size reduction, factors affecting size reduction, laws governing energy and power requirements of a mill, types of mills including ball mill, hammer mill, fluid energy mill etc.

LO : To understand theory of size reduction, factors involved in size reduction,equipments- Construction working and applications-selection of size reduction equipment.

UNIT-VI

Mixing: Theory of mixing, solid-solid, solid-liquid and liquid-liquid mixing equipment, double cone, twin-shell, silverson mixer, colloid mill, sigma blade mixer, planatery mixer, propeller mixer and turbine mixer.

LO : Theories of mixing solid-solid, solid-liquid & liquid-liquid mixing equipments.

TEXT BOOKS

1. S.J. Carter, Cooper and Gunn's Tutorial Pharmacy, 6th ed., CBS publisher, Delhi.
2. CVS Subhramanyam, Pharmaceutical Engineering.
3. K. Samba Murthy, Pharmaceutical Engineering.
4. Mc Cabe & Smidth.Unit Operations.

REFERENCE BOOKS

1. W.I. Macebe and J. C. Smith Macro, Unit Operations To Chemical Engineering, Hill Int. Book Co., London.
2. L. Lachman, H. Lieberman & J**.** L Kaniz, The Theory And Practice of Industrial Pharmacy, Lee & Febiger Philadelphia, USA.
3. Badzer & Banchoro, Introduction to Chemical Engineering.
4. Perry's Handbook of Chemical Engineering.
5. M.E.Aulton, Pharmaceutics - The science of dosage form design, 2nd ed.
6. E.A. Rawlin's, Bentley's Text Book of Pharmaceutics, 8th ed ELBS.

II Year – II SEMESTER

T	P	C
3+1	0	3

PHARMACEUTICAL ANALYSIS –I

Unit-I

1. A general introduction to pharmaceutical analysis and general aspects of standardization of pharmaceutical chemicals and formulated products mentioned in Indian pharmacopoeia. Importance of proper sampling and general books for pharmaceutical standards like pharmacopoeias, National formularies.
2. Computation of analytical results, significant numbers, rejection of doubtful values with reference to volumetric and gravimetric analysis, sources of errors and calibration of analytical equipment used in volumetric and gravimetric analysis.

LO : To understand the concept of standardization by gravimetric and volumetric methods.

Unit-II

3. Acid-Base titrations: theoretical basis of neutralization reactions including electrolytic dissociation, application of law of mass action, relative strength of acids and bases, hydrolysis of salts and buffer solutions, theory of neutralization indicators and factors involved in the selection of indicators for different types of acid-base titrations. Procedures involved in different types of titrations using strong acid, week base, strong base, week base and back titration with blank determination. Assay of Boric acid Sodium bicarbonate, Borax, calcium hydroxide, zinc oxide, calcium carbonate, Acetyl salicylic acid, Formaldehyde, NaOH in presence of sodium carbonate.
4. Non-aqueous titrations: principles, advantages and pharmaceutical applications, solvents reagents and indicators used in Nonaqueous titrimetry, other methods of detecting end points. Examples of titrations of alkali metal and alkaline earth metal salts of organic acids, primary, secondary and tertiary amines, halogen acid salts of bases, titration of acidic substances. Assay of thiamine hydrochloride.

LO : To understand the concept of standardization by aqueous and non-aqueous titrations.

Unit-III

5. Oxidation-reduction titrations: theoretical considerations including standard potentials, calculation of redox potentials, redox indicators, principle and procedure involved in different types of redox titrations using potassium permanganate, iodine. Titrations of released iodine and back titration of excess iodine, potassium iodate, ammonium ceric sulphate and titanous chloride. Assay of ferrous sulphate, Hydrogen peroxide, Sodium nitrate, Estimation of ascorbic acid with 2,6-dichlorophenol indophenols, Assay of mercuric chloride, Assay of sodium metabisulphite, Assay of copper sulphate.

LO : To understand the concept of standardization by oxidation – reduction methods.

Unit-IV

6. Precipitation titrations: principles and procedures involved in argentimetry, use of silver nitrate and ammonium thiocyanate. Indicators used in precipitation titrations including adsorption indicators, Mohr's and Volhard's methods with examples. Assay of potassium chloride, Ammonium thiocyanate, Assay of mercuric oxide.
7. Complexometric titrations: basic principles of complexometric analysis including theories of complex ions, chelating agents, properties of metal complexes with particular reference to EDTA. Basic principles of complexometric analysis including theories of complex formation. Werener's coordination number and structure of complex ions, chelating agents, properties of metal complexes with particular reference to EDTA, various examples of titrations of metal ions using disodium acetate, indicators and end point detection using indicators and by physical methods, masking and demasking agents, pharmaceutical applications of complexometry with particular reference to I.P. Assay of calcium gluconate injection/tablets, Calcium lactate and Assay of Aluminium sulphate.

LO : To understand that standardization can be done for some compounds by precipitation titrations.

Unit-V

8. A detailed study of gravimetric analysis including principles involved, critical factors and typical methods involving precipitation, coagulation, digestion, filtration and incineration procedures with suitable examples. Advantages and disadvantages, sources of errors and their elimination in gravimetric analysis.

Determination of sulphate as barium sulphate, Estimation of magnesium as magnesium pyrophosphate, Determination of thiamine as silico tungstate.

LO : To understand that standardization can be done for some compounds by gravimetric method.

Unit-VI

9. Principles and procedures involved and application of nitrite titrations, titrations using 2, 6-dichlorophenol-indophenol. Aquametry including use of Karl-fisher reagent and moisture balances.
10. Gas analysis: principles of gas analysis use of hempel's gas burette and pipette, nitrometer, haldome's and orset's gas analysis apparatus and their operations. Examples of gas analytical methods of pharmaceutical significance.

LO : To understand that moisture in drugs can be determined by Karl-Fisher titration.

TEXT BOOKS:

1. Indian pharmacopoeia
2. Practical Pharmaceutical Chemistry by A.H. Becket and Stenlake.
3. Quantitative Inorganic Analysis by A.I. Vogel.

II Year – II SEMESTER

T	P	C
3+1	0	3

PHARMACOGNOSY – II(50 Hrs)

Definition, general tests and detailed pharmacognostic study of the following drugs.

UNIT I 08

Glycoside containing drugs:

a. **Saponin Glycosides** **:** Glycyrrhiza, Ginseng, Discorea, Sarasaparilla & Senega.

b. **Cardioactive Glycosides** **:** Digitalis, Squill, Strophanthus & Thevetia.

c. **Anthraquinone Glycosides :** Aloe, Senna, Rhubarb & Cascara.

d. **Bitter Glycosides** **:** Psoralea, Gentian & Chirata.

LO : To understand that Glycisides are isolated from plant sources and have varied action based on aglycone part.

UNIT II 10

Alkaloid containing drugs:

a. **Pyridine – Piperidine derivatives** : Tobacco & Lobelia

b. **Tropane** : Belladona, Hyoscyamus, Datura, Coca & Aswagandha.

c. **Quinoline & Isoquinoline** : Cinchona, Ipecac, Opium.

d. **Indole** **:** Ergot, Rauwolfia, Vinca, Nux-vomica

e. **Imidazole** **:** Pilocarpus

f. **Steroid** **:** Kurchi

a. **Alkaloidal amine** **:** Ephedra & Colchicum

b. **Glycoalkaloid** : Solanum

c. **Purine** **:** Coffee, Tea.

LO : To understand that Alkaloids of different structures are synthesized by different plants and possess varied activities based on structure.

UNIT - III 04

Study of Tannins & Tannin containing drugs: Gambir, Black catechu, Myroblan&Arjuna. S**tudy of resins &drugs contining resins**: Benzoin, Asafoetida, Balsam of Tolu, Podophyllum.

LO : To understand that Tannins and Resins and their combination products are produced by different plants.

UNIT- IV 02

Biological sources, preparations, identification tests and uses of the following enzymes: Diastase, Papain, Pepsin, Trypsin, Pancreatin.

LO : To understand that different enzymes of useful nature are produced by plants.

UNIT-V 10

Biogenesis of Phytopharmaceuticals:

General techniques of biosynthetic studies and basic metabolic pathways.

Brief introduction to biogenesis of secondary metabolites of pharmaceuitcal importance.

Biosynthesis of -Tropane, Quinoline, Opium and Indole alkaloids, Steroids and Anthraquinone glycosides.

LO : To understand that Compounds of varied chemical nature are produced by plants (chemodiversity).

UNIT – VI 04

Study of plant fibers like cotton, cotton wood pulp, jute, hemp and flaxused in surgical dressing and related products.

Theapplications of natural dyes like turmeric, henna, saffron, cochineal and marigold in pharmacy.

LO : Plants exhibit a lot of diversity in producing fibres useful for fabrics as well as Dyes to colour them.

TEXT BOOKS

1. Kokate C.K , Purohit AP &Gokhale, The Pharmacognosy S.B (Nirali)
2. Trease and Evans, Pharmacognosy, Latest Edition.
3. Tyler, Brady & Robert, Pharmacognosy.
4. Khare C.P, Indian Medicinal plants – An Illustrated dictionary.

REFERENCES

1. Atal C.K & Kapur B.M, Cultivation & Utilization of Medicinal Plants.
2. Wallis, Textbook of pharmacognosy, Pub by CBS Publishers and distributors, New Delhi.
3. Ayurvedic Pharmacopoeia of India, Pub by Govt. Of India.

II Year – II SEMESTER

T	P	C
3+1	0	3

MEDICINAL CHEMISTRY-I

UNIT-I

Heterocyclic compounds:

1. Five and six membered ring systems with heteroatoms: Furan, pyrrole, thiophene, pyridine, imidazole, pyrazole, oxazole, isoxazole, thiazole and pyrimidine.
2. Fused ring systems with heteroatoms: Quinolines, isoquinolines, acridine, benzimidazole and phenothiazine.

LO : Nomenclature (numbering), one or two methods of preparation, important reactions, mechanisms and examples of drugs having the above ring systems.

UNIT-II

1. **Drug activity and physico-chemical properties:** solubility, partition coefficient, hydrogen bonding, chelation, surface activity, bioisosterism, optical and geometrical isomerism**,** prodrugs and soft drugs.
2. **Mechanism of drug action:** receptor theories, enzyme stimulation and enzyme inhibition.
3. **Drug metabolism:** Phase I and Phase II reactions, factors affecting drug metabolism.

LO : Concepts involving receptors, drug-receptor interaction forces, mechanisms, equations, structures, advantages.

UNIT-III

Drugs acting on CNS:

1. Hypnotics and anxiolytics: Phenobarbital, diazepam and alprazolam.
2. Antipsychotics: chlorpromazine and haloperidol.
3. Antiepileptics: phenytoin, carbamazepine, valproate sodium.
4. Antidepressants: imipramine, amitriptyline, Isocarboxazide, iproniazide.
5. General anaesthetics: ketamine, halothane and thiopental sodium.

LO : Definition, scope, classification, mode of action, Structure-Activity Relationship (SAR) wherever applicable, therapeutic uses and synthesis of compounds as given above under each class.

UNIT-IV

1. **Adrenergic drugs:** Amphetamine, salbutamol, ephedrine, phenylephrine and dopamine.
2. **Adrenergic blockers:** Prazosine, tolazoline, Propranolol, atenolol
3. **Cholinergic drugs:** Carbachol, bethanichol.
4. **Anticholinergics:** propantheline, dicyclomine.
5. **Neuromuscular blockers:** succinyl choline.

LO : Definition, scope, classification, mode of action, Structure-Activity Relationship (SAR) wherever applicable, therapeutic uses and synthesis of compounds as given above under each class.

UNIT-V

1. **Analgesics and Non-steroidal anti-inflammatory agents (NSAIDs) :** paracetamol, aspirin, ibuprofen, indomethacin, diclofenac.
2. **Narcotic analgesics :** mepridine, methadone.
3. **Local anaesthetics :** benzocaine, procaine, lignocaine and dibucaine

LO : Definition, scope, classification, mode of action, Structure-Activity Relationship (SAR) wherever applicable, therapeutic uses and synthesis of compounds as given above under each class, an understanding of morphinans, its agonists and antagonists.

UNIT-VI

1. **Oral antihyperglycemic agents**: tolbutamide, gliclazide, glipizide, glibenclamide, metformin and pioglitazone.
2. **Thyroid drugs:** methimazole, propylthiouracil.
3. **H1-receptor antagonists:** diphenhydramine, chlorpheniramine, chlorcyclizine, cetrizine.
4. **H2-receptor antagonists:** ranitidine
5. **Proton pump inhibitors:** Omeprazole, rabeprazole, lansaprazole.

LO : Definition, scope, classification, mode of action, Structure-Activity Relationship (SAR) wherever applicable, therapeutic uses and synthesis of compounds as given above under each class, an understanding of morphinans, its agonists and antagonists.

TEXT BOOKS

1. William O. Foye, Textbook of Medicinal Chemistry, Lea Febiger, Philadelphia.

2. JH Block & JM Beale (Eds), Wilson & Giswold's Text book of organic Medicinal Chemistry and pharmaceutical chemistry, 11th Ed, Lipcott, Raven, Philadelphia, 2004.
3. S. N. Pandeya, Textbook of mediacinal chemistry, SG Publ. Varanasi, 2003.
4. Rama Rao Nadendla, Medicinal Chemistry.

REFERENCES

1. D. Abraham (Ed), Burger Medicinal chemistry ad Drug discovery, Vol. 1 & 2. John Wiley & Sons, New York 2003, 6th Ed.
2. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences; 20th Edition.
3. M. Atherden, Bentley and Driver's Textbook of Pharmaceutical Chemistry Ed: l. Oxford University Press, Delhi.
4. B.N. Lads, MG.Mandel and F.I. way, Fundamentals of drug metabolism & disposition, William & welking co, Baltimore USA.
5. C. Hansch, Comprehensive medicinal chemistry, Vol 1 – 6 Elsevier pergmon press, Oxford.

II Year – II SEMESTER

T	P	C
3+1	0	3

HEALTH EDUCATION & PATHOPHYSIOLOGY(50 Hrs)

UNIT-I

Concepts of health & disease: Disease causing agents and prevention of disease. 05

Classification of food requirements, balanced diet, nutritional deficiency disorders, their treatment and prevention, specifications for drinking water.

First aid: Emergency treatment of shock, snake bites, burns, poisoning, fractures and resuscitation methods.

LO : To understand that disorder is a physiological change while disease is caused by infecting organisms. Prevention is better than cure concept. First aid for emergency conditions before the patient is moved for medical treatment.

UNIT – II 05

Demography and family planning: Demography cycle, family planning and various contraceptive methods. Medical termination of pregnancy.

LO : Problems of over population in providing basic amenities and measures to be adopted for control.

UNIT-III

Basic Principles of cell injury and adaptation: 10

i) Causes, pathogenesis and morphology of cell injury.
ii) Abnormalities in lipoproteinemia, glycogen infiltration and glycogen storage disease.
iii) Cellular adaptations, atrophy, hypertrophy.
iv) Disturbances of growth of cells
v) General biology of tumors
vi) Differences between benign and malignant tumors
vii) Classification of tumors
viii) Etiology and pathogenesis of cancer
ix) Patterns of spread of cancer.

LO : Different phases of cell growth and disorders, to understand normal and tumor cells.

UNIT-IV

Inflammation& Repair : 08

A) i. Pathogenesis of acute inflammation
ii. Chemical mediators in inflammation
iii. Pathogenesis of chronic inflammation

B) i. Wound healing mechanisms and
ii. Factors affecting wound healing.

C) Pain and its types.

LO : To understand that several substances are involved in producing inflammation and to understand different reasons for causing pain.

UNIT-V

Diseases of Immunity: 03

i) Introduction to T and B cells
ii) MHC proteins or transplantation antigens
iii) Immune Tolerance

A) Hypersensitivity 04

i. Hypersensitivity type I, II, III, IV.
ii. Biological significance of hypersensitivity.
iii. Allergy due to food, chemicals and drugs

B) Auto-Immunity 05

i. Mechanism of autoimmunity.
ii. Classification of autoimmune diseases in man.
iii. Transplantation and allograft reactions, mechanism of rejection of allograft.
iv. Acquired Immuno Deficiency Syndrome (AIDS).

LO : To understand about allergy and body's resistance against diseases (Natural and adoptive immunity).

UNIT-VI

Pathophysiology of Cardiac disorders: 03

Shock, stroke, hypertension, Angina, Myocardial infarction, Congestive

cardiac failure, Atherosclerosis.

Pathophysiology of Common Disorders: 04

Diabetes Mellitus, Peptic ulcer, Alcoholic liver diseases, Acute and chronic renal failure, Asthma, Parkinsonism, Schizophrenia, Depression and Mania.

Infectious diseases: 03

Infective hepatitis, STD – Syphilis, Gonorrhea, HIV; Pneumonea, Typhoid, UTI, Tuberculosis, Leprosy, Malaria, Dysentery (Bacterial and amoebic).

LO : Abnormalities of cardiovascular system, metabolism, respiration, behavior and diseases caused by microorganisms and disorders caused by smoking and alcoholism.

TEXT BOOKS

1. Text book of Robbins Pathology basis of Disease – Robins, Cotran, Kumar.
2. Mary V. Buras, Pathophysiology: A self Instructional programme.
3. Mary Lou Mulvihill, Human Diseases: A Systemic approach.
4. General Pathology – Y M Bhende, S G Deodhare, SS Kelkar
5. Essentials of Pathophysiology for Pharmacy. Martin M. Zdanowicz. Published by Pharma Med Press.

REFERENCE BOOKS

1. A.C Guyton, Textbook of medicinal physiology by W.B.Prism books Pvt. Ltd., Delhi.
2. Joseph Dipiro, Patho Physiology and applied therapeutics.
3. M.P. Rang, M.N.Dale, J.M Riter, Anatomy & Physiology.

II Year – II SEMESTER

T	P	C
0	3	2

PHARMACEUTICAL UNIT OPERATIONS - LAB

1. Measurement of flow of fluids and their pressure, determination of Reynolds's number and calculation of frictional losses.
2. Evaluation of filter media, determination of rate of filtration and study of factors affecting filtration including filter aids.
3. Experiments to demonstrate applications of centrifugation.
4. Determination of Humidity-use of Dry Bulb and Wet Bulb thermometers and Psychometric charts.
5. Determination of overall Heat Transfer Coefficient.
6. Determination of rate of evaporation.
7. Experiments based on steam. Extractive and Azeotropic distillations.
8. Determination of rate of drying, free moisture content and bound moisture content.
9. Experiments to illustrate the influence of various parameters on the time of drying.
10. Experiments to illustrate principles of size reduction, Laws governing energy and power requirements of a size reduction.
11. Experiments to illustrate solid-solid mixing, determination of mixing efficiency using different types of mixers.

II Year – II SEMESTER **T P C**
0 3 2

PHARMACEUTICAL ANALYSIS –I LAB

Acid-base titrations :

1. Standardization of HCl
2. Standardization of H_2SO_4
3. Standardization of NaOH
4. Assay of boric acid
5. Assay of sodium bicarbonate
6. Assay of borax
7. Assay of calcium hydroxide
8. Assay of zinc oxide
9. Assay of calcium carbonate
10. Assay of acetyl salicylic acid
11. Assay of formaldehyde
12. Assay of NaOH in presence of sodium carbonate.

Redox titrations:

13. Standardization of iodine
14. Standardization of $KMnO_4$
15. Assay of ferrous sulphate
16. Assay of hydrogen peroxide
17. Assay of sodium nitrate
18. Estimation of ascorbic acid with 2,6-dichlorophenol indophenols
19. Assay of mercuric chloride 20. Assay of sodium metabisulphite
20. Assay of copper sulphate

Precipitation titrations :

21. Standardization of silver nitrate
22. Assay of potassium chloride
23. Assay of ammonium thiocyanate
24. Assay of mercuric oxide

Complexation titrations :

25. Standardization of EDTA
26. Assay of calcium Gluconate injection/tablets

27. Assay of aluminium sulphate

Non-aqueous titrations :

28. Assay of thiamine hydrochloride
29. Any other assay involving perchloric acid

Gravimetry

30. Determination of sulphate as barium sulphate.
31. Estimation of magnesium as magnesium pyrophosphate.
32. Determination of thiamine as silico tungstate.

Limit tests :

33. Limit test for chlorides
34. Limit test for sulphates
35. Limit test for iron

II Year – II SEMESTER

T	P	C
0	3	2

PHARMACOGNOSY – II LAB

1. Study of Microscopy, Macroscopy and powder characters of any three to four crude drugs under each type.

2. a. Glycoside s b. Alkaloids c. Tannins d. Resins

3. Identification test for two enzymes papain and casein.

4. Chemical tests for Asafoetida, Benzoin, Tannic acid, Pale catechu, Black catechu, Aloes, Digitalis, Senna and Quinine.

5. Quantitative microscopy:
   a. Ratio values: Stomatal number and Stomatal Index.
   b. Determination of dimension of starch grains and fibre lengths using eye piece micrometer and camera lucida methods.
   c. Determination of purity of ginger powder using lycopodium spore method.

6. Determination of proximate values:
   a. Moisture content
   b. Ash value
   c. Extractive values

7. Identification of markers of different phytoconstituents like glycerrhiza, aloe and cinchona by chromatographic techniques.

III Year – I SEMESTER

T	P	C
3+1	0	3

PHARMACEUTICAL BIOCHEMISTRY

UNIT - I

Introduction to Biochemistry: Outlines of the biochemsitry organization of cell organelle, Molecular constituents of cell membrane, active and passive transport processes across the cell membranes.

LO **:** Introduction, essentials of biochemistry with respect to pharmacy, cell, structure and functions.

UNIT - II

Brief chemistry of carbohydrates

Carbohydrate metabolism: Brief chemistry, Glycolysis, Citric acid cycle (TCA cycle), HMP shunt, Glycogenolysis, Gluconeogenesis, Glycogenesis. Metabolic disorders of carbohydrate metabolism.

LO : Introduction to metabolism. Structure, cycles, biological significance and metabolic disorders.

UNIT - III

Lipids, Proteins and nucleoproteins: Principles involved in biological oxidation.

Lipid metabolism: Brief chemistry, Oxidation of saturated (β - Oxidation), Ketogenesis and Ketolysis; Biosynthesis of Fatty acids, Lipids; Metabolism of cholesterol; Hormonal regulation of Lipid Metabolism. Defective metabolism of Lipids.

LO : Introduction to metabolism. Structure, cycles, biological significance and metabolic disorders.

UNIT - IV

Protein Metabolism: Protein turnover. Ketabolism of Amino acids (Trans-amination, deamination, de-carboxylation). Urea cycle and it's metabolic disorders. Outlines of the Metabolism and regulation of Protein synthesis.

LO : Introduction to metabolism. Structure, cycles, biological significance and metabolic disorders.

UNIT - V

1. Enzymes: Classification, mode of action**,** factors affecting enzymes action, Coenzymes.

2. Brief outline of Energy rich compounds, Phosphate metabolism and detoxification mechanisms of the body.

LO : Introduction, properties, classes, biochemical role and mode of action.

UNIT - VI

1. Cell division and metastasis.
2. Biomolecules: Biological functions of Nucleic acids, Vitamins & Minerals.
3. Detoxification mechanisms and their biological significance.

LO : Introduction, basic concepts, structures, properties, significance and uses.

TEXT BOOKS

2. Harper, Biochemistry
3. A.L. Lehninger, Principles of Biochemistry.
4. J.L .Jain, Fundamentals of Biochemistry
5. Satyanarayana, Text Book of Biochemistry
6. Rama Rao, Text Book of Bio Chemistry.
7. Conn, Outlines of biochemistry

REFERENCES

1. L.Stryer, Text Book of Bio Chemistry.
2. E.E Conn & P.K. Stumpf, Outlines of Biochemistry by John Wiley & sons, New York.
3. B.Harrow and A. Mazur, Text Book of Biochemistry, WB Saunders Co., Philadelphia.
4. Boyer Rodney, Modern experimental Bio Chemistry.
5. West, Edward Text Book of Biochemistry.
6. Conn, Outlines of Biochemistry.
7. Plummer, Practical Bio Chemistry.
8. Denniston, Topping & Caret; General, Organic, and Biochemistry, McGraw-Hill.

III Year – I SEMESTER

T	P	C
3+1	0	3

MEDICINAL CHEMISTRY-II

UNIT - I

1. **Introduction to principles of chemotherapy,** chemotherapeutic index, drug resistance.
2. **Sulphonamides:** Sulfisoxazole, Sulphamethazole and Sulphathiazole.
3. **Antitubercular agents:** PASA, Isoniazid, Ethambutol
4. **Antileprotic agents:** Dapsone

LO : Definition, current status, classification, mode of action, Structure-Activity Relationship (SAR) wherever applicable, therapeutic uses and synthesis of compounds as given above under each class.

UNIT - II

1. **Antimalarials:** Chloroquine, Primaquine and Pyrimethamine
2. **Anthelmintics:** Diethyl Carbamazine Citrate, Mebendazole, Tinidazole,
3. **Antiamoebic agents:** Metronidazole and Diloxanide furoate.
4. **Antifungal agents:** Clotrimazole, Fluconazole and Tolnaftate.

LO : Definition, current status, classification, mode of action, Structure-Activity Relationship (SAR) wherever applicable, therapeutic uses and synthesis of compounds as given above under each class.

UNIT - III

1. **Antiviral agents:** Acyclovir, Zidovudine, Idoxuridine and Amantadine.
2. **Cytostatic agents:** Chlorambucil, Cyclophospamide, Carmustine, 5-Flouro Uracil and
   Mercaptopurine

LO : Definition, current status, classification, mode of action, Structure-Activity Relationship (SAR) wherever applicable, therapeutic uses and synthesis of compounds as given above under each class.

UNIT - IV

Antibiotics:

1. **Penicillins:** Ampicillin, Amoxycillin

2. **Cephalosporins:** structures of important Cephalosporins (not synthesis)
3. **Tetracyclins:** Oxytetracycline, Doxycycline
4. **Aminoglycosides:** Streptomycin and Neomycin (structures).
5. **Miscellaneous:** Chloramphenicol, Rifampicin (only structure)

LO : Chemistry, structures of currently used drugs, classification, mode of action, Structure-Activity Relationship (SAR) wherever applicable, therapeutic uses and synthesis of compounds as given above under each class.

UNIT - V

Water soluble vitamins: structures of B1, B2, B6, B12, Nicotinic acid, Nicotinamide, Folic acid and Ascorbic acid.

LO : Chemistry, structural features, classification, mode of action, Structure-Activity Relationship (SAR) wherever applicable, therapeutic uses, biological role.

UNIT - VI

Fat soluble vitamins: structures of Vitamin A, Retinoic acid, Vitamin D, Ergosterol

LO: Chemistry including reactions, structural features, interconversions, classification, mode of action, Structure-Activity Relationship (SAR) wherever applicable, therapeutic uses, biological role.

TEXT BOOKS

1. William O. Foye, Textbook of Medicinal Chemistry, Lea & Febiger, Philadelphia.
2. JH Block & JM Beale, Wilson & Giswold's Text book of organic Medicinal Chemistry and

   pharmaceutical chemistry by (Eds), 11th Ed, Lipincott, Raven, Philadelphia, 2004.
3. S. N. Pandeya, Textbook of medicinal chemistry, SG Publ. Varanasi, 2003.
4. Sri Ram, Medicinal Chemistry.
5. Rama Rao Nadendla, Medicinal Chemistry.

REFERENCES

1. D. Abraham (Ed), Burger Medicinal chemistry and Drug discovery, Vol. 1 & 2. John Wiley

   & Sons, New York 2003.

2. Lippincott Williams and Wilkins: Remington Pharmaceutical Sciences .
3. L. M. Atherden, Bentley and Driver's Textbook of Pharmaceutical Chemistry. Oxford University Press, Delhi.
4. B.N. Lads, M.G.Mandel and F.I.Way, Fundamentals of drug metabolism & disposition,

   William & welking co, Baltimore USA.

5. C. Hansch, Comprehensive medicinal chemistry, Vol 1 – 6 Elsevier pergmon press, oxford 1991.
6. Daniel lednicer, Strategies For Organic Drug Synthesis And Design, John Wiley, N. Y. 1998.
7. D. Lednicer, Organic drug synthesis, Vol, 1 – 6, J.Wiley N.Y.
8. Kadam, Textbook of Medicinal Chemistry Vol. 1 & 2.
9. O.P.Agarwal, Text book of natural products. Vol. 1 & 2.

III Year – I SEMESTER

T	P	C
3+1	0	3

PHARMACEUTICAL TECHNOLOGY - I

UNIT - I

Preformulation: Physicochemical properties like physical form, particle size, shape, density, wetting, dielectric constant, solubility, dissolution, organoleptic additives, hydrolysis, oxidation reduction, recemization, polymerization, e.t.c. and their effect on formulation, stability and bioavailability study of prodrugs in solving problems related to stability & bioavailability in formulations. Stability testing of finished products as per ICH guidelines.

LO : To understand performulation parameters and their significance, methods, stability testing protocols, ICH guidelines.

UNIT - II

Liquid dosage forms: Introduction, types of additives used in formulations, vehicles, stabilizers, preservatives, suspending agents, emulsifying agents, solubulizers, colors, flavours and other manufacturing, packaging and evaluation of clear liquids, suspensions and emulsions official in pharmacopoeia.

LO : To understand liquid dosage formulations, additives, manufacturing, evaluation, packaging procedures, official preparations.

UNIT - III

Semisolid dosage forms: Definitions, types, mechanisms of drug penetration, factors influencing penetration, semisolid bases and their selection. General formulation of semi solids, clear gels manufacturing procedure, evaluation and packaging.

Suppositories: Ideal requirements of bases, Different types of bases, manufacturing procedure packing and evaluation.

LO : To understand semisolid and suppositories preparations, their formulations, methods of preparations, evaluations and packaging.

UNIT - IV

Pharmaceutical aerosols: Definition, propellants general formulation, manufacturing and packaging methods, pharmaceutical applications.

Opthalmic Preparations: Requirements, formulation, methods of preparation, containers, evaluation.

LO : To understand aerosols, ophthalmic preparations, their formulation, types, preparations, packaging and evaluation methods.

UNIT - V

Cosmeticology and Cosmetic Preparations - I: Fundamentals of cosmetic science, structures and functions of skin and hair. Formulation, preparation and packaging of cosmetics for skin & hair.

LO : To understand cosmetics science, functions of skin and hair, cosmetic properties and their formulations, preparations and evaluation methods.

UNIT - VI

Cosmeticology and Cosmetic Preparations – II: Formulation, preparation & packaging of dentrifices like tooth powders, pastes, gels etc., and manicure preparations like nail polish, lipsticks, eye lashes, baby care products etc.

LO : To understand formulation, preparations and packaging of various cosmetics preparations.

TEXT BOOKS

1. L. Lachman, H.A, Lieberman and J.L. Kanig, Theory & Practice of Industrial Pharmacy, Lea & Febieger, Philadelphia Latest Edn.
2. CVS. Subramanyam, Pharmaceutical production and management, Vallabh Prakashan,
New Delhi 2005.

REFERENCES

1. Shobha Rani, Text of Industrial Pharmacy, Hiremath Orient Longman.
2. Sagarian & MS Balsam, Cosmetics Sciences &Technology Vol.1, 2 & 3
3. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences.
4. E.A.Rawlkins, Bentley's Text Book of Pharmaceutics, Elbs publications.
5. HC Ansel Introduction to Pharmaceutical Dosage forms
6. S.H. Willing, M.M Tucherman and W.S. Hitchings IV, Good Manufacturing Practices for Pharmaceuticals: A Plan for Total Quality Control, Marcel Dekker, Inc., New York 1998.
7. Gilbert S. Banker and Christopher T Rhodes, Modern Pharmaceutics, IV Ed, Marcel Dekker, USA, 2005.
8. Yiew Chien, novel drug delivery systems, Marcel Dekker 2003.
9. Robert. A. Nash, Pharmaceutical Process Validation, 3rd Ed Marcel Dekker, 2003.
10. Good Manufacturing Practices – Schedule M Read With The Drugs and Cosmetic Rules 1945.

III Year – I SEMESTER

T	P	C
3+1	0	3

PHARMACOLOGY – I

UNIT - I

General Pharmacology: Introduction to pharmacology, sources of drugs, dosage forms and routes of administration, mechanism of action, Structural activity and relationship (SAR), factors modifying drug action, tolerance and dependence; Pharmacogenetics; Enzyme Induction & Inhibition; Absorption, distribution metabolism and excretion of drugs; Principles of drug discovery and development of new drugs.

LO : Knowledge imparting basic concepts of Pharmacology, mechanism of action of drugs, SAR, Pharmacokinetics and drug discovery.

UNIT - II

Pharmacology of Autonomic Nervous System:

Neurohumoral transmission in peripheral nervous system (autonomic and Somatic).

Parasympathomimetics & parasympatholytics, sympathomimetics & sympatholytics.

Ganglionic-stimulants and blocking agents, skeletal muscle relaxants.

LO : To understand the basics of physiology and neurotransmitters and their roles. To gain knowledge on the drugs acting on ANS and muscle relaxants.

UNIT - III

Drugs acting on Central Nervous System:

Neurohumoral transmission in the C.N.S, General anesthetics, Alcohols and Disulfiram, Sedatives, hypnotics, & anti-anxiety agents.

LO : To understand the role of neurotransmitters in the CNS and pharmacology of various classes of drugs acting on CNS.

UNIT - IV

Analgesics, Antipyretics, Anti-inflammatory and Anti-gout drugs, Narcotic analgesics & antagonists, Pharmacology of Local Anaesthetics

LO : To have knowledge on the pathophysiology on Analgesia, pyretics, inflammation, gout and drugs used in the above treatment.

UNIT - V

Antipsychotics & Lithium, Antidepressants, Pharmacology of Anti-epileptic drugs,

Pharmacological management of Parkinsonism & other movement disorders, C.N.S. stimulants, Drug Addiction & Drug Abuse.

LO : To impart knowledge on pathophysiology of various disease conditions of the above topics and pharmacology of drugs.

UNIT - VI

Drugs Acting on the Gastrointestinal Tract

Antacids, Antisecretory & Anti-ulcer Drugs, Laxatives & Antidiarrhoeal drugs, Appetite Stimulants & Suppressants, Emetics & Anti-emetics, Carminatives, Demulcents, Protectives, Adsorbents, Astringents, Digestants, Enzymes & Mucolytics.

LO : To impart knowledge on pathophysiology and conditions relating to peptic ulcers and emesis and to understand the pharmacology of drugs used in GIT disorders.

TEXT BOOKS

1. Sathoskar, Pharmacology and pharmacotherapeutics Vol. 1 & 2, Publ by Popular Prakashan, Mumbai.
2. Bertram. G. Katzung, Basic and clinical pharmacology, 9th Edn.
3. Tripathi, Text book of Pharmacology.
4. Rang & Dale, Text book of Pharmacology.

REFERENCE BOOKS

1. J.G. Hardman and Lee E. Limbard, Good Mann & Gilmann, The Pharmacological basis of therapeutics, Mc Graw hill, Health Professions Dvn.
2. H.P Rang, M. M. dale & J.M. Ritter, Pharmacology, Churchill living stone, 4th Ed.
3. J. Crossland, Lewis‘s Pharmacology, Church living stone.
4. Ruth Woodrow, Essentials of Pharmacology for Health Occupations.

III Year – I SEMESTER

T	P	C
3+1	0	3

PHARMACEUTICAL MANAGEMENT

UNIT - I

Features of Business Organisations & New Economic Environment:

Characteristic features of Business, Features and evaluation of Sole Proprietorship, Partnership, Joint Stock Company, Public Enterprises and their types, Changing Business Environment in Post-Liberalisation scenario.

LO : To understand business organization – types – functions.

UNIT - II

Manufacturing Management: Goals of Production Management and Organisation – Production, Planning and Control – Plant location - Principles and Types of Plant Layout-Methods of production (Job, batch and Mass Production), New Product Development.

LO : To understand production management and organization – Planning and control – Layout – Product development.

UNIT - III

Work Study - Basic procedure involved in Method Study and Work Measurement-Statistical Quality Control: $\overline{X}$ chart, R chart, *c* chart, *p* chart, (simple Problems), Acceptance Sampling, Deming's contribution to quality.

LO : To understand principles of work study – Methods – Control charts – Principles – Contribution – Quality concepts.

UNIT - IV

Organisation of Distribution and Marketing: Functions of Marketing, Marketing Mix, Marketing Strategies based on Product Life Cycle., Channels of distribution – Factors influencing channels of distribution, sales organization and sales promotion.

LO : To understand concepts in organization – Distribution – Marketing – Functions – Strategies –Factors – Sales – Sales promotions.

UNIT - V

Pharma Industry: Growth of Pharma Industry in India – current status and its role in building national economy and national health – Structure of Pharma Industry in India – PSUs in Pharma Industry –Progress in the

manufacture of basic drugs, synthetic and drugs of vegetable origin. Export and import of drugs and pharmaceuticals – Export and import trade.

LO : To understand Pharma industry – Structure – Manufacturing of drugs and Pharmaceuticals – Exports and imports.

UNIT - VI

Insurance and Pharma: Various types of insurance including marine and health insurance.

Pharmaceutical associations and societies, statutory councils governing the profession. General Principles of medical detailing.

LO : To understand insurance – types – health insurance – association and society governing pharmacy profession.

TEXT BOOK

1. Aryasri and Subbarao, Pharmaceutical Administration, TMH.
2. Smarta, Strategic Pharma Marketing.
3. G.Vidya Sagar, Pharmaceutical Industrial Management.

REFERENCES

1. Subbarao Chaganti, Pharmaceutical Marketing in India – Concepts and Strategy Cases, BS Publications.
2. O.P.Khanna, Industrial Management, Dhanpatrai, New Delhi.

III Year – I SEMESTER **T P C**
0 3 2

PHARMACEUTICAL BIOCHEMISTRY LAB

Experiments:

1. To prepare standard buffers (citrate, phosphate & carbonate) and measure the pH.
2. Titration curve for amino acids.
3. Separation of amino acids by two dimensional paper chromatography & gel
   electrophoesis.
4. The separation of lipids by T.L.C.
5. Identification of carbohydrates
6. Identification of amino acids.
7. Identification of lipids.
8. Estimation of glucose in urine.
9. Estimation of creatinine in urine.
10. Estimation of urea in blood.
11. Estimation of creatinine in blood.
12. Estimation of Serum protein.
13. Estimation of bile pigments in serum.
14. Estimation of alkaline phosphatase in serum
15. Effect of temperature on the activity of alpha-amylase.

III Year – I SEMESTER

T	P	C
0	3	2

PHARMACEUTICAL TECHNOLOGY – I LAB

A total of atleast 50 preparations are to be prepared belonging to various categories.

Preparation, evaluation and packaging of solutions, suspensions and emulsions, ointments. Suppositories, aerosols, eye drops, eye ointments etc.
Formulation of various types of cosmetics for skin, hair, dentrifices and manicure preparations.

III Year – I SEMESTER

T	P	C
0	3	2

MEDICINAL CHEMISTRY LAB

I. Synthesis of some medicinal compounds and their analogues.

i. Barbituric acid from Diethyl Malonate.
ii. Phenytoin from Benzoin or Benzyl.
iii. Paracetamol from *para*- nitro phenol or *para*- aminophenol.
iv. 1,4- di hydro pyridine from ethyl aceto acetate.
v. Quinazolinone from anthranilic acid via benzoxazinone.
vi. Sulfanilamide from acetanilide
vii. Isoniazid from γ-picoline.
viii. Antipyrine from ethyl aceto acetate.
ix. Benzocaine from *para*- nitro benzoic acid.

II. Qualitative estimation of some functional groups.

i. Halogens (Strepheno's method).
ii. Hydroxyl groups (Acetylation method)
iii. Methoxyl groups (Zeissel's method)
iv. Carboxyl groups (Silver salt method).

REFERENCES

1. A.I. Vogel, Text Book of Practical Organic Chemistry, 5th Edition.
2. R.K. Bansal, Laboratory Manual of Organic Chemistry.
3. F.G. Mann & B.C. Saunders, Practical Organic Chemistry, 4th Edition.

III Year –I I SEMESTER

T	P	C
3+1	0	4

PHARMACEUTICAL TECHNOLOGY - II

UNIT - I

Capsules: Advantage and disadvantages of capsule dosage forms, material for production of hard and soft gelatin capsules, sizes of capsules, capsule filling, soft processing problems in capsule manufacturing, importance of base absorption and minimum/gm factors in soft capsules, quality control, stability testing and storage of capsule dosage forms.

LO : To understand Capsule formulation, Types, Manufacturing and evaluation – Quality Control – Stability testing-storage**.**

UNIT - II

Microencapsulation: Types of microencapsulation and importance of microencapsulation in pharmacy, microcapsulation by coacervation phase separator, multi orifice centrifugal separation. Spray drying, spray congealing, polymerization complex emulsion, air suspension technique, and pan coating techniques, evaluation of microcapsules.

LO : To understand microencapsulation – Applications, Methods of Preparations. evaluation – Applications of Microcapsules.

UNIT - III

Tablets: Formulation of different types of tablets, granulation technology on large-scale by various techniques, types of tablet compression machinery and the equipments employed evaluation of tablets.

LO : To understand tablet formulations, additives- manufacturing methods-equipment-Evaluation of quality & Control.

UNIT - IV

Coating of Tablets: Types of coating, coating materials and their selection, formulation of coating solution, equipment for coating, coating processes, evaluation of coated tablets.

LO : To understand types of tablet coating – coating solutions- Equipment-Process- Evaluation of Coating tablets.

UNIT - V

Parenteral Products

a. Preformulation factors, routes of administration, water for injection, treatment

   apyrogenicity, non-aqueous vehicles, isotonicity and methods of its adjustment.

b. Formulation details, container and closures and selection.

c. Prefilling treatment, washing and sterilization of containers and closures, preparation of

   solution and suspensions, filling and closing of ampules, vials, infusion fluids,

   lyophilization & preparation of sterile powders, equipment for large-scale manufacture

   and evaluation of parenteral products.

d. Aseptic techniques, sources of contamination and method of prevention. Design of

   aseptic area, laminar flow benches, services and maintenance.

LO : To understand Formulations, Preformulations, additives, Manufacturing methods, containers, Packaging, evaluation of Parentrals – quality control, Types of sterile powders, aseptic processing facilities.

UNIT - VI

Packaging of Pharmaceutical products:

Packaging components, types, specifications and methods of evaluation as per I.P. Factors influencing choice of containers, package testing, legal and other official requirements for containers, packing testing.

Methods of packing of solid, liquid and semi-solid dosage forms, Factors influencing packing material, stability aspects of packaging.

LO : To understand Packaging components- types, specifications and evaluation methods of packaging materials and containers- legal and official requirements.

TEXT BOOKS

1. L. Lachman, H.A, Lieberman and J.L. Kanig, Theory & Practice of industrial pharmacy, Lea & Febieger, Philadelphia Latest Edn.
2. HC Ansel introduction to Pharmaceutical Dosage forms .
3. Pharmaceutical Dosage forms Tablet by Lieberman, Lachman.

4. CVS. Subramanyam, Pharmaceutical production and management, Vallabh Prakashan, New Delhi 2005.

REFERENCES

1. Sagarian & MS Balsam, Cosmetics Sciences &Technology,Vol.1, 2 & 3
2. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences
3. E.A.Rawlkins Bentley's Text Book of Pharmaceutics, Elbs publ
4. S.H. Willing, M.M Tucherman and W.S. Hitchings IV, Good Manufacturing Practices for

   Pharmaceuticals: A Plan for Total Quality Control, 2nd ed, Marcel Dekker, Inc., New York

   1998.
5. Gilbert S. Banker and Christopher T Rhodes, Modern Pharmaceutics, IVth ed, marcel

   dekker, usa, 2005.
6. Yiew chien, novel drug delivery systems, 2nd ed, marcel dekker 2003.
7. Robert. A. Nash, Pharmaceutical Process Validation, 3rd Ed Marcel Dekker, 2003.
8. Good Manufacturing Practices – Schedule M. Read With The Drugs And Cosmetic Rules

   1945
9. M.E. Aulton, Pharmaceuitcs- The science of Dosage form Design 2nd ed.

III Year –I I SEMESTER

T	P	C
3+1	0	4

PHARMACEUTICAL BIOTECHNOLOGY

UNIT - I

Fermentation Technology: Isolation, Selection, Screening of Industrial important microbes, Strain improvement. Types, design & operation of Bioreactor. Types of fermentations, optimization of fermentation process, Principle and Procedure involving in downstream process and effluent treatment.

LO : To understand principles of fermentation technology- types of bioreactor – optimization of fermentation process – principles of effluent treatment.

UNIT - II

Specific Fermentations: Selection of organism, fermentation & purification of various antibiotics, vitamins, aminoacids, organic acids, solvents like Penicillin, Streptomycin, Tetracycline, Erythromycin, Riboflavin, Cynacobalamin, Glutamic Acid, Lysin, Citric Acid, Lactic Acid, Alcohol, Acetone etc.

LO : To understand Fermentations of various types of industrial and medicinal compounds.

UNIT - III

Microbial Transformations: Types, Methods of bioconversions & Application in Pharma Industry, Steroidal transformation.

Recombinant DNA Technology: Introduction to R-DNA technology and genetic engineering, steps involved, isolation of enzymes, vectors, recombination and cloning of genes.

Production of bio technology derived therapeutic proteins like humulin, humatrop, activase, intron a, monoclonal antibodies by hybridoma technique, recombivax HB (Hepatitis B).

LO : To understand types, methods and applications of bioconversion – principles and production technology of recombinant DNA technology with examples.

UNIT – IV

Immunology & Immunological Preparations: Principles of Immunity, Humoral immunity, cell mediated immunity, antigen – antibody reactions, hypersensitivity and its applications.

Active & passive immunizations vaccine preparation, standardization & storage of BCG, cholera, smallpox, polio, typhus, tetanus toxoide, immuno serum & diagnostic agents.

LO : To understand principles of Immunology, Antigen- Antibody reactions – applications, active and passive immunizations – study of various vaccines and sera.

UNIT – V

Enzyme Technology: Techniques of immobilization of enzymes, factors affecting enzyme kinetics, advantages of immobilization over isolated enzymes.

Study of enzymes such as hyaluronidas, penicillinase, streptokinase, streptodornase, amylase, protease etc. immobilization of bacteria & plant cells.

LO : To understand techniques, applications and productions enzymes of medicinal importance.

UNIT - VI

Introduction, role, collection, process & storage of blood products, plasma substitutes and sutures & ligatures like whole human blood, human normal eg, dextran, catgut etc.

Introductory study & applications of bioinformatics, proteomics and genomics.

LO : To understand Blood products – collection processing, storage and uses of various blood products.

TEXT BOOKS

1. Wulf Crueger and Anneliese Crueger, Biotechnology, 2nd Ed, Publ- Panima publication

   co-operation, New Delhi.

2. P. F. Stanbury & A. Whitaker, Principles of fermentation technology, Pergamon Press
3. B.P. Nagori & Roshan Issari, Foundations in Pharmaceutical Biotechnology
4. Sambamurthy. K, Text Book of Pharmaceutical Biotechnology.
5. S. S. Kori, Pharmaceutical biotechnology.

REFERENCES

1. Prescott and Dunne, “Industrial Microbiology” MC Caraw Hill Bool Company.
2. Peppler “Microbial Technology” Vol. 1 & 2.
3. K. Kielsliched “Biotechnology” Vol 6, Verlegchemic, Switzerland.
4. PF Standury & A. Whitaker, “Principles of fermentation Technology” Pergamon Press.
5. OP Ward” Fermentation Technology, Principles, Processes products” Open University press, Milton Keynes, UK.
6. A. M. Campbelli, Monoclinical antibody technology.
7. A. Wiseman, Handbook of enzyme biotechnology.
8. J. D. Watson, Recombinant DNA technology.
9. Smith and Hood, Molecular biology and biotechnology.
10. E.A. Rawlins, Bentley’s, A text book of pharmaceutics, 8th Ed, 1982 Bailler Tindall & Co.
11. Alexander N. Glazer & Hiroshi Nikaido, Microbial biotechnology, W. H. Freeman Co.
12. Ahwood.T.K, Introduction to Bio Informatics.
13. Cassida, Industrial microbiology.
14. H.K. Das, Textbook of Biochemistry.

III Year –I I SEMESTER

T	P	C
3+1	0	4

PHARMACOLOGY – II

UNIT - I

Pharmacology of Cardiovascular System – Drugs used in congestive heart failure & Stimulants

Drugs used in cardiac arrythmias, Antihypertensives, Drugs used in the treatment of Angina pectoris,

Drugs used in the therapy of shock.

LO : To acquire knowledge on CVS and its regulatory mechanisms, pathophysiology related to CVS diseases and disorders and Pharmacology of drugs used in the Cardio vascular diseases.

UNIT - II

Drugs acting on hematopoietic system

Anti-coagulants, Anti-platelets, Thrombolytics & hematinics.

Drugs acting on urinary system

Fluid and electrolyte balance, Diuretics & Antidiuretics.

LO : Grasping knowledge on pathophysiology of blood and blood forming organs, kidney – urine formation and the Pharmacology of drugs.

UNIT - III

Drugs acting on Endocrine system

Pancreatic hormone and Anti-Diabetic drugs, Thyroid & Anti-thyroid drugs, Gonadal hormones & Inhibitors, Adrenocortico steroids & Adrenocortical antagonists, Hypothalamic & Pituitary Hormones.

LO : Grasping knowledge on Physiological role of Endocrine glands and its pathological conditions and the Pharmacology of drugs used.

UNIT - IV

Autacoids: Histamine, Serotonin (5-HT) & their antagonists, Prostaglandins & leukotrienes, Pentagastrin, cholecystokinin, angiotensin, vasoactive peptides.

LO : To acquire knowledge on Autocoids, synthesis, metabolism and their Pharmacology.

UNIT - V

Drugs Acting on the Respiratory System

Anti-asthamatic drugs including bronchodilators, Anti-tussives & expectorants, Respiratory stimulants.

LO : Impart knowledge on respiratory diseases and the Pharmacology of drugs.

UNIT - VI

Chemotherapeutic agents and their applications: General principles of chemotherapy,

Sulphonamides and co-trimoxazole, Antibiotics : Penicillins, cephalosoporins, Beta lactams,

Chemotherapeutic agents and their applications: Tetracyclines aminoglycosides, chloramphenicol, erythromycin, quinolones and miscellaneous antibiotics.

Chemotherapy of tuberculosis & leprosy.

Chemotherapy of fungal diseases, viral diseases, urinary tract infections and sexually transmitted diseases.

Chemotherapy of malignancy and immune suppressive Agents.

LO : To gain knowledge on Chemotherapeutics and various classes of drugs used for infection and diseases.

TEXT BOOKS

1. Rang & Dale, Textbook of Pharmacology.
2. Sathoskar, Pharmacology and pharmaco therapeutics Vol. 1 & 2, Publ by Popular Prakashan, Mumbai.
3. Bertram. G. Katzung, Basic and clinical pharmacology, 9th Edn, Mc Graw hill
4. Tripathi, Textbook of Pharmacology, JAYPEE.
5. Leilani Grajeda, Understanding Pharmacology: A physiological Approach
6. F.S.K Barar, Essentials of Pharamcotheraptics.

REFERENCES

1. J.G. Hardman and Lee E. Limbard, Good Mann & Gilmann: The Pharmacological basis of therapeutics, Mc Graw hill, Health Professions Dvn.
2. H.P Rang, M. M. dale & J.M. Ritter, Pharmacology, Churchill living stone, 4th Ed.
3. J. Crossland, Lewis ‘s Pharmacology, Church living stone.

III Year –I I SEMESTER

T	P	C
3+1	0	4

MEDICINAL CHEMISTRY-III

UNIT I

A general introduction to advances in medicinal chemistry with emphasis on the principles of combinatorial chemistry, high throughput screening and QSAR studies.

LO : General concepts, principles, procedures, advantages, equations and methodologies.

UNIT II

1. Types of receptors, interaction forces
2. Preliminary aspects of molecular modeling studies: docking, pharmacophore modeling

LO : General concepts, principles, procedures, advantages and methodologies.

UNIT III

1. **Steroidal anti-inflammatory agents:** classification, structures, SAR, uses and toxicity
2. **Bile acids:** classification, structures and functions
3. **Estrogens and Progesterone:** structures, functions, interconversion of estrogens, uses of natural and synthetic estrogens, synthesis of Progesterone from Diosgenin.

LO : Acquaintance with steroidal structures, features, properties, uses, mode of action.

UNIT IV

1. **Antiarrhythmics:** classification, mode of action, uses and synthesis of Procainamide.
2. **Cardiac glycosides:** classification, structures and structural features, mode of action and therapeutic uses.

LO : Introduction to cardiovascular diseases**,** uses, mode of action.

UNIT V

1. **Antihypertensives:** classification, mode of action, SAR, currently used drugs and synthesis of Methyldopa, Clonidine, Losartan.

2. **Antianginals and coronary vasodilators:** classification, mode of action, SAR and uses, synthesis of Isosorbide dinitrate.

LO : Introduction to cardiovascular diseases**,** uses, mode of action.

UNIT VI

1. **Diuretics:** Definition, classification, mode of action, SAR of different classes, uses and synthesis of Acetazolamide, Ethacrynic acid and Hydrochlorthiazide.

LO : Introduction, structures, methodology of synthesis, advantages.

TEXT BOOKS

1. William O. Foye, Textbook of Medicinal Chemistry by, Lea Febiger, Philadelphia.
2. JM Beale, Wilson & Giswold's Textbook of organic Medicinal Chemistry and pharmaceutical chemistry by (Eds), 11th Ed, Lipcott, Raven, Philadelphia, 2004.
3. S. N. Pandeya, Textbook of mediacinal chemistry, SG Publ. Varanasi, 2003.

REFERENCES

1. D. Abraham (Ed), Burger Medicinal chemistry ad Drug discovery, Vol. 1 & 2. John Wiley & Sons, New York 2003, 6th Ed.
2. Lippincott Williams and Wilkins: Remington Pharmaceutical Sciences
3. L. M. Atherden, Bentley and Driver's Textbook of Pharmaceutical Chemistry. Oxford University Press, Delhi.
4. B.N. Lads, MG.Mandel and F.I. way, Fundamentals of drug metabolism & disposition, William & welking co, Baltimore USA.
5. C. Hansch, Comprehensive medicinal chemistry, Vol 1 – 6 Elsevier pergmon press, oxford
6. Daniel lednicer, Strategies For Organic Drug Synthesis And Design, John Wiley, N. Y. 1998.
7. D. Lednicer, Organic drug synthesis, Vol, 1 – 6, J.Wiley N.Y.

III Year –I I SEMESTER

T	P	C
3+1	0	2

REGULATORY AFFAIRS, IPR & PATENTS

Unit-I

Preformulations and Formulation Development – Regulatory requirements in Preformulations and Formulation Development of Solid, liquid and Semisolid dosage.

LO : To understand preformulations – protocols – regulatory – requirements – Formulation Development of Solid, liquid and Semisolid dosage.

Unit-II

Manufacturing- Regulatory requirements related to manufacturing-manufacturing formula,Records, Validations involved-GMP

Validations: Types- Validation of Process and Equipment – Raw materials, Excipients and solvents.

LO : To understand regulatory requirements related to manufacturing, validation – types, Validation of process, equipment, raw materials, excipients.

Unit-III

Regulatory requirements of packaging materials- Evaluation of Packaging materials.

Stability – Regulation for Stability testing of API, Solid and liquid dosage form as per ICH guidelines.

LO : To understand regulatory requirements of packaging materials, evaluation of packaging materials, stability testing as per ICH.

Unit – IV

Clinical Trials : Phase –I, II, III & IV studies – Regulations involved

LO : To understand regulatory requirements of Clinical Trials, Phase –I, II, III & IV studies.

Unit- V

A Study of Intellectual Property Rights : Definitions – Guidelines – National and international – Examples.

LO : To understand IPR with examples .

Unit- VI

Patents: patenting laws and Regulations – Procedures for obtaining and writing a patent – Examples.

LO : To understand patents, patent laws, procedures with examples.

References :

1. Quality Assurance guide by organization of Pharmaceutical Procedures of India
2. Drug formulation manual by D.P.S.Kohli and D.H.Shah. Eastern Publishers, New Delhi.
3. How to Practice GMPs By P.P.Sharma, Vandhana Publications, Agra.
4. Pharmaceutical Process Validation by FRA.R.Berry and Robert.A.Nash.
5. Pharmaceutical Preformulations by J.J.Wells.
6. Applied Production and Operations management by Evans, Anderson, Sweeny and Williams.
7. Basic principles of Clinical Research and methodology by Guptha.
8. Biopharmaceutics and Clinical Pharmacokinetics – An Introduction ; 4th Edition, Revised and Expanded by Robert E. Notary, Marcel Dekker incm, New york and Basel, 1987.

III Year –II SEMESTER

T	P	C
0	3	2

PHARMACEUTICAL TECHNOLOGY – II LAB

At least 25 Pharmaceutical preparations related to the topics are to be prepared

1. Experiments to illustrate preparation, stabilization, physical, chemical and biological evaluation of pharmaceutical products like capsules, tablets, parenterals, microcapsules etc.
2. Evaluation of materials used in pharmaceutical packaging.

III Year –II SEMESTER

T	P	C
0	3	2

PHARMACOLOGY LAB

1. To calculate the p^{A2} value of mepyramine or chloramphenіramine using histamine as agonist on guinea pig ileum.
2. To record the CRC of 5-HT on rat fundus preparation.
3. To record the CRC of histamine on guinea pig ileum preparation.
4. To study the inotropic and chronotropic effects of drugs on isolated frog heart.
5. To study the effects of drugs on isolated normal and hypodynamic frog heart.
6. Experiments pertaining to analgesia. (*Only demonstration).*
7. Experiments pertaining to anti-convulsant activity. (*Only demonstration).*
8. Experiments pertaining to anti-inflammatory activity (*Only demonstration).*
9. To study the effect of drugs on rat ileum.
10. To determine the hypoglycemic activity of drugs (second generation anti-diabetic drugs) on rabbits / albino rats. **(*Only demonstration)*.**

III Year –II SEMESTER

T	P	C
0	3	2

PHARMACEUTICAL BIOTECHNOLOGY LAB

1. Isolation of antibiotic producing microorganism from soil.
2. Enzyme immobilization by Ca-alginate method.
3. Determination of minimum inhibitory concentration of the given antibiotic. Antibiotic assay by cup plate method.
4. Collection, Processing, Storage and fractionation of blood.
5. Standardization of Cultures.
6. Microbiological assay of Antibiotics / Vitamins.
7. Production of alcohol by fermentation techniques.
8. Comparison of efficacy of immobilized cells.
9. Sterility testing of Pharmaceutical products.
10. Isolation of mutants by gradient plate technique.
11. Preparation of bacterial vaccine.
12. Preparation of blood products / Human normal immunoglobulin injection.
13. Extraction of DNA.
14. Separation techniques : Various types of Gel Electrophoresis, Centrifugation.

IV Year –I SEMESTER

T	P	C
3+1	0	4

PHARMACEUTICAL ANALYSIS – II

UNIT – I

Visible, UV & IR Spectrophotometry: Principle, Electron Transition, Beer-Lamberts Law & Deviations, Chromophores, Instrumentation – Construction of Single Beam and Double Beam Spectrophotometers, Applications.

LO : To understand principles, instrumentations and working of UV and its Spectrophotometers – applications with examples.

UNIT - II

NMR, Electron Spin Resonce Spectroscopy and Mass Spectrometry: Basic Principle, Instrumentation and Applications.

LO : To understand principles, instrumentations, applications with examples of NMR, ESR, Mass spectrometry.

UNIT - III

Basic Principles and applications of differential thermal analysis (DTA) and differential scanning colorimetry (DSC).

Basic Principles and applications of Atomic absorption spectroscopy, XRD, Emission spectroscopy and Raman spectroscopy.

Optical rotatory dispersion (ORD) and Circular dichroism: General Principle and Applications.

Radio Immuno Assay & Enzyme Linked Immuno Sorbate Assay.

LO : To understand basic principles and applications of DTA, DSC, XRD, Atomic absorption, Emission, Raman, ORD and Radio Immuno Assay.

UNIT – IV

Chromatography: Column chromatography, Paper chromatography, TLC, Ion exchange chromatography, Gel chromatography.

LO : To understand principles and procedures of various types of chromatography with examples.

UNIT – V

GLC, HPLC, HPTLC

LO : To understand principles, instrumentations and applications of GLC, HPLC, HPTLC .

UNIT – VI

LCMS and Electrophoresis: Scope, Different types Electrophoresis and applications.

LO : To understand principles, instrumentations and applications of LCMS and Electrophoresis.

TEXT BOOKS

1. R.M. Silvesterin and G.C. Bassler.Spectrometric Identification of Organic Compounds.
2. AH Beckett & Stenlake, Text book of Practical Pharmaceutical chemistry, Vol.I&II CBS Publ.
3. AI Vogel, Quantitative Chemical Analysis.
4. Hobart. H. Willard and others, Instrumental methods of analysis, CBS publ and Distributors New Delhi.
5. Robert D. Brown, Introduction to Instrumental Analysis.
6. Skoog, Principles of Instrumental Analysis.
7. B.K.Sharma, Instrumental and Chemical Analysis, Goel Publ House , Hyderabad.

REFERENCES

1. Settle, Handbook of Instrumental Techniques for Analytical Chemistry.
2. Y.Anjaneyulu & Maraiah, Quality Assurance & Quality Management in Pharmaceutical Industry.
3. P.D. Sethi, Quantitative analysis of Drugs and Pharmaceuticals.
4. K. A. Connors, A Textbook of pharmaceutical analysis, Wiley Interscienc, NY.
5. A.M. Knevel & F.E. Digengl, Jenkin's quantitative pharmaceutical chemistry, Mc Graw Hill Book Co., NY.
6. Pharmacopoeia (IP, BP, USP, PhI, Eu. PhI).

IV Year –I SEMESTER

T	P	C
3+1	0	4

BIOASSAYS & TOXICOLOGY

Unit I:

Basic principles of Bioassays, merits and demerits, methods of bioassays.

Test for pyrogens and test for freedom undue toxicity.

LO : To gain knowledge on bioassays and its applications, its importance and need in the present context.

UNIT II

Bioassays of digoxins, posterior pituitary extract, Insulin and tetanus anti toxin.

LO : Principles and procedures involved in bioassays and their limitations.

UNIT III

History, scope of toxicology, principles of toxicology, mechanisms and risk assessment, biotransformation of xenobiotics and toxicokinetics.

LO : To grasp knowledge on scope, principles , mechanisms and risk assessment.

UNIT IV

Acute toxicity, subacute toxicity and chronic toxicity, Determination of LD_{50}.

Chemical Carcinogens: Definitions, mechanisms of action of chemical carcinogens, Test systems for carcinogenicity assessment, Chemical carcinogenesis in humans.

LO : To get an overview on acute, sub-acute and chronic toxicity studies, Carcinogenicity and chemical carcinogenesis in humans.

UNIT V

Target Organ Toxicity:

- Toxic responses of the blood.
- Toxic responses of the liver.
- Toxic responses of the kidney.
- Toxic responses of heart and vascular system.

General Principles of Poisoning: Signs, symptoms, treatment of acute and chronic poisoning due to heavy metals, snake venom.

LO : To acquire knowledge on toxic responses of target organs, poisoning and its treatment strategies.

UNIT VI

Toxic Agents:

- Toxic effects of pesticides.
- Toxic effects of metals.
- Toxic effects of solvents and vapours.
- Toxic effects of plants.

LO : To learn about intoxication produced by various toxicants.

Text Books:

1. Casarett&Doull's Toxicology The Basic Science of Poisons, Seventh edition. Editor- Curtis D. Klaassen, Ph.D.
2. Niesink R.J.M. de Vries J and Hollingers M.A. Toxicology, Principal and Applications, CRC Press1996.
3. Harrisons Principles of Internal Medicine. Medical Toxicology (Ellen Horns).
4. Toxicology – Principles and Applications, Raymond J.M.Niesink, John de.Vries, Mannfred A. Hollinger.
5. Basis of Toxicology Testing Edited by Douald J Ecobichon.
6. Ellenhorns Medical toxicology 2nd Edition Williams and Wilkins, Baltimore, 1997.
7. Goldfrank's Toxicological Emergencies, ninth edition.

IV Year –I SEMESTER

T	P	C
3+1	0	4

CHEMISTRY OF NATURAL PRODUCTS

UNIT-I

Carbohydrates : Classification and general properties. Knowledge of structure including Sterio Chemistry of glucose. General treatment of pharmaceutically important carbohydrates-maltose, lactose, starch, cellulose and dextrin.

LO : Introduction, basic understanding, structures, features, stabilities and uses.

UNIT-II

Amino acids and proteins : Classification and general reactions of amino acids and their relationship to proteins and polypeptides. Methods of preparation of amino acids, classification and general reactions of proteins, degradation of proteins-hydrolysis and end group analysis-protein hormones, oxytocin.

LO : Introduction, basic understanding, structures, features and uses.

UNIT-III

1. **Purines and xanthine derivatives:** Structure and synthesis of uric acid, Theobromine, theophylline, and caffeine. General aspects of nucleoproteins and nucleic acids,
2. **Lipids:** Fixed oils and fats. Fatty acids: chemistry and analysis of oils and fats.

LO : Introduction, basic understanding, structures, methodologies, significance and uses.

UNIT-IV

Terpenes : Occurrence, general methods of isolation and classification, chemistry of citral, limonene, ∝-terpeneiol, carvone, camphor and menthol.

LO : Introduction, basic understanding, structures, chemistry and structural features, important degradative reactions, uses.

UNIT-V

Alkaloids : Classification, general methods of isolation, general methods of structural determination, chemical tests for alkaloids, Chemistry and uses of Ephedrine, Nicotine, Papaverine and Atropine.

LO : Introduction, basic understanding, structures, chemistry and structural features, important degradative reactions, uses.

UNIT-VI

1. Vitamins: Classification, chemistry, physiological role and uses of Thiamine, Riboflavin and Ascorbic acid. Skeletal structures of vitamins official in I.P.
2. Steroids: Nomenclature and skeletal structures of Ergosterol, Stigmasterol, Cholesterol Diosgenin, Hecogenin. Chemical tests for steroids.

LO : Introduction, basic understanding, structures, chemistry and structural features, important degradative reactions, uses.

TEXT BOOKS

1. O.P.Agarwal, Natural products by. Vol.1 & 2, Goel publications – Meerut.
2. JB Harborne, Phyto Chemical methods.
3. I L Finar, Organic chemistry, Vol. 1 & 2, the English language book society, London, New Delhi.

REFERENCES

1. RT Morrison and R.N BOYD, Organic chemistry, Allyn and Bacon, inc., boston
2. Me – Wolf, ed., Burger's medicinal chemistry, J. Wiley & sons, NY.
3. F.G. Mann & B. Saunders, Practical Organic chemistry Longmans green & Co. Ltd., UK.
4. RM. Acheson, an introduction to the chemistry of heterocyclic compounds, Interscience NY.
5. Duquesn & others, Practical Pharmacognosy, CBS Publ.

IV Year –I SEMESTER

T	P	C
3+1	0	4

HOSPITAL & COMMUNITY PHARMACY

UNIT-I

Hospital Pharmacy: Organization and structure, organization of a hospital and hospital pharmacy, responsibilities of a hospital pharmacist, pharmacy and therapeutic committee, Budget preparation and implementation hospital formulary, organization of drug store, purchase and inventory control, patient counseling, role of pharmacist in community health care and education.

LO : To understand Hospital Pharmacy – organisation structure - Budget preparation and implementation hospital formulary, organization of drug store, purchase and inventory control, patient COUNSELLING, role of pharmacist in community health care and education.

UNIT-II

The pharmacy procedural manual, drug distribution, dispensing to out-patients, in-patients and ambulatory Patient - dispensing of ancillary and controlled substances, drug information center.

LO : To understand The pharmacy procedural manual, drug distribution, dispensing to out-patients, in-patients and ambulatory

Patient - dispensing of ancillary and controlled substances, drug information center.

UNIT-III

Records and Reports: Prescription filling, drug profile, patient medication profile, cases on drug interaction and adverse reactions, idiosyncratic cases etc.

LO : To understand Prescription filling, drug profile, patient medication profile, cases on drug interaction and adverse reactions, idiosyncratic cases.

UNIT-IV

Introduction to community Pharmacy

- Community pharmacy Practice — definition.
- The role of the community pharmacy and its relationship to other local health care providers and services to nursing homes and clinics.

- Professional responsibilities of community pharmacist (FIP & WHO Model).
- Prescribed medication order - interpretation and legal requirements

LO: To understand Community pharmacy – role and relationship, professional responsibilities and prescribed medication order.

UNIT-V

Communication skills - communication with prescribers and patients

Over-the-counter (OTC) Drugs

- Rational use of common OTC medications (Vitamins and tonics, iron preparations, analgesics, NSAIDs, cough mixtures, anti-diarrhoeal preparations)

LO : To understand communication with prescribers and patients, Rational use of common OTC medications.

UNIT-VI

1. **Primary health care in community pharmacy**

   Family planning, First aid, Participation in primary health programs, Smoking cessation, Screening programs, Nutrition, Responding to common ailments

2. Community pharmacy management

   Financial, materials, staff, infrastructure requirements, drug information resources, in community pharmacies, computer applications in community pharmacy, Education and training

3. Home Medicines Review (HMR) program: introduction and guidelines

LO : To understand Family planning, First aid, Participation in primary health programs, Smoking cessation, Screening programs, Nutrition, Responding to common ailments and Community pharmacy management and Home Medicines Review (HMR).

Text Books

1. Hospital Pharmacy - Hassan WE. Lee and Febiger publication.
2. Textbook of hospital pharmacy - Aliwood MC and Blackwell. Reference books (Latest editions)
3. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
4. Remington Sciences and Practice of Pharmacy, 21st edition.

5. Relevant review articles from recent medical and pharmaceutical literature.
6. Cooper & Gunns Dispensing Pharmacy, CBS, Publ. and Distributors New Delhi.
7. Gupta AK, Health Education and Community Pharmacy, CBS, Publ. and Distributors New Delhi.
8. JS Quadry, Hospital Pharmacy.
9. K.Sampath, Hospital & Clinical Pharmacy, Vikas Publications.
10. Lorria & William, Essential dosage calculations.

REFERENCES

1. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences.
2. William Hassan, Hospital Pharmacy.
3. R.M Metha, Dispensing Pharmacy.
4. E.A. Rawlkins, Bentley's Text Book of Pharmaceutics, Elbs publ.
5. Hoover, Dispensing of Medication.
6. NK Jain, Health Education and Community Pharmacy by, CBS, Publ. and Distributors New Delhi.

IV Year –I SEMESTER

T	P	C
3+1	0	3

PHARMACEUTICAL JURISPRUDENCE

UNIT-I

Introduction

a. Pharmaceutical Legislations - A brief review
b. Drugs & Pharmaceutical Industry - A brief review
c. Pharmaceutical Education - A brief review.
d. Pharmaceutical ethics & policy

LO : To understand Pharmaceutical Legislations, Drugs & Pharmaceutical Industry, Pharmaceutical Education and Pharmaceutical ethics & policy.

UNIT-II

Pharmacy Act 1948 and Drugs (Price control) order.

LO : To understand rules prescribed order, Pharmacy act, Drugs (Price control) order.

UNIT-III

Drugs and Cosmetics Act 1940 and Rules 1945

LO : To understand rules, schedules of Drugs and Cosmetics Act in detail.

UNIT-IV

Medicinal & Toilet Preparations (Excise Duties) Act 1955

Narcotic Drugs & Psychotropic Substances Act 1985 &A.P. N. D. P.S Rules 1986

LO : To understand and procedures under medicinal and toilet preparations act and Narcotic Drugs & Psychotropic Substances Act.

UNIT-V

Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 and Rules 1955.

LO : To understand the rules and procedures under drugs and magic remidies.

UNIT-VI

A study of the salient features of the following.

a. Prevention of Cruelty to animals Act 1960.

b. AP State Shops & Establishments Act 1988 & Rules 1990.
c. Factories Act 1948.
d. WTO, GATT and The Indian Patents Act 1970
e. Pharmaceutical Policy 2002.

LO : To understand the salient features of the above.

TEXT BOOKS

1. B.M.Mithal, Text book of Forensic Pharmacy, publ by Vallabh Prakashan.
2. Prof. Suresh Kumar J.N, Text book of Forensic Pharmacy by Frontline publications.
3. C.K.Kokate & S.B.Gokhale, Textbook of Forensic Pharmacy.

REFERENCE BOOK

1. Bare Acts and Rules Publ by Govt of India/state Govt from time to time.
2. AIR – reported judgments of Supreme Court of India and other High Courts.
3. Pharmaceutical policy of India
4. Notification from NPPA
5. Vijay Malik, Drugs & Cosmetics act 1940 and Rules, Eastern Law House Co. Delhi, Kolkata.
6. K.Sampath, Pharmaceutical Jurisprudence (Forensic Pharmacy).

IV Year –I SEMESTER

T	P	C
0	3	2

PHARMACEUTICAL ANALYSIS – II LAB

Experiments

1. Interpretation of IR Spectra.
2. Determination of λ- max of a drug.
3. Determination of concentration of glycerine by Abbe's refractometer.
4. Assay of ibuprofen - UV-spectro photometry.
5. Assay of paracetomol - UV-spectro photometry.
6. Assay of riboflavin - Colorimetric method.
7. Assay of rifampicin - Colorimetric method.
8. Ascending paper chromatography.
9. Radial paper chromatography.
10. Two dimension chromatography
11. Thin layer chromatography.
12. Column chromatography (***Demonstration Only***).
13. Paper electrophoresis of amino acids.
14. Gel electrophoresis (***Demonstration Only***).
15. HPLC ***(Demonstration Only***).

IV Year –I SEMESTER

T	P	C
0	3	2

BIOASSAYS & TOXICOLGY LAB

To find the potency of test sample using a suitable isolated tissue

1. Matching point assay
2. Two-point assay
3. Three point assay
4. To calculate the p^{A2} value of Atropine using Acetyl Choline as an agonist on rat Ileum.
5. To find the acute toxicity of the given test drug (Digoxin, Nicotine, Aspirin, Paracetamol).
6. Test for Pyrogen
7. Test for freedom from undue toxicity
8. 4 point bioassay
9. Toxic responses of liver against chemical induced intoxication (Paracetamol, CCl_4).

IV Year –I SEMESTER

T	P	C
0	3	2

CHEMISTRY OF NATURAL PRODUCTS LAB

1. Preparation of different alkaloids testing reagents like Dragondroff, Mayer, Wagner's, etc., and testing some alkaloids and plant extracts using these reagents.
2. Identification of alkaloids by specific colour tests.
3. Test for steroids, steroidal glycosides and cardiac glycosides. Liberman-Burchard test, Salkowski reaction, Kedde reaction etc.
4. Tests for flavanoids and their glycosides. Shinoda test (Mg/Hcl test), $Fecl_3$ test.
5. TLC and examination of alkaloids, steroids, steroidal glycosides and cardiac glycosides.
6. Identification of natural products.
7. Extraction of caffeine from tea leaves.
8. Extraction of lactose from milk.
9. Extraction of nicotine from tobacco.
10. Extraction of piperine from black pepper.
11. Extraction of lycopene from tomatoes.
12. Extraction of β-carotene from carrots.
13. Volatile oil production by steam distillation ***(demonstration only).***

TEXT BOOKS

1. Indian Pharmacopoeia-1996.
2. Weagners, Phytochemical methods of Drug Analysis.
3. C.K.Kokate, Practical Pharmacognosy.

IV Year –I SEMESTER

T	P	C
0	0	0

PROJECT COMMENCEMENT

IV Year –II SEMESTER

T	P	C
3+1	0	4

BIOPHARMACEUTICS AND PHARMACOKINETICS

UNIT - I

Introduction to Biopharmaceutics and Pharmacokinetics and their role in formulation development and clinical setting

Biopharmaceutics: Passage of drugs across biological barrier (passive diffusion, active transport, facilitated diffusion and pinocytosis) factors influencing absorption – physiochemical, physiological and pharmaceutical.

LO : To understandBiopharmaceutics, Pharmacokinetics and their applications –absorption mechanisms, factors, their application with examples.

UNIT - II

Drug distribution in the body, Factors influencing distribution.

Plasma protein binding, binding sites, factors influencing protein binding

LO : To understand drug distribution, protein binding – factors.

UNIT - III

Pharmacokinetics

Significance of plasma drug concentration measurement.

Compartment model: Definition and scope.

Pharmacokinetics of drug absorption – Zero order and first order absorption rate constant using Wagner Nelson and Loo-riegelman method.

Volume of distribution and distribution coefficient.

LO : To understand the significance of plasma drug concentrations, compartment models - kinetics, parameters.

UNIT - IV

Comparative kinetics: One compartment and two compartment models. Determination of Pharmacokinetic parameters from plasma and urine data after drug administration by oral parenteral and other routes.

Curve fitting (Method of Residuals) Regression procedures.

Clearance concept, Mechanism of Renal clearance, clearance ratio, determination of renal clearance.

Non-linear pharmacokietics with special reference to one compartment model after I.V.Drug administration, MichalesMente Equation, detection of non-linearity (Saturation mechanism).

LO : To understand pharmacokinetic models, Linear and Non-Linear kinetics, mechanisms and method of assessments.

UNIT - V

Clinical pharmacokinetics

Definition and scope

Dosage adjustment in patients with and without renal and hepatic failure.

Pharmakokinetic drug interactions and its significance in combination therapy.

LO : To understand clinical pharmacokinetics and their significance, drug interactions – Adjustment of dose.

UNIT - VI

Bioavailability and Bioequivalance.

Measures of bioavailability, C-max, T-max and Area Under the Curve (AUC)

Design of single dose bioequivalance study and relevant statistics.

Overview of regulatory requirements for conduction of bio-equivalence studies.

Bio availability and bio equivalence including evaluation testing protocols.

a. In vitro dissolution studies for solid dosage forms methods, interpretation of dissolution

   data in vitro, in vivo correlations.

b. Bioavailability testing protocol and procedures.

c. In vivo methods of evaluation – statistical treatment.

LO : To understand bioavailability, bioequivalence, concepts, assessments, design, regulation, invitro dissolution methods, Invitro-invivo correlation.

TEXT BOOKS

1. Venkateshulu, Fundamentals of Biopharmaceutics and Pharmacokinetics, Pharma Book Syndicate.
2. Milo Gibaldi, Biopharmaceutics and clinical pharmacokinetics 4/Edn. Pharma Book Syndicate.
3. DM Brahmankar and SB Jaiswal, biophamaceutics and pharmacokinetics- a treatise, vallabhprakasham, Delhi.

4. P.L. Madan, Biopharmaceuticas and Pharmacokinnetics, Jaypee Bros.

REFERENCES

1. Remington's pharmaceutical sciences, Mac Pub. Co., Easton Pensylvania.
2. Modern pharmaceutics by banker Marcel Dekker Inc., NY
3. L. lachman, H.A.Lieberman, JL. Kanig, the theory aad practice of industrial pharmacy, Varghese publ house, Mumbai.
4. AR. Gennerio Remington: the science andpractice of pharmacy, vol 1 & 2 Lippincott Williams &wilkins, Philadelphia, 2004.
5. Robert E notary, Biopharmaceutics and pharmacokinetics – an introduction, arceldekkerinc., NY
6. L. Shargel and ABC Yu, textbook of applied biopharmaceutics& pharmacokinetics, 4thedn, Appleton – centuary – crofts, Connecticut, 2004.

IV Year –II SEMESTER

T	P	C
3+1	0	3

CLINICAL PHARMACY, THERAPEUTICS AND PHARMACOVIGILANCE

UNIT - I

General concept: Clinical Pharmacokinetics, Drug interactions, Adverse Drug Reactions, Parenteral Nutritions.

LO : To understand several concepts of clinical pharmacokinetics, Drug interactions and Adverse Drug Reactions

UNIT - II

Pharmacoeconomics, Pharmacogenomics, Pharmacovigilance, Therapeutic drug Monitoring, Neutraceuticals, Essential drugs and Rational drug usage, related drug therapy: Concept of posology, drug therapy for Neonates, Pediatrics and Geriatrics, drug used in Pregnancy and Lactation.

LO : To understand the concepts of Pharmacoeconomics, Pharmacogenomics, TDM, Posology etc.

UNIT - III

Drug therapy in Gastro intestinal, hepatic, renal, cardio vascular and respiratory disorders.

Drug therapy for Neurological and Psychological disorders.

Drug therapy in infections of Respiratory systems, Urinary system, Infective Meningitis, TB, HIV, Malaria and Filaria.

LO : To understand drug therapy of above mentioned disorders.

UNIT - IV

Drug therapy for Thyroid and Para Thyroid disorders, Diabetes mellitus, menstrual cycle disorders, menopause and male sexual dysfunction.

LO : To understand the drug therapy of Endocrine disorders.

UNIT - V

Drug therapy for Malignant disorders like Leukemia, Lymphoma and solid tumors.

Drug therapy for Rheumatic, eye and skin disorders.

LO : To understand drug therapy of above mentioned disorders.

UNIT - VI

Pharmacovigilance: Definition, history, importance, scope and outcomes.

Stake holders and their role in Pharmacovigilance.

Data reporting form, banned drug – regulatory considerations.

LO : To understand importance of Pharmacovigilance role in clinical practice as described above.

TEXTBOOKS

1. Clinical Pharmacy and Therapeutics: Roger Walker and Clive Edwords.
2. Clinical Pharmacy & Therapeutics, 4th edition by Eric T. Herfindal, Dick R. Gourley

   and Linda Lloyd hart.
3. A text book of Clinical Pharmacy Practice – Essential Concepts and skills by

   G. Parthasarathi, Karin Nyfort-Hansen, Malip C. Nahata.
4. Clinical Pharmacy by Dr. H. P. Tipnis, Dr. Amrita Bajaj; Career Publications.
5. Fundamentals of Clinical Pharmacy Practice by D. Sudheer Kumar, J. Krishnaveni, P.

   Manjula.
6. Contemporary perspectives on Clinical Pharmacotherapeutics: Kamlesh. Kohli.

REFERENCES

1. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences.
2. Pharmacotherapy – A Pathophysiologic Approach by Joseph T. Dipiro, Robert L. Talbert, Gary C. Yee, Gary R. Matzke, Barbara G. Wells, L. Michael Posey – 7th Edition – Mc Graw Hill Medical Publications.
3. Basic Principles of Clinical Research and Methodology by Sk Gupta, Institute of Clinical Research (India),Jaypee Brothers Medical Publishers (P) Ltd, New Delhi.

IV Year –II SEMESTER

T	P	C
3+1	0	4

CONTROLLED RELEASE AND NOVEL DRUG DELIVERY SYSTEMS

UNIT - I

Controlled and sustained release: Factors to be considered – Principles involved in their design – regulatory considerations.

LO : To understand Controlled and sustained release: Factors to be considered – Principles involved in their design – regulatory considerations.

UNIT - II

Oral Control Drug Delivery Systems: Fundamentals, Dissoultion Controlled, Diffusion Controlled, Ion Exchange Resins, Osmotic based systems, pH Independent Systems and altered density systems.

LO : To understand fundamentals, Dissoultion Controlled, Diffusion Controlled, Ion Exchange Resins, Osmotic based systems, pH Independent Systems and altered density systems.

UNIT - III

Transdermal Drug Delivery Systems: Fundamentals, types of TDDS, Materials Employed and Evaluation of TDDS.

LO : To understand fundamentals, types of TDDS, Materials Employed and Evaluation of TDDS.

UNIT - IV

Mucoadhesive Delivery Systems: Mechanism of bioadhesion, mucoadhesive materials, forumulation and evaluation of mucoadhesive-based systems.

LO : To understand mechanism of bioadhesion, mucoadhesive materials, forumulation and evaluation of mucoadhesive-based systems.

UNIT - V

Targeted Drug Delivery Systems: Fundamentals and applications, formulation and evaluation of liposomes, resealed erythrocytes and nano particles.

LO : To understand fundamentals and applications, formulation and evaluation of liposomes, resealed erythrocytes and nano particles.

UNIT - VI

Study of polymers for controlled release – Classification, study of biodegradable polymers & hydrogels – their applications.

LO : To understand classification, study of biodegradable polymers & hydrogels – their applications.

TEXT BOOKS

1. N.K. Jain, Control Drug Delivery Systems by
2. Y.Anjaneyulu&Maraiah, Quality Assurance & Quality Management in Pharmaceutical
   Industry.
3. L. Lachman, H.A, Lieberman and J.L. Kanig, Theory & Practice of industrial pharmacy by,
   Lea &Febieger, Philadelphia Latest Edn.
4. Shobhan Rani Hiremath Text Book of Industrial Pharmacy.

REFERENCES

1. Leon ShargelIsadoreKanfer, Generic Drug Product Development, Solid Oral Dosage
   Forms, Marcel Dekker.
2. Sagarian& MS Balsam, Cosmetics Sciences &Technology.Vol.1, 2 & 3
3. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences
4. E.A Rawlkins, Bentley's Text Book of Pharmaceutics, ELBS publ
5. HC Ansel, Introduction to Pharmaceutical Dosage forms
6. S.H. Willing, M.M Tucherman and W.S. Hitchings IV, Good Manufacturing Practices for
   Pharmaceuticals: A Plan for Total Quality Control, Marcel Dekker, Inc., New York
7. Gilbert S. Banker and Christopher T Rhodes, Modern Pharmaceutics, IVthed, marcel
   dekker, USA, 2005.
8. YiewChien, novel drug delivery systems, 2nd ed, marcel dekker 2003.
9. Robert. A. Nash, Pharmaceutical Process Validation, 3rd Ed Marcel Dekker, 2003.
10. Good Manufacturing Practices – Schedule M, Read with The Drugs And Cosmetic Rules
    1945.
11. M.E. Aulton, Pharmaceuitcs- The science of Dosage form Design 2nd ed.
12. AukunuruJithan, Oral Drug Delivery Technology.

IV Year –II	T	P	C
SEMESTER	3+1	3	3

QUALITY ASSURANCE, GMP & GLP

UNIT - I

Concept of Quality assurance, philosophy of GMP, CGMP and GLP.

LO : To understand Concept of Quality assurance, philosophy of GMP, CGMP and GLP.

UNIT - II

Organization and personnel, responsibilities, training hygiene - Premises: Location, design, plant layout, construction, maintenance and sanitations, environmental control, sterile areas, control of contamination.

LO : To understand organization and personnel, responsibilities, training hygiene - Premises: Location, design, plant layout, construction, maintenance and sanitations, environmental control, sterile areas, control of contamination.

UNIT - III

Equipments: Selection, purchase specifications, maintenance, clean in place, sterilize in place - Raw materials: Purchase specifications, maintenance of stores, selection of vendors, controls and raw materials.

LO : To understand selection, purchase specifications, maintenance, clean in place, sterilize in place - Raw materials: Purchase specifications, maintenance of stores, selection of vendors, controls and raw materials.

UNIT - IV

Manufacture and controls on dosage forms, manufacturing documents master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities - In process quality control on various dosage forms: sterile, biological products and non-sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating. Packaging and labeling controls.

LO : To understand manufacture and controls on dosage forms, manufacturing documents master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities - In process quality control on various dosage

forms: sterile, biological products and non-sterile, standard operating procedures for various operations. Packaging and labeling controls.

UNIT - V

Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities - Finished products release: quality review, quality audits and batch release document.

LO : To understand responsibilities, good laboratory practices, routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities - Finished products release: quality review, quality audits and batch release document.

UNIT - VI

Distribution and Distribution records: Handling of returned goods, recovered materials and reprocessing Complaints and recalls, evaluation of complaints, recall procedures, related records and documents.

LO : To understand handling of returned goods, recovered materials and reprocessing. Complaints and recalls, evaluation of complaints, recall procedures, related records and documents.

TEXT BOOKS

1. The International Pharmacopoeia Vol. 1,2,3,4, 3rd edition General methods of analysis quality specifications for Pharmaceutical substances, Excipients, dosage forms.
2. Quality Assurance of Pharmaceuticals: A compendium of guidelines and related material Vol. 1 and Vol. 2., WHO, (1999).
3. GMP-Mehra.
4. Pharmaceutical Process validation by Berry and Nash

REFERENCE BOOKS

1. Basic tests for Pharmaceutical substances - WHO (1988 &1991)
2. How to practice GMP's – P.P.Sharma
3. The Drugs and Cosmetic Act 1940- Vijay Malik.
4. Q.A Manual by D.H.Shah.
5. SOP Guidelines by D.H.Shah.
6. Quality Assurance Guide by OPPI.

IV Year –II SEMESTER

T	P	C
0	3	2

BIOPHARMACEUTICS AND PHARMACOKINETICS LAB

1. Experiments designed for the estimation of various pharmacokinetic parameters with given data.
2. Analysis of biological specifications for drug content and estimation of the pharmacokinetic parameters.
3. In vitro evaluation of different dosage forms for drug release.
4. Absorption studies – *in vitro* and *in vivo*.
5. Statistical treatment of pharmaceutical data.

IV Year –II SEMESTER	T	P	C
	0	0	4

PROJECT WORK

IV Year –II SEMESTER	T	P	C
	0	0	4

PROJECT SEMINAR

IV Year –II SEMESTER	T	P	C
	0	0	2

COMPREHENSIVE VIVA