

CRITERIA 1.1.2

The Programmes offered by the institution focus on employability/entrepreneurship/ skill development and their course syllabi are QM adequately revised to incorporate contemporary requirements.

Programme – B.Pharm

Color Coding: -

1)	EMPLOYABILITY
2)	
3)	SKILL DEVELOPMENT

COURSES HAVING FOCUSED ON THE EMPLOYABILITY (EM)/SKILL DEVELOPMENT (SD)/ ENTREPRENEURSHIP (EN) OFFERED IN PHARMACY DEPARTMENT.

- 1) LIST OF B.PHARM COURSES (OFFERED IN 2019-2023) WITH MAPPING TO (EMPLOYABILITY (EM)/SKILL DEVELOPMENT (SD)/ ENTREPRENEURSHIP (EN) OFFERED IN PHARMACY DEPARTMENT.)
- 2) LIST OF D.PHARM COURSES (OFFERED IN 2019-2021) WITH MAPPING TO (EMPLOYABILITY (EM)/SKILL DEVELOPMENT (SD)/ ENTREPRENEURSHIP (EN) OFFERED IN PHARMACY ' DEPARTMENT)

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Principal Netaji Subhas Institute of Phar Pokhari, Jamshedpur, Jharkhand



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Dean Academics Netaji Subhas University Jamshedpur, Jharkhand Table1: Mapping each B.PHARM subjects with Employability (EM), Skill Development (SD), and Entrepreneurship (EN).

Paper Code	Paper Name	EM	SD	EN
BP101T	Human Anatomy and Physiology I–Theory	~	V	
BP102T	Pharmaceutical Analysis I – Theory	V	~	V
BP103T	Pharmaceutics I – Theory	V	~	V
BP104T	Pharmaceutical Inorganic Chemistry – Theory	V	~	
BP105T	Communication skills – Theory	V	V	~
BP106RBT BP106RMT	Remedial Biology/ Remedial Mathematics – Theory	v	~	
BP201T	Human Anatomy and Physiology II – Theory	~	V	
BP202T	Pharmaceutical Organic Chemistry I – Theory	~		~
BP203T	Biochemistry – Theory	V	V	
BP204T	Pathophysiology – Theory	~	~	
BP205T	Computer Applications in Pharmacy – Theory	~	V	V
BP206T	Environmental sciences – Theory	~	V	V
BP301T	Pharmaceutical Organic Chemistry II - Theory	V	~	
BP302T	Physical Pharmaceutics I – Theory	V	V	
BP303T	Pharmaceutical Microbiology – Theory	V	~	
BP304T	Pharmaceutical Engineering – Theory	~	V	
BP401T	Pharmaceutical Organic Chemistry III- Theory	V	V	V
BP402T	Medicinal Chemistry I – Theory	~	V	V
BP403T	Physical Pharmaceutics II – Theory	V	~	
BP404T	Pharmacology I – Theory	~	V	
BP405T	Pharmacognosy and Phytochemistry I- Theory	~	V	
BP501T	Medicinal Chemistry II – Theory	V	V	
BP502T	Industrial Pharmacy I– Theory	V	V	
BP503T	Pharmacology II – Theory	~	V	
BP504T	Pharmacognosy and Phytochemistry II– Theory	~	~	~
BP505T	Pharmaceutical Jurisprudence – Theory	~		~
BP601T	Medicinal Chemistry III – Theory	~	~	
BP602T	Pharmacology III – Theory	~	~	
BP603T	Herbal Drug Technology – Theory	~	V	~
BP604T	Bio-pharmaceutics and Pharmacokinetics – Theory	~		~



Paper Code	Paper Name	EM	SD	EN
BP605T	Pharmaceutical Biotechnology – Theory	~	V	~
BP606T	Quality Assurance – Theory	~	V	~
BP701T	Instrumental Methods of Analysis – Theory	~	V	
BP702T	Industrial Pharmacy II – Theory	~	V	
BP703T	Pharmacy Practice – Theory	~	V	~
BP704T	Novel Drug Delivery System – Theory	~	V	~
BP706PS	Practice School	~	V	V
BP801T	Biostatistics and Research Methodology	V	~	
BP802T	Social and Preventive Pharmacy	V	~	
BP803ET	Pharma Marketing Management	V	V	~
BP804ET	Pharmaceutical Regulatory Science	V		~
BP805ET	Pharmacovigilance	~	V	~
BP806ET	Quality Control and Standardization of Herbals	~	~	
BP807ET	Computer Aided Drug Design	~	V	
BP808ET	Cell and Molecular Biology	~	V	
BP809ET	Cosmetic Science	~	~	
BP810ET	Experimental Pharmacology	V	~	~
BP811ET	Advanced Instrumentation Techniques	~		~
BP812ET	Dietary Supplements and Nutraceuticals	~	~	~
BP813PW	Project Work	~	V	~





NETAJI SUBHAS UNIVERSITY

SCHOOL OF PHARMACY

PROGRAMME: B.PHARM DETAILED SYLLABUS As per Pharmacy Council of India (W.E.F 2019)

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Principal Netaji Subhas Institute of Pharmacy Pokhari, Jamshedpur, Jharkhand



Dean Academics Netaji Subhas University Jamshedpur, Jharkhand Courses having focused on the employability (EM)/skill development (SD)/ entrepreneurship (EN) offered in pharmacy department.

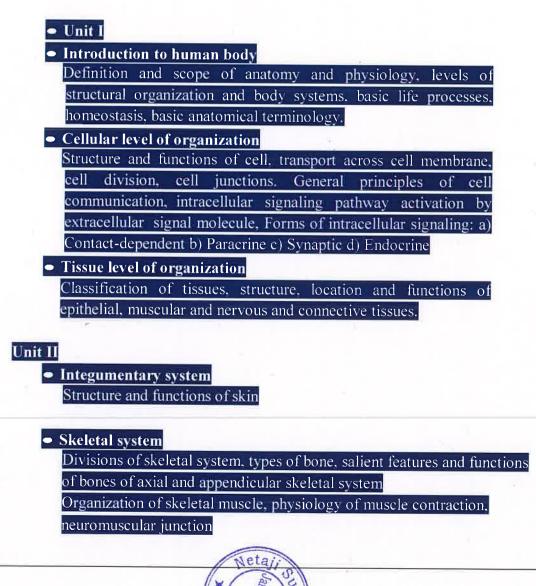
EM, SD and EN have been instructed with the use of yellow, blue and green colour.

Syllabus of B.Pharm

HUMAN ANATOMY AND PHYSIOLOGY-I (Theory)

Paper Code: BP101T

Course Content:



Joints

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

Unit III

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

Lymphatic system

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

Unit IV

Peripheral nervous system:

- Classification of peripheral nervous system: Structure and functions of
- sympathetic and parasympathetic nervous system.
- Origin and functions of spinal and cranial nerves.
- Special senses

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

Unit V

Cardiovascular system

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



PHARMACEUTICAL ANALYSIS (Theory) Paper Code: BP102T

Course Content:

UNIT-I

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

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

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

UNIT-II

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

UNIT-III

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

Basic Principles, methods and application of diazotisation titration.



UNIT-IV

Redox titrations

(a) Concepts of oxidation and reduction

(b) Types of redox titrations (Principles and applications)

Cerimetry, lodimetry, lodometry, Bromatometry, Dichrometry, Titration

withpotassium iodate

UNIT-V

Electrochemical methods of analysis

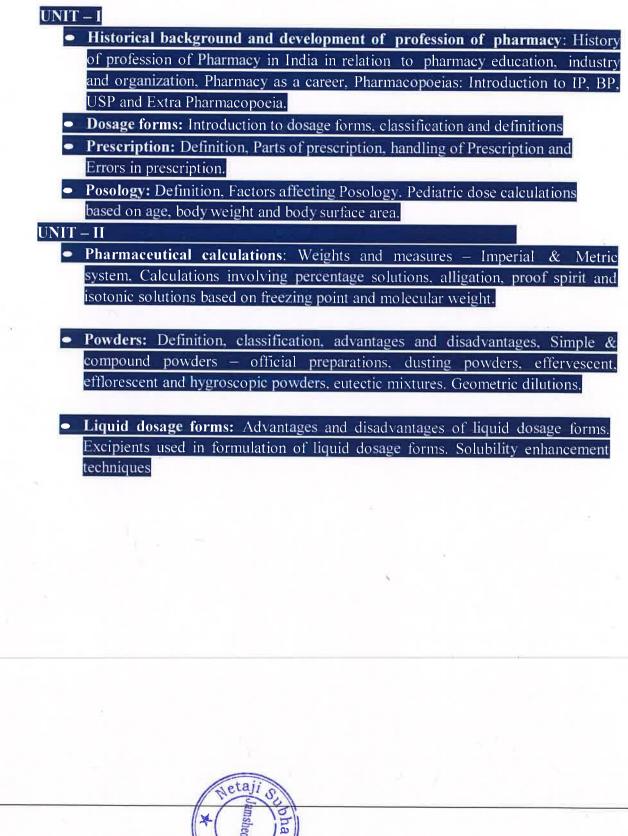
- Conductometry- Introduction, Conductivity cell, Conductometric titrations, applications.
- Potentiometry Electrochemical cell, construction and working of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode),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

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PHARMACEUTICS-I (Theory)

Paper Code: BP103T

Course Content:



UNIT – III

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

Biphasic liquids:

- Suspensions: Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome.
- Emulsions: Definition, classification, emulsifying agent, test for the identification of type of Emulsion, Methods of preparation & stability problems and methods to overcome.

UNIT – IV

- Suppositories: Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories.
- Pharmaceutical incompatibilities: Definition. classification, physical, chemical and therapeutic incompatibilities with examples.

UNIV – V

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



PHARMACEUTICAL INORGANIC CHEMISTRY (Theory)

Paper Code: BP104T

Course Content:

UNIT I

• Impurities in pharmaceutical substances: History of Pharmacopoeia, Sources and types of impurities, principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals, modified limit test for Chloride and Sulphate

General methods of preparation, assay for the compounds superscripted with **asterisk** (*), properties and medicinal uses of inorganic compounds belonging to the following classes

UNIT II

- Acids, Bases and Buffers: Buffer equations and buffer capacity in general, buffers in pharmaceutical systems, preparation, stability, buffered isotonic solutions, measurements of tonicity, calculations and methods of adjusting isotonicity.
- Major extra and intracellular electrolytes: Functions of major physiological ions, Electrolytes used in the replacement therapy: Sodium chloride*, Potassium chloride, Calcium gluconate* and Oral Rehydration Salt (ORS), Physiological acid base balance.

• **Dental products**: Dentifrices, role of fluoride in the treatment of dental caries, Desensitizing agents, Calcium carbonate, Sodium fluoride, and Zinc eugenol cement.

UNIT III

Gastrointestinal agents

Acidifiers: Ammonium chloride* and Dil. HCl

Antacid: Ideal properties of antacids, combinations of antacids, Sodium



Bicarbonate*, Aluminum hydroxide gel, Magnesium hydroxide mixture

Cathartics: Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite

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

UNIT IV

Miscellaneous compounds

Expectorants: Potassium iodide, Ammonium chloride*.

Emetics: Copper sulphate*, Sodium potassium tartarate

Haematinics: Ferrous sulphate*, Ferrous gluconate

Poison and Antidote: Sodium thiosulphate*, Activated charcoal, Sodium nitrite333

Astringents: Zinc Sulphate, Potash Alum

UNIT V

 Radiopharmaceuticals: Radio activity, Measurement of radioactivity, Properties of α, β, γ radiations. Half life, radio isotopes and study of radio isotopes - Sodium iodide 1¹³¹, Storage conditions, precautions & pharmaceutical application of radioactive substances.



COMMUNICATION SKILLS (Theory)

Paper Code: BP105T



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REMEDIAL BIOLOGY (Theory)

Paper Code: BP 106RBT

UNIT I

Living world:

- Definition and characters of living organisms
- Diversity in the living world
- Binomial nomenclature
- Five kingdoms of life and basis of classification. Salient features of Monera, Potista, Fungi, Animalia and Plantae, Virus,

Morphology of Flowering plants

- Morphology of different parts of flowering plants Root, stem, inflorescence, flower, leaf, fruit, seed.
- General Anatomy of Root, stem. leaf of monocotyledons & Dicotylidones.

UNIT II

Body fluids and circulation

- Composition of blood, blood groups, coagulation of blood
- Composition and functions of lymph
- Human circulatory system
- Structure of human heart and blood vessels
- Cardiac cycle, cardiac output and ECG

Digestion and Absorption

- Human alimentary canal and digestive glands
- Role of digestive enzymes
- Digestion, absorption and assimilation of digested food

Breathing and respiration

- Human respiratory system
- Mechanism of breathing and its regulation
- Exchange of gases, transport of gases and regulation of respiration
- Respiratory volumes



UNIT III

Excretory products and their elimination

- Modes of excretion
- Human excretory system- structure and function
- Urine formation
- Rennin angiotensin system

Neural control and coordination

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

Chemical coordination and regulation

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

Human reproduction

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

UNIT IV

Plants and mineral nutrition:

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

Photosynthesis

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

UNIT V

Plant respiration: Respiration, glycolysis, fermentation (anaerobic). Plant growth and development

Phases and rate of plant growth. Condition of growth.Introduction to plant growth regulators

Cell - The unit of life

Structure and functions of cell and cell organelles.Cell division

Tissues

Definition, types of tissues, location and functions.



REMEDIAL MATHEMATICS (Theory)

Paper Code: BP 106RMT

Course Content:

UNIT – I

Partial fraction

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

Logarithms

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

• Function:

Real Valued function, Classification of real valued functions.

Limits and continuity:

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Introduction . Limit of a function. Definition of limit of a function (\in - δ

definition), $\lim_{n \to \infty} \frac{x^n - a^n}{a^n} = na^{n-1}$, $\lim_{n \to \infty} \frac{\sin \theta}{\sin \theta} = 1$,

$\theta \rightarrow 0 \quad \Theta$

UNIT-II

Matrices and Determinant:

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



UNIT – III

Calculus

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

UNIT – IV

Analytical Geometry

Introduction: Signs of the Coordinates, Distance formula.

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

Integration:

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

UNIT-V

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



HUMAN ANATOMY AND PHYSIOLOGY-II (Theory)

Paper Code: BP 201T

Course Content:

Unit I

 Nervous system
Organization of nervous system, neuron, neuroglia, classification and
properties of nerve fibre, electrophysiology, action potential,
nerve impulse, receptors, synapse, neurotransmitters.
Central nervous system: Meninges, ventricles of brain and
cerebrospinal fluid.structure and functions of brain (cerebrum, brain
stem. cerebellum), spinal cord (gross structure, functions of afferent
and efferent nerve tracts, reflex activity)

Unit II

Digestive system

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

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

Energetics

Formation and role of ATP. Creatinine Phosphate and BMR.

Unit III

Respiratory system

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

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

Urinary system

Anatomy of urinary tract with special reference to anatomy of kidney and nephrons, functions of kidney and urinary tract, physiology of urine formation.



micturition reflex and role of kidneys in acid base balance, role of RAS in kidney and disorders of kidney.

Unit IV

Endocrine system

Classification of hormones, mechanism of hormone action, structureand functions of pituitary gland, thyroid gland, parathyroid gland, adrenal

gland, pancreas, pineal gland, thymus and their disorders.

Unit V

Reproductive system

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

Introduction to genetics

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



PHARMACEUTICAL ORGANIC CHEMISTRY -I (Theory)

Paper Code: BP202T

Course Content:

UNIT-I

Classification, nomenclature and isomerism

Classification of Organic Compounds

Common and IUPAC systems of nomenclature of organic

compounds(up to 10 Carbons open chain and carbocyclic

compounds)

Structural isomerisms in organic compounds

UNIT-II

Alkanes*, Alkenes* and Conjugated dienes*

SP³ hybridization in alkanes, Halogenation of alkanes, uses

of paraffins. Stabilities of alkenes, SP² hybridization in

alkenes

 E_1 and E_2 reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and evidences. E_1 verses E_2 reactions, Factors affecting E_1 and E_2 reactions. Ozonolysis, electrophilic addition reactions of alkenes, Markownikoff's orientation, free radical addition reactions of alkenes, Anti Markownikoff's orientation.

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

UNIT-III

Alkyl halides*

SN₁ and SN₂ reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations.

SN1 versus SN2 reactions, Factors affecting SN1 and SN2 reactions

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

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

UNIT-IV



Carbonyl compounds^{*} (Aldehydes and ketones)

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

UNIT-V

Carboxylic acids*

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

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

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



BIOCHEMISTRY (Theory) Paper Code: BP203T

Course Content:

UNIT I

Biomolecules

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

Bioenergetics

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

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

UNIT II

Carbohydrate metabolism

Glycolysis – Pathway, energetics and significance

Citric acid cycle- Pathway, energetics and significance

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

Glycogen metabolism Pathways and glycogen storage diseases (GSD)

Gluconeogenesis- Pathway and its significance

Hormonal regulation of blood glucose level and Diabetes mellitus

Biological oxidation

Electron transport chain (ETC) and its mechanism.

Oxidative phosphorylation & its mechanism and substratephosphorylation Inhibitors ETC and oxidative phosphorylation/Uncouplers

UNIT III

Lipid metabolism

 β -Oxidation of saturated fatty acid (Palmitic acid)

Formation and utilization of ketone bodies; ketoacidosis

De novo synthesis of fatty acids (Palmitic acid)

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

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

Amino acid metabolism

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

Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenyketonuria, Albinism, alkeptonuria, tyrosinemia)

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

Catabolism of heme; hyperbilirubinemia and jaundice

UNIT IV

Nucleic acid metabolism and genetic information transfer

Biosynthesis of purine and pyrimidine nucleotides

Catabolism of purine nucleotides and Hyperuricemia and Gout disease

Organization of mammalian genome

Structure of DNA and RNA and their functions

DNA replication (semi conservative model)

Transcription or RNA synthesis

Genetic code, Translation or Protein synthesis and inhibitors

UNIT V

Enzymes

Introduction, properties, nomenclature and IUB classification of enzymes

Enzyme kinetics (Michaelis plot, Line Weaver Burke plot)

Enzyme inhibitors with examples

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

Therapeutic and diagnostic applications of enzymes and isoenzymes

Coenzymes – Structure and biochemical functions

PATHOPHYSIOLOGY (THEORY)

Paper Code: BP204T

Course content:

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Unit I	
-	Basic principles of Cell injury and Adaptation:
	Introduction, definitions, Homeostasis, Components and Types of Feedback system
	Causes of cellular injury, Pathogenesis (Cell membrane damage, Mitochondri
	damage, Ribosome damage, Nuclear damage), Morphology of cell injury – Adaptiv
	changes(Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia), Cell swelling, Int
	cellularaccumulation, Calcification, Enzyme leakage and Co
	Death Acidosis & Alkalosis, Electrolyte imbalance
•	Basic mechanism involved in the process of inflammation and repair:
	Introduction, Clinical signs of inflammation, Different types of Inflammation, Mechanis of Inflammation – Alteration in vascular permeability and blood flow, migration
	WBC's, Mediators of inflammation, Basic principles of wound healing in the ski
	Pathophysiology of Atherosclerosis
Unit II	
-	Cardiovascular System:
	Hypertension, congestive heart failure, ischemic heart disease (angina, myocardia
	infarction, atherosclerosis and arteriosclerosis)
•	Respiratory system: Asthma. Chronic obstructive airways diseases.
2	Renal system: Acute and chronic renal failure .
Unit II	
	Haematological Diseases:
-	Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia
	thalasemia, hereditary acquired anemia, hemophilia
-	Endocrine system: Diabetes. thyroid diseases, disorders of sex hormones
-	Nervous system: Epilepsy. Parkinson's disease, stroke, psychiatric disorders:
	depression, schizophrenia and Alzheimer's disease.
-	Gastrointestinal system: Peptic Ulcer
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Unit IV	
•	Inflammatory bowel diseases, jaundice, hepatitis (A.B.C,D,E,F) alcoholic liver
	disease.
-	Disease of bones and joints: Rheumatoid arthritis, osteoporosis and gout
•	Principles of cancer: classification, etiology and pathogenesis of cancer
	Diseases of bones and joints: Rheumatoid Arthritis, Osteoporosis, Gout

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

Unit V

Infectious diseases: Meningitis, Typhoid, Leprosy, TuberculosisUrinary tract infections
 Sexually transmitted diseases: AIDS, Syphilis, Gonorrhea

COMPUTER APPLICATIONS IN PHARMACY (Theory)

Paper Code: BP205T

Course content:

UNIT – I

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

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

UNIT-II

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

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

UNIT – III

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

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

UNIT – IV

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

UNIT-V

Computers as data analysis in Preclinical development:

Chromatographic dada analysis (CDS), Laboratory Information

managementSystem (LIMS) and Text Information Management System

(TIMS)

ENVIRONMENTAL SCIENCES (Theory) Paper Code: BP206T

Course content:

Unit-I

The Multidisciplinary nature of environmental studies

Natural Resources

Renewable and non-renewable resources.

Natural resources and associated problems

a) Forest resources; b) Water resources; c) Mineral resources; d) Food

resources; e) Energy resources; f) Land resources: Role of an individual in

conservation of natural resources.

Unit-II

Ecosystems

Concept of an ecosystem.

Structure and function of an ecosystem.

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

Unit- III

Environmental Pollution: Air pollution: Water pollution: Soil pollution

PHARMACEUTICAL ORGANIC CHEMISTRY -II (Theory)

Paper Code: BP301T

UNIT I

Benzene and its derivatives

- A. Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule
- **B.** Reactions of benzene nitration, sulphonation, halogenationreactivity, Friedelcrafts alkylation- reactivity, limitations, Friedelcrafts acylation.
- C. Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction
- D. Structure and uses of DDT, Saccharin, BHC and Chloramine

UNIT II

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

UNIT III

Fats and Oils

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

UNIT IV

Polynuclear hydrocarbons:

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

UNIT V

Cyclo alkanes*

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

PHYSICAL PHARMACEUTICS-I (Theory)

Paper Code: BP302T

Course Content:

UNIT-I

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

UNIT-II

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

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

UNIT-III

Surface and interfacial phenomenon: Liquid interface, surface & interfacial tensions,

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

UNIT-IV

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

UNIT-V

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

PHARMACEUTICAL MICROBIOLOGY (Theory)

Paper Code: BP 303T

Course content:

Unit I

Introduction, history of microbiology, its branches, scope and its importance.

Introduction to Prokaryotes and Eukaryotes

Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count).

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

Unit II

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

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

Equipments employed in large scale sterilization.

Sterility indicators.

Unit III

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

Classification and mode of action of disinfectants

Factors influencing disinfection, antiseptics and their evaluation. For bacteriostatic and bactericidal actions

Evaluation of bactericidal & Bacteriostatic.

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

Unit IV

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

Principles and methods of different microbiological assay. Methods for

standardization of antibiotics, vitamins and amino acids. Assessment of a new antibiotic.

Unit V

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

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

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

Application	of	cell	cultures	in	pharmaceutical	industry	and	research
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PHARMACEUTICAL ENGINEERING (Theory)

Paper Code: BP304T

Course content:

	Size Reduction: Objectives, Mechanisms & Laws governing size reductions affecting size reduction, principles, construction, working, uses, merits demerits of Hammer mill, ball mill, fluid energy mill, Edge runner mill & runner mill.
1211 22	Size Separation: Objectives, applications & mechanism of size separa official standards of powders, sieves, size separation Principles, construct working, uses, merits and demerits of Sieve shaker, cyclone separator, separator, Bag filter & elutriation tank.
[-]	I,
	Heat Transfer: Objectives, applications & Heat transfer mechanisms. Four law, Heat transfer by conduction, convection & radiation. Heat interchange heat exchangers.
	Evaporation: Objectives, applications and factors influencing evaporal differences between evaporation and other heat process, principles, construct working, uses, merits and demerits of Steam jacketed kettle, horizontal evaporator, climbing film evaporator, forced circulation evaporator, mu effect evaporator& Economy of multiple effect evaporator.
	Distillation: Basic Principles and methodology of simple distillation, distillation, fractional distillation, distillation under reduced pressure, s distillation & molecular distillation

 Mixing: Objectives, applications & factors affecting mixing, Difference between solid and liquid mixing, mechanism of solid mixing, liquids mixing and semisolids mixing. Principles, Construction, Working, uses, Merits and Demerits of Double cone blender, twin shell blender, ribbon blender, Sigma blade mixer,

planetary mixers, Propellers, Turbines, Paddles & Silverson Emulsifier.

UNIT-IV

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

UNIT- V

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

PHARMACEUTICAL ORGANIC CHEMISTRY –III (Theory) Paper Code: BP401T

Course Content:

UNIT-I

Stereo isomerism

Optical isomerism –

Optical activity, enantiomerism, diastereoisomerism, meso compounds

Elements of symmetry, chiral and achiral molecules

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

Reactions of chiral molecules

Racemic modification and resolution of racemic mixture.

Asymmetric synthesis: partial and absolute

UNIT-II

Geometrical isomerism

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

Methods of determination of configuration of geometrical isomers.

Conformational isomerism in Ethane, n-Butane and Cyclohexane.

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

Stereospecific and stereoselective reactions

UNIT-III

Heterocyclic compounds:

Nomenclature and classification

Synthesis, reactions and medicinal uses of following compounds/derivatives

Pyrrole, Furan, and Thiophene

Relative aromaticity and reactivity of Pyrrole, Furan and Thiophene

UNIT-IV

Synthesis, reactions and medicinal uses of following compounds/derivatives

Pyrazole, Imidazole, Oxazole and Thiazole,

Pyridine, Quinoline, Isoquinoline, Acridine and Indole. Basicity of pyridine

Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives

UNIT-V

Reactions of synthetic importance

Metal hydride reduction (NaBH₄ and LiAlH₄), Clemmensen reduction, Birch reduction, Wolff Kishner reduction.

Oppenauer-oxidation and Dakin reaction.

Beckmanns rearrangement and Schmidt rearrangement.

Claisen-Schmidt condensation

MEDICINAL CHEMISTRY – I (Theory)

Paper Code: BP402T

Course Content:

UNIT- I

Introduction to Medicinal Chemistry

History and development of medicinal chemistry

Physicochemical properties in relation to biological action

Ionization, Solubility, Partition Coefficient, Hydrogen bonding, Protein binding, Chelation, Bioisosterism, Optical and Geometrical isomerism.

Drug metabolism

Drug metabolism principles- Phase I and Phase II.

Factors affecting drug metabolism including stereo chemical aspects.

UNIT- II

Drugs acting on Autonomic Nervous System

Adrenergic Neurotransmitters:

Biosynthesis and catabolism of catecholamine.

Adrenergic receptors (Alpha & Beta) and their distribution.

Sympathomimetic agents: SAR of Sympathomimetic agents

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

 Indirect acting agents: Hydroxyamphetamine, Pseudoephedrine, Propylhexedrine.

Agents with mixed mechanism: Ephedrine, Metaraminol.

Adrenergic Antagonists:

Alpha adrenergic blockers: Tolazoline*, Phentolamine, Phenolamine, Phenolamine, Methysergide.

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

UNIT-III

Cholinergic neurotransmitters:

Biosynthesis and catabolism of acetylcholine.

Cholinergic receptors (Muscarinic & Nicotinic) and their distribution.

Parasympathomimetic agents: SAR of Parasympathomimetic agents

Direct acting agents: Acetylcholine, Carbachol*, Bethanechol. Methacholine, Pilocarpine.

Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible): Physostigmine, Neostigmine*, Pyridostigmine, Edrophonium chloride, Tacrine hydrochloride, Ambenonium chloride, Isofluorphate, Echothiophate iodide, Parathione, Malathion.

Cholinesterase reactivator: Pralidoxime chloride.

Cholinergic Blocking agents: SAR of cholinolytic agents

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

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

UNIT-IV

Drugs acting on Central Nervous System

A. Sedatives and Hypnotics:

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

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

Miscelleneous:

Amides & imides: Glutethmide.

Alcohol & their carbamate derivatives: Meprobomate, Ethchlorvynol.

Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

B. Antipsychotics

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

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

Fluro buterophenones: Haloperidol, Droperidol, Risperidone.

Beta amino ketones: Molindone hydrochloride.

Benzamides: Sulpieride.

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

Barbiturates: Phenobarbitone, Methabarbital. Hydantoins:

Phenytoin*, Mephenytoin, Ethotoin Oxazolidine diones:

Trimethadione, Paramethadione Succinimides:

Phensuximide, Methsuximide, Ethosuximide* Urea and

monoacylureas: Phenacemide, Carbamazepine*

Benzodiazepines: Clonazepam

Miscellaneous: Primidone, Valproic acid , Gabapentin, Felbamate

UNIT - V

Drugs acting on Central Nervous System General anesthetics:

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

Ultra short acting barbitutrates: Methohexital sodium*, Thiamylal sodium, Thiopental sodium.

Dissociative anesthetics: Ketamine hydrochloride.*

Narcotic and non-narcotic analgesics

Morphine and related drugs: SAR of Morphine analogues. Morphine sulphate. Codeine, Meperidine hydrochloride, Anilerdine hydrochloride. Diphenoxylate hydrochloride, Loperamide hydrochloride, Fentanyl citrate*, Methadone hydrochloride*, Propoxyphene hydrochloride, Pentazocine, Levorphanol tartarate.

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

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

PHYSICAL PHARMACEUTICS-II (Theory)

Paper Code: BP403T

Course Content:

UNIT-I

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

UNIT-II

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

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

UNIT-III

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

UNIT-IV

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

UNIT-V

Drug stability: Reaction kinetics: zero, pseudo-zero, first & second order, units of basic rate constants, determination of reaction order. Physical and chemical factors influencing the chemical degradation of pharmaceutical product: temperature, solvent, ionic strength, dielectric constant, specific & general acid base catalysis, Simple numerical problems. Stabilization of medicinal agents against common reactions like hydrolysis & oxidation. Accelerated stability testing in expiration dating of pharmaceutical dosage forms. Photolytic degradation and its prevention

PHARMACOLOGY-I (Theory) Paper Code: BP404T

Course Content:

UNIT-I

1. General Pharmacology

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

UNIT-II

General Pharmacology

- a. Pharmacodynamics- Principles and mechanisms of drug action. Receptor theories and classification of receptors, regulation of receptors. drug receptors interactions signal transduction mechanisms, G-protein-coupled receptors, ion channel receptor, transmembrane enzyme linked receptors, transmembrane JAK-STAT binding receptor and receptors that regulate transcription factors, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action.
- b. Adverse drug reactions.
- c. Drug interactions (pharmacokinetic and pharmacodynamic)
- d. Drug discovery and clinical evaluation of new drugs -Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.

UNIT-III

2. Pharmacology of drugs acting on peripheral nervous system

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

UNIT-IV

3. Pharmacology of drugs acting on central nervous system

a. Neurohumoral transmission in the C.N.S.special emphasis on importance of various neurotransmitters like with GABA, Glutamate, Glycine, serotonin, dopamine.

b. General anesthetics and pre-anesthetics.

c. Sedatives, hypnotics and centrally acting muscle relaxants.

d. Anti-epileptics

e. Alcohols and disulfiram

UNIT-V

3. Pharmacology of drugs acting on central nervous system

 a. Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens.

b. Drugs used in Parkinsons disease and Alzheimer's disease.

c. CNS stimulants and nootropics.

d. Opioid analgesics and antagonists

e. Drug addiction, drug abuse, tolerance and dependence.

PHARMACOGNOSY AND PHYTOCHEMISTRY I (Theory)

Paper Code: BP405T

Course Content:

Introduction to Pharmacognosy;
(a) Definition, history, scope and development of Pharmacognosy
(b) Sources of Drugs - Plants, Animals, Marine & Tissue culture
(c) Organized drugs, unorganized drugs (dried latex, dried julices, dried extracts, gums and
musilages, electrosins and electory gum -resins).
Classification of drugs: Alphabetical, morphological, taxonomical, chemical, pharmacological, chemo and sero
taxonomical classification of drugs
Quality control of Drugs of Natural Origin;
Adulteration of drugs of natural origin. Evaluation by organoleptic, microscopic, physical,
chemical and biological methods and properties.
Quantitative microscopy of crude drugs including lycopodium spore method, leafconstants,
camera lucida and diagrams of microscopic objects to scale with camera lucida,
Cultivation, Collection, Processing and storage of drugs of natural origin:
Cultivation and Collection of drugs of natural origin
Factors influencing cultivation of medicinal plants. Plant hormones and their applications.
Polyploidy, metation and hybridization with reference to medicinal plants
Conservation of medicinal plants
UNIT-III
Plant tissue cultures flistorical development of plant tissue culture, types of cultures, Natritional requirements,
growth and their maintenance.
Applications of plant tissue oulture in pharmacognosy.
Edible vaccines

UNIT IV

Pharmacognosy in various systems of medicine:

Role of Pharmacognosy in allopathy and traditional systems of medicine namely, Ayurveda, Unani, Siddha, Homeopathy and Chinese systems of medicine.

Introduction to secondary metabolites:

Definition, classification, properties and test for identification of Alkaloids, Glycosides, Playonoids, Tannins, Volatile oil and Resins

UNITE V

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

Plant Products:

Fibers Cotton, Jute, Hemp

Hallucinogens, Teratogens, Natural allergens

Primary metabolites:

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

Carbohydrates: Acacia, Agar, Tragacanth, Honey

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

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

Novel medicinal agents from marine sources

MEDICINAL CHEMISTRY – II (Theory) Paper Code: BP501T

Course Content:

UNIT- I

Antihistaminic agents: Histamine, receptors and their distribution in the humanbody

H₁-antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines cuccinate, Clemastine fumarate, Diphenylphyraline hydrochloride, Tripelenamine hydrochloride. Chlorcyclizine hvdrochloride. Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*. Phenidamine tartarate. Promethazine hydrochloride*. Azatidine maleate. Trimeprazine tartrate. Cyproheptadine hydrochloride, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium

H2-antagonists: Cimetidine*, Famotidine, Ranitidin.

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

Anti-neoplastic agents:

Alkylating agents: Meclorethamine*, Cyclophosphamide, Melphalan. Chlorambucil, Busulfan, Thiotepa

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

Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin

Plant products: Etoposide. Vinblastin sulphate. Vincristin sulphate

Miscellaneous: Cisplatin. Mitotane.

UNIT – II

Anti-anginal:

Vasodilators: Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, Isosorbide dinitrite*, Dipyridamole.

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

Diuretics:

Carbonic anhydrase inhibitors: Acetazolamide^{*}, Methazolamide, Dichlorphenamide. Thiazides: Chlorthiazide^{*}, Hydrochlorothiazide, Hydroflumethiazide. Cyclothiazide, Loop diuretics: Furosemide*, Bumetanide, Ethacrynic acid.

Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride.

Osmotic Diuretics: Mannitol

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

UNIT- III

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

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

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

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

UNIT- IV

Drugs acting on Endocrine system

Nomenclature. Stereochemistry and metabolism of steroids

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

Drugs for erectile dysfunction: Sildenafil, Tadalafil.

Oral contraceptives: Mifepristone, Norgestril. Levonorgestrol

Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone

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

UNIT – V

Antidiabetic agents:

Insulin and its preparations

Sulfonyl ureas: Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride.

Biguanides: Metformin.

Thiazolidinediones: Pioglitazone, Rosiglitazone.

Meglitinides: Repaglinide, Nateglinide.

Glucosidase inhibitors: Acrabose, Voglibose. Local Anesthetics: SAR of Local anesthetics

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

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

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

Miscellaneous: Phenacaine, Diperodon, Dibucaine.*

Industrial Pharmacy I (Theory) Paper Code: BP502T

Course content:

UNIT-I

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

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

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

BCS classification of drugs & its significant

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

UNIT-II

Tablets:

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

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

UNIT-III

Capsules:

- a. Hard gelatin capsules: Introduction, Production of hard gelatin capsule shells. size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules.
- b. *Soft gelatin capsules:* Nature of shell and capsule content, size of capsules, importance of base adsorption and minim/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules and their applications.

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

UNIT-IV

Parenteral Products:

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

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

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

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

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

UNIT-V

10 Hours

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

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

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

PHARMACOLOGY-II (Theory)

Paper Code: BP503T

Course Content:

UNIT-I

1. Pharmacology of drugs acting on cardio vascular system

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

UNIT-II

1. Pharmacology of drugs acting on cardio vascular system

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

2. Pharmacology of drugs acting on urinary system

- a. Diuretics
- b. Anti-diuretics.

UNIT-III

3. Autocoids and related drugs

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

UNIT-IV

Pharmacology of drugs acting on endocrine system

- a. Basic concepts in endocrine pharmacology.
- b. Anterior Pituitary hormones- analogues and their inhibitors.
- c. Thyroid hormones- analogues and their inhibitors.
- d. Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D.
- d. Insulin, Oral Hypoglycemic agents and glucagon.
- e. ACTH and corticosteroids.

UNIT-V

5. Pharmacology of drugs acting on endocrine system

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

6. Bioassay

a. Principles and applications of bioassay. b.Types of bioassay

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- c. Bioassay of insulin, oxytocin, vasopressin, ACTH,d-tubocurarine,digitalis, histamine and 5-HT

PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)

Paper Code: BP504T

Course Content:

UNIT'-I

Metabolic pathways in higher plants and their determination a) Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway.

b) Study of utilization of radioactive isotopes in the investigation of Biogenetic studies.

UNIT-H

Concrat introduction, composition, chemistry & chemical classes, biosources, therapeutic uses and commercial applications of following

Secondary metabolites:

Alkaloids: Vinca, Rauwolfia, Belladonna, Opium,

Phenylpropanoids and Flavonoids: Lignans, Tea. Ruta

Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Diescorea, Digitalis

Volatile oils: Mentha, Clove, Clinnamon, Fennel, Coriander,

Tannins: Catechu, Pterocarpus

Resias: Benzoin, Gaggul, Ginger, Asafoetida, Myrrh, Colophony,

Glycosides: Sehna, Aloes, Bittor Almond

Iridoids, Other terpenoids & Naphthaquinones: Contian, Artemisia, taxas, carotenoids

UNFEIT

solation. Identification and Analysis of Phytoconstituents

- a) Terpenoids: Menthol, Citral, Artemisin
- b) Glycosides: Glycyrhetinic acid & Ratin
- 3) Alkaloids: Atropine, Quinine, Reserpine, Caffeine
- d) Resins: Podophyllotoxín, Curcumin

UNIT-IV

Industrial production, estimation and utilization of the following phytoconstituents: Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atrophne, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine

UNIT V

Basics of Phytochemistry

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

PHARMACEUTICAL JURISPRUDENCE (Theory)

Paper Code: BP505T

Course Content:

UNIT-I

Drugs and Cosmetics Act, 1940 and its rules 1945:

Objectives, Definitions, Legal definitions of schedules to the Act and Rules

Import of drugs – Classes of drugs and cosmetics prohibited from import. Import under license or permit. Offences and penalties.

Manufacture of drugs – Prohibition of manufacture and sale of certain drugs.

Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

UNIT-II

Drugs and Cosmetics Act, 1940 and its rules 1945.

Detailed study of Schedule G, H, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA)

Sale of Drugs - Wholesale, Retail sale and Restricted license. Offences and penalties

Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics. List of permitted colors. Offences and penalties.

Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors

UNIT-III

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

Penalties

- Medicinal and Toilet Preparation Act –1955: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.
- Narcotic Drugs and Psychotropic substances Act-1985 and Rules: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties

UNIT-IV

- Study of Salient Features of Drugs and Magic Remedies Act and its rules: Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties
- Prevention of Cruelty to animals Act-1960: Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties
- National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO)-2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

UNIT-V

- Pharmaceutical Legislations A brief review. Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee
- Code of Pharmaceutical ethics D efinition. Pharmacist in relation to his job, trade, medical profession and his profession. Pharmacist's oath
- Medical Termination of Pregnancy Act
- Right to Information Act
- Introduction to Intellectual Property Rights (IPR)

MEDICINAL CHEMISTRY – III (Theory)

Paper Code: BP601T

Course Content:

UNIT – I

Antibiotics

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

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

Aminoglycosides: Streptomycin, Neomycin, Kanamycin

Tetracyclines: Tetracycline,Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

UNIT – II

Antibiotics

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

Macrolide: Erythromycin Clarithromycin, Azithromycin.

Miscellaneous: Chloramphenicol*, Clindamycin.

Prodrugs: Basic concepts and application of prodrugs design.

Antimalarials: Etiology of malaria.

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

Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil.

Miscellaneous: Pyrimethamine, Artesunete, Artemether, Atovoquone.

UNIT – III

Anti-tubercular Agents

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

Anti tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine Streptomycine, Capreomycin sulphate.

Urinary tract anti-infective agents

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

Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine.

Antiviral agents:

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

UNIT – IV

Antifungal agents:

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

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

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

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

ulphonamides and Sulfones

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

Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.

Sulfones: Dapsone*.

UNIT – V

Introduction to Drug Design

Various approaches used in drug design.

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

Pharmacophore modeling and docking techniques.

Combinatorial Chemistry: Concept and applicationschemistry: solid phase and solution phase synthesis.

PHARMACOLOGY-III (Theory)

Paper Code: BP602T

UNIT-I

1. Pharmacology of drugs acting on Respiratory system

a. Anti -asthmatic drugs

b. Drugs used in the management of COPD

c. Expectorants and antitussives

d. Nasal decongestants

e. Respiratory stimulants

2. Pharmacology of drugs acting on the Gastrointestinal Tract

a. Antiulcer agents.

b. Drugs for constipation and diarrhoea.

c. Appetite stimulants and suppressants.

d. Digestants and carminatives.

e. Emetics and anti-emetics.

UNIT-II

3. Chemotherapy

a. General principles of chemotherapy.

b. Sulfonamides and cotrimoxazole.

c. Antibiotics- Penicillins, cephalosporins, chloramphenicol. macrolides, quinolones and fluoroquinolins, tetracycline and aminoglycosides

UNIT-III

3. Chemotherapy

a. Antitubercular agents

b. Antileprotic agents

c. Antifungal agents

d. Antiviral drugs

e.Anthelmintics

f. Antimalarial drugs

g. Antiamoebic agents

UNIT-IV

3. Chemotherapy

Urinary tract infections and sexually transmitted diseases.
 Chemotherapy of malignancy.

4. Immunopharmacology

a. Immunostimulants

b. Immunosuppressant

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

UNIT-V 5. Principles of toxicology

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

organophosphosphorus compound and lead, mercury and arsenic poisoning.

6. Chronopharmacology

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

HERBAL DRUG TECHNOLOGY (Theory)

Paper Code: BP603T

Course content:

UNIT-I

Herbs as raw materials

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

Processing of herbal raw material

Biodynamic Agriculture

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

Indian Systems of Medicine

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

UNIT-II

Nutraceuticals

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

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

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

UNIT-III

Herbal Cosmetics

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

Herbal excipients:

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

Herbal formulations :

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

UNIT- IV

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

Patenting and Regulatory requirements of natural products:

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

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

Regulatory Issues - Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.

UNIT-V

General Introduction to Herbal Industry

Herbal drugs industry: Present scope and future prospects.

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

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

Infrastructural requirements, working space, storage area, machinery and equipments,

standard operating procedures, health and hygiene, documentation and records.

BIOPHARMACEUTICS AND PHARMACOKINETICS

Paper Code: BP604T

Course Content:

UNIT-I Hours

Introduction to Biopharmaceutics

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

UNIT- II

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

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

UNIT- III

Pharmacokinetics: Definition and introduction to Pharmacokinetics. Compartment models. Non compartment models, physiological models. One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra vascular administrations. Pharmacokinetics parameters - K_E .t1/2.Vd.AUC.Ka, Clt and CL_R- definitions methods of eliminations, understanding of their significance and application

UNIT- IV

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

UNIT- V

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

<u>PHARMACEUTICAL BIOTECHNOLOGY (Theory)</u> Paper Code: BP 605 T

Unit I

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

Unit II

- a) Study of cloning vectors, restriction endonucleases and DNA ligase.
- b) Recombinant DNA technology. Application of genetic engineering in medicine.
- c) Application of r DNA technology and genetic engineering in the production of:
- i) Interferon ii) Vaccines- hepatitis- B iii) Hormones-Insulin.
- d) Brief introduction to PCR

Unit III

Types of immunity- humoral immunity, cellular immunity

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

Unit IV

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

Unit V

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

PHARMACEUTICAL QUALITY ASSURANCE (Theory)

Paper Code: BP606T

Course content:

UNIT – I

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP

Total Quality Management (TQM): Definition, elements, philosophies

ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines

Quality by design (QbD): Definition, overview, elements of QbD program, tools

ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration

NABL accreditation : Principles and procedures

UNIT - II

Organization and personnel: Personnel responsibilities, training, hygiene and personal records. Premises: Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination. Equipments and raw materials: Equipment selection, purchase specifications, maintenance,

purchase specifications and maintenance of stores for raw materials.

UNIT – III

Quality Control: Quality control test for containers, rubber closures and secondary packing materials.

Good Laboratory Practices: General Provisions, Organization and Personnel. Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities

UNIT – IV

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

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

UNIT – V

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

Warehousing: Good warehousing practice, materials management

INSTRUMENTAL METHODS OF ANALYSIS (Theory) Paper Code: BP701T

Course Content:

UNIT –I

UV Visible spectroscopy

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

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

Applications - Spectrophotometric titrations, Single component and multi component analysis

Fluorimetry

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

UNIT –II

IR spectroscopy

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

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

Flame Photometry-Principle, interferences, instrumentation and applications

Atomic absorption spectroscopy- Principle, interferences, instrumentation and applications

Nepheloturbidometry- Principle, instrumentation and applications

UNIT –III

Introduction to chromatography

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

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

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

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

UNIT –IV

Gas chromatography - Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications

High performance liquid chromatography (HPLC)-Introduction, theory, instrumentation, advantages and applications.

UNIT –V

Ion exchange chromatography- Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications

Gel chromatography- Introduction, theory, instrumentation and applications

Affinity chromatography- Introduction, theory, instrumentation and application

INDUSTRIAL PHARMACYII (Theory) Paper Code: BP702T

UNIT-I

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

UNIT-II

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

UNIT-III

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

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

UNIT-IV

Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept. Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP

UNIT-V

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

PHARMACY PRACTICE (Theory) Paper Code: BP703T

Unit I:

a) Hospital and it's organization

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

b) Hospital pharmacy and its organization

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

c) Adverse drug reaction

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

d) Community Pharmacy

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

Unit II:

a) Drug distribution system in a hospital

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

b) Hospital formulary

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

c) Therapeutic drug monitoring

Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring.

d) Medication adherence

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

e) Patient medication history interview

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

f) Community pharmacy management

Financial, materials, staff, and infrastructure requirements.

Unit III:

Pharmacy and therapeutic committee

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

Patient counseling

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

a) Education and training program in the hospital

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

b) Prescribed medication order and communication skills

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

Unit IV

a) Budget preparation and implementation

b) Clinical Pharmacy

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

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

c) Over the counter (OTC) sales

Introduction and sale of over the counter, and Rational use of common over the counter medications.

Unit V

a) Drug store management and inventory control

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

b) Investigational use of drugs

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

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

NOVEL DRUG DELIVERY SYSTEMS (Theory)

Paper Code: BP 704T

Course content:

Unit-I

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

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

Unit-II

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

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

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

Unit-III

Transdermal Drug Delivery Systems: Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches

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

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

Unit-IV

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

Unit-V

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

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

BIOSTATISITCS AND RESEARCH METHODOLOGY (Theory)

Paper Code: BP801T

Course content:

Unit-I

Introduction: Statistics, Biostatistics, Frequency distribution

Measures of central tendency: Mean, Median, Mode- Pharmaceutical examples **Measures of dispersion**: Dispersion, Range, standard deviation, Pharmaceutical problems

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

Unit-II

Regression: Curve fitting by the method of least squares, fitting the lines y= a + bx and x = a + by, Multiple regression, standard error of regression– Pharmaceutical Examples **Probability:** Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties - problems

Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples

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

Unit-III

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

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

Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph **Designing the methodology:** Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

Unit-IV

Blocking and confounding system for Two-level factorials

Regression modeling: Hypothesis testing in Simple and Multiple regressionmodels **Introduction to Practical components of Industrial and Clinical Trials Problems**: Statistical Analysis Using Excel, SPSS, MINITAB[®], DESIGN OF EXPERIMENTS, R -Online Statistical Software's to Industrial and Clinical trial approach

Unit-V

Design and Analysis of experiments:

Factorial Design: Definition, 2², 2³design. Advantage of factorial design **Response Surface methodology**: Central composite design, Historical design, Optimization Techniques

SOCIAL AND PREVENTIVE PHARMACY Paper Code: BP 802T

Course content:

Unit I:

Concept of health and disease: Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick.

Social and health education: Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention.

Sociology and health: Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health

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

Unit II:

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

Unit III:

National health programs, its objectives, functioning and outcome of the following: HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National

programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.

Unit IV:

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

Unit V:

Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school.

<u>PHARMA MARKETING MANAGEMENT (Theory)</u> <u>Paper Code: BP803ET</u>

Unit I

Marketing

Definition, general concepts and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behavior; industrial buying behavior.

Pharmacoutical market:

Quantitative and quplitative aspects, size and composition of the market, demographic descriptions and socio-psychological characteristics of the consumer; market segmentation& targeting. Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist. Analyzing the Market; Role of market research.

Unit II

Product decision:

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

Unit III

Promotions

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

Unit IV

Pharmaceutical marketing channels:

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

Professional sales representative (PSR):

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

Unit V

Pricing:

Meaning, importance, objectives, determinants of price: pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Ordenand NPPA (National Pharmacentical Pricing Authority):

Emerging concepts in marketing:

Vertical & Horizontal Marketing; RuralMarketing; Consumerism; Industrial Marketing; Global Marketing.

PHARMACEUTICAL REGULATORY SCIENCE (Theory) Paper Code: BP804ET

Course content:

Unit I

New Drug Discovery and development

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

Unit II

Regulatory Approval Process

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

Regulatory authorities and agencies

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

Unit III

Registration of Indian drug product in overseas market

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

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

Unit IV

Clinical trials

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

Unit V

Regulatory Concepts

Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book

PHARMACOVIGILANCE (Theory)

Paper Code: BP 805T

Course Content

Unit I

Introduction to Pharmacovigilance

- History and development of Pharmacovigilance
- Importance of safety monitoring of Medicine
- WHO international drug monitoring programme
- Pharmacovigilance Program of India(PvPI)

Introduction to adverse drug reactions

- Definitions and classification of ADRs
- Detection and reporting
- Methods in Causality assessment
- Severity and seriousness assessment
- Predictability and preventability assessment
- Management of adverse drug reactions

Basic terminologies used in pharmacovigilance

- Terminologies of adverse medication related events
- Regulatory terminologies

Unit II

Drug and disease classification

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

Drug dictionaries and coding in pharmacovigilance

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

Information resources in pharmacovigilance

- Basic drug information resources
- Specialised resources for ADRs

Establishing pharmacovigilance programme

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

Unit III

Vaccine safety surveillance

- Vaccine Pharmacovigilance
- Vaccination failure

Adverse events following immunization

Pharmacovigilance methods

- Passive surveillance Spontaneous reports and case series
- Stimulated reporting
- Active surveillance Sentinel sites, drug event monitoring and registries
- Comparative observational studies Cross sectional study, case control study and cohort study
- Targeted clinical investigations

Communication in pharmacovigilance

- Effective communication in Pharmacovigilance
- Communication in Drug Safety Crisis management
- Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media

Unit IV

Safety data generation

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

ICH Guidelines for Pharmacovigilance

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

Unit V

Pharmacogenomics of adverse drug reactions

Genetics related ADR with example focusing PK parameters.

Drug safety evaluation in special population

- Paediatrics
- Pregnancy and lactation
- Geriatrics

CIOMS

- CIOMS Working Groups
- CIOMS Form

CDSCO (India) and Pharmacovigilance

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

QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Theory)

Paper Code: BP 806 ET

Unit I

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

WHO guidelines for quality control of herbal drugs.

Evaluation of commercial crude drugs intended for use

Unit II

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

WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines WHO Guidelines on GACP for Medicinal Plants.

Unit III

EU and ICH guidelines for quality control of herbal drugs. Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

Unit IV

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

Preparation of documents for new drug application and export registration

GMP requirements and Drugs & Cosmetics Act provisions.

Unit V

Regulatory requirements for herbal medicines.

WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems

Comparison of various Herbal Pharmacopoeias.

Role of chemical and biological markers in standardization of herbal products

COMPUTER AIDED DRUG DESIGN (Theory)

Paper Code: BP807ET

Course Content:

UNIT-I

Introduction to Drug Discovery and Development

Stages of drug discovery and development

Lead discovery and Analog Based Drug Design

Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation.

Analog Based Drug Design:Bioisosterism, Classification, Bioisosteric replacement. Any three case studies

UNIT-II

Quantitative Structure Activity Relationship (QSAR)

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

UNIT-III

Molecular Modeling and virtual screening techniques

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

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

UNIT-IV

Informatics & Methods in drug design

Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

UNIT-V

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

CELL AND MOLECULAR BIOLOGY (Elective subject)

Paper Code: BP808ET

Course content:

- () Cell and Molecular Biology: Definitions theory and basics and Applications.
-) Cell and Molecular Biology: History and Summation.
- Properties of cells and cell membrane.
- I) Prokaryotic versus Eukaryotic
- Cellular Reproduction
- O Chemical Foundations an Introduction and Reactions (Types)

Unit II

Unit I

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

Unit III

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

Unit IV

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

Unit V

- a) Cell Signals: Introduction
- b) Receptors for Cell Signals
- c) Signaling Pathways: Overview
- d) Misregulation of Signaling Pathways
- e) Protein-Kinases: Functioning

COSMETIC SCIENCE (Theory) Paper Code: BP809ET

UNIT'I

lassification of cosmetic and cosmeccutical products

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

Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients,

preservatives. Classification and application

Skin: Basic structure and function of skin,

Hair: Basic structure of hair. Hair growth cycle.

Oral Cavity: Common problem associated with teeth and guins,

UNIT II

Principles of formulation and building blocks of skin care products: Face wash,

Moisturizing cream, Cold Cream, Vanishing cream and their advantages and

disadvantages. Application of these products in formulation of cosmecuticals.

Antiperspants & deadorants- Actives & mechanism of action.

Principles of formulation and building blocks of Hair care products;

Conditioning shampoo, Hair conditioner, anti-dandruff shampoo.

tair oils.

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

Principles of formulation and building blocks of oral care products.

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

UNITE HI

Sun protection, Classification of Sunscreens and SPF.

Role of herbs in cosmetics:

Skin Care: Aloo and turmeric

Hair care: Henna and amfa,

Oral care: Neem and clove

Analytical cosmetics: BIS specification and analytical methods for shampoo, skincream and tootliposte.

UNIT IV

Principles of Cosmetic Evaluation:Principles of sebumeter, corneometer. Measurement of TEWL, Skin Color, Hair tensile strength. Hair combing properties Scaps and syndet bars. Evolution and skin bentits,



UNIT V

Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dematitis.

Cosmetic problems associated with Hair and sealp: Dandruff, Hair fall causes

Cosmetic problems associated with skin: blemishes, wrinkles, acre, prickly heat and body odor.

Antiperspirants and Deodorants- Actives and mechanism of action



PHARMACOLOGICAL SCREENING METHODS Paper Code: BP810 ET

Unit –I

Laboratory Animals:

Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals.

Techniques for collection of blood and common routes of drug administration in laboratory animals. Techniques of blood collection and euthanasia.

Unit –II

Preclinical screening models

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

b. Study of screening animal models for

Diuretics, nootropics, anti-Parkinson's, antiasthmatics.

Preclinical screening models: for CNS activity- analgesic,

antipyretic.anti-inflammatory, general anaesthetics, sedative and

hypnotics, antipsychotic, antidepressant, antiepileptic,

antiparkinsonism, alzheimer's disease





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

Unit –IV

Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslepidemic, anti aggregatory, coagulants, and anticoagulants

Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.



ADVANCED INSTRUMENTATION TECHNIQUES

Paper Code: BP 811 ET

Course Content:

UNIT-I Nuclear Magnetic Resonance spectroscopy Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications Mass Spectrometry- Principles, Fragmentation, Ionization techniques – Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications

UNIT-II

Thermal Methods of Analysis: Principles, instrumentation and applications of ThermogravimetricAnalysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC)

X-Ray Diffraction Methods: Origin of X-rays, basic aspects of crystals, Xray

Crystallography, rotating crystal technique, single crystal diffraction.powder diffraction, structural elucidation and applications.

UNIT-III

Calibration and validation-as per ICH and USFDA guidelines Calibration of following Instruments

Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer, Fluorimeter, Flame Photometer, HPLC and GC

UNIT-IV

Radio immune assay:Importance, various components. Principle, different methods, Limitation and Applications of Radio immuno assay

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

UNIT-V

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



Semester VIII – Elective course on Pharmaceutical Product Development

Unit-I

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

Unit-II

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

Solvents and solubilizers

- ii. Cyclodextrins and their applications
- iii. Non ionic surfactants and their applications

iv. Polyethylene glycols and sorbitols

- Suspending and emulsifying agents
- vi. Semi solid excipients

Unit-III

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

Tablet and capsule excipients

Directly compressible vehicles

iii. Coat materials

iv. Excipients in parenteral and aerosols products

Excipients for formulation of NDDS

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

Unit-IV

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

Unit-V

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

Dry. Sai Kal Ghonh Principal

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