DETAILED SYLLABUS FOR THE POST OF ANALYST GRADE-III IN DRUGS CONTROL DEPATRMENT

(Cat.No: 026/2024)

(Total Mark:100)

MODULE 1 **8 MARKS**

HUMAN ANATOMY AND PHYSIOLOGY & PATHOPHYSIOLOGY

HUMAN ANATOMY & PHYSIOLOGY

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

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

2. **Structure and functions of skin**
3. **Skeletal system**

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

4**. Body fluids and blood**

Composition and functions of blood, hemopoeisis, formation of hemoglobin, anemia, mechanisms of coagulation, blood grouping, Rh factors

Lymphatic system

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

5. Sense organs

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

6. Cardiovascular system

Heart − anatomy of heart, elements of conduction system of heart and heartbeat, its regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of blood pressure, pulse, electrocardiogram.

7. Nervous system

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

Classification of peripheral nervous system

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

8. Digestive system

Anatomy of GI Tract with special reference to anatomy and functions of stomach, small intestine and large intestine, anatomy and functions of salivary glands, pancreas and liver, movements of GIT, digestion and absorption of nutrients.

9. Respiratory system

Anatomyof 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.

10. 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 disorders of kidney

11..Endocrine system

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

12. 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

PATHOPHYSIOLOGY

1. Basic mechanism involved in the process of inflammation and repair:

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

2. Haematological Diseases:

Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalasemia, hereditary acquired anemia, hemophilia

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

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

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

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

7. Principles of cancer: classification, etiology and pathogenesis of cancer

8. Infectious diseases: Meningitis, Typhoid, Leprosy, Tuberculosis Urinary tract infections

9. Sexually transmitted diseases: AIDS, Syphilis, Gonorrhea

MODULE II **(10 MARKS)**

PHARMACEUTICS, PHYSICAL PHARMACEUTICS, FORMULATIVE PHARMACY&PHARMACEUTICAL ENGINEERING

PHARMACEUTICS

1. **Pharmacopoeias**: Introduction to IP, BP, USP and Extra Pharmacopoeia.

2. Dosage form, classification and definitions

3. Prescription: Definition, Parts of prescription, handling of Prescription and Errors in prescription.

4. Posology: Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area.

5.Pharmaceutical calculations: Weights and measures − Imperial & Metric system, Calculations involving percentage solutions, alligation, proof spirit and isotonic solutions based on freezing point and molecular weight.

3. Powders: Definition, classification, advantages and disadvantages, Simple & compound powders official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.

4. Liquid dosage forms: Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms.

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

b. **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.

5. Suppositories: Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories.

6. Pharmaceutical incompatibilities: Definition, classification, physical, chemical

and therapeutic incompatibilities with examples.

7. 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

PHYSICAL PHARMACEUTICS

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

2. 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.

3. 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.

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

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

FORMULATIVE PHARMACY

1. Tablets: Ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling.

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

2. Capsules:

Hard gelatin capsules: Introduction, Extraction of gelatin and production of hard gelatin capsule shells. size of capsules, filling, finishing and special techniques of formulation of hard gelatin capsules. In process and final product quality control tests for capsules.

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

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

3. Parenteral Products: Types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity.Formulation of injections, sterile powders, emulsions, suspensions, large volume parenterals and lyophilized products, Sterilization..Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests.

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

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

6. Pharmaceutical Aerosols: Definition, propellants, containers, valves, types of

aerosol systems; formulation and manufacture of aerosols; Evaluation of aerosols

7. 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.

PHARMACEUTICAL ENGINEERING

1. Flow of fluids: Types of manometers, Reynolds number and its significance, Bernoulli's theorem and its applications, Orifice meter, Venturimeter, Pitot tube and Rotometer.

Size Reduction: Laws governing size reduction, factors affecting size reduction, principles, construction, working, uses, merits and demerits of Hammer mill, ball mill, fluid energy mill, Edge runner mill & end runner mill.

Size Separation: mechanism of size separation, official standards of powders, sieves, size separation Principles, construction, working, uses, merits and demerits of Sieve shaker, cyclone separator, Air separator, Bag filter & elutriation tank.

Mixing: , 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.

2. Evaporation:,. principles, construction, working, uses, merits and demerits of Steam jacketed kettle, horizontal tube evaporator, climbing film evaporator, forced circulation evaporator, multiple effect evaporator& Economy of multiple effect evaporator.

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

3. Drying: principles, construction, working, uses, merits and demerits of Tray dryer, drum dryer spray dryer, fluidized bed dryer, vacuum dryer and freeze dryer.

4. Distillation: Objectives, applications & types of distillation. principles, construction, working, uses, merits and demerits of (lab scale and industrial scale)

Simple distillation, preparation of purified water and water for injection BP by distillation, flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation

5. 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.

6. 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.

7. Material handling systems: Objectives & applications of Material handling systems, different types of conveyors such as belt, screw and pneumatic conveyors.

MODULE III **(16 MARKS)**

PHARMACOLOGY

1. General Pharmacology Essential drugs concept and routes of drug administration, Agonists, antagonists (competitive and non competitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy.

Pharmacokinetics− Membrane transport, absorption, distribution, metabolism and excretion of drugs

Enzyme induction, enzyme inhibition, kinetics of elimination

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.

Adverse drug reactions.

Drug interactions (pharmacokinetic and pharmacodynamic)

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

Principles of toxicology - Definition and basic knowledge of acute, subacute and chronic toxicity. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity General principles of treatment of poisoning.

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

2. Study of Pharmacology of following classes of drugs

Drugs acting on Autonomous nervous system, Drugs acting on Central nervous system, Drugs acting on Cardiovascular system Drugs acting on blood and blood forming organs, Drugs acting on Urinary system , Drugs acting on Respiratory system, Autocoids & related drugs, Drugs acting on endocrine system, Drugs acting on the Gastrointestinal Tract, Local anaesthetics,&Drugs acting on skin

3. Bioassay

Principles and applications of bioassay, Types of bioassay, Bioassay of insulin, oxytocin, vasopressin, ACTH, d−tubocurarine, digitalis, histamine, Heparin sodium, Anti rabies vaccine, Diphtheria antitoxin

4. Chemotherapy

a. General principles of chemotherapy. including classification of chemotherapeutic agents, microbial resistance, chemoprophylaxis
b. Sulfonamides and cotrimoxazole. Urinary antiseptics
c. Antibiotics- Penicillins, cephalosporins, monobactam, carbapenem chloramphenicol, macrolides Lincosamides, quinolones and fluoroquinolones, tetracycline and aminoglycosides, oxazolidinediones
d. Antitubercular agents
e. Antileprotic agents

f. Antifungal agents

g. Antiviral drugs including anti HIV drugs

h. Anthelmintics

i. Antimalarial drugs

j. Antiamoebic agents

k. Drugs used in UTI &STDs

l. Anticancer agents

5. Immunopharmacology

Immunostimulants, Immunosuppressants .Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

6. **Gene therapy-** concepts, approaches, gene transfer techniques and application Stem cell therapy

MODULE IV (14 MARKS)

PHARMACOGNOSY AND PHYTOCHEMISTRY& HERBAL DRUG TECHNOLOGY

PHARMACOGNOSY&PHYTOCHEMISTRY

1. Quality control of Drugs of Natural Origin: Adulteration of drugs of natural origin. Evaluation by organoleptic, microscopic, physical, chemical and biological methods.Quantitative microscopy of crude drugs including lycopodium spore method, leaf constants, Camera Lucida, and calibration of eye piece micrometer using stage micrometer.

2. Plant tissue culture:, types of cultures, nutritional requirements, growth and their maintenance. Applications of plant tissue culture in Pharmacognosy. Edible vaccines

3. secondary metabolites: Definition, classification, properties and general tests for identification of Alkaloids, Glycosides, Flavonoids, Tannins, Volatile oil and Resins.

4. Biological source, chemical constituents and uses of following Plant drugs /Products

Fibers - Cotton, Jute, Hemp

Hallucinogen- Cannabis,

Teratogens- Tobacco, Colchicum, Veratrum

Natural allergens-Classification, Preparation and standardization of allergenic extract.

5. Primary metabolites:sources, preparation, chemical constituents, evaluation, preservation, storage, therapeutic uses of the following Primary metabolites:

Carbohydrates: Acacia, Agar, Starch, Tragacanth, Honey.

Proteins and Enzymes: Gelatin, Casein, Proteolytic enzymes (Papain, Bromelain, Serratiopeptidase, Urokinase, Streptokinase, Pepsin).

Lipids (Waxes, fats, fixed oils): Castor oil, Chaulmoogra oil, Wool Fat, Bees wax.

6.. **Marine Drugs:** Novel medicinal agents from marine sources: Antiviral, Antimicrobial, Anticancer and Cardiovascular agents.

7. 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.

HERBAL DRUG TECHNOLOGY

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

2. Nutraceuticals 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: Alfalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina

3. Herbal Cosmetics
Sources and description of raw materials of herbal origin used in herbal cosmetics such as

a) Fixed oils: Almond oil ,Arachis oil, castor oil ,olive oil, coconut oil
b) Waxes: Bees wax, Carnauba wax, Paraffin wax, Spermaceti
c) Gums: Guar gum, Sodium Alginate, Tragacanth

d) Colours: Cochineal, Saffron, Indigo, Henna
e) Perfumes: Rose oil, Jasmine oil, Lavender oil.
f) Protective agents: Neem, Cucumber, Aloe
g) Bleaching agents: Lemon, Turmeric
Antioxidants: Green tea, Sesame oil in products such as skin care, hair care and oral hygiene products

MODULE V **(12 marks)**

PHARMACEUTICAL JURISPRUDENCE

1.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.

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

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

3.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.

4.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

5. Drugs and magic remedies Act and its rules: Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties

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

7. 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)

8. Pharmaceutical Legislations A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee

9. Code of Pharmaceutical ethics Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist s oath

10.Medical Termination of pregnancy act

11. Right to information Act

12. Introduction to Intellectual Property Rights (IPR)

MODULE VI **(12 MARKS)**

PHARMACEUTICAL ANALYSIS, INORGANIC CHEMISTRY,ORGANIC CHEMISTRY

PHARMACEUTICAL ANALYSIS

1.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,

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

2. Types of redox titration. Iodimetry, Iodometry, Bromatometry, Dichrometry,

PHARMACEUTICAL INORGANIC CHEMISTRY

1. Principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals, modified limit test for Chloride and Sulphate

2. Properties, and medicinal uses of inorganic compounds belonging to the following classes

a. Major extra and intracellular electrolytes: Potassium chloride, Calcium gluconate

b. Dental products: Dentifrices, Desensitizing agents, Calcium carbonate, Sodium fluoride, and Zinc eugenol cement.

c. Gastrointestinal agents

Acidifiers: Ammonium chloride ,Dilute Hydrochloric acid

Antacids: Sodium Bicarbonate, Aluminum hydroxide gel, Magnesium hydroxide mixture

Cathartics**:** Magnesium sulphate, Sodium orthophosphate**,**

d. Pharmaceutical Aid: Kaolin and Bentonite

e.Antimicrobials:, Potassium permanganate, Boric acid, Hydrogen peroxide, Chlorinated lime, Iodine and its preparations

f. Expectorant**s:** Potassium iodide, Ammonium chloride

g. Emetics: Copper sulphate, Antimony potassium tartarate

h. Haematinic**s:** Ferrous sulphate, Ferrous gluconate

i. Poison and Antidote**:** Sodium thiosulphate, Activated charcoal

j. Astringents: Zinc Sulphate, Potash Alum

ORGANIC CHEMISTRY

1. Structural isomerisms in organic compounds

2.Markownikoff's orientation, free radical addition reactions of alkenes, Anti Markownikoff's orientation. Stability of conjugated dienes,

3. Alkyl halides SN_1 and SN_2 reactions − kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations.

SN_1 versus SN_2 reactions, Factors affecting SN_1 and SN_2 reaction

4. Carbonyl compounds (Aldehydes and ketones)

Nucleophilic addition, Electromeric effect, aldol condensation, Crossed Aldol condensation, Cannizzaro reaction, Crossed Cannizzaro reaction, Benzoin condensation, Perkin condensation,

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

6. Aliphatic amines - Basicity, effect of substituent on Basicity. Qualitative test,

7. Benzene and its derivatives

Huckel's rule

Reactions of benzene - nitration, sulphonation, halogenation- reactivity, Friedel crafts alkylation reactivity, limitations, Friedel craftsacylation.

Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction

Structure and uses of DDT, Saccharin, BHC and Chloramine

8. Phenols - Acidity of phenols, effect of substituents on acidity, qualitative tests, Structure and uses of phenol, cresols, resorcinol, naphthols

9. Aromatic Amines - Basicity of amines, effect of substituents on basicity, and synthetic uses of aryl diazonium salts

10. Fats and Oils

Fatty acids – reactions.

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

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

11. Polynuclear hydrocarbons: Synthesis, Reactions and Structure of Naphthalene, Phenanthrene, Anthracene, Diphenyl methane, Triphenyl methane and medicinal uses of their derivatives.

12. Cyclo alkanes

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

13. 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

Racemic modification and resolution of racemic mixture.

Asymmetric synthesis: partial and absolute

14. 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 stereo selective reactions

15. Heterocyclic compounds

Synthesis, reactions and medicinal uses of following compounds/derivatives Pyrrole, Furan, and Thiophene − Relative aromaticity, reactivity and Basicity of pyrrole

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 Reactions of synthetic importance- Metal hydride reduction ($NaBH_4$ and $LiAlH_4$), Clemmensen reduction, Birch reduction, Wolff Kishner reduction, Oppenauer oxidation, Dakin reaction, Beckmanns rearrangement.schimidt rearrangement, & Claisen schimidt condensation.

MODULE VII (10 MARKS)

MEDICINAL CHEMISTRY, INSTRUMENTAL METHODS OF ANALYSIS, BIOCHEMISTRY

MEDICINAL CHEMISTRY (Study the synthesis of compounds superscripted)

1. Drugs acting on Autonomic Nervous System

i). Sympathomimetic agents:

SAR of Sympathomimetic agents

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

Indirect acting agents: Hydroxyamphetamine, Pseudoephedrine,

Agents with mixed mechanism: Ephedrine.

Adrenergic Antagonists:

- Alpha adrenergic blockers**:** Tolazoline*, Phentolamine, Prazosin.
- Beta adrenergic blockers**:** SAR of beta blockers, Propranolol*, Atenolol, , Esmolol, Metoprolol, Labetolol, Carvedilol.

ii). 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.

iii). Cholinesterase reactivator: Pralidoxime chloride.

iv). Cholinergic Blocking agents: SAR of cholinolytic agents

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

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

2. Drugs acting on Central Nervous System

A. Sedative and Hypnotics

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

Barbiturates: SAR of barbiturates, Barbital*, Phenobarbital, Mephobarbital, , Pentobarbital, Secobarbital

Miscelleneous:

Amides & imides: Glutethmide.

Alcohol & their carbamate derivatives: Meprobomate.

Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

A. Antipsychotics

Phenothiazeines: SAR of Phenothiazeines − Promazine hydrochloride, Chlorpromazine hydrochloride*, Triflupromazine, Thioridazine 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.

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

Barbiturates: Phenobarbitone,

Hydantoins: Phenytoin*.

Oxazolidine diones : Trimethadione, Paramethadione

Succinimides : Phensuximide, Methsuximide, Ethosuximide*

Urea and monoacylureas : Carbamazepine*

Benzodiazepines : Clonazepam

Miscellaneous : Primidone, Valproic acid , Gabapentin, Felbamate

D. General Anesthetics:

Inhalation anesthetics: Halothane*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane. Ultra-short acting barbitutrates: Methohexital sodium*, , Thiopental sodium.

Dissociative anesthetics: Ketamine hydrochloride.*

E.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.

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

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

3. Antihistaminic agents:

H_1 –antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Tripelennamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Promethazine hydrochloride*, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Cromolyn sodium

H_2 -antagonists: Cimetidine*, Famotidine, Ranitidine.

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

4. Anti-neoplastic agents:

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

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

Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin

Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate

Miscellaneous: Cisplatin, Mitotane.

5. Anti-anginal:

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

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

6. Diuretics:

Carbonic anhydrase inhibitors: Acetazolamide*, Methazolamide, Thiazides:Chlorthiazide*, Hydrochlorothiazide,

Loop diuretics: Furosemide*, Bumetanide, Ethacrynic acid. Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride. Osmotic Diuretics: Mannitol

7. Anti-hypertensive Agents: Timolol, Captopril, Lisinopril, Enalapril, Benazepril hydrochloride, Clonidine hydrochloride, Sodium nitroprusside, Diazoxide, Minoxidil, Hydralazine hydrochloride.

8. Anti-arrhythmic Drugs: Quinidine sulphate, Procainamide hydrochloride, Disopyramide phosphate*,Phenytoin sodium, Lidocaine hydrochloride, Tocainide 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, Bosentan, Tezosentan.

9. Drugs acting on Endocrine system

Nomenclature, Stereochemistry and metabolism of steroids

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

Drugs for erectile dysfunction: Sildenafil, Tadalafil.

Oral contraceptives: Mifepristone, Norgestrel, Levonorgestrel

Corticosteroids : Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone

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

Antidiabetic agents:

Insulin and its preparations

Sulfonyl ureas: Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride. Biguanides: Metformin. Thiazolidinediones: Pioglitazone, Rosiglitazone. Meglitinides: Repaglinide, Nateglinide. Glucosidase inhibitors: Acarbose, Voglibose.

10. Local Anesthetics: SAR of Local anesthetics

Benzoic Acid derivatives: Cocaine, Cyclomethycaine, Piperocaine.

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

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

Miscellaneous: Phenacaine, Dibucaine.*

11. Antibiotics

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

β-Lactam antibiotics: Penicillin, Cepholosporins, - Lactamase inhibitors, Monobactams Aminoglycosides: Streptomycin, Neomycin, Kanamycin

Tetracyclines: Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

Macrolide: Erythromycin, Clarithromycin, Azithromycin. Miscellaneous: Chloramphenicol* Clindamycin.

12. Prodrugs: Basic concepts and application of prodrugs design.

13. Antimalarials:

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

Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil. Miscellaneous: Pyrimethamine, Artesunate, Artemether, Atovaquone.

14. Anti-tubercular Agents

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

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

15. Urinary tract anti-infective agents

Quinolones: SAR of quinolones, Nalidixic Acid, Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin Miscellaneous**:** Furazolidone, Nitrofurantoin*, Methenamine.

16. Antiviral agents:

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

17. 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*.

18. Anti-protozoal Agents:

Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine.

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

20. Sulphonamides and Sulfones

Historical development, chemistry, classification and SAR of Sulfonamides:

Sulphamethizole, Sulfisoxazole, Sulphamethazine, Sulfacetamide*, Sulphapyridine, Sulfamethoxazole*, Sulphadiazine, Mefenide acetate, Sulfasalazine.

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

21. Introduction to Drug Design

Various approaches used in drug design. Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammett‘s electronic parameter, Tafts steric parameter and Hansch analysis. Pharmacophore modeling and docking techniques.

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

INSTRUMENTAL METHODS OF ANALYSIS

1. 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

2. Fluorimetry

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

3.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

4. Flame Photometry-Principle, interferences, instrumentation and applications

5. Atomic absorption spectroscopy- Principle, interferences, instrumentation and applications

6. Nepheloturbidometry- Principle, instrumentation and applications

BIOCHEMISTRY

1. 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.

2. Biological oxidation

Electron transport chain (ETC) and its mechanism. Oxidative phosphorylation & its mechanism and substrate level phosphorylation.

Inhibitors, ETC and oxidative phosphorylation/Uncouplers.

3. 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 hormones and vitamin D

4. Amino acid metabolism

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

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

5. 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 of protein synthesis.

6. Introduction to chromatography

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

a. **Thin layer chromatography &High performance thin layer chromatography:** Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications.

b. **Paper chromatography –**

Introduction, methodology, development techniques, advantages, disadvantages and applications

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

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

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

f. **Ion exchange chromatography-** Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors

affecting ion exchange, methodology and applications

g. **Gel filtration chromatography-** Introduction, theory, instrumentation and applications

h. **Affinity chromatography-** Introduction, theory, instrumentation and applications

MODULE VIII **(06 MARKS)**

INDUSTRIAL PHARMACY, NOVEL DRUG DELIVERY SYSTEMS, PHARMACEUTICAL BIOTECHNOLOGY

INDUSTRIAL PHARMACY

1.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, packing materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies

TT agencies in India - APCTT, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT or Technology of Transfer (ToT) related documentation - confidentiality agreements, licensing, MoUs, legal issues

2. 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, General considerations of Investigational New Drug (IND) Application, Investigator‘s Brochure (IB) and New Drug Application(NDA), Data Presentation for FDA Submissions.

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

PHARMACEUTICAL BIOTECHNOLOGY

1. Enzyme Biotechnology- Methods of enzyme immobilization and applications.

Biosensors- Working and applications of biosensors in Pharmaceutical Industries..

Use of microbes in industry. Production of Enzymes- General consideration - Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase.

Basic principles of genetic engineering.

2.

a) Study of cloning vectors, restriction endonucleases and DNA ligase.

b) Recombinant DNA technology. Application of genetic engineering in medicine.

c) Application of r DNA technology and genetic engineering in the products: i) Interferon ii) hepatitis- B vaccine iii) Insulin hormone.

d) Brief introduction to PCR

e) Types of immunity- humoral immunity, cellular immunity

3.

a) Structure and Function of MHC

b) General method of the preparation of bacterial vaccines, toxoids, viral vaccines, antitoxins, serum- immuno blood derivatives and other products relative to immunity.

c) Storage conditions and stability of official vaccines.

d) Hybridoma technology- Production, Purification and Applications

4.

a) Immuno blotting techniques- ELISA, Western blotting, Southern blotting.

b) Microbial genetics including transformation, transduction, conjugation, plasmids and transposons.

5.

a) Mutation --Types of mutation/mutants

b) Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring.

c) Study of the production of - penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin,

NOVEL DRUG DELIVERY SYSTEMS

1. **Microencapsulation:** Definition, advantages and disadvantages, microspheres/ microcapsules, micro particles, methods of microencapsulation, applications
2. **Transdermal Drug Delivery Systems:** Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches.
3. **Nanotechnology and its Concepts:** Concepts and approaches for targeted drug delivery systems, advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications.
4. **Ocular Drug Delivery Systems:** Introduction, intra ocular barriers and methods to overcome– Preliminary study, ocular formulations and ocuserts

MODULE IX (6 MARKS)

PHARMACY PRACTICE, SOCIAL &PREVENTIVE PHARMACY, PHARMACEUTICAL QUALITY ASSURANCE

PHARMACY PRACTICE

1. 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 staff involved in the hospital and their functions.

2. Hospital pharmacy and its organization

Definition, functions of hospital pharmacy, staff requirements, and Responsibilities and functions of hospital pharmacists.

3. 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

4. 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.

5. 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.

6. Clinical Pharmacy

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

7. Patient medication history interview

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

8. Therapeutic drug monitoring

Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring

8. Medication adherence

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

9. Rational use of drugs- rational use of injections, antibiotics and over the counter drugs, sale of over the counter drugs.

10. 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.

a) Drug store management and inventory control

Organization 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.

SOCIAL AND PREVENTIVE PHARMACY

1.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

2. National health programs, its objectives, functioning and outcome of the following: HIV AND AIDS control program, TB, Integrated disease surveillance program (IDSP), National leprosy control program, National mental health program, National program for prevention and control of deafness, Universal immunization program, National program for control of blindness, Pulse polio program.

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

PHRMACEUTICAL QUALITY ASSURANCE

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

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

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

Quality by design (QbD): Definition, overview, elements of QbD program, tools **ISO 9000 & ISO 14000**: Overview, Benefits, Elements, steps for registration **NABL accreditation** : Principles and procedures.

MODULE X (6 MARKS)

BIOPHARMACEUTICS AND PHARMACOKINETICS, PHARMACEUTICAL MICROBIOLOGY, RESEARCH METHODOLOGY & BIOSTATICS

BIOPHARMACEUTICS AND PHARMACOKINETICS

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

2. Pharmacokinetics: Pharmacokinetics models, Compartment models, Non compartment models, physiological models, One compartment open model.

a. Intravenous Injection (Bolus) b. Intravenous infusion, extra vascular administrations, calculations of Ka and KE. From plasma and urinary excretion data

3. Multicompartment models: Two compartment open model. IV bolus Multiple Dosage Regimens: a). Repititive Intravenous injections- One Compartment Open Model

b). Repititive Extravascular dosing- One Compartment Open model

PHARMACEUTICAL MICROBIOLOGY (Theory)

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

Study of principle, procedure, merits, demerits and applications of Physical, chemical and mechanical method of sterilization.

Evaluation of the efficiency of sterilization methods.

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

Classification and mode of action of disinfectants

Factors influencing disinfection, antiseptics and their evaluation for bacteriostatic and bactericidal actions

Evaluation of bactericidal & Bacteriostatic.

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

3. 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.

4. Nonlinear Pharmacokinetics: Introduction, Factors causing Non-linearity, Michaelis-menton method of estimating parameters

RESEARCH METHODOLOGY AND BIOSTATISTICS

1. Different types of data: Different methods for data collection. Experimental and observational studies. Questionnaires and rating scales. Primary and secondary data. Different types of data distribution. Coding and tabulation of data. Graphical representation of data.

2. Introduction to Epidemiological methods: Types of epidemiology studies. Standard measures in epidemiological studies. Measures of disease frequency, Measures of association. Study designs in epidemiology studies.

Validity and Reliability. Bias and confounding.

Intervention studies, Controlled clinical trial

Errors in Epidemiological studies

3. Biostatistics: Definition and application. Various terms in statistics, Descriptive statistics: Measures of central tendency. Measures of dispersion. Inferential statistics: Different areas of inferential statistics. Sampling Fundamentals: Need for sampling. Probability and nonprobability samplings. Sample size, criteria for inclusion and exclusion, dropouts.

4. **Research question and Hypothesis:** Characteristics of good Hypothesis, Testing of Hypothesis. Procedure for hypothesis testing, Tests for significance. P value, Type I and Type II errors, Different Parametric and Nonparametric tests and their applications. Interpretation of results. Computer software‘s in Bio statistical Analysis.

NOTE: - It may be noted that apart from the topics detailed above, questions from other topics prescribed for the educational qualification of the post may also appear in the question paper. There is no undertaking that all the topics above may be covered in the question paper.