## FURTHER DETAILS REGARDING MAIN TOPICS OF PROGRAMME No. 11/2020 (Item No: 20)

### ANALYST GR.III DRUGS CONTROL DEPARTMENT

## Category Numbers: 133/2019

## **MODULE I**

## PHARMACEUTICAL CHEMISTRY - I (INORGANIC CHEMISTRY)

1. Introduction: Pharmacopoeia and monograph.

**2. Quality control and test for purity**: Sources of impurities in Pharmaceutical substances. Limit tests: Definition, importance, general procedure for limit test for chlorides, sulphates, iron, arsenic, heavy metals, lead and modifications with suitable examples

**3. Study of pharmaceutically important compounds**: Method of preparation, properties, assay (of compounds with asterisk ), identification test, test for purity, official preparation, storage conditions and uses of inorganic compounds listed in I.P belonging to the following categories.

a. Gastrointestinal agents and related compounds *(i)Acidifiers*: Dilute hydrochloric acid, Ammonium chloride\*

(*ii*) Antacids: Classification, Qualities of an ideal antacid, side effects, advantages of combination therapy, acid neutralizing capacity, sodium bicarbonate\*, Potassium citrate, Aluminium hydroxide gel\*, Magnesium hydroxide\*, magnesium trisilicate, light and heavy magnesium carbonate, Calcium carbonate, Dimethicone, Magaldrate, Bismuth carbonate.

*(iii) Adsorbents and protectives*: Light Kaolin, Activated charcoal, Bismuth subcarbonate, Titanium dioxide. (iv) Saline cathartics: Magnesium sulphate, Magnesium carbonate.

b. Topical Agents

- (i) *Protectives*: Talc, Zinc Oxide, Calamine, Zinc Stearate, Silicon Polymers and Dimethicone.
- (ii) Astringents: Alum, Zinc Sulphate and Zinc chloride\*.
  - (iii) *Anti-microbials*: Hydrogen Peroxide\*, Potassium Permanganate, Chlorinated Lime, Boric Acid\*, Silver Nitrate, Povidone-Iodine, Selenium Sulphide\* and Zinc Undecenoate.

#### c. Dental products

(*i*) Anti-caries Agents: Role of Fluorides as anti-caries agents, Sodium fluoride\*

(*ii*) *Dentifrices*: Calcium carbonate, dibasic calcium phosphate, Zinc chloride.

d. Major intra and extra cellular electrolytes:

*(i.)* Physiological role of Chloride, Phosphate, Bicarbonate, Sodium, Potassium, Calcium and Magnesium.

*(ii.)* Electrolytes used for replacement therapy: Sodium chloride, Potassium chloride, Calcium chloride, Calcium gluconate\*, Calcium lactate, Tribasic calcium phosphate.

(*iii* )Physiological acid-base balance and its importance.

*(Iv )*Electrolytes used in the acid-base therapy: Sodium acetate, Potassium acetate, Sodium citrate, Potassium citrate, Sodium lactate, Ammonium chloride. Electrolyte combination therapy, Compound sodium chloride solution, Sodium chloride injection and Oral rehydration salt.

e. Gases: Oxygen\*, Carbon dioxide, Nitrogen\* and Nitrous Oxide\*.

f. Essential and Trace ions: Definition, Physiological role of Iron, Copper, Zinc, Chromium, Manganese, Molybdenum, Selenium, Sulphur and Iodine. Ferrous fumarate, Ferrous gluconate, Ferrous sulphate\*, Iron and Ammonium citrate, Zinc chloride and Potassium iodide. Official formulation: Iron dextran injection, Official solutions of iodine.

g. Pharmaceutical Aids: Sodium bisulphite, Sodium metabisulphite, oxide, Bentonite, Magnesium stearate, Aluminium sulphate, Sodium benzoate, Sodium carboxy methyl cellulose, Sodium methylparaben, Sodium lauryl sulphate, Purified water, Water for injection, sterile water for injection.

#### h. Miscellaneous:

(*i.*) Sclerosing agents: Hypertonic saline, Sodium tetra decyl sulphate.

- (ii). Expectorants: Ammonium chloride, Potassium iodide.
- (iii) Sedative: Potassium bromide.
- (*iv*) Antidotes: Sodium nitrite, Sodium thiosulphate, Charcoal.

(v). Respiratory stimulant: Ammonium carbonate. (Assay of compounds marked\* only)

# **4.** Theory of co-ordination compounds with special reference to application in Pharmacy and Pharmaceutical analysis: EDTA, Dimercaprol, Penicillamine, 1, 10- phenanthroline

**5. Test for purity for the following**: a. Swelling property of bentonite. b. Acid neutralizing capacity of aluminium hydroxide gel. c. Ammonium salts in potash alum. d. Adsorption power in heavy kaolin. e. Presence of iodates in potassium iodide. f. Ferric ion and reducing sugars in ferrous gluconate

#### 6. Determination of specific rotation of a compound.

- 7. Determination of refractive index.
- 8. Determination of partition co-efficient.

## **MODULE II**

### **PHARMACEUTICAL ANALYSIS -I**

**Introduction:** Importance of quality control, different techniques of analysis, preliminaries and definitions, significant figures, concept of error, precision, accuracy, mean and standard deviation, calibration of analytical equipments, fundamentals of volumetric analysis, methods of expressing concentrations, primary and secondary standards.

#### **1** Neutralization titrations:

Acid-base concepts, relative strength of acids and bases, law of mass action, common ion effect, ionic product of water, pH, Henderson– Hasselbach equation, buffer solutions, theory of indicators, neutralization curves, choice of indicators, mixed and universal indicators, titration of polyprotic system

**2. Non-aqueous titrations:** Theoretical basis, types of solvents, scope, limitations, preparation and standardization of titrant solutions used in non-aqueous titrations of weak acid and weak bases.

**3. Precipitation titrations** : Principles of precipitation titrations, solubility product, effect of acids, temperature and solvent on the solubility of precipitate. Argentometric titrations- different methods, and mercurimetric titrations.

**4. Complexometirc titrations**: Complexation, chelation, Werner's coordination number, stability of complexes, titration curves, importance of buffer, types of complexometric titration, methods of end point detection. pM indicator, masking and demasking agents.

**5. Oxidation - reduction titrations**: Concepts of oxidation-reduction, standard oxidation potential, Nernst equation, theory of redox titrations, redox indicators, titrations involving cerric ammonium sulphate, potassium permanganate, titanous chloride, sodium-2,6- dichlorophenol-indophenol, iodimetry, iodometry,

**6. Gravimetric analysis:** Basic concepts, precipitation techniques, organic and inorganic precipitants, co-precipitation, post-precipitation. Various steps involved in gravimetric analysis. Thermogravimetry. Pharmaceutical applications.

Determination of barium sulphate as barium sulfate, calcium as calcium oxalates, Magnesium as magnesium pyrophosphate, silver as silver chloride.

#### 7. Miscellaneous methods:

- 1. Diazotisation titrations
- 2. Kjeldhal method of nitrogen estimation
- 3. Oxygen Flask combustion method
- 4. Gasometry5.Karl Fischer method

## MODULE III

## PHARMACEUTICAL CHEMISTRY -II (CHEMISTRY OF NATURAL PRODUCTS)

1. **Carbohydrates:** Definition, classification, nomenclature, structure of sucrose, maltose, lactose, properties of sucrose, glycosidic linkage, non reducing nature; structure of starch, cellulose, cellulose derivatives and deoxy sugars. A brief account on pharmaceutical importance of various carbohydrates.

**2. Proteins and Amino acids Amino acids**: Definition, classification, essential amino acids, configuration, important methods of preparation of amino acids, physical properties-Zwitter ionic nature, isoelectric point, chemical properties, peptides, peptide synthesis and determination of structure of peptides [End group analysis] Proteins: Definition, classification, denaturation, primary, secondary and tertiary structure of proteins. pharmaceutical importance of amino acids, polypeptides and proteins. Analysis of proteins: C-terminal & N-terminal analysis. Synthesis of simple peptides

**3. Terpenoids**: Introduction, classification, isoprene rules, chemistry and uses of geroniol, alpha-terpineol, camphor, ionones.

**4. Alkaloids** Introduction, Chemical classification, general isolation, Structural elucidation of alkaloids-General methods, chemistry Structural elucidation and pharmacological activity of Atropine, morphine, &ephedrine Identification of alkaloids by specific colour tests

**5. Glycosides:** Introduction, Chemistry of Cardiac glycosides including their chemical structures with SAR, Chemistry of sapogenins. Test for cardiac glycosides, flavanoides, and their glycosides.

**6. Vitamins:** Classification, structural elucidation, chemistry and pharmaceutical uses of vitamin A, D, B1, B2, B6 and C.

**7. Purines:** Chemistry and structural elucidation of uric acid &caffeine. Interrelationship of caffeine, theobromine and theophylline

**8. Fats &Oils:** Introduction, Analytical constant of fats &oils, methods for their determination & significance. Determination of chemical constituents of fats & oils (Acid value, Saponification value, Iodine value , Acetyl value and peroxide value of fixed oils)

**9. Steroids:** Introduction, Nomenclature of steroids, stereochemistry and numbering the ring system. Chemistry of cholesterol, ergosterol, &bile acids. Tests for steroids. Liberman- Burchard test, Salkowski reaction etc.

**10. Estimation** of drugs coming under alkaloids, antibiotics, vitamins & other pharmaceutically significant products of natural origin.

## MODULE IV

## PHARMACEUTICAL JURISPRUDENCE

**1. Introduction :** Definition and scope of Forensic pharmacy. Pharmaceutical legislation in India. Historical developments. Pharmacist's role in drug treatment and drug usage. Pharmacist as a member of the Health Care Scheme.
 Professional ethics in Pharmacy practice. Legal and ethical responsibilities of pharmacists.

**2. A detailed study** of the following Acts and their significance to the profession of Pharmacy

(a) Pharmacy Act.(b) Drugs and Cosmetics Act.(c) Medicinal and Toiletpreparations (Excise Duties) Act and Rules.(d) Narcotic Drugs and PsychotropicSubstances Act.(e) Drugs and Magic Remedies (Objectionable Advertisements)Act.

3. A brief study of the following Acts and their significance in Pharmacy

(a) Drugs Prices Control Order. (b) A.I.C.T.E. Act. (c) Patents Act. (d) Trade and Merchandise marks Act. (e) States Shops and Establishments Act. (f) Minimum Wages Act. (g) Factories Act. (h) Prevention of Food Adulteration Act and Rules.
(i) Prevention of Cruelty to Animals Act. (j) Medical Termination of Pregnancy Act.
(k) The Poisons Act

4. Drug tragedies. Drug poisoning, drug accidents and drugs in suicides.
Committee reports on drug accidents. Trade names. Combination preparations, banned drugs & combinations. Newly introduced and out dated drugs.
Important case decisions published in drug cases relating to various topics covered in the subject.

## MODULE V

#### PHARMACOGNOSY

**1.Study of the biological sources**, commercial varieties, chemical constituents, substitutes, adulterants, uses, diagnostic, macroscopic and microscopic features and specific chemical tests of the following groups of drugs containing glycosides:

Saponins: Liquorice\*#, Ginseng, Dioscorea\* and Sarasparilla Cardioactive sterols: Digitalis\*#, Squill\*, Strophanthus, Thevetia# Anthrquinone cathartics: Aloes\*, Senna\*#, Rhubarb and Cascara. Others: Psorelea, Gentian\*, Saffron\* and Quassia.

**2. Studies of traditional drugs**, common vernacular names, botanical sources, morphology, and chemical nature of chief constituents, pharmacology, categories and common uses and marketed formulations of indigenous drugs:

Amla, Kantakari, Satavari, Tylophora, Bhilwa, Arjuna, Asokha, Kalijiri, Rasna, Punarnava, Apmarg, Gokhru, Shankapushpi, Brahmi, Methi, Lahsun, Palash, Guggal, Gymnema, Shilajit, Chitrak, Sida and Neem.

**3. Introduction to alternative systems of medicine** The Holistic concept of drug administration in traditional system of medicine. Introduction to Ayurvedic preparations like Asavas, Gutikas, Tailas, Choornas, Lehyas and Bhasmas.

**4. Systematic study of source**, commercial varieties, chemical constituents, adulterants, uses, diagnostic macroscopic and microscopic features and specific chemical tests of following alkaloid containing drugs:

Tropane: Belladonna\*#, Hyoscyamus, Datura\*#, Coca and Withania. Quinoline & Isoquinoline: Cinchona\*#, Ipecac#, Opium\*. Indole: Ergot\*, Rauwolfia\*#, Catharanthus# and Physostigma. Imidazole: Pilocarpine. Steroidal: Veratrum and Kurchi\*. Alkaloidal amines: Ephedra\*# and Colchicum\*. Glycoalkaloid: Solanum Purines: Coffee\* and Tea\* (Cultivation, collection of drugs marked \* only) (Detailed microscopical studies of drugs marked # only

**5. General techniques** of biosynthetic studies and basic metabolic pathways. Brief introduction to biogenesis of secondary metabolites of pharmaceutical importance.Shikimic acid pathway, Acetate mevalonate Pathway, Isoprenoid synthesis

**6.** *Introduction*, classification and study of different chromatographic methods and their application in evaluation of herbal drugs.

**7. Preparation** of the extracts and various extraction techniques including supper critical fluid extraction.

9. Marine pharmacognosy, novel medicinal agents from marine sources.

**10. Plant allergens** and allergenic substances. Classification and preparation of allergenic extracts.

**11.** *Biological sources*, preparation, identification tests and uses of the following enzymes: Diastase, Papain, Bromalein, Maltase

12. Protein containing drugs: Gelatin, Collagen, spirulina

**13. Introduction to herbal drug technology**. Development and evaluation of herbal formulations

**14. Adulteration and evaluation of crude drugs.** Standards for herbal formulations. WHO guidelines in evaluation of drugs

15. Herbaceous health foods.

16. Herbal cosmetics – including classifications with examples, standards and biological sources, chemical constituents and uses of at least 10 drugs used in herbal cosmetics
 16. Patenting of Herbal Drugs

**17.Estimation of phytopharmaceuticals** : Atropine, Quinine, Curcumine, Aloin, Caffeine

**18.** *Physicochemical evaluation* of crude drugs and formulations including ash values, extractive values, refractive index

## MODULE VI

#### PHARMACOLOGY- I & BIOPHARMACEUTICS

A. 1. General Pharmacology a) Dose response relationship-graded and quantitative relationship, LD50, ED50, therapeutic index, therapeutic window, margin of safety Combined effect of drugs-Additive effect, synergism, drug receptor antagonism. Factors modifying drug action

b) Drug dose & dosage: Fixed dose combination-Advantages & disadvantages. Banned drugs

c) Rational use of medications, rational prescribing irrationalities in prescription P drug concept and P treatment, essential drugs, spurious drugs, expiry dates of medication

d). Pharmacogenetic variation in drug action

e) Principles of Toxicology

1. Definition of poison, general principles of treatment of poisoning.

2. Definition for acute, sub-acute and chronic toxicity, genotoxicity, Carcinogenicity, teratogenicity and mutagenicity studies. Acute, subacute and chronic toxicity and genotoxicity studies, various organ toxicities

3. Drug interactions .Definition, epidemiology, classification & pharmacological mechanisms of drug interactions with suitable examples and management

#### 4. Adverse effects of drugs

Adverse drug reactions: Definition and classification, epidemiology, predisposing factors, mechanism of adverse drug reactions, Drug allergy-Mechanism, types and treatment Drug dependence: Tolerance, habituation, addiction, treatment

5.. Pharmacology of drugs in special groups-

Pregnancy, lactation pediatrics and elderly

#### 6. Chronopharmacology

Definition of rhythm and cycles, Biological clock and their significance leading to chronotherapy

#### B) Pharmacology of following classes of drugs

Emphasize on classification, molecular mechanism of action, pharmacological actions, pharmacokinetics, adverse effects, contraindications, drug interaction, clinical uses, preparation and dosages

1. Drugs acting on autonomic nervous system

*a. Cholinergic system* –receptors of acetylcholine, cholinergic drugs, anticholineesterases, anticholinergic drugs, ganglionic stimulants and blockers, neuromuscular blocking drugs,drugs in myasthenia gravis

*b.* Adrenergic system –Adrenergic receptors, adrenergic drugs , antiadrenergic drugs c. Ocular pharmacology: Mydriatics, miotics and drugs used in glaucoma

2. Autocoids and their antagonists.

Histamin, antihistamins, 5HT, 5HT blockers. Renin -Angiotensin system and drugs modifying it. Kinins, enkephalins, prostaglandins and other polypeptides

3. Cardiovascular drugs

a. Cardiac glycosides, management of digitalis toxicity, drugs for heart failure, Pharmacotherapy of heart failure.

b. Antiarrhythmic drugs and pharmacotherapy of cardiac arrhythmias.

c. Vasodilators and antianginal drugs and pharmacotherapy of angina pectoris.

d. Hypolipidemic drugs and plasma expanders

e. Anti-hypertensive drugs and pharmacotherapy of hypertension

4. Drugs acting on respiratory tract: mucolytic agents, Antitussives, Expectorants, Drugs for bronchial asthma, Pharmacotherapy of bronchial asthma.

5. Drugs acting on endocrine system:

Anterior pituitaty hormones, Thyroid hormones & antithyroid drugs, Parathyroid hormones. Insulin & oral antidiabetic agents, Pharmacotherapy of diabetes mellitus.Adrenal cortical steroids,Gonadotropins, Oestrogens&Progesterones. Antifertility agents &ovulation inducing agents. Androgens, antiandrogens & anabolic steroids

## **BIOPHARMACEUTICS**

#### 1. Elimination-

Biotransformation – phase I and phase II reactions Excretion –Mechanism of renal clearance, Concept of clearance, Clearance ratio, Determination of renal clearance, Dosage adjustment in patient with renal failure, Extraction ratio, Hepatic clearance, Biliary excretion, Entero Hepatic Circulation. Factors affecting elimination.

2.Compartment models- Definition, One compartment model- IV Bolus, IV Infusion, ExtraVascular administration. Determination of pharmacokinetic parameters from plasma and urine data. Two compartment model- IV Bolusdetermination of pharmacokinetic parameters

3.Non-linear pharmacokinetics- One compartment model IV Bolus administration, MichaelisMenten equation. 4.Measurement of Bioavailability- Cmax, t max, AUC. Design of single dose Bioequivalent study, dissolution and disintegration

## **MODULE VII**

## PHARMACOLOGY -II & CLINICAL PHARMACY

**A).Measurements in pharmacology**: Bioassay:- Principles, indications types and requirements of bioassay Bioassay of insulin, digitalis, adrenaline, acetyl choline, histamine, oxytocin, d-tubocurarine, Antihaemophillic fraction, Heparin Sodium, Diphtheria anti toxin, Anti rabies vaccine. Radioimmunoassay: principles and application

**B. Drug discovery and new drug development:** a) Approaches to drug discovery, preclinical studies, clinical trials, design, phases and conduct of clinical trial, ethical issues, informed consent, role of placebo, different terminologies related to clinical trial b) Bioinformatics- definition, aim and applications in drug development

#### C) Pharmacology of the following groups of drugs -with emphasis on

Classification, Mechanism of action, Pharmacokinetics, Pharmacodynamics, Adverse effects, Drug interactions, Contra indications, Clinical uses& Preparations and dosages. And pharmacotherapy of the following mentioned diseases. 1) Drugs acting on central nervous system

a. General anaesthetics, sedatives & hypnotics, management of barbiturate poisoning b. Alcohols, management of methanol poisoning c. Analgesicsantipyretics, narcotic analgesics, Non- steroidal anti- inflammatory agents, antigout remedies, drugs in rheumatoid arthritis.d. Management of Paracetamol poisoning, morphine poisoning, salicylate poisoning. e .Pharmacotherapy of gout and hyper-uricemia , rheumatoid arthritis f.Antiepilepics and pharmacotherapy of epilepsy g. Drugs used in Parkinsonism & Pharmacotherapy of Parkinsonism.h. CNS stimulants i. Psychopharmacological agents- antipsychotics, antidepressants, anti-anxiety agents, pharmacotherapy of psychosis and depression. j Drugs in Alzheimers disease

- 2) Local anaesthetics
- 3) Drugs acting on uterus- Oxytocics, uterine relaxants

4) Drugs affecting renal function Diuretics & antidiuretics

5) Drugs acting on the blood and blood forming organs

a. Dugs effective in different types of anaemia – Iron defiency anaemia, aplastic anaemia, megaloblastic anaemia. Pharmacotherapy of anaemias b. Drugs effecting coagulation of blood -coagulants, anticoagulants, thrombolytic agents, drugs affecting platelet function,Bloodproducts and plasma volume expanders c. Drugs used in shock, Pharmacotherapy of shock

6) Pharmacology of vitamins. Source, absorption, fate, action, therapeutic uses and adverse effects

7) Heavy metals and heavy metal antagonists

8) Enzyme in therapy Hyaluronidase, L-asparaginase, seratiopeptidase

9) Therapeutic gases:Oxygen, Helium, CO2, water vapour

10) Drugs acting on gastro-intestinal tract-

Appetizers, `digestants, carminatives, appetite suppressants,

Emetics, antiemetics, antidiarrhoeals, Cathartics, Antacids & Drugs used in the treatment of peptic ulcer. Pharmacotheraapy of constipation, diarrhea, vomiting, peptic ulcer disease.

11) Drugs acting on Skin: Drugs used in skin disorders, sclerosis, melanizing and demelanizing agents

#### D) Antimicrobial drugs & Chemotherapy

i. History of Chemotherapy. Bacterial resistance, combined use of antimicrobials, prophylactic use of antimicrobials. Classification based on mechanism of action of antimicrobial agents

ii. Classification including recent drugs, Mechanism of action, Spectrum of activity, Pharmacokinetics, Pharmacodynamics, Adverse effects, Drug interactions, Contra indications, Clinical uses& Preparations and dosages of the following :- Sulphonamides, quinolones, pencillins, cephalosporins, Monobactams, tetracyclines, Chloramphenicol, polypeptide antibiotics, macrolide antibiotics, Aminoglycoside antibiotics, Monobactams, Lincosamides, Oxazolidinones, Urinary antiseptics., Antiseptics and disinfectants

iii. Pharmacotherapy of Urinary tract infection, Upper respiratory tract infection, Enteric infection.

iv. Antifungal agents

v. Antiviral agent-Drugs in different viral infections, non selective antiviral drugs

vi. Anti HIV agents and therapy of AIDS

vii. Antitubercular agents and Pharmacotherapy of tuberculosis

viii. Anti protozoal agents

ix. Anthelmintics

x Chemotherapy of neoplastic disease: Cell cycle kinetics, Genesis of cancer cells, Characteristics of cancer cells, Antineoplastic agents.

#### E) Immunoparmacology.

i. Immunity & hypersensitivity. Chemical mediators of immune response and drugs that block their actions

ii. Immunosuppressant and immunostimulant drugs.

iii. Vaccine therapy-Different types & mechanism of action Indications, dosage schedule & adverse effects of typhoid vaccine, BCG vaccine, Oral polio vaccine, Rabies vaccine, Hepatitis vaccine, Tetanus toxoid

iv. Immunoglobulins in therapy- Indications, dosage schedule & adverse effects of Human Immunoglobulins, tetanus Immunoglobulins, rabies Immunoglobulins.

Proteins and polypeptides as therapeutic agents 3. Stem cell therapy-General terminologies, stem cells, cell potency types, types of stem cells, potential uses of stem cells.

## **Clinical Pharmacy**

1. Drug & Poison information services Introduction, sources of information, design of literature searches, critical evaluation of drug information and literature. Preparation of written and verbal reports.

#### 2. Clinical pharmacokinetics & individualization of drug therapy:

a. Drug use in special population:- infants ,elderly , pregnancy & lactationtherapeutic consideration b. Dosage adjustments in renal failure, hepatic failure. Therapeutic Drug Monitoring. TDM indications for measuring drugs in blood, choice of drugs to be monitored. Timings of measurements, measuring techniques. Clinical applications – Estimation of serum concentration of Digoxin, Theophylline, Gentamycin, Lithium, Phenytoin, Cyclosporin & Amiodarone

**3.** Adverse drug reactions: Detection, monitoring & reporting of ADRs.

4. **Definition and implications** of Evidence based medicine, Practice based research & laboratory based research

5. Preparation of drug profiles, leaflets, packaging inserts.

**6. Drug interactions**: clinical significane, potentially dangerous interations, role of pharmacist in identification, assessment and ways to overcome interations.

7. Concept of Essential drugs and rational drug use.

**8. Clinical management** (including clinical manifestations, clinical investigations/ assessment, treatment algorithms, management of adverse effects of therapy, and patient education) of the following organ disorders.

a) Cardiovascular disorders : Hypertension, Congestive heart failure, Angina, Acute Myocardial infraction , Cardiac arrhythmias

b) Central nervous disorders : Epilepsy, Parkinsonism, Schizophrenia, Depression

c) Respiratory disorders : Asthma , COPD

d) Gastro intestinal disorders : Peptic ulcer, Ulcerative colitis, Hepatitis, Cirrhosis

e) Endocrine disorders : Diabetes mellitus, Thyroid disorders

f) Infectious disorders : Tuberculosis, Urinary tract infections, Enteric infection, Upper respiratory tract infection & HIV

g) Hemopoietic disorders : Anaemias,

h) Joint & connective disorders : Rheumatic diseases, Osteoporosis

i) Neoplastic disorders : Acute leukaemias, Hodgkins disease& carcinoma of breast.

## **MODULE VIII**

## PHARMACEUTICAL CHEMISTRY - III (MEDICINAL CHEMISTRY)

#### Basic Concepts and Applications of Prodrug Design

Study of Classification, Mechanism of Action, uses and Structure of selected drugs (Only drugs marked with asterisk) on the following categories of drugs:

a) General Anaesthetics: Halothane\*, Diethyl ether, Thiopentone Sodium, Thiamylal sodium\*, Ketamine.

b) Local Anaesthetics: Benzocaine, Procaine, Lignocaine\*, Mepivacaine, Dibucaine\*, Phenacaine.

c) Anxiolytics, Sedatives and Hypnotics: Chlordiazepoxide, Diazepam\*, Oxazepam, Alprazolam, Triclofos Sodium, Buspirone.

d) Antipsychotics: Chlorpromazine\*, Thioridazine, Prochlorperazine\*, Chlorprothixene, Thiothixene, Haloperidol, Risperidone.

e) Anticonvulsants: Phenytoin\*, Fosphenytoin, Trimethadione, Ethosuximide, Carbamazepine, Sodium Valproate\*, Clonazepam

f) Antidepressants: Imipramine\*, Amitryptiline, Doxepine\*, Fluoxetine

g) Adrenergic agents: Adrenaline \*, Isoprenaline, Salbutamol\*, Naphazoline, Xylometazoline.

h) Adrenergic antagonists: Tolazoline, Prazosin, Propranolol\*, Metoprolol\*.

i) Cholinergic Drugs: Acetylcholine, Carbachol\*, Neostigmine, Pyridostigmine\*.

j) Cholinergic Blocking agents Cyclopentolate\*, Dicyclomine\*, Clidinium bromide, Propantheline bromide

k) Antipyretics. Aspirin, Salsalate, Paracetamol\*

 Narcotic Analgesics: Morphine, Codeine, Levorphanol, Pethidine\*, Pentazocine.

m) Non-steroidal anti-inflammatory agents: Oxyphenbutazone, Indomethacin\*, Ibuprofen\*, Diclofenac, Naproxen, Piroxicam\*, Nimesulide.

n) Antihistaminic agents: Diphenhydramine\*, Tripelenamine, Chlorpheniramine, Triprolidine, Promethazine\*, Cyclizine\*, Cetrizine, Astemizole.

o) H2 Receptor antagonist and Proton Pump Inhibitors: Cimetidine, Ranitidine, Famotidine, Omeprazole, Pantoprazole.

p) Diuretics Acetazolamide, Hydrochlorthiazide, Furosemide\*, Ethacrynic acid,
 Spironolactone, Triamterene\*, Indapamide\*.

q) Antihypertensive agents Methyl dopa\*, Hydralazine, Diazoxide, Enalapril, Nifedipine, Losartan.

r) Antihyperlipidemic Agents: Clofibrate, Niacin, Lovastatin, Ezetimibe.

s) Oral Hypoglycemic agents and Antithyroid drugs: Tolbutamide\*, Glipizide, Metformin\*, Glimepride, Rosiglitazone, Carbimazole\*.

t.Local Anti-infective agents: Liquified Phenol, Benzalkonium chloride, Chlorhexidine.

u) Antifungal agents: Griseofulvin, Clotrimazole, Fluconazole, Tolnaftate\*.

v) Antitubercular agents: INH\*, PAS\*, Pyrazinamide, Ethionamide.

w) Antiprotozoal agents: Metronidazole\*, Tinidazole, Diloxanide.

x) Anthelmintics: DEC\*, Mebendazole\*, Niclosamide, Ivermectin

y) Antimalarials. Chloroquine\*, Hydroxychloroquine, Mefloquine, Trimethoprim, Sulfadoxine.

z) Sulfonamides and Sulfones: Sulfacetamide\*, Sulfapyridine,
 Sulfamethoxazole, Sulfamethizole, Silver Sulfadiazine\*, Sulfasalazine, Dapsone\*,
 Solapsone.

aa) Antibiotics: Chloramphenicol \* Penicillin and Cephalosporins: Methicillin,
Ampicillin\*, Carbencillin, Cephalexine, Cefachlor, Cefotaxime. Tetracyclines
Flouroquinolones: Ciprofloxacin, Norfloxacin. Macrolide Antibiotics: Azithromycin.
bb) Antiviral agents: Amantadine, Idoxuridine, Acyclovir\*, Zidovudine,
Saquinavir, Ribavirin. cc) Antineoplastic agents: Chlorambucil,
Cyclophosphamide, Carmustine, Thiotepa, Busulfan, Dacarbazine, Methotrexate\*,
6 -mercaptopurine, 5-flourouracil\*, Tamoxifen, Cisplatin, Azathioprine

## **MODULE IX**

## PHARMACEUTICAL ANALYSIS II (MODERN METHODS OF PHARMACEUTICAL ANALYSIS)

## Theoretical consideration and application in drug analysis and quality control of the following analytical techniques.

#### 1. Chromatography

i) Column chromatography: Adsorption and Partition theory, preparation, procedure and methods of detection. ii) Thin layer chromatography: Theoretical consideration, preparation, procedure and detection of compounds. iii) Paper chromatography: Theory of partition, different techniques employed and different grades of papers used, quantitative and qualitative detection. iv) Gas
Chromatography: Introduction, fundamentals of column operation and detection. v) Ion Exchangers: Types of exchangers, mechanism of ion exchange and column operation. vi) Counter current extraction, ultra centrifugation and gel filtration. vii) HPLC and HPTLC.

2. Potentiometric titrations: Introduction, Electrochemical cells, half-cells, electrodes, measurement of potential and application in pharmaceutical analysis.

3. Conductometric titrations: Basic concepts, different types of conductometric titrations, apparatus used and applications in Pharmaceutical Analysis.

4. Thermal Analysis: Basic Concepts and Applications in Pharmaceutical Analysis.

5. Polarography: Basic concept, theoretical considerations, Basic instrumentation, apparatus, principles, general polarography analysis and applications in pharmaceutical analysis.

6. Amperometry: Amperometric titrations with one polarized electrode, general procedure, titration curves and applications.

7. Electrophoresis: Principle, instrumentation and application.

8. Turbidimetry and Nephelometry: (1 hour) Theory of light scattering, Nephelometry, Turbidimetry for Practical Analysis of dispersions, study of the working principles of instrument used for analysis and applications in Pharmacy.

9. Theoretical aspects, basic instrumentation, elements of interpretation of spectra and applications of the following analytical techniques should be discussed.

a. UV and Visible Spectrophotometry.

- b. Fluorimetry.
- c. Infrared Spectrophotometry.
- d. Nuclear Magnetic Resonance Spectroscopy including 13C-NMR.
- e. Mass Spectrometry.
- f. Flame Photometry.
- g. Emission Spectroscopy.
- h. Atomic Absorption Spectroscopy
- . i. X-ray diffraction.
- j. Radio Immuno Assay

#### 10. Quality Assurance

a. GLP, ISO 9000, TQM, Quality Review, quality documentation and International Conference of Harmonization (ICH). b. Regulatory control, regulatory drug analysis and interpretation of analytical data. c. Validation, quality audit, quality of equipment, validation of equipment and validation of analytical procedures.

## **MODULE X**

#### **PHARMACEUTICS & MICROBIOLOGY**

 Tablets Characteristics, advantages and disadvantages. Types of tablets, excipients, granulation methods and machinery involved. Tablet compression operation-single punch and rotary tablet presses, processing problems, evaluation, packaging.

**2. Tablet coating**: Types-sugar coating, film coating, compression coating, electrostatic and enteric coating. Film forming materials, formulation of coating solution, equipments for coating, Processing problems in coating, evaluation.

**3. Capsules:** Advantages and disadvantages of capsules. Materials and method of production of hard gelatin capsule, size of capsules, Formulation, method of filling, equipments involved, finishing techniques and evaluation. Storage of capsules. Soft gelatin capsules-shell and capsule content, manufacture, processing and control.

#### 4. Sterile products:

a) Injections- classification, routes and volume of administration, methods of production and storage, vehicles-water for injection, non aqueous vehicles. Isotonicity and methods of adjustment of Isotonicity.

b) Formulation details, containers, closures and their selection.

 c) Prefilling treatment, washing of containers and closures-relevant standard operating procedures, preparation of solutions and suspensions, filling and sealing of ampoules and vials. Manufacture of large volume parenterals.
 Equipments for large scale manufacture, quality control tests for parenterals.

d) Lyophilisation and preparation of sterile powders and dry mixtures.

e) Aseptic techniques, source of contamination and methods of prevention, design and maintenance of aseptic area-classification, air handling units, laminar airflow units.

f) Total parenteral nutrition and dialysis fluids.

g) Ophthalmic preparations-ideal requirements, types, components, formulation, methods of preparation, containers, closures and evaluation.

**5.** *Pharmaceutical aerosols*: components, propellants, containers, valves and actuators, types of aerosol systems, manufacture, quality control, pharmaceutical applications.

**6.** Surgical ligatures and sutures, types, Catgut-preparation and standardization. Cotton-absorbent and non absorbent

#### 7. Blood products and plasma.

**8.** Packaging materials. Types of glasses and plastics employed for packing and their evaluation.

**9.** Cosmetics. Introduction, fundamentals of cosmetic science. Formulation, preparation, packaging and evaluation of following Cosmetics:

a) cosmetics for skin and face-vanishing cream, cold cream, face powder.

b) Nail polish, lipstick, rouge

c) Hair preparation-Shampoo, Hair dyes, depilatories, shaving cream, after shave lotion.

d) Oral hygiene preparation-dentifrices, mouth washes.

**10. Controlled drug delivery systems**-Advantages of controlled drug delivery systems.

a) An introduction to novel drug delivery systems- Liposomes, niosomes, nanoparticles and osmotically conrolled systems.

b) Micro encapsulation

c) Transdermal drug delivery systems-Formulation and evaluation.

#### 11. Process validation and performance evaluation

#### 12. Pharmaceutical calculations:

Posology- Calculation of paediatric doses, enlarging and reducing recipes, percentage solutions,

alligations, alcohol dilution, proof spirit.

13 Principles involved and dispensing procedures adopted (Definition, advantages,

disadvantages, ingredients, classification, theory, method (s) of preparation, containers and

packaging, labeling requirements, storage) for prescription of powders, solutions, aromatic

waters, mixtures, emulsions, lotions, liniments, ointments, paints, lozenges, jellies, pastes,

suppositories

14. Extraction and galenical products-Principles and methods of extraction, preparation of infusions, tinctures; Dry, soft and liquid extracts.

## MICROBIOLOGY

1. *Introduction* to the scope of microbiology,Microscopy-compound, dark field, phase contrast, UV, fluorescence and electron microscopy.

2. *Classification* of microbes and bacterial taxonomy. Elementary study of important pathogenic microorganisms, biochemical methods for identification.

a) **Structure** of bacterial cell. Endospores and mechanism of spore formation. L forms. Identification methods of microbes; stains and types of staining techniques.

b) Bacterial Nutrition, cultivation of bacteria. Culture media, its classification with examples. Aerobic and anaerobic culture methods. Isolation of Pure culture.
c) Classification & Structure of Viruses. Cultivation of Viruses, Viral replication.
Virus-Host interactions. Bacteriophages, phage typing. Bacteriocins. d)
Introduction to fungi of Medical and pharmaceutical importance. Fungal reproduction and cultivation.

#### 3. Immunity.

a) Immunological Preparations: Principles, Antigens and Haptens, Immune System, Cellular and Humoral Immunity, Antibodies, Immunological Tolerance. Hypersensitivity. Active and Passive immunization, Vaccines and Sera, their preparation, standardization and storage. Development of Hybridoma for Monoclonal Antibodies.

b) Antigen – Antibody reactions and their applications.

#### 4. Control of microbes by Physical and Chemical methods:

a) Disinfection, factors influencing disinfectants, dynamics of disinfection, Evaluation of Disinfectants. b) Sterilisation- different methods, validation of sterilisation methods and equipments. Sterility testing of pharmaceutical products as per the I P.

## 5 a) Antibiotics: Antimicrobial Spectrum and methods used for standardization. Microbial assay of antibiotics.

b)Fermentation technology; Basic principlsfo fermentation, isolation and screening of industrially important microbes, types of fermentation, downstream process, Fermenter design and control of different parameters. Fermentation process. Screening of soil for organisms producing antibiotics. Extraction of fermentation products with special reference to Penicillin, alcohol, amylase and Vitamin B12.

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