

GOVERNMENT OF NAGALAND  
DIRECTORATE OF HEALTH AND FAMILY WELFARE  
NAGALAND : KOHIMA

SYLLABUS  
of  
Pharmaceutical Sciences  
(As per B. Pharm Regulation 2014)

For  
Direct recruitment to the post of

DRUGS INSPECTORS

Through  
Nagaland Public Service Commission [NPSC]

Prepared & Submitted by

DRUGS CONTROL ADMINISTRATION  
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### **PAPER – I**

<b>SUBJECT</b>	<b>% OF MARK</b>
➤ PHARMACEUTICAL JURISPRUDENCE	40
➤ PHARMACY PRACTICE	10
➤ PHARMACEUTICS	50

### **PAPER – II**

➤ PHARMACEUTICAL INORGANIC CHEMISTRY	10
➤ MEDICINAL CHEMISTRY	40
➤ HUMAN ANATOMY AND PHYSIOLOGY	10
➤ PHARMACOLOGY	40

## PAPER - I

### 1. Pharmaceutical Jurisprudence

- 40%

#### **Drugs and Cosmetics Act, 1940 and its rules 1945:**

Objectives, Definitions, Legal definitions of schedules to the Act and Rules pertaining to Import, Manufacture, Sale of drugs, manufacture of new drug, loan license and repacking license.

#### **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-Powers and functions.

**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

**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. Essential Narcotic Drugs(END)- Provisions under NDPS Rules.

**Drugs and Magic Remedies Act and its rules:** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, 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).

### 2. Pharmacy Practice

- 10%

#### **a) Drug distribution & 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, stocking and distribution, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure.

## **b) 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.

## **c) Introduction to Pharmacovigilance**

History and development, Importance of safety monitoring of Medicine, WHO international drug monitoring programme, Pharmacovigilance Program of India(PvPI), Basic drug information resources, Specialised resources for ADRs

## **3.Pharmaceutics**

- 50%

**Dosage forms:** Introduction to dosage forms, classification and definitions

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

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

**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.

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

**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.

### **Tablets:**

a. 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.

c. Quality control tests: In process and finished product tests

### **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.

**Parenteral Products:**

- a. Definition, types, advantages and limitations. Pre-formulation factors and essential requirements, vehicles, additives, importance of isotonicity.
- b. Production procedure, production facilities and controls, aseptic processing
- c. 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.

**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

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

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

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

**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.

**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.

**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

**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

## PAPER - II

### 1. Inorganic Chemistry

- 10%

**Impurities in pharmaceutical substances:** 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

**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.

#### Gastrointestinal agents

**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

### 2. Medicinal Chemistry

- 40%

**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.

**Sympathomimetic agents: SAR of Sympathomimetic agents.** Direct acting: Epinephrine, Phenylephrine\*, Dopamine, Methyldopa, Clonidine, Terbutaline, Salbutamol, Oxymetazoline and Xylometazoline.

**Alpha adrenergic blockers:** Prazosin, Dihydroergotamine, Methysergide.

**Beta adrenergic blockers:** SAR of beta blockers, Propranolol, Atenolol, Metoprolol, Labetolol, Carvedilol.

**Parasympathomimetic agents: SAR of** Acetylcholine, Carbachol\*, Bethanechol, Methacholine, Pilocarpine, Physostigmine, Neostigmine\*, Pyridostigmine.

### **Drugs acting on Central Nervous System**

#### **A. Sedatives and Hypnotics:**

**Benzodiazepines:** SAR of Benzodiazepines, Chlordiazepoxide, Diazepam, Chlorazepate, Alprazolam.

**Barbiturates:** SAR of barbiturates, Phenobarbital, Amobarbital, Butobarbital, Pentobarbital.

#### **Antipsychotics**

**Phenothiazines:** SAR of Promazine hydrochloride, Chlorpromazine hydrochloride, Thioridazine hydrochloride, Prochlorperazine maleate, Trifluoperazine hcl.

#### **Narcotic and non-narcotic analgesics**

**Morphine and related drugs:** SAR of Morphine sulphate, Codeine, Fentanyl citrate, Methadone hydrochloride, Propoxyphene hydrochloride, Pentazocine,

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

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

#### **Antihistaminic agents:**

**H1-antagonists:** Diphenhydramine hydrochloride, Doxylamines succinate, Diphenylpyraline hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride, Promethazine hydrochloride, Azatidine maleate, Astemizole, Cetirizine.

**H2-antagonists:** Cimetidine\*, Famotidine, Ranitidin.

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

#### **Anti-anginal:**

**Vasodilators:** Amyl nitrite, Nitroglycerin, Isosorbide dinitrite\*, Dipyridamole.

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

**Anti-hypertensive Agents:** Captopril, Lisinopril, Enalapril, Clonidine hydrochloride, Sodium nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.

**Antidiabetic agents:**

Insulin and its preparations, Chlorpropamide, Glipizide, Glimepiride. Metformin, Pioglitazone, Rosiglitazone. Repaglinide, Acarbose, Voglibose.

**Antibiotics**

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

**$\beta$ -Lactam antibiotics:** Penicillin, Cephalosporins,  $\beta$ -Lactamase inhibitors,

**Aminoglycosides:** Streptomycin, Neomycin.

**Tetracyclines:** Tetracycline, Oxytetracycline, Chlortetracycline, Doxycycline

**Macrolide:** Erythromycin, Clarithromycin, Azithromycin.

**Quinolones:** SAR of quinolones, Nalidixic Acid, Norfloxacin, Ciprofloxacin, Ofloxacin, Sparfloxacin, Gatifloxacin.

**Antiviral agents:**

Amantadine hydrochloride, Idoxuridine trifluoride, Acyclovir, Zidovudine, Zalcitabine, Lamivudine, Ribavirin, Saquinavir, Indinavir.

**Antifungal agents:**

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

**Synthetic Antifungal agents:** Clotrimazole, Miconazole, Ketoconazole, Itraconazole, Fluconazole, Tolnaftate.

**Anti-protozoal Agents:** Metronidazole, Tinidazole, Ornidazole, Diloxanide, Iodoquinol,

**Anthelmintics:** Diethylcarbamazine citrate, Mebendazole, Albendazole, Niclosamide.

**Sulphonamides and Sulfones**

Sulfacetamide\*, Sulphapyridine, Sulfamethoxazole, Sulphadiazine, Sulfasalazine.

**Folate reductase inhibitors:** Trimethoprim.

**Antimalarials:**

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

**Biguanides and dihydro triazines:** Cycloguanil pamoate, Proguanil.

**Miscellaneous:** Pyrimethamine, Artesunate, Artemether, Atovaquone.



### **3. Human Anatomy & Physiology, Pathophysiology**

**-10 %**

#### **Introduction to human body**

Definition and scope of anatomy and physiology, levels of structural organization and body systems, basic life processes, homeostasis, basic anatomical terminology.

#### **Cellular level of organization**

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

#### **Tissue level of organization**

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

#### **Integumentary system**

Structure and functions of skin

#### **Skeletal system**

Divisions of skeletal system, types of bone, salient features and functions of bones of axial and appendicular skeletal system. Organization of skeletal muscle, physiology of muscle contraction.

#### **Blood**

Composition and functions of blood, hemopoiesis, formation of hemoglobin, anemia, mechanisms of coagulation, blood grouping, Rh factors, transfusion.

#### **Cardiovascular system**

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

#### **Nervous system**

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

#### **Digestive system**

Anatomy of GI Tract with special reference to anatomy and functions of stomach.

#### **Energetics**

Formation and role of ATP, Creatinine Phosphate and BMR.

#### **Respiratory system**

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

## 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,.

### 4. Pharmacology

- 40 %

#### 1. General Pharmacology

- a. Introduction to Pharmacology- Definition, historical landmarks and scope of pharmacology.
- b. Pharmacokinetics- Membrane transport, absorption, distribution, metabolism and excretion of drugs. Enzyme induction, enzyme inhibition, kinetics of elimination.
- c. Pharmacodynamics- Principles and mechanisms of drug action. Receptor theories and classification of receptors, regulation of receptors. drug receptors interactions, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action.

**Biopharmaceutics to Absorption;** Mechanisms of drug absorption through GIT, factors influencing drug absorption through 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.

**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.

#### 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.

#### 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. Alcohols and disulfiram

#### 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.
- d. Opioid analgesics and antagonists.
- e. Drug addiction, drug abuse, tolerance and dependence

### **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.
- g. Hematinics, coagulants and anticoagulants.
- h. Fibrinolytics and anti-platelet drugs
- i. Plasma volume expanders

### **Pharmacology of drugs acting on urinary system**

- a. Diuretics
- b. Anti-diuretics.

### **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

### **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.

### **Chemotherapy**

- a. General principles of chemotherapy.
- b. Sulfonamides and cotrimoxazole.
- c. Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolins, tetracycline and aminoglycosides
- d.** antitubercular agents
- e. Antifungal agents
- f. Antiviral drugs
- g. Anthelmintics
- h. Antimalarial drugs
- i. Antiamoebic agents