

TAMIL NADU PUBLIC SERVICE COMMISSION

SYLLABUS

PHARMACY, CLINICAL PHARMACOLOGY AND MICRO BIOLOGY

DEGREE STANDARD

CODE:516

UNIT I: (20 Questions)

1) Historical background and development of profession of pharmacy: History of profession of Pharmacy in India in relation to pharmacy education, industry and organization, Pharmacy as a career, Pharmacopoeias: Introduction to IP, BP, USP and Extra Pharmacopoeia.

2) Calculations:

Posology: Pediatric Dose calculations based on age, body weight and surface area.

Pharmaceutical calculations: Percentage solutions, Alligation, Proof spirit and isotonic solutions based on freezing point and molecular weight.

3) Unit Operations: Size reduction, Size separation, Mixing, Filtration, Centrifugation, Evaporation, Drying, Distillation, Heat transfer, Tablet Compression and Tablet coating.

4) Coarse Dispersion:

Suspension, interfacial properties of suspended particles, settling in suspensions, formulation of flocculated and deflocculated suspension. Emulsions and theories of emulsification, micro emulsion and multiple emulsion, stability of emulsions, preservation of emulsions, rheological properties of emulsions and emulsion formation by HLB method.

5) Pre-formulation studies: Introduction to pre-formulation, goals and objectives, study of physicochemical characteristics of drug substances

a. Physical Properties: Crystal & amorphous form, particle size distribution and determination, shape, flow properties, derived properties, solubility profile (Pka, pH, Partition co-efficient) Polymorphism.

b. Chemical properties: Hydrolysis, Oxidation, reduction racemisation, polymerisation.

BCS classification of drugs and its significant

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

6) Pharmaceutical Excipients – Used in Liquid, Semisolids and Solid dosage forms.

7) Quality Control Tests of the following formulations: Oral Solid dosage forms, Semi solids, Oral Liquid dosage forms, Parenteral, Ophthalmic preparation and Pharmaceutical Aerosols.

8) Cosmetics: Formulation and preparation of the following cosmetics preparations- Lipsticks, Shampoos, Cold Cream, Vanishing Cream, Tooth Paste, Hair Dyes, Sunscreens.

9) Packaging Material Sciences: Materials used for packaging of Pharmaceutical products, factors influencing choice of containers, legal and official requirement for containers, Quality control tests for containers and rubber closures.

10) Bio availability and Bioequivalence: Definitions 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 dissolution rates and bioavailability of poorly soluble drugs.

UNIT II: (15 Questions)

1) Pharmacokinetics: Definition and introduction of Pharmacokinetics, Compartment models, Non-compartment models, Physiological models, One compartment open model

a) Intravenous Injection (bolus)

b) Intravenous infusion

c) Extra vascular administrations.

Pharmacokinetic parameters – Elimination rate constant (K_E), Half life ($t_{1/2}$), Volume of distribution (V_d), Area under curve (AUC), Absorption rate constant (K_a), Total body clearance (CL_t) and Renal Clearance (CL_R) – definitions, methods of elimination, understanding of their significance and application.

2) Good manufacturing practices (GMP)

3) Good Laboratory Practices (GLP): Organisation and personnel, Facilities, equipment, Testing facilities operation, Test and control articles, Protocol for conduct of a Nonclinical Laboratory Study, Records and reports, Disqualification of Testing facilities.

4) Warehousing: Good Warehousing practice, Materials Management.

5) Quality management systems: Quality management and certification: 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 system standards, ISO 14000, NABL.

6) Over the counter (OTC) Sales: Introduction and sale of over the counter and Rational use of common over the counter medications.

7) Drug Store Management and Inventory Control: Organisation of Drug Store, types of materials stocked and storage conditions. Purchase and inventory control: Principles, Purchase procedures, Purchase order, Procurement and stocking, Economic order quantity, Reorder quantity level and methods used for the analysis of the drug expenditure.

8) Novel Drug Delivery Systems: Ocular Drug Delivery Systems, Transdermal Drug Delivery Systems, Implantable Newer Drug Delivery Systems, Targeted Drug Delivery and Controlled Drug Delivery Systems.

9) Blood products and Plasma Substitutes: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substitutes

10) Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring. Large scale production fermenter design and its various controls. Study of the production of – Penicillins, Citric acid, Vitamin B12, Glutamic acid, Griseofulvin.

UNIT III: (15 Questions)

GENERAL MICROBIOLOGY & IMMUNOLOGY

1. Morphology, classification and identification of Bacteria, Virus, Fungus & Parasite
2. Normal microbial flora & Bacterial genetics
3. Culture Media & Equipments in Microbiology Laboratory
4. Sterilization and disinfection
5. Testing of Sterilization & disinfection including sterility testing of pharmaceutical products.
6. Bio Safety in Microbiology Laboratory
7. Cultivation of Bacteria
8. Structures, Cells and functions of Immune system
9. The complement system
10. Antigen-Antibody reactions
11. Hypersensitivity
12. Tumour Immunity & Immuno Haematology
13. Immuno Prophylaxis against infectious Diseases

14. Immunotherapy

UNIT IV: (20 Questions)

CLINICAL & APPLIED MICROBIOLOGY

1. C.N.S infections
2. Respiratory Infections
3. Urinary Tract Infections
4. Gastro intestinal Infections
5. Genital Tract Infections
6. Congenital Infections
7. Infections of Eye, Ear & Skin
8. Infections of Cardio vascular System
9. Pyrexia of Unknown Origin (P.U.O)
10. Zoonotic Infections
11. Collection, Transport and Disposal of Specimens
12. Environmental Microbiology (Food, Water, Milk and Air)
13. Microbial Control – anti microbial susceptibility testing
14. Microbiological Assays for Standardisation of Antibiotics and Vitamins
15. Bio medical waste management
16. Emerging and reemerging infections – Bio Terrorism
17. Advanced Molecular Techniques in Relation to Diagnosis of Infectious diseases & Basic molecular biology related to infections
18. Anti microbial resistance and antibiotic policy
19. Newer Vaccines
20. Quality Control, Audit and Accreditation of Standard Microbiology Laboratory.

Unit V: (15 Questions)

- 1)** Atomic structure and valency, Radioactivity, Radio isotopes and Pharmaceutical applications of Radio Pharmaceuticals, hazards and precautions.
- 2)** Sources of impurities in Pharmaceutical substances: Limit test as per I.P; Fundamentals of volumetric Analysis. Errors: Sources, types, methods of minimizing errors, Accuracy, Precision, significant figures.
- 3)** A systematic study of inorganic compounds for their preparation, assay and use which includes Gastrointestinal agents, Topical agents and Dental products.
- 4)** Preparation and use of Chemical reagents and Volumetric Solutions as per Pharmacopeia in Pharmaceutical Analysis.

Unit VI: (25 Questions)

1) Principles and Pharmacopoeial Assay Procedures involving Non-aqueous Titration, Redox, Diazotization, complexometric methods, electrometric titration, gravimetric analysis.

2) Chromatography – Thin Layer Chromatography (TLC), Column, Paper, Gas Chromatography (GC), Ion exchange, High Performance Liquid Chromatography (HPLC), High Performance Thin Layer Chromatography (HPTLC), Gel electrophoresis.

3) Theory, principle, instrumentation and applications of colorimetry, UV-Visible Spectrophotometry, Spectrofluorimetry, Nepheloturbidometry, Infra-Red (IR), Mass, Nuclear Magnetic Resonance (NMR), Radio Immuno Assay (RIA), Polarimetry, Refractometry, Thermal method of analysis – Thermo Gravimetric Analysis (TGA), Differential Scanning Calorimetry (DSC), Differential Thermal Analysis (DTA), Atomic absorption spectroscopy.

4) ICH guidelines – Calibration and validation, calibration of electronic balance, UV spectrophotometer, IR spectrophotometer, Fluorimeter, High Performance Liquid Chromatography (HPLC), Gas Chromatography (GC), Flame photometer.

UNIT VII: (20 Questions)

1) GENERAL PHARMACOLOGY

Sources of drugs, Routes of drug administration, Dosage formulations, Pharmacokinetics, Pharmacodynamics - Good Clinical Practice- Patient compliance, and self medication, Placebo medicines and pharmacoconomics.

Discovery and development of drugs - Preclinical studies in animals - Clinical trials - Official regulatory guidelines.

Orphan drugs, Pharmacovigilance – Pharmacogenetics - Adverse drug reactions and monitoring - Clinical importance of drug interactions (both pharmacokinetic and pharmacodynamic interactions with special reference to antimicrobials, NSAIDs and cardiovascular drugs).

2) DRUGS ACTING ON NERVOUS SYSTEM – CENTRAL NERVOUS SYSTEM

General anaesthetics and Pre anaesthetic medication – Antiepileptics – Sedatives and Hypnotics – Alcohols and disulfiram – Psychopharmacological drugs (Anti-Psychotics, Anti-depressants, anti-anxiety agents, anti-manic and hallucinogens) – CNS Stimulants – Neurodegenerative disorders – Deaddiction – Drugs of abuse, drug tolerance and drug dependence.

3) PERIPHERAL NERVOUS SYSTEM & AUTONOMIC NERVOUS SYSTEM

Neurohumoral transmission in Automatic nervous system, Para Sympathomimetics, Parsympatholytics, Sympathomimetics, Sympatholytics, neuromuscular blocking agents, Skeletal muscle relaxants (peripheral), Local anaesthetic agents, Drugs used in Myasthenia gravis and glaucoma.

4) CARDIOVASCULAR DRUGS

Drugs used in congestive heart failure, Anti-hypertensive drugs, Anti-Anginal Drugs, Anti-arrhythmic drugs, Hypolipidemic Drugs, Drugs used in the therapy of shock.

5) DRUGS ACTING ON HEMOPOEITIC AND RENAL SYSTEM

Haematinics - Coagulants & Anticoagulants - Fibrinolytics & Antifibrinolytics - Antiplatelets- Diuretics.

UNIT VIII: (20 Questions)

1) DRUGS ACTING ON THE GASTRO INTESTINAL SYSTEM

Anti-ulcer agents, Drugs for constipation and diarrhea, appetite stimulants and Suppressants, Digestants and carminatives, Emetics and anti-emetics.

2) DRUGS ACTING ON ENDOCRINE SYSTEM

Anterior pituitary Hormones - Thyroid Hormones - Corticosteroids - Insulin & Oral Hypo glycemic drugs - Male & Female sex Hormones - Oral contraceptives - Uterine stimulants & relaxants.

3) IMMUNOPHARMACOLOGY & AUTACOIDS

Cell and biochemical mediators involved in allergy, immuno modulation and inflammation, hypersensitivity reactions - therapeutic agents for allergy, asthma and COPD - NSAIDs & DMARDs & gout - Antihistamines - Serotonin agonists & Antagonists.

4) CHEMOTHERAPY

General Principles of Chemotherapy, Sulfonamides and co-trimoxazole, Anti-biotics: Penicillins, Cephalosporins, Chloramphenicol, macrolides, Quinolones and fluoroquinolones, tetracycline and amino glycosides, Anti-tubercular agents, Anti-leprotic agents, Anti-fungal agents, Anti-viral drugs, Anthelmintics, Anti-malarial drugs, Anti-amoebic agents, Urinary tract infection and sexually transmitted diseases, Chemotherapy of malignancy.

5) BIO-ASSAY

Principles and applications of Bio-assay, types of bio-assay, bio-assay of insulin, oxytocin, Vasopressin, ACTH, d-tubocurarine, digitalis, histamine and 5HT.

6) MISCELLANEOUS

Vaccines - Dermatological preparations - Chelating Agents.

UNIT IX: (20 Questions)

1) Alphabetical, Morphological, Taxonomical, Chemical and Pharmacological classification of crude drugs.

2) Adulteration and evaluation of drugs of natural origin. WHO guidelines for the assessment of herbal drugs.

3) General introduction, composition, chemistry and chemical classification, general methods of extraction and analysis, bio-sources, therapeutic uses and commercial application of following secondary metabolites.

- a) Alkaloids - Vinca, Rauwolfia, Belladonna, Opium
- b) Steroids, Cardiac Glycosides and Triterpenoids - Liquorice, Dioscorea, Digitalis
- c) Glycosides - Senna, Aloes
- d) Tannins - Black & Pale catechu
- e) Volatile oils - Mentha, Clove, Cinnamon, Fennel, Coriander
- e) Resins - Benzoin, Ginger, Asafoetida, Colophony

4) Isolation, Identification and Analysis of following phytoconstituents

- (i) Terpenoids- Menthol, Citral, Artemisin
- (ii) Glycosides -Glycyrrhetic acid, Rutin
- (iii) Alkaloids - Atropine, Quinine, Reserpine, Caffeine
- (iv) Resins - Podophyllotoxin, Curcumin

5) Homeopathy: Introduction, Basic principles, Preparation and evaluation of Various Dosage forms of homeopathy system of medicine

6) Marine Drugs: Novel Medicinal agent from marine sources.

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

UNIT X: (30 Questions)

1) The Drugs and Cosmetics Act,1940 (As Amended from time to time)

2) The Drugs Rules 1945 (As Amended from time to time)

3) The Cosmetics Rules, 2020 (As Amended from time to time)

- 4)** The Medical Devices Rules, 2017 (As Amended from time to time)
- 5)** The New Drugs and Clinical Trials (NDCT) rules, 2019 (As Amended from time to time)
- 6)** The Drugs (Price Control) Order 2013 (As Amended from time to time)
- 7)** The Pharmacy Act, 1948 (As Amended from time to time)
- 8)** The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 and Rules, 1955 (As Amended from time to time)
- 9)** The Narcotic Drugs and Psychotropic substances Act and Rules, 1985 (As Amended from time to time)

Note: The Medium of Instruction is only in English.

Dated: 20.02.2025