



UPSC

DRUG INSPECTOR SYLLABUS



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SYLLABUS

PHARMACEUTICAL CHEMISTRY

1. Physical Chemistry

- States of matter, intermolecular forces, gases, liquid state, vapour pressure and critical phenomena.
- Thermodynamics, thermochemistry, free energy, entropy, chemical equilibrium and phase rule.
- Solutions, ideal/non-ideal behaviour, colligative properties, solubility and partition law.
- Electrochemistry, conductance, ionic equilibrium, buffers, pH and Nernst equation.
- Chemical kinetics, reaction order, rate constants, activation energy and stability kinetics.

2. Organic Chemistry

- Bonding, hybridisation, resonance, inductive/hyperconjugative effects, acidity/basicity and reactive intermediates.
- IUPAC nomenclature, stereochemistry, optical/geometrical isomerism, conformations and R/S configuration.
- Alkanes, alkenes, alkynes, alcohols, phenols, ethers, halides, carbonyls, carboxylic acids and derivatives.
- Aromaticity; electrophilic/nucleophilic substitution; orientation and reactivity of substituted benzene.
- Heterocyclic chemistry of important N-, O- and S-containing rings used in drugs.
- Named reactions, rearrangements, protection/deprotection, carbohydrates, amino acids and proteins.

3. Pharmaceutical Inorganic Chemistry

- Sources and control of impurities; pharmacopoeial limit tests and elemental impurities.
- Acidifiers, antacids, cathartics, electrolytes, haematinics, expectorants and emetics.
- Topical agents, dental products, antimicrobial inorganic agents and antidotes.
- Official compounds: preparation, identification, purity tests, assay, storage and uses.
- Radioactivity, isotopes, radiopharmaceuticals, diagnostic/therapeutic applications and radiation safety.

4. Medicinal Chemistry

- Drug-receptor interactions, physicochemical properties, pKa, lipophilicity, stereochemistry and drug action.
- SAR, bioisosterism, prodrugs, soft drugs, pharmacophores, QSAR and basic computer-aided drug design.
- Drug metabolism, metabolic soft spots, active/toxic metabolites and enzyme induction/inhibition.
- Chemistry and SAR of autonomic, CNS, cardiovascular, renal, respiratory, GI and endocrine drugs.
- Chemistry and SAR of antimicrobials, antituberculars, antimalarials, antivirals and anticancer drugs.
- For important drugs: synthesis, identification, assay, mechanism, uses and major toxic effects.

5. Pharmaceutical Technology and Dosage Forms

- Pharmacopoeias, monographs, specifications, sampling, reference standards and official test methods.
- Preformulation: solubility, pKa, partition coefficient, polymorphism, particle properties and compatibility.
- Powders, granules, tablets and capsules: formulation, manufacturing, coating, defects and evaluation.
- Solutions, syrups, suspensions, emulsions, semisolids, suppositories and pharmaceutical calculations.
- Sterile products: parenterals, ophthalmics, water systems, aseptic processing, sterilisation and endotoxins.
- Aerosols, inhalers, transdermals, modified-release systems and novel drug-delivery systems.
- Packaging materials, container-closure systems, stability studies, shelf life and storage conditions.

6. Physical Pharmacy

- Micromeritics: particle size, surface area, porosity, density, packing, flow and powder rheology.
- Surface/interfacial tension, adsorption, surfactants, HLB, wetting, detergency and solubilisation.
- Rheology: Newtonian/non-Newtonian flow, thixotropy and pharmaceutical viscometers.
- Colloids, suspensions and emulsions: flocculation, sedimentation, creaming, phase inversion and stability.
- Complexation, buffers, isotonicity, diffusion, dissolution and factors affecting drug solubility.
- Pharmaceutical calculations: concentration expressions, dilution, alligation, isotonicity and dose calculations.

7. Industrial Pharmacy and Pharmaceutical Engineering

- Unit operations: size reduction/separation, mixing, filtration, centrifugation, extraction and crystallisation.
- Drying, evaporation, distillation, heat transfer, fluid flow, mass transfer and psychrometry.
- Major equipment: construction, working, applications, critical variables, cleaning and qualification.
- Pilot plant, scale-up, technology transfer, process optimisation and production planning.
- Utilities: HVAC, water, steam, compressed gases, refrigeration, material handling and waste management.

8. Pharmaceutical Analysis and Quality Control

- Volumetric analysis: acid-base, non-aqueous, redox, precipitation, complexometric and diazotisation titrations.
- UV-Visible, IR, fluorimetry, nephelometry, turbidimetry, polarimetry, refractometry, AAS/ICP, NMR and MS basics.
- TLC/HPTLC, HPLC/UPLC, GC, ion-exchange, size-exclusion and electrophoretic methods.
- Method validation, system suitability, forced degradation, impurity profiling and stability-indicating methods.

- Dissolution, disintegration, content uniformity, microbial assays, sterility, endotoxin and dosage-form tests.

9. Quality Assurance, GMP, GLP, Validation and Data Integrity

PHARMACOLOGY & TOXICOLOGY

10. Pharmacology –

10.1 General Pharmacological Principles

- Introduction and routes of drug administration.
- Pharmacokinetics: membrane transport, absorption and distribution of drugs.
- Pharmacokinetics: metabolism and excretion of drugs; kinetics of elimination.
- Pharmacodynamics: mechanisms of drug action and receptor pharmacology.
- Aspects of pharmacotherapy, clinical pharmacology and drug development.
- Adverse drug effects.

10.2 Drugs Acting on the Autonomic Nervous System

- Autonomic nervous system: general considerations.
- Cholinergic system and drugs.
- Anticholinergic drugs and drugs acting on autonomic ganglia.
- Adrenergic system and drugs.
- Antiadrenergic drugs (adrenergic receptor antagonists) and drugs for glaucoma.

10.3 Autacoids and Related Drugs

- Histamine and antihistaminics.
- 5-Hydroxytryptamine, its antagonists and drug therapy of migraine.
- Prostaglandins, leukotrienes (eicosanoids) and platelet-activating factor.
- Nonsteroidal anti-inflammatory drugs and antipyretic-analgesics.
- Antirheumatoid and antigout drugs.

10.4 Respiratory System Drugs

- Drugs for cough and bronchial asthma.

10.5 Hormones and Related Drugs

- Introduction to hormones and related drugs.
- Anterior pituitary hormones.
- Thyroid hormone and thyroid inhibitors.
- Insulin, oral hypoglycaemic drugs and glucagon.
- Corticosteroids.

- Androgens and drugs for erectile dysfunction.
- Estrogens, progestins and contraceptives.
- Oxytocin and other drugs acting on the uterus.
- Drugs affecting calcium balance.

10.6 Drugs Acting on the Peripheral (Somatic) Nervous System

- Skeletal muscle relaxants.
- Local anaesthetics.

10.7 Drugs Acting on the Central Nervous System

- General anaesthetics.
- Ethyl and methyl alcohols.
- Sedative-hypnotics.
- Antiepileptic drugs.
- Antiparkinsonian drugs.
- Drugs used in mental illness: antipsychotic and antimanic drugs.
- Drugs used in mental illness: antidepressant and antianxiety drugs.
- Opioid analgesics and antagonists.
- CNS stimulants and cognition enhancers.

10.8 Cardiovascular Drugs

- Cardiac electrophysiological considerations.
- Drugs affecting the renin-angiotensin system and plasma kinins.
- Cardiac glycosides and drugs for heart failure.
- Antiarrhythmic drugs.
- Antianginal and other anti-ischaemic drugs.
- Antihypertensive drugs.

10.9 Drugs Acting on the Kidney

- Relevant physiology of urine formation.
- Diuretics.
- Antidiuretics.

10.10 Drugs Affecting Blood and Blood Formation

- Haematinics and erythropoietin.
- Drugs affecting coagulation, bleeding and thrombosis.
- Hypolipidaemic drugs and plasma expanders.

10.11 Gastrointestinal Drugs

- Drugs for peptic ulcer and gastroesophageal reflux disease.

- Antiemetic, prokinetic and digestant drugs.
- Drugs for constipation and diarrhoea.

10.12 Antimicrobial Drugs

- Antimicrobial drugs: general considerations.
- Sulfonamides, cotrimoxazole and quinolones.
- Beta-lactam antibiotics.
- Tetracyclines and chloramphenicol (broad-spectrum antibiotics).
- Aminoglycoside antibiotics.
- Macrolide, lincosamide, glycopeptide and other antibacterial antibiotics; urinary antiseptics.
- Antitubercular drugs.
- Antileprotic drugs.
- Antifungal drugs.
- Antiviral drugs.
- Antimalarial drugs.
- Antiamoebic and other antiprotozoal drugs.
- Anthelmintic drugs.

10.13 Chemotherapy of Neoplastic Diseases

- Anticancer drugs.

10.14 Miscellaneous Drugs

- Immunosuppressant drugs.
- Drugs acting on skin and mucous membranes.
- Antiseptics, disinfectants and ectoparasiticides.
- Chelating agents.
- Vitamins.
- Vaccines and sera.
- Drug interactions.

11. Toxicology and Pharmacovigilance

- Acute, subacute and chronic toxicity; organ toxicity; reproductive toxicity; mutagenicity and carcinogenicity.
- NOAEL, LOAEL, therapeutic index, safety margin, toxicokinetics and risk assessment.
- Poisoning by organophosphates, opioids, sedatives, paracetamol, salicylates, alcohols, metals and corrosives.
- Antidotes, decontamination, supportive care, enhanced elimination and poison-information services.
- ADRs, medication errors, causality assessment, signal detection, PSUR/PBRER and risk-minimisation measures.

12. Pharmacognosy and Phytochemistry

- Classification, cultivation, collection, processing, storage and evaluation of crude drugs.
- Adulteration, quality control, microscopy, quantitative microscopy and pharmacognostic constants.
- Carbohydrates, glycosides, alkaloids, tannins, volatile oils, resins, steroids, terpenoids and flavonoids.
- Extraction, isolation, identification and chromatography of phytoconstituents.
- Important medicinal plants: biological source, family, constituents, uses and substitutes/adulterants.
- Herbal formulations, standardisation, nutraceuticals, traditional systems and herbal-drug interactions.

13. Human Anatomy, Physiology and Health Education

- Cell, tissues, homeostasis and basic anatomical terminology.
- Blood, cardiovascular, lymphatic, respiratory, digestive, urinary and reproductive systems.
- Nervous system, special senses, endocrine system and musculoskeletal system.
- Physiology of blood coagulation, immunity, renal regulation, respiration and gastrointestinal function.
- Nutrition, vitamins, first aid, sanitation, communicable diseases, family planning and public-health programmes.

14. Pathophysiology

- Cell injury, adaptation, inflammation, repair, immunity, hypersensitivity and neoplasia.
- Cardiovascular disorders: hypertension, atherosclerosis, heart failure, shock and ischaemic heart disease.
- Respiratory, renal, hepatic, gastrointestinal and haematological disorders.
- Diabetes, thyroid disorders, obesity, metabolic syndrome and endocrine diseases.
- Neurological and psychiatric disorders; rheumatoid arthritis, gout and osteoporosis.
- Infectious diseases and correlation of pathogenesis with pharmacotherapy.

15. Biochemistry

- Biomolecules: carbohydrates, lipids, proteins, nucleic acids and biological membranes.
- Enzymes, coenzymes, kinetics, inhibition and clinical/diagnostic importance.
- Metabolism of carbohydrates, lipids, amino acids, proteins and nucleotides; bioenergetics and ETC.
- DNA replication, transcription, translation, gene regulation and molecular biology basics.
- Vitamins, minerals, hormones, acid-base balance and organ-function tests.
- Clinical biochemistry, biomarkers, inborn errors and interpretation of common laboratory values.

16. Pharmaceutical Microbiology and Immunology

- Microbial structure, classification, growth, nutrition, genetics and identification.
- Sterilisation, disinfection, antiseptics, preservatives and sterility assurance.
- Microbial contamination, microbial limits, preservative-efficacy testing and environmental monitoring.
- Culture media, staining, biochemical tests, microbiological assay and antibiotic sensitivity.
- Innate/adaptive immunity, antigens, antibodies, complement, hypersensitivity, autoimmunity and immunodeficiency.

- Hospital infections, biosafety, biofilms, antimicrobial resistance and infection control.

17. Biotechnology, Vaccines, Sera and Biological Products

- Recombinant DNA, vectors, hosts, cloning, expression systems, PCR, blotting and genetic engineering.
- Fermentation, cell culture, upstream/downstream processing, purification and process control.
- Monoclonal antibodies, recombinant proteins, enzymes, hormones, biosimilars and advanced therapies.
- Live, killed, toxoid, subunit, conjugate, recombinant, vector, DNA and mRNA vaccines.
- Seed-lot/cell-bank systems, adjuvants, formulation, filling, lyophilisation and cold chain.
- Antisera, antitoxins, immunoglobulins and antivenoms: production, purification, safety and potency testing.
- Biological quality control: identity, potency, sterility, endotoxin, adventitious agents, mycoplasma and lot release.

18. Blood Collection, Components and Blood-Bank Regulation

- Blood-centre licensing, organisation, personnel, premises, equipment, records and quality system.
- Donor selection, consent, deferral, phlebotomy, anticoagulants, donor reactions and apheresis.
- ABO/Rh grouping, antibody screening, cross-match, antiglobulin tests and transfusion-transmitted infection testing.
- Transfusion reactions, haemovigilance, look-back, recall and plasma-fractionation products.

BASIC PRINCIPLES OF BIOPHARMACEUTICS & PHARMACOKINETICS

19. Biopharmaceutics and Pharmacokinetics

- Absorption, distribution, metabolism and excretion; membrane transport and factors affecting bioavailability.
- BCS, dissolution, permeability, food effect, first-pass metabolism and biowaiver concepts.
- One-/two-compartment and non-compartmental analysis; AUC, clearance, volume, half-life and MRT.
- IV bolus, infusion, oral dosing, multiple dosing, accumulation, loading/maintenance dose and steady state.
- Bioavailability/bioequivalence study design, C_{max}, T_{max}, AUC, confidence intervals and BA/BE-centre inspection.
- Nonlinear kinetics, renal/hepatic dose adjustment, TDM, population PK and IVIVC.

LAW, REGULATION AND DRUG INSPECTION

20. Pharmaceutical Jurisprudence and Regulatory Affairs

- Drugs and Cosmetics Act, 1940 and Rules, 1945: definitions, authorities, standards, import, manufacture, sale and distribution.

- Drug Inspector/Government Analyst: qualifications, duties, powers, sampling, seizure, reports, prosecution and evidence.
- Licences, loan/repacking/test licences, records, storage, labelling, prescription-drug sale and exemptions.
- Schedules: C/C(1), F/F(I)/F(II), FF, G, H, H1, J, K, M, M-I, M-II, N, O, P, Q, S, T, U, X and Y.
- New Drugs and Clinical Trials Rules, 2019: permissions, ethics committees, consent, SAE, compensation and BA/BE.
- Pharmacy Act; Drugs and Magic Remedies Act; NDPS Act; Poisons Act; DPCO/NPPA; Medicinal and Toilet Preparations law.
- Regulatory submissions: CTD/eCTD, DMF, product permissions, variations, post-approval changes and pharmacovigilance.

21. Medical Devices and Cosmetics

- Medical Devices Rules, 2017: definitions, Classes A-D, licensing authorities, manufacture, import and sale.
- Quality-management system, essential safety/performance principles, labelling, IVDs and sterile devices.

COMPUTER AND ENGLISH

22. Computer Applications and Digital Systems

- Computer hardware/software, operating systems, files, networking, internet and cybersecurity basics.
- MS Word, Excel and PowerPoint; formulas, sorting/filtering, pivot tables, charts and document control.
- Databases, LIMS, ERP, eQMS, electronic document systems and regulatory submission portals.
- Electronic records, audit trails, user access, electronic signatures, backups and data lifecycle.

23. English Language

- Grammar: tenses, articles, prepositions, subject-verb agreement, voice, narration, clauses and punctuation.
- Vocabulary: synonyms, antonyms, idioms, one-word substitutions and scientific/legal terminology.
- Reading comprehension, inference, précis, summary, sequencing and interpretation of technical passages.
- Error spotting, sentence correction, rearrangement.



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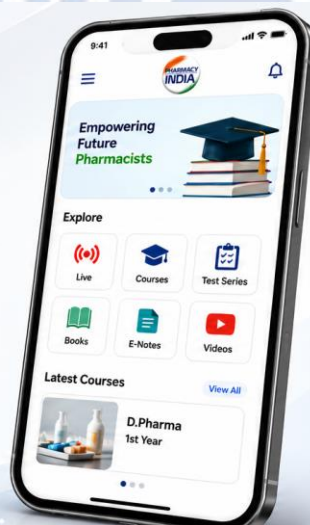


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