

AURCET - 2013
PHARMACY SYLLABUS
PAPER – I

50 MARKS

1. Modern Analytical Techniques

UV SPECTROSCOPY

Theory – Beer and Lambert's law and its limitations – energy levels and selection rules, Woodward-Fieser, Fieser-Kuhn and Nelson rules – Influence of substituent, ring size and strain on spectral characteristics – solvent effect, stereochemical effect – Non-conjugated interactions, spectral correlation with structure – Applications of UV spectroscopy.

HIGH PRESSURE LIQUID CHROMATOGRAPHY

Theory of chromatography – Principle – Instrumentation – Column efficiency (theoretical plates), HETP, selectivity, resolution – Tailing and fronting – Applications and recent trends in chromatography.

2. Biostatistics

Analysis of Variance: 1-way, 2-way and 3-way classification.

Design of Experiments: Principles of randomization, replication and local control; CRD, RBD, LSD- their applications and analysis of data; Factorial Experiments-Principles and applications

3. Quality Assurance and Drug Regulatory Affairs

The concepts of quality assurance, GMP, TQM- Principles and objectives, process control, sources and control of quality variation, statistical quality control, in process quality control, dosage forms control, specifications.

GMP- Schedule M of Drugs and Cosmetics Act, special emphasis on premises, personnel, sanitation, equipment, manufacturing operations and documentation.

Validation: Types of validation, protocol for process validation, cleaning validation, validation of air handling, validation of equipment and facilities in sterile and non-sterile areas. Analytical method validation

ICH for technical requirements for registration of biopharmaceuticals for human use- History and constitution of ICH. ICH guidelines relating to quality, safety, efficacy and multi disciplinary topics.

4. Pharmaceutical Analysis

Spectrophotometric analysis: Basic principles including interaction of matter with electro-magnetic radiation, absorption, emission, luminescence and scattering phenomena, units of measurement and definition of terms: a) absorptiometry: quantitative consideration of absorption phenomena including Beer and Lambert's laws and their mathematical expression, deviations from the laws and methods used in absorption spectrophotometry (visible, UV and IR) including sources, monochromators, detectors, preparation of calibration curves and pharmaceutical applications. Sources of errors and their correction and validation of spectrophotometric methods. B) Basic principles, equipment and methods used and pharmaceutical applications of flame photometry, photofluorimetry, turbidimetry and nephelometry.

5. Pharmaceutical Chemistry

Mechanism of free radical addition, substitution, electrophilic addition and substitution, mechanism of nucleophilic addition and substitution with suitable examples; Mannich reaction, Beckmann rearrangement, Bayer-Villiger oxidation, Oppenauer Oxidation and their applications in organic synthesis.

Methods of isolation, structural elucidation/structural features of alkaloids, cardiac steroids, cholesterol, ergosterol and ergocalciferols.

Introduction, classification, SAR, uses and synthesis (important drugs in each class) as given below: a) Antineoplastic agents. b) Antilipidemic agents. c) Antipsychotics and antidepressants

Prodrugs and soft drugs: Objectives of prodrug design, strategies of designing prodrugs: QSAR-Hansch Analysis and Free-Wilson Analysis: Drug Biotransformations involving Phase-I and Phase-II reactions.

6. Pharmaceutical Technology

Pre – formulation: Objectives – Protocols – Physical, chemical, Micromeritic studies in pre – formulation, stability considerations, drug – excipient compatibility.

A study of the formulation, process and equipment used in the large scale manufacture, evaluation, and quality control of the following dosage forms. (i) Suspensions (ii) Emulsions (iii) Liquid orals (Syrups and Elixirs), (iv) Tablets, (v) Capsules – hard and soft, (vi) semisolids and Parenterals.

Mixing: Solid – solid mixing mechanism of mixing. Mixers: V type, drum, paddle and Rotocube mixers – selection of mixer, mixing of viscous masses: kneading machines and ointment mills. Liquid – liquid and gas – liquid mixing equipment. Impellers – their characteristics and field of operation.

Size reduction : Classification of equipment – cutting roll, edge runner and end runner mills, disintegrators, hammer mills, ball and tube mills, colloid mills – impact mills, fluid energy mill, choice of size reduction machinery

Size separation: Screens and screening equipment – air and hydraulic separators, sedimentation, particle size distribution and its measurement – representation of data.

Biopharmaceutics: Fate of drug after administration, routes of drug administration, drug absorption and disposition. Drug absorption: Oral, Percutaneous, rectal, factors involved, mechanisms and kinetics – a detailed study of physicochemical, biological and dosage form considerations in drug absorption.

Drug dissolution and bioavailability: Concepts, definitions, factors involved, assessment, official methods, applications and significance.

7. **Biotechnology**

Sterilization methods: Moist heat, dry heat, filtration, gaseous and radiation methods. Sterilization indicators. Introduction to test for sterility. Concept of asepsis and maintenance of aseptic conditions.

General principles of antibiotics, clinically useful antibiotics, mode of action, sensitivity tests and antibiotic resistance.

Dynamics of disinfection, merits and demerits of different disinfectants, commonly used disinfectants, their mechanism of action. Evaluation of disinfectants (Rideal Walker and Chick Martin coefficients and their limitations)

8. **Pharmacology**

General Principles of Pharmacology: Definition, agonist, antagonist (reversible & irreversible), Bio-availability, Pharmacokinetic variables: (A) Absorption (B) Clearance (C) Volume of distribution (D) Half-life.

Theories of drug action: Principles of drug action, Ion Channels, Enzymes, Receptors, G-proteins, Second messengers and Interplay among signaling mechanisms. Neurohumoral transmission in Central nervous system and Autonomic nervous system, Autonomic receptor, Therapeutic application of sympathomimetics & sympatholytics and parasymphomimetics & parasympholytics.

Drugs acting on cardiovascular system: Congestive heart failure, Hypertension, Angina pectoris, Diuretics.

Abnormal action of drugs such as tolerance, addiction, habituation, idiosyncrasy, allergy, adverse drug reactions.

Sedatives- Hypnotic Drugs, Opioids, Anti-diabetics, Antipeptic ulcers, Local anesthetics.

9. **Pharmacognosy**

General Pharmacognosy: Advantages and disadvantages of obtaining drugs from cultivated and wild plants. Variability of drug constituents due to exogenous and endogenous factors like altitude, temperature, rain fall, light, propagation by seed vegetative means, mutation, hybridization; Deterioration of crude drugs during storage by insects, pests and enzymes. Factors influencing the storage of crude drugs. Methods of storage.

Evaluation of crude drugs: Identity, purity and quality of crude drugs by organoleptic microscopic, physical, chemical and biological evaluation; Methods of adulteration, detection and identification of adulterants types and significance of standards for crude drugs included in I.P. and B.P. Quantitative pharmacognosy.

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100 MARKS

Pharmacognosy & Phytochemistry: Chemistry of natural products, tests, isolation, purification & characterization and estimation of phytopharmaceuticals belonging to the group of Alkaloids, Glycosides, Terpenoids, Steroids, Bioflavonoids, Purines, lipids, proteins. Pharmacognosy of crude drugs and herbal products. Standardization of raw materials. Modern techniques used for evaluation.

Pharmaceutical Chemistry: Structure, nomenclature, classification, synthesis, SAR and metabolism of the following category of drugs, which are official in Indian Pharmacopoeia and British Pharmacopoeia. Introduction to drug design. Stereochemistry of drug molecules. Hypnotics and Sedatives, Analgesics, NSAIDS, Neuroleptics, Antidepressants, Anxiolytics, Anticonvulsants, Antihistaminics, Local Anaesthetics, Cardio Vascular drugs - Antianginal agents Vasodilators, Adrenergic & Cholinergic drugs, Cardiotonic agents, Diuretics, Antihypertensive drugs, Hypoglycemic agents, Antileptic agents, Coagulants, Anticoagulants, Antiplatelet agents. Chemotherapeutic agents - Antibiotics, Antibacterials, Sulphadugs. Antiparasitic drugs, Antiviral, Antitubercular, Antimalarial, Anticancer, Antiamoebic drugs. Diagnostic agents..

Pharmaceuticals:

Formulation, Development and Storage of different dosage forms and new drug delivery systems. Biopharmaceutics and Pharmacokinetics and their importance in Pharmaceutical calculations. Study of physical properties of drugs: Particle size and shape, pKa, solubility, partition coefficient, crystallinity, polymorphism and hygroscopicity. Study of chemical properties of drugs: Hydrolysis, oxidation, reduction, racemization, polymerization and their influence on formulation and stability of drug products.

Pharmacology General pharmacological principles including Toxicology. Drug interaction and Pharmacology of drugs acting on Central nervous system, Cardiovascular system, Autonomic nervous system, Gastro intestinal system and Respiratory System Pharmacology of Autocoids, chemotherapeutic agents including anticancer drugs, Bioassays, Immuno Pharmacology. Drugs acting on the blood & blood forming organs. Clinical Pharmacy Therapeutic Drug Monitoring Dosage regimen in Renal and hepatic impairment. Drug - Drug interactions and Drug -food interactions, Adverse Drug reactions. Medication History, interview and Patient counseling

Pharmaceutical Analysis and quality assurance:

Concepts of qualitative and quantitative analysis, fundamentals of volumetric analysis, methods-of expressing concentration, primary and secondary standards; concept of error, precision, accuracy, specificity, sensitivity, detection limit, linearity and range. Ruggedness, standards, standardization, calibration of analytical equipments. Principles, instrumentation and applications of the following: Absorption spectroscopy (UV, visible &IR). Fluorimetry, Flame photometry, Potentiometry. Conductometry and Polarography. Pharmacopoeial assays and chromatography methods. Quality assurance and quality control methods, concepts of GMP and GLP and forensic pharmacy.