Pharmdbm

Bpharm 7th Semester Syllabus

INSTRUMENTAL METHODS OF ANALYSIS

UNIT 1

UV-Visible Spectroscopy
Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, derivation and deviations.
Instrumentation: sources of radiation, wavelength selectors, sample cells, detectors—photo tubes, photomultiplier tubes, photovoltaic cells, silicon photodiodes.
Applications: spectrophotometric titrations, single-component, and multi-component analysis.

Fluorimetry
Theory, concepts of singlet, doublet, and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching.
Instrumentation: factors affecting fluorescence, quenching, and applications.

UNIT 2

IR Spectroscopy
Introduction, fundamental modes of vibrations in polyatomic molecules, sample handling, factors affecting vibrations.
Instrumentation: sources of radiation, wavelength selectors, detectors—Golay cell, bolometer, thermocouple, thermistor, pyroelectric detector and applications.

Flame Photometry
Principle, interferences, instrumentation, and applications.

Atomic Absorption Spectroscopy
Principle, interferences, instrumentation, and applications.

Nepheloturbidometry
Principle, instrumentation, and applications.

UNIT 3

Introduction to Chromatography
Adsorption and partition column chromatography: Methodology, advantages, disadvantages, and applications.

Thin Layer Chromatography
Introduction, principle, methodology, Rf values, advantages, disadvantages, and applications.

Paper Chromatography
Introduction, methodology, development techniques, advantages, disadvantages, and applications.

Electrophoresis
Introduction, factors affecting electrophoretic mobility, techniques of paper, gel, capillary electrophoresis, and applications.

UNIT 4

Gas Chromatography
Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages, and applications.

High-Performance Liquid Chromatography (HPLC)
Introduction, theory, instrumentation, advantages, and applications.

UNIT 5

Ion Exchange Chromatography
Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology, and applications.

Gel Chromatography
Introduction, theory, instrumentation, and applications.

Affinity Chromatography
Introduction, theory, instrumentation, and applications.

INDUSTRIAL PHARMACY-II

UNIT 1

Pilot Plant Scale-Up Techniques
General considerations, including the significance of personnel requirements, space requirements, and raw materials. Pilot plant scale-up considerations for solids, liquid

orals, semi-solids, and relevant documentation. SUPAC guidelines and an introduction to platform technology.

UNIT 2

Technology Development and Transfer

WHO guidelines for Technology Transfer (TT): Terminology, technology transfer protocol, quality risk management, transfer from R&D to production (process, packaging, and cleaning). Granularity of TT process (API, excipients, finished products, packaging materials). Documentation, premises and equipment, qualification and validation, quality control, analytical method transfer. Approved regulatory bodies and agencies. Commercialization: Practical aspects and problems (case studies). TT agencies in India: APCTD, NRDC, TIFAC, BCIL, TBSE/SIDBI. TT-related documentation: Confidentiality agreement, licensing, MoUs, legal issues.

UNIT 3

Regulatory Affairs

Introduction, historical overview of Regulatory Affairs, regulatory authorities, role of Regulatory Affairs department, responsibility of Regulatory Affairs professionals.

Regulatory Requirements for Drug Approval

Drug development teams, non-clinical drug development, pharmacology, drug metabolism, and toxicology. General considerations of Investigational New Drug (IND) application, Investigator's Brochure (IB), and New Drug Application (NDA). Clinical research/BE studies, clinical research protocols, biostatistics in pharmaceutical product development, data presentation for FDA submissions, and management of clinical studies.

UNIT 4

Quality Management Systems

Quality management & certifications: Concept of quality, Total Quality Management (TQM), 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, and GLP.

UNIT 5

Indian Regulatory Requirements

Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, responsibilities, Certificate of Pharmaceutical Product (COPP), regulatory requirements, and approval procedures for new drugs.

PHARMACY PRACTICE

UNIT 1

a) Hospital and its organization
Definition, classification of hospital—Primary, Secondary, and Tertiary hospitals, classification based on clinical and non-clinical basis, organization structure of a hospital, and medical staff involved in the hospital and their functions.

b) Hospital pharmacy and its organization
Definition, functions of hospital pharmacy, organization structure, location, layout, and staff requirements, and responsibilities and functions of hospital pharmacists.

c) 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.

d) Community Pharmacy
Organization and structure of retail and wholesale drug stores, 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 stores.

UNIT 2

a) Drug distribution system in a hospital
Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labeling, dispensing of drugs to ambulatory patients, and dispensing of controlled drugs.

b) Hospital formulary
Definition, contents of hospital formulary, differentiation of hospital formulary and drug list, preparation and revision, and addition and deletion of drugs from hospital formulary.

c) Therapeutic drug monitoring
Need for therapeutic drug monitoring, factors to be considered during the therapeutic drug monitoring, and Indian scenario for therapeutic drug monitoring.

d) Medication adherence
Causes of medication non-adherence, pharmacist's role in medication adherence, and monitoring of patient medication adherence.

e) Patient medication history interview
Need for the patient medication history interview, medication interview forms.

f) Community pharmacy management
Financial, materials, staff, and infrastructure requirements.

UNIT 3

a) Pharmacy and therapeutic committee
Organization, functions, policies of the pharmacy and therapeutic committee including drugs into formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation.

b) Drug information services
Drug and poison information center, sources of drug information, computerized services, and storage and retrieval of information.

c) Patient counseling
Definition of patient counseling; steps involved in patient counseling, and special cases that require the pharmacist.

d) Education and training program in the hospital
Role of pharmacist in the education and training program, internal and external training program, services to nursing homes/clinics, code of ethics for community pharmacy, and role of pharmacist in interdepartmental communication and community health education.

e) Prescribed medication order and communication skills
Prescribed medication order – interpretation and legal requirements, and communication skills – communication with prescribers and patients.

UNIT 4

a) Budget preparation and implementation
Budget preparation and implementation.

b) Clinical Pharmacy
Introduction to Clinical Pharmacy, concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, drug therapy monitoring – medication chart review, clinical review, pharmacist intervention, ward round participation, medication

history, and pharmaceutical care.
Dosing pattern and drug therapy based on pharmacokinetics & disease pattern.

c) Over the counter (OTC) sales
Introduction and sale of over the counter medications, and rational use of common over-the-counter medications.

UNIT 5

a) Drug store management and inventory control
Organization of drug store, types of materials stocked and storage conditions.
Purchase and inventory control: principles, purchase procedure, purchase order, procurement, and stocking, Economic order quantity, reorder quantity level, and methods used for the analysis of drug expenditure.

b) Investigational use of drugs
Description, principles involved, classification, control, identification, role of hospital pharmacist, and advisory committee.

c) Interpretation of Clinical Laboratory Tests
Blood chemistry, hematology, and urinalysis.

NOVEL DRUG DELIVERY SYSTEMS

UNIT 1

Controlled drug delivery systems:
Introduction, terminology/definitions, and rationale.
Advantages, disadvantages, and 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.

Polymers: Introduction, classification, properties, advantages, and applications of polymers in the formulation of controlled release drug delivery systems.

UNIT 2

Microencapsulation:
Definition, advantages, and disadvantages.
Microspheres/microcapsules, microparticles.
Methods of microencapsulation.
Applications.

Mucosal Drug Delivery System: Introduction, principles of bioadhesion/mucoadhesion. Concepts, advantages, and disadvantages.
Transmucosal permeability and formulation considerations of buccal delivery systems.

Implantable Drug Delivery Systems: Introduction, advantages, and disadvantages. Concept of implants and osmotic pump.

UNIT 3

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

Gastroretentive Drug Delivery Systems: Introduction, advantages, disadvantages. Approaches for GRDDS: Floating, high-density systems, inflatable and gastroadhesive systems, and their applications.

Nasopulmonary Drug Delivery System: Introduction to nasal and pulmonary routes of drug delivery. Formulation of inhalers (dry powder and metered dose), nasal sprays, nebulizers.

UNIT 4

Targeted Drug Delivery: Concepts and approaches, advantages and disadvantages. Introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications.

UNIT 5

Ocular Drug Delivery Systems: Introduction, intraocular barriers and methods to overcome—Preliminary study, ocular formulations, and ocuserts.

Intrauterine Drug Delivery Systems: Introduction, advantages and disadvantages, development of intrauterine devices (IUDs), and applications.