

SEMESTER VII
BP701T.INSTRUMENTALMETHODSOFANALYSIS(Theory)

45Hours

Scope: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart fundamental knowledge on the principles and instrumentation of spectroscopic and chromatographic technique. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

Objectives: Upon completion of the course the students shall be able to

1. Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis
2. Understand the chromatographic separation and analysis of drugs.
3. Perform quantitative & qualitative analysis of drugs using various analytical instruments

Course Content:

UNIT-I

10Hours

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- Phototube, Photomultiplier tube, Photovoltaic cell, Silicon Photodiode.

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 and applications

UNIT-II

10Hours

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, Thermister, Pyroelectric detector and applications

Flame Photometry- Principle, interferences, instrumentation and applications

Atomic absorption spectroscopy-
Principle, interferences, instrumentation and applications

Nephelometry- Principle, instrumentation and applications

UNIT-III

10Hours

Introduction to chromatography

Adsorption and partition column chromatography-
Methodology, advantages, disadvantages and applications.

Thin layer chromatography-
Introduction, Principle, Methodology, R_f 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, applications

UNIT-IV

08Hours

Gas chromatography - Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications

High performance liquid chromatography (HPLC)- Introduction, theory, instrumentation, advantages and applications.

UNIT-V

07Hours

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

BP702T.INDUSTRIAL PHARMACYII(Theory)

45Hours

Scope: This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market

Objectives: Upon completion of the course, the students shall be able to:

1. Know the process of pilot plant and scale up of pharmaceutical dosage forms
2. Understand the process of technology transfer from lab scale to commercial batch
3. Know different Laws and Acts that regulate pharmaceutical industry
4. Understand the approval process and regulatory requirements for drug products

Course Content:

UNIT-I

10Hours

Pilot plant scale up techniques: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology

UNIT-II

10Hours

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 equipments, 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-III

10Hours

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, Management of Clinical Studies.

UNIT-IV**08Hours**

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

UNIT-V**07Hours**

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.

Recommended Books: (Latest Editions)

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http://en.wikipedia.org/wiki/Regulatory_Affairs.
2. International Regulatory Affairs Updates, 2005. available at <http://www.iraup.com/about.php>
3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
4. Regulatory Affairs brought by learning plus, inc. available at <http://www.cgmp.com/ra.htm>.

BP703T.PHARMACY PRACTICE(Theory)

45Hours

Scope: In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. In community

pharmacy, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling for improved patient care in the community set up.

Objectives: Upon completion of the course, the students shall be able to

1. know various drug distribution methods in a hospital
2. appreciate the pharmacy stores management and inventory control
3. monitor drug therapy of patient through medication chart review and clinical review
4. obtain medication history interview and counsel the patients
5. identify drug related problems
6. detect and assess adverse drug reactions
7. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states
8. know pharmaceutical care services
9. do patient counselling in community pharmacy;
10. appreciate the concept of Rational drug therapy.

Unit I:

10Hours

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 staffs 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 Adversedrugreactionreportingand management.

d) Community Pharmacy

Organization and structure of retail and wholesale drug store, types and design, Legalrequirementsforestablishmentandmaintenanceofadrugstore,Dispensingofproprieta ryproducts, maintenanceof records ofretailandwholesaledrugstore.

UnitII:

10Hours

a) Drugdistribution system in ahospital

Dispensingofdrugsto inpatients,typesofdrugdistributionsystems,chargingpolicyandlabell ing,Dispensingofdrugstoambulatorypatients,andDispensingofcontrolledrugs.

b) Hospitalformulary

Definition, contents of hospital formulary, Differentiation of hospital formulary andDrug list, preparation and revision, and addition and deletion of drug from hospitalformulary.

c) Therapeuticdrugmonitoring

NeedforTherapeuticDrugMonitoring,FactorstobeconsideredduringtheTherapeuticDrug Monitoring,andIndianscenarioforTherapeuticDrugMonitoring.

d) Medicationadherence

Causesofmedicationnon- adherence,pharmacistroleinthemedicationadherence,andmonitoringofpatientmedication adherence.

e) Patientmedicationhistoryinterview

Needfor the patient medicationhistoryinterview,medicationinterviewforms.

f) Communitypharmacymanagement

Financial,materials,staff,andinfrastructurerequirements.

UnitIII:

10Hours

a) Pharmacyandtherapeuticcommittee

Organization,functions,Policiesofthepharmacyandtherapeuticcommitteeincludingdrug sintoformulary,inpatientandoutpatientprescription,automaticstoporder,andemergencydr uglisterpreparation

Druginformationservice:

Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.

Patient counseling

Definition of patient counseling; steps involved in patient counseling, and Special cases that require the pharmacist

b) Education and training program in the hospital

Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education.

c) Prescribed medication order and communications skills

Prescribed medication order- interpretation and legal requirements, and Communications skills- communication with prescribers and patients.

Unit IV

8 Hours

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 Pharmacokinetic & disease pattern.

c) Over the counter (OTC) sales

Introduction and sale of over the counter, and Rational use of common over the counter medications.

Unit V

7 Hours

a) Drug 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 and stocking, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure

b) Investigational use of drugs

Description, principles involved, classification, control, identification, role of hospital pharmacist, advisory committee.

c) Interpretation of Clinical Laboratory Tests

Blood chemistry, hematology, and urinalysis

Recommended Books (Latest Edition):

1. Merchant S.H. and Dr. J.S. Quadry. *A text book of hospital pharmacy*, 4th ed. Ahmadabad: B.S. Shah Prakakshan; 2001.
2. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. *A text book of Clinical Pharmacy Practice- essential concepts and skills*, 1st ed. Chennai: Orient Longman Private Limited; 2004.
3. William E. Hassan. *Hospital pharmacy*, 5th ed. Philadelphia: Lea & Febiger; 1986.
4. Tipnis Bajaj. *Hospital Pharmacy*, 1st ed. Maharashtra: Career Publications; 2008.
5. Scott LT. *Basic skills in interpreting laboratory data*, 4th ed. American Society of Health System Pharmacists Inc; 2009.
6. Parmar N.S. *Health Education and Community Pharmacy*, 18th ed. India: CBS Publishers & Distributors; 2008.

Journals:

1. Therapeutic drug monitoring. ISSN: 0163-4356
2. Journal of pharmacy practice. ISSN: 0974-8326
3. American journal of health system pharmacy. ISSN: 1535-2900 (online)
4. Pharmacy times (Monthly magazine)

BP704T:NOVEL DRUG DELIVERY SYSTEMS(Theory)

45Hours

Scope: This subject is designed to impart basic knowledge on the area of novel drug delivery systems.

Objectives: Upon completion of the course students shall be able

1. To understand various approaches for development of novel drug delivery systems.
2. To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation

Course content:

Unit-I

10Hours

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

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

Unit-II

10Hours

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-III

10Hours

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-IV

08Hours

Targeted drug Delivery: Concepts and approaches, advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications

Unit-V

07Hours

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

Recommended Books:(Latest Editions)

1. YW.Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J.R., Lee V.H.L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim
4. N.K.Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P. Vyas and R.K. Khar, Controlled Drug Delivery- concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

Journals

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian Drugs (IDMA)
3. Journal of Controlled Release (Elsevier Sciences)
4. Drug Development and Industrial Pharmacy (Marcel & Decker)
5. International Journal of Pharmaceutics (Elsevier Sciences)

BP705P.INSTRUMENTALMETHODSOFANALYSIS(Practical)

4Hours/Week

- 2 Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
- 3 Estimation of dextrose by colorimetry
- 4 Estimation of sulfanilamide by colorimetry
- 5 Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy
- 6 Assay of paracetamol by UV-Spectrophotometry
- 7 Estimation of quinine sulfate by fluorimetry
- 8 Study of quenching of fluorescence
- 9 Determination of sodium by flame photometry
- 10 Determination of potassium by flame photometry
- 11 Determination of chlorides and sulphates by nepheloturbidometry
- 12 Separation of amino acids by paper chromatography
- 13 Separation of sugars by thin layer chromatography
- 14 Separation of plant pigments by column chromatography
- 15 Demonstration experiment on HPLC
- 16 Demonstration experiment on Gas Chromatography

Recommended Books(Latest Editions)

1. Instrumental Methods of Chemical Analysis by B. K. Sharma
2. Organic spectroscopy by Y. R. Sharma
3. Textbook of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Textbook of Quantitative Chemical Analysis by A. I. Vogel
5. Practical Pharmaceutical Chemistry by A. H. Beckett and J. B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein