TECHNO INDIA UNIVERSITY
WESTBENGAL

B.PHARM SYLLABUS

SEMESTER –VII

Instrumental methods of analysis – Theory (TIU-UBP-701T)
Credit points-4

Course Outcomes

On completion of this course, the students will be able to

CO1	**Understand** the interaction of matter with electromagnetic radiations through UV visible spectroscopy and fluorimetry and its applications in drug analysis.	K2
CO2	**Demonstrate** the analysis of drugs through flame photometry, IR spectroscopy, atomic absorption spectroscopy	K2
CO3	**Analyze** the chromatographic separation and analysis of drugs	K4
CO4	**Apply** gas chromatography and HPLC in quantitative & qualitative analysis of drugs	K3
CO5	**Describe** gel and ion exchange chromatography in quantitative & qualitative analysis of drugs	K2

Course Content

UNIT-I

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 tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode.

Applications - Spectrophotometric titrations, Single component and multi component. Analysis

Fluorimetry

Theory, Concepts of singlet, doublet and triplet electronic Describes, internal and external conversions, factors affecting fluorescence, quenching, instrumentation andapplications

UNIT-II

IR spectroscopy

Introduction, fundamental modes of vibrations in poly atomic molecules, samplehandling, factors affecting vibrations

Instrumentation - Sources of radiation, wavelength selectors, detectors - Golaycell,Bolometer, Thermocouple, Thermistor, Pyroelectric detector and applications

Flame Photometry-Principle, interferences, instrumentation and applications

Atomic absorption spectroscopy- Principle, interferences, instrumentation andapplications

Nepheloturbidometry- Principle, instrumentation and applications

UNIT-III

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, Techniquesof paper, gel, capillary electrophoresis, applications

UNIT-IV

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

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

Instrumental methods of analysis – Practical (TIU-UBP-705P)
Credit points-2

Course Outcomes

On completion of this course, the students will be able to

CO1	**Understand** the interaction of matter with electromagnetic radiations and its applications in	**K2**

	drug analysis.	
CO2	**Understand** the chromatographic separation and analysis of drugs	**K2**
CO3	**Describe** quantitative & qualitative analysis of drugs using various analytical instruments	**K2**
CO4	**Demonstrate** operation of HPLC	**K3**
CO5	**Demonstrate** operation of gas chromatography	**K3**

Course Content

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

Industrial Pharmacy II – Theory (TIU-UBP-702T)
Credit points-4

Course Content

Unit – I

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

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

Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatoryauthorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs ProfessionalsRegulatory 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

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

Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and Describe Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

Pharmacy practice –Theory (TIU-UBP-703T)
Credit points-4

Course Outcomes

Upon completion of the course, the student shall be able

CO1	**Describe** the importance of the process of pilot plant and scale up of pharmaceutical dosage forms.	K2

CO2	**Identify** the various process of technology transfer from lab scale to commercial batch.	K3
CO3	**Examine** regulatory requirements for drug approval in pharma industry	K4
CO4	**Explain** different Laws and Quality management systems that govern pharmaceutical industry	K2
CO5	**Demonstrate** the different approval process and regulatory requirements for drug products in India.	K2

Course Content

UNIT-I

Hospital and it's organization

Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals,
Classification based on clinical and non- clinical basis, Organization Structure of aHospital, and Medical staffs involved in the hospital and their functions.

Hospital pharmacy and its organization

Definition, functions of hospital pharmacy, Organization structure, Location, Layoutand staff requirements, and Responsibilities and functions of hospital pharmacists.

c) Adverse drug reaction

Classifications - Excessive pharmacological effects, secondary pharmacologicaleffects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicityfollowing 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 Adversedrug reaction reporting and management.

Community Pharmacy

Organization and structure of retail and wholesale drug store, types and design, Legalrequirements for establishment and maintenance of a drug store, Dispensing ofproprietary products, maintenance of records of retail and wholesale drug store.

UNIT-II

Drug distribution system in a hospital

Dispensing of drugs to inpatients, types of drug distribution systems, charging policyand labelling, Dispensing of drugs to ambulatory patients, and Dispensing ofcontrolled drugs.

Hospital formulary

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

Therapeutic drug monitoring

Need for Therapeutic Drug Monitoring, Factors to be considered during theTherapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring.

Medication adherence

Causes of medication non-adherence, pharmacist role in the medication adherence,and monitoring of patient medication adherence.

Patient medication history interview

Need for the patient medication history interview, medication interview forms.

Community pharmacy management

Financial, materials, staff, and infrastructure requirements.

UNIT-III

Pharmacy and therapeutic committee

Organization, functions, Policies of the pharmacy and therapeutic committee inincluding drugs into formulary, inpatient and outpatient prescription, automatic stoporder, and emergency drug list preparation.

Drug information services

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

Patient counselling

Definition of patient counseling; steps involved in patient counseling, and Specialcases that require the pharmacist.

Education and training program in the hospital

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

Prescribed medication order and communication skills

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

UNIT IV

Budget preparation and implementation: Budget preparation and implementation

Clinical Pharmacy

Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions andresponsibilities of clinical pharmacist, Drug therapy monitoring - medication chartreview, clinical review, pharmacist intervention, Ward round participation, Medicationhistory and Pharmaceutical care.

Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern.

Over the counter (OTC) sales

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

UNIT V

Drug store management and inventory control

Organisation of drug store, types of materials stocked and storage conditions, Purchaseand inventory control: principles, purchase procedure, purchase order, procurementand stocking, Economic order quantity, Reorder quantity level, and Methods used forthe analysis of the drug expenditure

Investigational use of drugs

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

Interpretation of Clinical Laboratory Tests

Blood chemistry, hematology, and urinalysis

Novel Drug Delivery System-Theory (TIU-UBP-704T)
Credit points-4

Course Outcomes

Upon completion of the course, the student shall be able:

CO1	I**dentify** the various approaches that help in designing the controlled and sustained release dosage forms.	K3
CO2	**Summarize** about microencapsulation, Mucosal Drug Delivery System and Implantable Drug Delivery System	K2
CO3	**Summarize** about Transdermal, Gastroretentive and Nasopulmonary drug delivery system	K2
CO4	**Identify** the Concepts and various approaches of Targeted drug delivery system	K3
CO5	**Compare** Ocular and Intrauterine Drug delivery system.	K2

Course content:

UNIT-I

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

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 implantsand osmotic pump

UNIT-III

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

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

Unit-V

Ocular Drug Delivery Systems: Introduction, intra ocular barriers and methods to overcome – Preliminary study, ocular formulations and ocuserts

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