NIRMA UNIVERSITY
Institute of Pharmacy

(B. Pharm)
(Semester - VII)

L	T	P	C
3	1	-	4

Course Code	**BP701T**
Course Title	**Instrumental Methods of Analysis – Theory**

Scope:

This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart a 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 student 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 Learning Outcomes (CLO):

At the end of the course, students will be able to –

1. Describe the fundamentals of UV Visible spectroscopy and Fluorimetry, its instrumentation and applications
2. Understand principle, instrumentation and applications of IR spectroscopy, Atomic Spectroscopy and Nepheloturbidometry
3. Explain basic theories and applications of conventional chromatographic methods
4. Apply knowledge of GC and HPLC for evaluation of pharmaceutical compounds
5. Discuss theory, instrumentation and application of ion exchange, gel and affinity chromatography

Syllabus: **Teaching hours**: **45 Hours**

UNIT I **10 Hours**

- **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 states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications

UNIT II **10 Hours**

- **IR spectroscopy**
  Introduction, fundamental modes of vibrations in poly atomic 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
- **Nepheloturbidometry**- Principle, instrumentation and applications

UNIT III **10 Hours**

- **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 **08 Hours**

- **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 **07 Hours**

- **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

Suggested Readings^: (Latest edition)

1. Sharma, B. K. Instrumental methods of chemical analysis. Krishna Prakashan Media.
2. Sharma, Y. R. Elementary organic spectroscopy. S. Chand Publishing.
3. Connors, K. A. A textbook of pharmaceutical analysis. John Wiley & Sons.
4. Vogel, A. I., & Jeffery, G. H. Vogel's textbook of quantitative chemical analysis. Wiley.
5. Beckett, A. H., & Stenlake, J. B. (Eds.). Practical Pharmaceutical Chemistry: Part I & II. A&C Black.
6. Finar, I. L. Organic Chemistry. Wiley.
7. Kemp, W. Qualitative organic analysis: spectrochemical techniques. McGraw-Hill Book Co Ltd.

8. Garratt, D. C. The quantitative analysis of drugs. Springer Science & Business Media.
9. Sethi, P. D. Quantitative analysis of drugs in pharmaceutical formulations. Unique Publishers.
10. Silverstein, R. M., Bassler, G. C., & Morrill, T. C. Spectrometric Identification of Organic Compounds, John Wiley& Sons. Inc., New York.

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L	T	P	C
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Course Code	**BP702T**
Course Title	**Industrial Pharmacy II -Theory**

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 student should 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 Learning Outcomes (CLO):
At the end of the course, students will be able to -

1. Define criteria for the pilot plant scale up and SUPAC guidelines for post approval changes.
2. Understand technology transfer process, parameters and documentation.
3. Describe regulatory requirements for drug approval process and licensing of pharmaceutical drugs.
4. Explain various concept used for quality management systems.
5. Correlate regulatory requirement for product approval in India and abroad.

Syllabus:

Teaching hours: **45**

Hours

UNIT I

10

Hours

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

10 Hours

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

10 Hours

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

8 Hours

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

UNIV – V

7 Hours

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

Tutorials

Teaching Hours: 15 Hours

Tutorials will be based on above syllabus.

Suggested Readings^: (Latest edition)

1. International Regulatory Affairs Updates, 2005. available at http://www.iraup.com/about.php
2. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
3. Regulatory Affairs brought by learning plus, inc. available at http.//www.cgmp.com/ra.htm.

(B. Pharm.)

(Semester - VII)

L	T	P	C
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Course Code	**BP703T**
Course Title	**Pharmacy Practice – Theory**

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 counseling for improved patient care in the community set up.

Objectives:

Upon completion of this course the student should 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 counseling in community pharmacy.
10. Appreciate the concept of rational drug therapy.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Recall about hospital pharmacy, community pharmacy and adverse drug reaction.
2. Outline the drug distribution system in a hospital, hospital formulary and therapeutic drug monitoring, budget preparation and implementation, clinical pharmacy and over the counter (OTC) sales.
3. Summarize pharmacy and therapeutic committee, drug information services, patient counseling, education and training program in the hospital as well as prescribing medication order.
4. Explain drug store management and inventory control, investigational use of drugs, as well as interpretation of clinical laboratory tests.
5. Elaborate medication adherence, interviewing patient medication history and community pharmacy management.

Syllabus: **Teaching hours: 45 Hours**

UNIT I **10 Hours**

Hospital and its organization- Definition, classification of hospital- primary, secondary and tertiary hospitals, classification based on clinical and non-clinical basis, organization as well as structure of a hospital and medical staffs involved in the hospital and their functions.

Hospital pharmacy and its organization- Definition, functions of hospital pharmacy, organization of structure, location, layout and staff requirements, as well as responsibilities and functions of hospital pharmacists.

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, as well as reporting and management of adverse drug reaction.

Community Pharmacy- Organization and structure of retail and wholesale drug store, 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 store.

UNIT II **10 Hours**

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.

Hospital formulary - Definition, contents of hospital formulary, differentiation of hospital formulary and drug list, preparation and revision, as well as addition and deletion of drug from hospital formulary.

Therapeutic drug monitoring - Need for therapeutic drug monitoring, factors to be considered during the therapeutic 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 and medication interview forms.

Community pharmacy management- Financial, materials, staff, and infrastructure requirements.

UNIT III **10 Hours**

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

Drug information services- Drug and poison information centre, sources of drug information, computerized 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.

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.

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

UNIT IV **08 Hours**

Budget preparation and implementation- Budget preparation and implementation.

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.

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

UNIT V **07 Hours**

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 the drug expenditure.

Investigational use of drugs- Description, principles involved in classification, control, identification, role of hospital pharmacist, advisory committee.

Interpretation of Clinical Laboratory Tests- Blood chemistry, hematology, and urinalysis

Tutorials Teaching hours: 15

Tutorials will be based on above syllabus

Suggested Readings: (Latest Edition)

1. Merchant S. H., Quadry J. S., A textbook of hospital pharmacy. B. S. Shah Prakashan, Ahmedabad.
2. Parthasarathi G., Nyfort-Hansen K., Nahata M. C., A textbook of Clinical Pharmacy Practice- Essential concepts and skills. Orient Longman Private Limited, Chennai.
3. William E. H., Hospital pharmacy. Lea & Febiger, Philadelphia.
4. Bajaj T., Hospital Pharmacy. Career Publications, Maharashtra.
5. Scott L. T., Basic skills in interpreting laboratory data. American Society of Health System Pharmacists Inc, USA.
6. Parmar N. S., Health Education and Community Pharmacy. CBS Publishers & Distributers, Ahmedabad.
7. Journals:
    a) Therapeutic drug monitoring. ISSN: 0163-4356, David Myers, Philadelphia.
    b) Journal of pharmacy practice. ISSN: 0974-8326, Association of Pharmaceutical Teachers of India, Lucknow.
    c) American journal of health system pharmacy. ISSN: 1535-2900, American Society of Health-System Pharmacists, USA.

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(B. Pharm)
(Semester - VII)

L	T	P	C
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Course Code	**BP704T**
Course Title	**Novel drug delivery systems -Theory**

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

Objectives:
Upon completion of the course the student should be able to:
1. Understand various approaches for development of novel drug delivery systems.
2. Understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation

Course Learning Outcomes (CLO):
At the end of the course, students will be able to -
1. Identify various approaches for controlled release formulations based on diffusion, dissolution and ion exchange principles.
2. Understand mucoadhesion, microencapsulation and osmotic system
3. Explain topical, oral and intranasal delivery of the formulations
4. Describe and select polymer for controlled release formulations
5. Apply the concept of nanotechnology for targeted drug delivery
6. Design ophthalmic formulations and intrauterine devices

Syllabus:

Teaching hours: **45 Hours**

UNIT I **10 Hours**

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 **10 Hours**

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 **10 Hours**

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 **8 Hours**

Nanotechnology and its Concepts: Concepts and approaches for targeted drug delivery systems, advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications

UNIT – V **7 Hours**

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

Tutorials **Teaching Hours: 15 Hours**

Tutorials will be based on above syllabus.

Suggested Readings^: (Latest edition)

1. Chien, Y.W. *Novel Drug Delivery Systems*. Marcel Dekker, Inc., New York, USA.
2. Robinson, J. R., & Lee V. H. L. *Controlled Drug Delivery Systems.* Marcel Dekker, Inc., New York, USA.
3. Edith M. *Encyclopedia of Controlled Delivery*, Wiley Interscience Publication, John Wiley and Sons Inc., New York, USA.
4. Jain, N.K. *Controlled and Novel Drug Delivery*. CBS Publishers & Distributors, New Delhi, India.
5. Vyas, S.P., & Khar, R.K. *Controlled Drug Delivery -concepts and advances.* Vallabh Prakashan, New Delhi, India.

Journals

1. Indian Journal of Pharmaceutical Sciences
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)

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(B. Pharm)
(Semester - VII)

L	T	P	C
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Course Code	**BP705P**
Course Title	**Instrumental Methods of Analysis – Practical**

Course Learning Outcomes (CLO):
After successful completion of the course student will be able to-

1. Perform quantitative & qualitative analysis of drugs using spectroscopic techniques.
2. Perform quantitative & qualitative analysis of drugs using chromatographic techniques.
3. Detect the compounds like amino acids, sugars and plant pigments by chromatographic techniques

4 Hours/Week

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

Suggested Readings^: (Latest edition)

1. Sharma, B. K. Instrumental methods of chemical analysis. Krishna Prakashan Media.
2. Sharma, Y. R. Elementary organic spectroscopy. S. Chand Publishing.
3. Connors, K. A. A textbook of pharmaceutical analysis. John Wiley & Sons.
4. Vogel, A. I., & Jeffery, G. H. Vogel's textbook of quantitative chemical analysis. Wiley.

5. Beckett, A. H., & Stenlake, J. B. (Eds.). Practical Pharmaceutical Chemistry: Part I & II. A&C Black.
6. Finar, I. L. Organic Chemistry. Wiley.
7. Kemp, W. Qualitative organic analysis: spectrochemical techniques. McGraw-Hill Book Co Ltd.
8. Garratt, D. C. The quantitative analysis of drugs. Springer Science & Business Media.
9. Sethi, P. D. Quantitative analysis of drugs in pharmaceutical formulations. Unique Publishers.
10. Silverstein, R. M., Bassler, G. C., & Morrill, T. C. Spectrometric Identification of Organic Compounds, John Wiley& Sons. Inc., New York.

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