Subject Code PH108701	Instrumental Method of Analysis-Theory	L=3	T =1	P =0	Credits= 4
Evaluation Scheme	ESE	CT	TA	Total	ESE Duration
	75	15	10	100	3 Hours

Course Objective	Course Outcomes
This course is designed to impart fundamental knowledge on pharmaceutical product Commercialization from laboratory to market	**CO1** Summarize the interaction of matter with electromagnetic radiations and its applications in drug analysis. **CO2** Demonstrate the chromatographic separation and analysis of drugs. **CO3** Relate quantitative & qualitative analysis of drugs using various analytical instruments. **CO4** Experiment on modern analytical instruments that are used for drug testing.

UNIT –I **10 Hours**

UV Visible spectroscopy

Electronic transitions, chromophores, auxochromes, spectral shifts, the 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 andapplications

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, 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, 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

Text Books:

S.No.	Title	Authors	Edition	Publisher
1	Intrumental Method of chemical analysis	Gurdeep k. Chatwal	5th edition	Himalaya Publishing house

Reference books:

S. No.	Title	Authors	Edition	Publisher
1	Intrumental Method of chemical analysis	B. K. Sharma	26th edition	Goel Publishing house
2	Intrumental Method of analysis	Willard Merritt	7th edition	CBS Publishers & Distributors

Subject Code PH108791	Instrumental Method of Analysis-Practical	L=3	T =1	P =0	Credits= 4
Evaluation Scheme	ESE	CT	TA	Total	ESE Duration
	75	15	10	100	3 Hours

Course Objective	Course Outcomes
This course is designed to impart fundamental knowledge on pharmaceutical product Commercialization from laboratory to market	**CO1** Summarize the interaction of matter with electromagnetic radiations and its applications in drug analysis. **CO2** Demonstrate the chromatographic separation and analysis of drugs. **CO3** Relate quantitative & qualitative analysis of drugs using various analytical instruments. **CO4** Experiment on modern analytical instruments that are used for drug testing.

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 nephelo turbidometry
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

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Text Books:

S.No.	Title	Authors	Edition	Publisher
1	Pharmaceutical Analysis	Dr. A. V. Kasture Dr. S. G. Wadodkar	19th edition	Nirali Prakashan

Reference books:

S. No.	Title	Authors	Edition	Publisher
1	Elementry organic spectroscopy	Y. R. Sharma	4th edition	S. Chand & company

Subject Code PH108702	Industrial Pharmacy – Theory	L=3	T =1	P =0	Credits= 4
Evaluation Scheme	ESE	CT	TA	Total	ESE Duration
	75	15	10	100	3 Hours

Course Objective	Course Outcomes
Upon completion of the course, the student 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 in India and US 4. Understand the approval process and regulatory requirements for drug products	On successful completion of the course, the student will be able to: **CO1:-**To judge the process and scale up technique of pilot plant . **CO2:-**To investigate the process of technology transfer from laboratory scale to commercial scale. **CO3:-**To appraise different laws and acts that regulate pharmaceutical industry in India and US. **CO4:-**To select and study various approval process and regulatory requirement for drug products.

UNIT I **10Hrs**

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, SUPACguidelines, Introduction to Platform technology

UNIT –II **10Hrs**

Technology development and transfer: WHO guidelines for Technology Transfer: Terminologies, Technology transfer protocol, Quality risk management, Transfer from R& D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packing materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (cases tudies), TOT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; Technology of Transfer (TOT) related documentation - confidentiality agreements, licensing, MoUs, legal issues

UNIT – III **10Hrs**

Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatoryauthorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals Regulatory requirements for drug approval: Drug Development Teams, Non-ClinicalDrug 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 **8Hrs**

Quality management systems: Quality management & Certifications: Concept ofQuality,Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications(OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO14000, NABL, GLP

UNIT – V **7Hrs**

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

Text Books:

S.No.	Title	Authors	Edition	Publisher
1	A Text Book Of Industrial Pharmacy -II	Gunjan Jeswani Swarnali Das Paul, Shilpi Prasad	I st Edition	Birla Publication
2	Lachman Liebermans The Theory And Practice Of Industrial Pharmacy	Khar R.K	Fourth Edition	CBS Publication
3	Remington The Science & Practice Of Pharmacy	Remington	Twenty-First Edition	Lippincott Williams and Wilkins

Reference books:

S. No.	Title	Authors	Edition	Publisher
1	FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics	Edited By Douglas J. Pisano, David S. Mantus	Second Edition	CRC Press
2	Lachman Liebermans The Theory And Practice Of Industrial Pharmacy	Khar R.K	Fourth Edition	CBS Publication
3	Remington The Science & Practice Of Pharmacy	Remington	Twenty-First Edition	Lippincott Williams and Wilkins

Subject Code PH108703	Pharmacy Practice- Theory	L=3	T =1	P =0	Credits= 4
Evaluation Scheme	ESE	CT	TA	Total	ESE Duration
	75	15	10	100	3 Hours

Course Objective	Course Outcomes
In the changing scenario of pharmacy practice in India, for the 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.	**CO1** To judge the management of pharmacy store and inventory control. **CO2** To judge patient therapy through medication chart review and clinical review. **CO3** To appraise the concept of rational drug therapy. **CO4** To judge and interpret selected laboratory results (as monitoring results in therapeutics) of specific disease state.

Unit I: **10 Hours**

a) Hospital and its organization

Definition, Classification of thehospital- 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, 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 Adverse drug reaction reporting and management.

d) 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 theretail and wholesale drug store.

Unit II: **10 Hours**

a) Drug distribution system in a hospital

Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, 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 the drug 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 role in the 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 III: **10 Hours**

a) 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.
b) Drug information services
Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.
c) Patient counseling
Definition of patient counselling; steps involved in patient counselling, 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 the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the 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 IV **8 Hours**
a)Budgetpreparation and implementation
Budget preparation and implementation
b) Clinical Pharmacy
Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of aclinical pharmacist, Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care.
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, haematology, and urinalysis

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Text Books:

S.No.	Title	Authors	Edition	Publisher
1	Pharmacy Practice	K.G. Revikumar	1st edition	Career Publication

Reference books:

S. No.	Title	Authors	Edition	Publisher
1	Principle of Pharmacy Practice	Dr. Ramandeep Singh	1st edition	S. Vikas and Company

Subject Code PH108704	Novel Drug Delivery System- Theory	L=3	T =1	P =0	Credits= 4
Evaluation Scheme	ESE	CT	TA	Total	ESE Duration
	75	15	10	100	3 Hours

Course Objective	Course Outcomes
Upon completion of the course student shall be ableto understand various approaches for the development of novel drug delivery systems. To understand the criteria for selection of drugs and polymers for the development tof Novel drug delivery systems, their formulation and evaluation	**CO1** To develop approaches for development of novel drug delivery systems. **CO2** To make criteria for selection of drugs and polymers for the development of delivering system **CO3** To formulate and evaluate Novel drug delivery systems **CO4** To select and study various approaches for development of novel drug delivery system.

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 polymerism the 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 gastro adhesive systems and their applications

Nasopulmonary drug delivery system: Introduction to Nasal and Pulmonary routes ofdrug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers

Unit-IV **08 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 **07 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

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Text Books:

S.No.	Title	Authors	Edition	Publisher
1	Controlled and Novel Drug Delivery	N.K. Jain	First edition 1997	CBS Publishers & Distributors
2	Controlled Drug Delivery -concepts and advances,	S.P. Vyas and R.K. Khar	First edition 2002	Vallabh Prakashan,

Reference books:

S. No.	Title	Authors	Edition	Publisher
1	Novel Drug Delivery Systems	Y W. Chien	2 nd edition	Marcel Dekker
2	Controlled Drug Delivery Systems	Robinson, J. R., Lee V. H. L,	1st Edition	Marcel Dekker
3	Encyclopedia of Controlled Delivery	James. G.Boylan	1996	Marcel Dekker Inc New York

Subject code PH108705	Pharmaceutical Quality Assurance – Theory	L=3	T =1	P =0	Credits= 4
Evaluation Scheme	ESE	CT	TA	Total	ESE Duration
	75	15	10	100	3 Hours

Course Objective	Course Outcomes
Upon completion of the course student shall be able to understand the cGMP aspects of a pharmaceutical industry appreciate the importance of documentation understand the scope of quality certifications applicable to pharmaceutical industries understand the responsibilities of QA & QC departments	**CO1-** To understand the importance of quality in pharmaceutical product. **CO2-** The factors affecting the quality of pharmaceutical is explored. **CO3**- The various documentation processes is highlighted to the student. **CO4-** The students are explored into importance of Good practices such as GMP, GLP etc.

UNIT – I **10 Hours**

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP

Total Quality Management (TQM): Definition, elements, philosophies

ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM,with special emphasis on Q-series guidelines, ICH stability testing guidelines

Quality by design(QbD): Definition, overview, elements of QbD program, tools

ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration

NABL accreditation : Principles and procedure

UNIT - II **10 Hours**

Organization and personnel: Personnel responsibilities, training, hygiene and personal records.

Premises: Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

Equipment and raw materials: Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

UNIT – III **10 Hours**

Quality Control: Quality control test for containers, rubber closures and secondary packing materials.

Good Laboratory Practices: General Provisions, Organization and Personnel, Facilities,Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities

UNIT – IV **08 Hours**

Complaints: Complaints and evaluation of complaints, Handling of return well, recalling andwaste disposal.

Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula, Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

UNIT – V **07 Hours**

Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation.

Warehousing: Good warehousing practice, materials management

Text Books:

S.No.	Title	Authors	Edition	Publisher
1	Quality assurance & quality management in pharmaceutical industry	Y anjaneyulu & R. marayya	1st	Pharma book and syndicate

Reference books:

S. No.	Title	Authors	Edition	Publisher
1	Pharmaceutical Quality assurance	Dr. Swarnali das paul & Mrs. Gunjan Jeswani	3rd	S. vikas and company medical publishers

Subject Code PH108792	Practice School	L=3	T =1	P =0	Credits= 4
Evaluation Scheme	ESE	CT	TA	Total	ESE Duration
	75	15	10	100	3 Hours

In the VII semester, every candidate shall undergo practice school for a period of 150hours evenly distributed throughout the semester. The student shall opt any one of the domains for practice school declared by the program committee from time to time. At the end of the practice school, every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages). Along with the exams of semester VII, the report submitted by the student, knowledge and skills acquired by the student through practice school shall be evaluated by the subject experts at college level and grade point shall be awarded.