M.Pharm (Industrial Pharmacy)

I SEMESTER	Theory	Practical
1. Pharmaceutical Formulation Technology	3	9
2. Bio Pharmaceutics & Pharmacokinetics	3	9
3. Quality Assurance (optional)	3	-
4. Pharmaceutical Production Management	3	-

II SEMESTER

5. Novel Drug Delivery Systems-I	3	9
6. Novel Drug Delivery Systems-II	3	9
7. Pharmaceutical Equipment	3	-
8. Regulatory Affairs (optional)	3	-

III SEMESTER

Comprehensive Viva-voce
Seminar on Dissertation Topic (Project Work) (Introductory)

IV SEMESTER

Final Seminar of Dissertation (Results)
Dissertation

I - PHARMACEUTICAL FORMULATION TECHNOLOGY

1. **Performulation studies:**

   a) Goals of performulation, preformulation parameters, Methodology, Solid state Properties, Solubility and Partition coefficient, Solubility, Drug excipient Compatibility.

   b) Excipients used in pharmaceutical dosage forms:

   c) Properties and selection criteria for various excipients like surfactant, viscosity Promoters, diluents, coating materials, plasticizers, preservatives, flavors and Colours.

2. **Formulation Development:**

   a) Solid dosage forms: Improved production techniques for tablets: New materials, process, equipments improvements, high shear mixers, compression machines, coating machines, coating techniques in tablet technology for product development , physics of tablet compression, computerization for in process quality control of tablets, types of tablets and their manufacture. Formulations, production and evaluation of hard and soft gelatin capsules.

   b) Powder dosage forms: Formulation development and manufacture of powder dosage form for internal and external use including inhalation dosage forms.

   c) Liquid and Semi-solid dosage forms: Recent advances in formulation aspects and manufacturing of monophasic dosage forms. Recent advances in formulation aspects and manufacturing of suspensions, dry syrups and semi-solid dosage forms.

   d) Parenteral dosage forms: Advances in materials and production techniques, filling machines, sterilizers and aseptic processing. Manufacturing of small and large volume parenterals and quality control.

   e) Aerosols: Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers and formulation aspects in aerosol formulation, Manufacture and quality control.

   f) Aseptic processing operation: Introduction, contamination control, microbial environmental monitoring, microbiological testing of water, Microbiological air testing, characterization of aseptic process, media and incubation condition, theoretical evaluation of aseptic operations.

   Practicals: Based on Theory

II. Bio Pharmaceutics & Pharmacokinetics:

1. Bio-availability, Bioequivalence and Therapeutic equivalence: Designing of bioavailability studies and interpretation of results. Tests of significance, Test, ANOVA.

2. Physico-Chemical properties affecting bioavailability, pH-partition theory, dissolution, surface area, adsorption, complexation, polymorphism etc., and techniques of enhancing dissolution rate.

3. Formulation factors affecting bioavailability of drug in dosage forms of tablets, capsules, Parenterals, liquid orals and topical dosage forms.

4. Basic concepts of Pharmacokinetics: Compartmental models: one, two and non compartmental approaches to pharmacokinetics. Recent trends, merits and limitation of these approaches. Application of these models to determine the various pharmacokinetic parameters pertaining to:

    i. Absorption: (wherever applicable) Absorption rate constant. Absorptiion half life, lag time and extent of absorption, AUC.
    ii. Distribution: Apparent volume of distribution and its determination.
    iii. Metabolism: Metabolic rate constant and its determination.
    iv. Elimination: Over all apparent elimination rate constant and half life.

    Under the following conditions:

    a) Intra venous bolus injection
    b) Intra venous infusion
    c) Single dose oral administration
    d) Multiple dose injections
    e) Multiple dosage oral administration

    v. Non invasive methods of estimating pharmacokinetic parameters with emphasis on salivary and urinary compartments.
    vi. Concept of clearance: Organ clearance, total clearance, hepatic clearance, gut wall clearance, lung clearance and renal clearance.

5. Non-linear Pharmacokinetics: concepts of linear and non linear pharmacokinetics, Michaelis-Menten kinetic characteristics. Basic kinetic parameters, possible causes of non induction, non linear binding, non linearity of pharmacological response.

6. Non compartmental Pharmacokinetics.

7. Time dependent Pharmacokinetics: Introduction, classification, physiologically induced time dependency: Chrono Pharmacokinetics.

8. Clinical Pharmacokinetics: Altered kinetics in pregnancy, child birth, infants and geriatrics, liver, and renal diseased states.

Practicals: Based on Theory.

III. Quality Assurance:

1. **Plant Design:** Design of manufacturing facility as per current good manufacturing practices for the bulk production of different pharmaceutical dosage forms.

2. **Equipment Validation:** Installation, validation and maintenance of typical equipment used in bulk manufacture of pharmaceutical dosage forms with reference to GMP requirement.

3. **Process Validation:** Regulatory basis, validation of solid dosage forms, liquid dosage forms, and sterile products, Process validation of raw materials, validation of analytical methods.

4. **Quality Control:** Process controls involved in manufacturing process of pharmaceutical dosage forms, statistical quality control charts and its applications in process control. Testing programme and methods for testing quality of pharmaceutical dosage forms. Adulteration and misbranding.

5. **Stability studies:** ICH guidelines and stability protocols for different pharmaceutical dosage forms.

6. **Industrial Safety:** Industrial hazards due to fire accidents, mechanical and electrical equipment, chemicals and pharmaceuticals. Monitoring and prevention systems.

7. **Applications of optimization techniques:** Optimization parameters, statistical design and techniques in product development and evaluation. Production optimization and its importance.

IV. Pharmaceutical Production Management:

1. Pilot Plant Scale-up techniques significance, Pilot study of some important dosage forms like tablets, capsules, sustained release dosage forms and liquid orals. Discussion of parameters like formula, equipment, product uniformity, raw material processing, physical layouts, personal requirements and reporting responsibilities.

2. Production, Planning, Control and documentation: Production scheduling, forecasting, Render development, Capacity assessment, Production management, Production organization, Productivity, guide to manufacturing facilities of tablets, liquid orals and capsules.

3. Human resource Development: Personnel training, job specification, job enlargement, labour welfare and training. Business leadership.

4. Pharma Promotion Management, Strategic issues in Pharma marketing, consumer behaviour in pharmaceuticals, market research, sales management, Brand management, supply chain management.

V - Novel Drug Delivery Systems - I

1. **Review of Fundamentals of controlled drug delivery systems:**
   Fundamentals, rationale of sustained/controlled drug delivery, factors influencing the design and performance of sustained/controlled release products, Pharmacokinetic/ Pharmacodynamic basis of controlled drug delivery. Types and structure of polymers, Use of polymers and biocompatible polymers in controlled release of active agents.
2. **Drug targeting principles and approaches:** Active and passive targeting, Tumor targeting, Bone marrow targeting, cell surface biochemistry and molecular basis of targeting. Tumourbiology-Extra cellular matrix- knowledge of cell adhesion molecules- selectins and fibronectins -lectins for tumour targeting.

   Monoclonal antibodies and engineered antibodies for drug delivery. Antibody-drug conjugates, Limitations of antibody targeting.

   Brain targeting, Blood brain barrier, structure, role in drug transport, targets for targeting.

   Receptor-structure, endocytosis, receptor mediated endocytosis and transcytosis.

   Knowledge of drug targeting through chemical drug delivery approaches to different organs like brain, eye, lung and lever etc. Colon specific systems.

3. Transdermal drug delivery systems, Iontophoresis, Electroporation and Microneedles, Gastro Retentive Drug Delivery System, orodispersible tablets Dendrimers.

4. **Design and fabrication of controlled release drug delivery system:**
   Principle involved and formulation of: Oral dosage forms – Diffusion system, Reservoir devices, Osmotic systems, Systems utilizing dissolution and ion exchange resins, prodrugs, Multiple Emulsions.

5. Parenteral dosage forms, intramuscular injections, implantable therapeutic systems, Transmucosal systems and mucoadhesive systems, Nasal delivery, intravaginal and intrauterine systems, Lung delivery systems. Ocular drug delivery, drug delivery to GIT.

6. **Carrier Based Delivery Systems:** Principle involved and formulation of Micro particulate drug carriers, Liposomes, Niosomes, Microspheres, Magnetic microspheres, Nanoparticles. Reseaeed erythrocytes.

Practicals: Based on theory

VI - NOVEL DRUG DELIVERY SYSTEMS – II

1. Cell membranes, epithelial barriers of Drug absorption and physiological factors affecting oral bioavailability.

    a. Plasma membrane – Phospholipids bilayer, membrane modulation of fluidity, models proteins.
    b. Epithlia – cell junctions – structure and role in drug absorption.
    c. Transport across cell membranes – efflux transporter systems (multi drug resistance).

2.

    a) Inter cellular routes of absorption, persorption.
    b) M cells and peyer's patches in GIT, mucus – structure and composition.
    c) Permeation enhancers – classification and mode of action.
    d) Lymphatic transport of drugs.

3. **Nucleic acid based therapeutic delivery systems:** Gene therapy, introduction (ex vivo & in-vivo gene therapy) potential target diseases for gene therapy (inherited disorder and cancer), gene expression system (viral & non viral gene transfer), gene delivery systems (liposomal),biodistribution and pharmacokinetics. Clinical applications. Knowledge of therapeutic antisense molecules and aptamers as drugs of future.

4. **Genomics, Proteomics:** Definitions of genomics and proteomics and Bioinformatics. Brief Knowledge of Human genome project Pharmacogenomics-genetic Polymorphisms influencing drug disposition and effect on drug response.

5. **Delivery of peptides and proteins Biotechnology based drugs: -** Formulation as pects. Preformulation studies and problems: Protectants, delivery kinetics. Overview of delivery systems, site specific proteins, Stability problems, Evaluation of recombinant proteins. Knowledge of engineered proteins-techniques of getting engineered Proteins by r-DNA technology. Insulin derivatives like- Lispro, tissue plasminogen activator like reteplase. Antibodies, derivatives of antibodies, Myelotarg, Herceptin, and Absciximab (Reopro).

6. **Vaccine Delivery:** Evidence and mechanism of uptake and transport of antigens. Delivery systems used to promote uptake. Absorption enhancers, Lipid carrier systems, oral immunization, peyer's patches, common mucosal immune system, controlled release micro particles for vaccine development, single dose vaccine delivery systems using biodegradable polymers. Knowledge of peptide based and nucleic acid based vaccines. Antigen adjutants in vaccine formulations.

Practicals: Based on Theory

VII - Pharmaceutical Equipment:

Installation, Validation, Maintenance and working of the following:

1) **Tablet Machines**: Rotary tablet, Multi punch
2) **Coating Equipment**: Pans, fluidized bed
3) **Dryers**: Freeze, spray, fluidized bed and tray dryer
4) **Granulators**: Rapid mixer, extruder-spheronizer
5) **Mixers/Milling**: Planetary, double cone, triple roller mill, colloidal mill
6) **Filters:** Plate and frame press, membrane filters, air filtration system (Laminar flow) and Aseptic Room
7) **Sterilization:** Autoclave
8) **Homogenizers** and High Pressure Homogenizer

VIII - Regulatory Affairs

1. New Drug Application: Steps involved in the development of a new drug. Procedure for submission of new drug application (NDA) and abbreviated NDA. Requirements and guidelines on clinical trials for import and manufacture of drug products as per Drugs and Cosmetics act. Clinical trials, study design, documentation and interpretation.

2. Documentation: Importance of documentation, statutory requirement and procedure for documentation, description of documents generated in manufacure of pharmaceutical dosage form.

3. Current good manufacturing practices (CGMP) as per WHO.

4. Good laboratory practices (GLP)

5. ISO 9000 series, GATT, TQM

6. Intellectual property rights and Patent laws in India

Kakatiya University

List of Equipment Required for M. Pharm. Industrial Pharmacy

1) Digital Disintegration Time apparatus	1.No
2) Dissolution apparatus (U.S.P.) with 8 flasks with paddles and baskets	1.No
3) Mini Rotary Tablet Machine 6/8 station	common
4) Hardness Testers Pfizer, Monsanto, advanced digital	1 each
5) Advanced screw guage digital	1.No
6) Top loading Electronic balance 0.1mg sensitivity	1.No
7) U.V spectrophotometer	1.No
8) Moisture determination apparatus digital	common
9) Stability Chambers	common
10) Deep freezer	common
11) Centrifuge digital with 3000-4000 rpm	1.No
12) Digital Micropipettes variable volume 20-200µl	1.No
13) Digital Micropipettes variable volume 100-1000µl	1.No
14) High Performance liquid Chromatograph with UV detector and soft ware	additional
15) Sonicator water bath	1.No
16) Probe Sonicator	1.No
17) Research Microscope with photographic arrangement	1.No
18) Rheometer with software preferably Brooke field	common
19) Oven Thermostatic	1.No
20) Refrigerator	1.No
21) Electronic Top loading balance 1 mg sensitivity	1.No
22) PH meter digital	common
23) Vacuum Oven	1.No
24) Freeze dryer	optional
25) Spray dryer	optional
26) I.R Press	1.No
27) All glass distilled water still	1.No
28) Tensile strength apparatus	optional
29) Cooling Centrifuge	optional
30) Rotary flash evaporator Buchi/Hidolf	1.No
31) Homogenizer high pressure	1.No
32) Magnetic stirrer cum hot plate with digital display	3.Nos
33) Vortex mixer	1.No
34) Mixer	1.No
35) Aseptic cabinet	optional 1.No
36) Gel electrophoresis	optional 1.No
37) Gel documentation system	optional 1.No
38) Injection pump	optional 1.No
39) Coating pan with speed regulator, hot & cold air& spraying device	1.No
40) Diffusion Cells (Franz/Chin type)	6.No
41) Peristaltic pump	1.No
42) Zeta sizer if both branches are available	1.No
43) Sicve shaker digital with set of sieves	1.No
44) Tray dryer	1.No