M.Pharm Syllabus

Semester 02

Industrial Pharmacy

Subjects

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MIP201T - Advanced Biopharmaceutics and Pharmacokinetics

Theory

Unit 1

- Drug Absorption From The Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting, pH-partition theory, Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

Unit 2

- Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance: Introduction, Biopharmaceutic Factors Affecting Drug Bioavailability, Rate-Limiting Steps in Drug Absorption, Physicochemical Nature of the Drug Formulation Factors Affecting Drug Product Performance, In Vitro: Dissolution and Drug Release Testing, Compendial Methods of Dissolution, Alternative Methods of Dissolution Testing, Meeting Dissolution Requirements, Problems of Variable Control in Dissolution Testing Performance of Drug Products: In Vitro-In Vivo Correlation, Dissolution Profile Comparisons, Drug Product Stability, Considerations in the Design of a Drug Product.

Unit 3

- Pharmacokinetics: Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model-IV bolus, IV infusion, Extra-vascular; Multi Compartment model: Two compartment - model in brief, Non-Linear Pharmacokinetics: Cause of non-linearity, Michaelis - Menten equation, Estimation Kmax and Vmax. Drug interactions: Introduction, The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters.

Unit 4

- Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability, , Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Evaluation of the Data, Bioequivalence Example, Study Submission and Drug Review Process, The Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products),Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution.

Unit 5

- Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Relationship between Pharmacokinetics including Pharmacodynamics: Generation of a pharmacokinetic-pharmacodynamic (PKPD) equation, Pharmacokinetic and pharmacodynamic, interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs: Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy),Gene therapies.

MIP202T - Scale Up and Technology Transfer

Theory

Unit 1

- Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parentral and semisolid preparations.
- Scale up: Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parentral, NDDS products - stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology

Unit 2

- Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vender qualification.

Unit 3

- Equipment Qualification: Importance, IQ, OQ, PQ for equipments - autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine. Aseptic room validation.

Unit 4

- Process validation: Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.

Unit 5

- Industrial safety: Hazards - fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution.

MIP203T - Pharmaceutical Production Technology

Theory

- Improved Tablet Production: Tablet production process, unit

Unit 1

- operation improvements, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments.
- Problems encountered.
- Coating Technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

Unit 2

- Parenteral Production: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.

Unit 3

- Lyophilization & Spray drying Technology: Principles, process, freeze-drying and spray drying equipments.

Unit 4

- Capsule Production: Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered.
- Disperse Systems Production: Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion, problems encountered.
- Packaging Technology: Types of packaging materials, machinery, labeling, package printing for different dosage forms.

Unit 5

- Air Handling Systems: Study of AHUs, humidity & temperature control, air filtration systems, dust collectors. Water Treatment Process: Techniques and maintenance - RO, DM, ultra - filtration, WFI.

MIP204T - Entrepreneurship Management

Theory

Unit 1

- Conceptual Frame Work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise - Merits and Demerits.
- Government policies and schemes for enterprise development.
- Institutional support in enterprise development and management.

Unit 2

- Entrepreneur: Entrepreneurial motivation - dynamics of motivation. Entrepreneurial competency -Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

Unit 3

- Launching And Organising An Enterprise: Environment scanning - Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilisation - finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

Unit 4

- Growth Strategies And Networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth - Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, co-ordination and feasibility study.

Unit 5

- Preparing Project Proposal To Start On New Enterprise Project work - Feasibility report; Planning, resource mobilisation and implementation.

MIP205P - Industrial Pharmacy II

Practical

- Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
- Comparison of dissolution of two different marketed products /brands
- Protein binding studies of a highly protein bound drug & poorly protein bound drug
- Bioavailability studies of Paracetamol (Animal).
- Pharmacokinetic and IVIVC data analysis by WinnolineR software
- In vitro cell studies for permeability and metabolism
- Formulation and evaluation of tablets
- Formulation and evaluation of capsules
- Formulation and evaluation of injections
- Formulation and evaluation of emulsion
- Formulation and evaluation of suspension.
- Formulation and evaluation of enteric coating tablets.
- Preparation and evaluation of a freeze dried formulation.
- Preparation and evaluation of a spray dried formulation.

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