M.Pharm Syllabus

Semester 01

Industrial Pharmacy

Subjects

Subject	PDF page	Open
Modern Pharmaceutical Analytical Techniques	2	Click here
Pharmaceutical Formulation Development	4	Click here
Novel Drug Delivery Systems	5	Click here
Intellectual Property Rights	6	Click here
Industrial Pharmacy I	7	Click here

MIP101T - Modern Pharmaceutical Analytical Techniques

Theory

Unit 1

- UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.
- IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
- Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

Unit 2

- NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

Unit 3

- Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

Unit 4

- Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:
- Paper chromatography b) Thin Layer chromatography
- Ion exchange chromatography d) Column chromatography
- Gas chromatography f) High Performance Liquid chromatography
- Affinity chromatography

Unit 5

- Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:
- Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
- X-ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

Unit 6

- Immunological Assays: Radioimmunology assay (RIA), ELISA (Theory & practical) and knowledge on Bioluminescence assays.

MIP102T - Pharmaceutical Formulation Development

Theory

Unit 1

- Preformulation Studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.

Unit 2

- Formulation Additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. Design of experiments - factorial design for product and process development.

Unit 3

- Solubility: Importance, experimental determination, phase-solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods - cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy.

Unit 4

- Dissolution: Theories, mechanisms of dissolution, in-vitro dissolution testing models - sink and non-sink. Factors influencing dissolution and intrinsic dissolution studies.
- Dissolution test apparatus - designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Biorelevent media, in-vitro and in-vivo correlations, levels of correlations.

Unit 5

- Product Stability: Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf life assignment. Stability protocols, reports and ICH guidelines.

MIP103T - Novel Drug Delivery Systems

Theory

Unit 1

- Concept & Models for NDDS: Classification of rate controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS - intermittent, zero order & first order release.
- Carriers for Drug Delivery: Polymers / co-polymers-introduction, classification, characterization, polymerization techniques, application in CDDS / NDDS, biodegradable & natural polymers.

Unit 2

- Study of Various DDS: Concepts, design, formulation & evaluation of controlled release oral DDS, Mucoadhesive DDS (buccal, nasal, pulmonary) Pulsatile, colon specific, liquid sustained release systems, Ocular delivery systems

Unit 3

- Transdermal Drug Delivery Systems: Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems.

Unit 4

- Sub Micron Cosmeceuticals: Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, eye etc and it's regulatory aspects.

Unit 5

- Targeted Drug Delivery Systems: Importance, concept, biological process and events involved in drug targeting, design, formulation & evaluation, methods in drug targeting - nanoparticles, liposomes, niosomes, pharmacosomes, resealed erythrocytes, microspheres, magnetic microspheres. Specialized pharmaceutical emulsions - multiple emulsions, micro-emulsions.

Unit 6

- Protein / Peptide Drug Delivery Systems: Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stabilization methods.

Unit 7

- Biotechnology in Drug Delivery Systems: Brief review of major areas-recombinant DNA technology, monoclonal antibodies, gene therapy.

Unit 8

- New trends for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.

MIP104T - Intellectual Property Rights

Theory

Unit 1

- Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filling of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in Patent.

Unit 2

- Role of GATT, TRIPS, and WIPO

Unit 3

- Brief introduction to Trademark protection and WHO Patents.
- IPR's and its types, Major bodies regulating Indian Pharmaceutical sector.

Unit 4

- Brief introduction to CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA

Unit 5

- Regulatory requirements for contract research organization.
- Regulations for Biosimilars.

MIP105P - Industrial Pharmacy I

Practical

- Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
- Simultaneous estimation of multi component containing formulations by UV spectrophotometry
- Experiments based on HPLC / GC
- Estimation of riboflavin/quinine sulphate by fluorimetry
- Estimation of sodium/potassium by flame photometry
- Effect of surfactants on the solubility of drugs.
- Effect of pH on the solubility of drugs.
- Stability testing of solution and solid dosage forms for photo degradation..
- Stability studies of drugs in dosage forms at 25°C, 60% RH and 40°C, 75% RH.
- Compatibility evaluation of drugs and excipients (DSC & FTIR).
- Preparation and evaluation of different polymeric membranes.
- Formulation and evaluation of sustained release oral matrix tablet/ oral reservoir system.
- Formulation and evaluation of microspheres / microcapsules.
- Formulation and evaluation of transdermal drug delivery systems.
- Design and evaluation of face wash, body-wash, creams, lotions, shampoo, toothpaste, lipstick.
- Electrophoresis of protein solution.
- Preparation and evaluation of Liposome delivery system.

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