M.Pharm Syllabus

Semester 01

Pharmaceutics

Subjects

Subject	PDF page	Open
Modern Pharmaceutical Analytical Techniques	2	Click here
Drug Delivery Systems	4	Click here
Modern Pharmaceutics	5	Click here
Regulatory Affairs	6	Click here
Pharmaceutics I	7	Click here

MPH101T - 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 diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

Unit 6

- Immunological assays : RIA (Radio immuno assay), ELISA, Bioluminescence assays.

MPH102T - Drug Delivery Systems

Theory

Unit 1

- Sustained Release(SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.

Unit 2

- Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems;Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.

Unit 3

- Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

Unit 4

- Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.

Unit 5

- Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.

Unit 6

- Protein and Peptide Delivery: Barriers for protein delivery.
- Formulation and Evaluation of delivery systems of proteins and other macromolecules.

Unit 7

- Vaccine deliverysystems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

MPH103T - Modern Pharmaceutics

Theory

Unit 1

- Preformation Concepts - Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental - physiological and formulation consideration, Manufacturing and evaluation.
- Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation

Unit 2

- Validation : Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.

Unit 3

- cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.

Unit 4

- Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.

Unit 5

- Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors - f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test.

MPH104T - Regulatory Affairs

Theory

Unit 1

- Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records.
- Generic drugs product development Introduction , Hatch-Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in -vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.
- Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs

Unit 2

- CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.

Unit 3

- Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).

Unit 4

- Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures.
- HIPAA-new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.

MPH105P - Pharmaceutics 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
- Experiments based on Gas Chromatography
- Estimation of riboflavin/quinine sulphate by fluorimetry
- Estimation of sodium/potassium by flame photometry
- To perform In-vitro dissolution profile of CR/ SR marketed formulation
- Formulation and evaluation of sustained release matrix tablets
- Formulation and evaluation osmotically controlled DDS
- Preparation and evaluation of Floating DDS-hydro dynamically balanced DDS
- Formulation and evaluation of Muco adhesive tablets.
- Formulation and evaluation of trans dermal patches.
- To carry out preformulation studies of tablets.
- To study the effect of compressional force on tablets disintegration time.
- To study Micromeritic properties of powders and granulation.
- To study the effect of particle size on dissolution of a tablet.
- To study the effect of binders on dissolution of a tablet.
- To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

First Hope

SYLLABUS

Click here to visit our website

PHARMACY SYLLABUS

Complete subject and semesters are available on FirstHope app only.

Scan or click here

Click here to get the app >

Available on Google Play

JOIN THE FIRSTHOPE COMMUNITY

Join our Telegram channel

Click here to join Telegram >

Scan or click here

@FirstHopeNotes

Instagram

@firsthope.official

Click here to follow >

YouTube channel

FirstHope-Pharmacy / Live streams

Click here to watch >

WhatsApp channel

Follow FirstHope on WhatsApp

Click here to join >

FirstHope website

firsthope.co.in

Click here to visit >

B.Pharm / D.Pharm / M.Pharm / Pharm.D

Explore complete subject and semester notes in the FirstHope app.