M.Pharm Syllabus

Semester 02

Pharmaceutical Analysis

Subjects

Subject	PDF page	Open
Advanced Instrumental Analysis	2	Click here
Modern Bio-Analytical Techniques	3	Click here
Quality Control and Quality Assurance	4	Click here
Herbal and Cosmetic Analysis	5	Click here
Pharmaceutical Analysis II	6	Click here

MPA201T - Advanced Instrumental Analysis

Theory

Unit 1

- HPLC: Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC-role and principles of ultra, nano liquid chromatography in pharmaceutical analysis. Immobilized polysaccharide CSP's: Advancement in enantiomeric separations, revised phase Chiral method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals.
- Preparative HPLC, practical aspects of preparative HPLC.

Unit 2

- Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.
- Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification.
- High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications.

Unit 3

- Super critical fluid chromatography: Principles, instrumentation, pharmaceutical applications.
- Capillary electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method development in CE, Crown ethers as buffer additives in capillary electrophoresis. CE-MS hyphenation.

Unit 4

- Mass spectrometry: Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrpole, Time of flight, FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF;Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap.

Unit 5

- 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 with reference to 13CNMR: Spin spin and spin lattice relaxation phenomenon. 13C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations.

MPA202T - Modern Bio-Analytical Techniques

Theory

Unit 1

- Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid - Liquid extraction and Solid phase extraction and other novel sample preparation approach.
- Bioanalytical method validation: USFDA and EMEA guidelines.

Unit 2

- Biopharmaceutical Consideration: Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

Unit 3

- Pharmacokinetics and Toxicokinetics: Basic consideration, Drug interaction (PK-PD interactions), The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics-Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics.

Unit 4

- Cell culture techniques Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry.

Unit 5

- Metabolite identification: In-vitro / in-vivo approaches, protocols and sample preparation.
- Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met -ID. Regulatory perspectives.
- In-vitro assay of drug metabolites & drug metabolizing enzymes.
- 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, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies.

MPA203T - Quality Control and Quality Assurance

Theory

Unit 1

- Concept and Evolution of Quality Control and Quality Assurance Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines.
- Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation.

Unit 2

- cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guidelines.

Unit 3

- Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3) Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials.

Unit 4

- Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles-How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports.
- Distribution records. Electronic data.

Unit 5

- Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging.

MPA204T - Herbal and Cosmetic Analysis

Theory

Unit 1

- Herbal remedies-Toxicity and Regulations: Herbals vs Conventional drugs, Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines.

Unit 2

- Adulteration and Deterioration: Introduction, types of adulteration/substitution of herbal drugs, Causes and Measure of adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations.
- Regulatory requirements for setting herbal drug industry: Global marketing management, Indian and international patent law as applicable herbal drugs and natural products and its protocol.

Unit 3

- Testing of natural products and drugs: Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products, protocol.
- Monographs of Herbal drugs: Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

Unit 4

- Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines.

Unit 5

- Evaluation of cosmetic products: Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.
- Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards.

MPA205P - Pharmaceutical Analysis II

Practical

- Comparison of absorption spectra by UV and Wood ward - Fiesure rule
- Interpretation of organic compounds by FT-IR
- Interpretation of organic compounds by NMR
- Interpretation of organic compounds by MS
- Determination of purity by DSC in pharmaceuticals
- Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
- Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis.
- Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques.
- Isolation of analgesics from biological fluids (Blood serum and urine).
- Protocol preparation and performance of analytical/Bioanalytical method validation.
- Protocol preparation for the conduct of BA/BE studies according to guidelines.
- In process and finished product quality control tests for tablets, capsules, parenterals and creams
- Quality control tests for Primary and secondary packing materials
- Assay of raw materials as per official monographs
- Testing of related and foreign substances in drugs and raw materials
- Preparation of Master Formula Record.
- Preparation of Batch Manufacturing Record.
- Quantitative analysis of rancidity in lipsticks and hair oil
- Determination of aryl amine content and Developer in hair dye
- Determination of foam height and SLS content of Shampoo.
- Determination of total fatty matter in creams (Soap, skin and hair creams)
- Determination of acid value and saponification value.
- Determination of calcium thioglycolate in depilatories

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