

PHARMACEUTICAL SCIENCES
CREDIT COURSE IN PHARMACY

Advanced techniques in Spectroscopy, Pharmacokinetics, screening
methods and Research methodologies in Pharmacy

UNIT I

Statistical Methods:

Error and its significance-Measures of Error- Control of Error in Experimental Investigations, Correlation and Regression.

Tests of Significance: Principles, t-test, z-test, F-ratio test, Chi-square test, Non-parametric tests- their applications in pharmacy research with examples.

Design of Experiments

Criteria of a good design with examples.

Principles- Randomization, replication and local control.

Study of CRD, RBD, LSD and factorial designs- their applications in Pharmacy research with examples.

Analysis of Variance (ANOVA) – one way, two way and three way – principles and applications in pharmacy research.

UNIT II

Bio-availability Bioequivalence and Therapeutic equivalence: Designing of bioavailability studies and interpretation of results. Regulatory considerations.

Pharmacokinetics: Compartmental models: One, Two and non-compartmental approaches to Pharmacokinetics. Recent trends, merits and limitations of these approaches. Application of these models to determine the various pharmacokinetic parameters.

UNIT III

Mass spectroscopy: Theory, ionization techniques: electron impact ionization, chemical ionization, field ionization, fast atom bombardment, plasma desorption, fragmentation process: types of fission, resolution.

GC/MS, interpretation of spectra and applications for identification and structure determination

NMR: Theory, instrumentation, chemical shift, shielding and deshielding effects, splitting of signals, spin-spin coupling, proton exchange reactions, coupling constant(J), nuclear overhauser effect(NOE), ¹³C NMR spectra and its applications, 2D-NMR, COSY and applications in pharmacy.

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UNIT IV

Quality Assurance and Regulatory Considerations

Concept of quality control and quality assurance

Study of regulations under CGMP, GLP and GCP.

Validations: Types and protocols of validation – validation of analytical methods and instruments, validation of process and equipments with specific examples.

Patents and IPR.

UNIT V

Screening Methods:

Organization of screening, neuropharmacological tests in Blind screening, Tests other than neuropharmacological tests, use of isolated organs in the evaluation of pharmacological activity of drugs.

Cell lines and their application in Drug Discovery. Transgenic animal models in the development of new drugs.

Pharmacological Evaluation of New Drugs.

Organization of screening for the following activities:

Diuretic, Cardiotonic, Anti-diabetic, Hyperlipidemia, Antiulcer, Hepatoprotective and Drugs against Alzheimer's disease.

Bio-assay guided evaluation of herbal drugs and medicinal plants.

Toxicity Studies: Acute, Sub-acute and Chronic toxicity studies - Regulatory Considerations.