

I/II M.PHARMACY (PHARMACOLOGY)
1st SEMESTER

ACHARYA NAGARJUNA UNIVERSITY

I/II M.PHARMACY (1st Semester)

1.1 T : ADVANCED INSTRUMENTAL METHODS OF ANALYSIS

- 1. UV-VISUAL SPECTROSCOPY :** Brief review of electromagnetic spectrum, UV-Visual range, energy-wavelength-color relationship. Interaction of electromagnetic radiation (UV-Vis) and matter and its effects. Chromophores and their interaction with Electromagnetic Radiation. Absorption spectra of organic compounds and complexes illustrating the phenomenon and its utilization in qualitative and quantitative analysis of drugs. Shifts and their Interpretation (including solvent effects)
- 2. INFRA-RED SPECTROSCOPY :** Nature of Intra-red radiation. Interaction of IR. Radiation with organic molecules and effects on bonds. Brief outline of classical I.R. instrumentation and the interpretation of spectra, including sample preparation for spectroscopy. Qualitative interpretation of I.R. spectra. Quantitative methods useful in drug analysis.
- 3. NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY :** Fundamental principles of NMR (Magnetic Properties of nuclei, applied field and precession; absorption and transition frequency). Chemical shifts concept; Isotopic nuclei, Reference standards; proton Magnetic spectra, their characteristics, presentation, terms used in describing spectra and their interpretation (Signal no. Position, intensity). Brief outline of instrumental arrangements and some practical details. Signal multiplicity phenomena in high resolution PMR Spin spin coupling. Application of Signal Split and coupling constant data to interpretation of spectra. Decoupling and shift reagent methods.

Brief outline of principles of FT-NMR with reference to ¹³CNMR; Spin-spin and spin-lattice relaxation phenomena. Free induction decay (FID) proton noise decoupling signal averaging time domain and frequency domain signals nuclear overhauser enhancement; ¹³CNMR spectra, their presentation, characteristics, interpretation examples and application in drug analysis.

- 4. MASS SPECTROMETRY :** Basic principles and brief outline of instrumentation. Ion formation and types, molecular ion, meta stable ions, fragmentation processes, fragmentation patterns and fragment characteristics in relation to parent structure and functional groups. Relative abundances of isotopes and their contribution to characteristics peaks. Mass spectrum, its characteristics, presentation and interpretation. Chemical ionization mass spectrometry, GC-MS other recent advances in MS, FAST ATOM BOMBARDMENT MASS spectroscopy. Application of mass spectrometry in the analysis of drug.
- 5. GAS CHROMATOGRAPHY :** Instrumentation packed and open tubular column, column efficiency parameters, the Van Deemeter equation, Resolution, liquid stationary phases, Derivatisation methods of GC including acylation, perfluoroacylation, alkylation and esterification. Detectors; FID, ECD, TCD, NPD. A critical comparison of sensitivity, selectivity and field of application of these detectors. Examples of GC applications in Pharmaceutical Analysis.
- 6. LIQUID CHROMATOGRAPHY :** Comparison of GC and HPLC, instrumentation in HPLC, analytical, preparative and microbore columns, normal and reversed-phase packing materials, Reverse-phases HPLC, column selection, mobile phase selection, efficiency parameters, resolution, detectors in HPLC; refractive index, Photometric and electrochemical. Comparison of sensitivity, selectivity and field of applications of these detectors. HPTLC-instrumentation and applications.
- 7. X-RAY DIFFRACTION AND DSC, DTA METHODS :** Introduction, Generation of X-Rays, Elementary crystallography; miller Indices, X-ray, diffraction Bragg's law, X-ray powder diffraction, X-ray powder diffractometer, obtaining and interpretation of X-ray powder diffraction data. Applications of XRD, DSC and DTA in the characterization of Pharmaceutical solids.
- 8. RADIO IMMUNO ASSAY METHODS :**

I/II M.PHARMACY (1st Semester)

1.1 P : ADVANCED INSTRUMENTAL METHODS OF ANALYSIS-(PRACTICALS)

1. Experiments in U.V.Spectrophotometry – 4 Nos.
2. Experiments in Visible spectrophotometry-4 Nos
3. Determiration of moisture content by KFR-1
4. Flame photometry experiments-2 nos. (Determination of sodium and potassium)
5. Experiments of HPLC-5 Nos.
6. Experiments on IR and MS in collaboration with M/s. Laila Impex

BOOKS

Textbook of Pharmaceutical Analysis 3 rd edition	Kenneth, A.Connors
Pharmaceutical Analysis	Watson
Organic Spectroscopy	William Kemp
Instrumental Methods of Analysis	Willard dean and Merrit
Pharmaceutical drug analysis	Ashouthosh Kar
Quantative analysis of Drugs and Formulations	Sethi

**I/II M.PHARMACY (1st Semester)
1.2T. ADVANCED PHARMACOLOGY - I**

I. "Drugs acting at Synoptic and neuro effecto junctional sites.

- A. Autonomic & somatic nervous systems.
- B. Muscarinic receptor agonists & antagonists
- C. Anticholinesterases
- D. Agents acting at NMJ and autonomic ganglia
- E. Sympathomimetic drugs. Catecholamines and adrenergic antagonists.

II. Drugs acting on the Central Nerevous Systems.

- A. Neurotransmission and CNS.
- B. Drugs used in the treatment of
 - 1. Anxiety & Psychosis
 - 2. Depression & Mania
 - 3. Epilepsy
 - 4. Migraine
 - 5. CNS degenerative disorders
 - 6. Parkinson's Disease
 - 7. Pain
- C. Drug addiction & abuse

III. Drugs affecting renal and cardiovascular function

- A. Diuretics
- B. Renin & Angiotensin
- C. Drugs used in the treatment of
 - 1. Myocardial Ischemia
 - 2. Hypertension
 - 3. CHF
 - 4. Hyperlipidemia

IV. Drugs acting on the blood & blood forming organs

- A. Growth factors
- B. Anticoagulants, thrombolytics & Antiplatelet drugs.

I/II M.PHARMACY (1st Semester)
1.2 P.ADVANCED PHARMACOLOGY-I (Practicals)

Practicals based on theory M.1.COL.T.1

I/II M.PHARMACY (1st Semester)
1.3 T. DRUG REGULATORY AFFAIRS

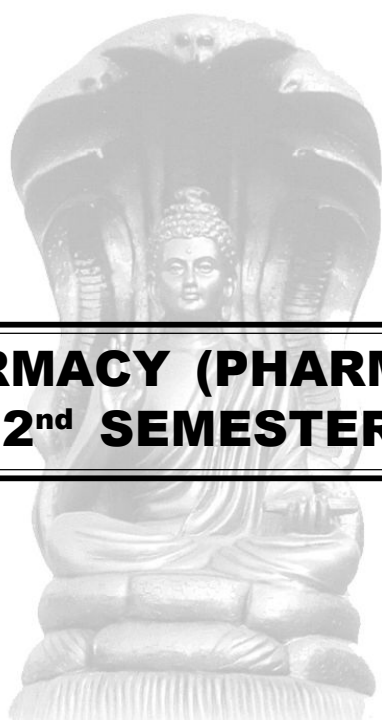
1. **Formulation Development :** Regulatory requirements involved in the preformulation studies, solid, liquid and semi-solid dosage forms, controlled release preparations, injections, ocular preparations as per the European community, United States and Indian regulatory authorities.
2. **Manufacturing :** Regulatory requirements as per European community, united states and Indian regulatory authorities for manufacturing information, manufacturing formula, process, validation of manufacturing process, equipment, documentation, inspection requirement of regulatory guidelines for active ingredients, data requirement for new drug, International aspects of Excipients, approval as per guidelines of all the territories. Regulatory guidelines for packaging materials, test and evaluation of packaging materials, biological test, elastomer test, microbiological test and evaluation of closures.
3. **Stability Testing :** Scientific and technical background to the design of stability testing regulatory requirements as per European community, united states and Indian regulatory authorities for testing of new active substances, bulk active drug substances, dosage form in their final packaging. Extension of self-life after authorization of drug international harmonization and current guidelines. Regulatory affairs in respect of residual solvents as per the ICH guidelines Analytical method validation, pharmacokinetic and toxicokinetic validation.
4. **Biopharmaceutics :** Different testing parameters and standards as per regulatory requirements of European community, United States and Indian regulatory authorities with respect to factors related to formulation, dosage form, manufacturing process, stability and storage.

5. **Preclinical Aspects of Biopharmaceutics** : Current guidelines and developments as per regulatory requirements of European community, united states and Indian regulatory authorities in respect of clinical bioavailability, study, design, presentation, documentation and statistical analysis.
6. **Clinical Pharmacology and Pharmacodynamics** : Regulatory guidelines as per European community, united states and Indian regulatory authorities on Clinical study design, documentation, presentation and interpretation.
Clinical Trials : Definition, phase I, phase II, Phase III and Phase IV studies, design documentation, presentation and interpretation, statistical analysis of clinical data and factorial design.
7. **Intellectual Property Rights** : Introduction, purpose, international scenario and Indian scenario, guidelines as per European community, United states and Indian regulatory authorities, documentation, presentation and application.

BOOKS

Drug Stability
New Drug Approval Process

J Carstensen
Richard A Guarine



**I/II M.PHARMACY (PHARMACOLOGY)
2nd SEMESTER**

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**I/II M.PHARMACY (2nd Semester)
2.1.T. ADVANCED PHARMACOLOGY - II**

- I. Autacoids, Drug therapy of Inflammation
 - A. Histamine, Bradykinin & their antagonists
 - B. Eicasonoids & PAF
 - C. Antiinflammatory, analgesic & antipyretic agents
 - D. Antiasthmatic agents.
- II. Drugs affecting gastro intestinal function.
 - A. Agents for control of acidity and antiulcer drugs
 - B. Emetics and anti emetics
- III. Chemotherapy of
 - A. Malaria
 - B. Microbial infections.
 - i. Fluroquinolones
 - ii. Cephalosporins and other newer agents
 - iii. Antifungal and antiviral drugs including Anti HIV drugs.
 - C. Neoplastic diseases
- IV. Oral hypoglycemic agents.
- V. Estrogens, Progestins and Androgens.

**I/II M.PHARMACY (2nd Semester)
2.1 P. ADVANCED PHARMACOLOGY-II (Practicals)**

Practicals based on theory

I/II M.PHARMACY (2nd Semester)

**2.2 T. SCREENING METHODS IN PHARMACOLOGY
AND CLINICAL RESEARCH**

1.
 - a. **Drug discovery process** : Principles, techniques and strategies used in new drug discovery. High throughput screening, human genomics, robotics and economics of drug discovery. Regulations for laboratory animal care and ethical requirements.
 - b. **Bioassays** : Basic principles of bioassays, official bioassays, experimental models and statistical designs employed in biological standardization. Biological standardization of vaccines and sera, vasopressin, oxytocin, Acetylcholine, Adrenaline, insulin, d-tubocurarine, HCG, hyaluronidase, corticotrophine, pertussia, rabies and plague.
 - c. **Introduction** to biostatistics, parametric and non parametric tests.
2. preclinical and clinical models employed in the screening of new drugs belonging to following categories.
Antifertility agents, sympathomimetics, parasympathomimetics, muscle relaxants (both central and peripheral), sedatives, hypnotics, antiarrhythmic agents, cardiac stimulants, cardiotonic agents, bronchodilators, antihistaminics, elcosanoids.
Antipsychotic agents, antianxiety agents, nootropic drugs, antidepressant drugs, antiparkinsonian agents, antiepileptics, analgesics and anti-inflammatory agents, antiulcer agents, infarction, antiatherosclerotic drugs, antimalarials, anthelmintics, antidiabetics, models for status epilepticus, intracerebroventricular and other newer techniques of drug administration and development, transgenic animals and other genetically prone animal models.
3. Alternatives to animal screening procedures, cell-line, patch-clamp technique, in-vitro models, molecular biology techniques.
4. Principles of toxicity evaluations, ED₅₀, LD₅₀ and TD values. International guidelines (ICH recommendations)

I/II M.PHARMACY (2nd Semester)

**2.2.P. SCREENING METHODS IN PHARMACOLOGY AND CLINICAL
RESEARCH (Practicals)**

Clinical pharmacology and pharmacotherapeutics practicals based on Theory

**I/II M.PHARMACY (2nd Semester)
(PHARMACOLOGY)**

2.3 T. CLINICAL PHARMACOLOGY & HARMACOTHERAPEUTICS

- I. Principles of Pharmacokinetics
 - A. Revision of basic concepts
 - B. Clinical Pharmacokinetics
 - i. Dose-response in man
 - ii. Influence of renal and hepatic disease on pharmacokinetics
 - iii. Therapeutic drug monitoring
 - iv. Population pharmacokinetics
- II. Adverse Drug Reactions, Drug Interactions and ADR monitoring
- III. Pathophysiology and drug therapy of the following disorders. Schizophrenia, anxiety, depression, epilepsy, Parkinson's, Alzheimer's diseases, migraine hypertension, angina pectoris, arrhythmias, atherosclerosis, myocardial infarction, TB, leprosy, leukemia, solid tumors, lymphomas, psoriasis, respiratory, urinary, g.l. tract infections, endocarditis, fungal and HIV infection, rheumatoid arthritis, glaucoma, menstrual disorders, menopause.
- IV. Drug therapy in
 - A. geriatrics
 - B. Pediatrics
 - C. Pregnancy & Lactation
- V. Pharmacogenetics : Interracial and individual variability in drug metabolism.