

Datta Meghe Institute of Medical Sciences
(Deemed to be University)
Name of Subject: Pharmaceutical Sciences
Faculty of Medicine,
Subject Code: _____

UNIT - I:

ANALYTICAL TECHNIQUES

1. Chromatographic Techniques: HPLC, HPTLC, GC, Flash Chromatography, Column Chromatography
2. UV-Visible Spectroscopy
3. Infra-Red Spectroscopy
4. Nuclear Magnetic Resonance Spectroscopy
5. Mass Spectrometry
6. Differential Thermal Analysis
7. Differential Scanning Calorimetry
8. Optical Rotatory Dispersion
9. X-ray Diffraction Methods
10. Electrophoresis

UNIT - II:

DRUG REGULATORY AFFAIRS

1. The Pharmacy Act 1948
2. Intellectual Property Rights Law:
 - a. Indian Patent Act 1970 and amendments there under,
 - b. Copyright (Indian) Act
 - c. Guide lines for filing patents in countries like US & UK.
 - d. Good Clinical Practice Guideline, Good Laboratory Practice Guidelines, GMP Guidelines
3. Drug Master File. Site Master File, Master Formula Record and DMF, Procedure for filing of Patent.
4. Drug and Cosmetics Act 1940 & rules 1945 with amendments.
5. Study of Compendia: IP, USP, BP, EP & GP.
6. NDA, INDA, ANDA.

UNIT - III:

VALIDATION and cGMP

1. Validation:

- a) Validation, Qualifications, Validation master plan.
- b) Validation of medical devices, pharmaceutical and biotechnology processes, pharmaceutical ingredients, Parenteral area, equipment's, HVAC systems, aseptic processes and sterilization methods, water system, water for injection.
- c) Analytical and Bioanalytical Method Validation

2. **cGMP:** Concepts and Philosophy of cGMP, Organization and Personnel, Buildings and Facilities, Raw materials

UNIT - IV:

BIOLOGICAL EVALUATION

1. Principles of Pharmacological and Pre-clinical Evaluation of drugs and related guidelines.

2. Bioassays.

3. Toxicology

4. Modern Methods of Pharmacological Evaluations

5. Alternatives to animal screening procedures: Cell line , In-vitro testing of drugs.

6. Preclinical Evaluation: Preclinical models employed and organization of screening of new drugs of following categories:

- i) Sedatives, hypnotics, anxiolytics, antidepressants, antipsychotics, nootropics, antiparkinsonian agents, analgesics, antipyretics.
- ii) Anti-inflammatory agents, anticonvulsants, local anesthetics, CNS stimulants.
- iii) Cardiac glycosides, antiarrhythmic, antihypertensive, antianginal, anti-atherosclerotic,
- iv) Antiulcer agents, Laxatives, Bronchodilators, antitussives,
- v) Diuretics.
- vi) Histamine antagonists.
- vii) Muscle relaxants, Anticholinesterases, anticholinergics, adrenolytics.
- viii) Hypoglycemics, antifertility agents, androgens.
- ix) Anti-thyroid agents, Dermatological agents, Antitumor agents.
- x) Anthelmintics, Antimalarials, Antileprotics.
- xi) Drugs used for glaucoma, cataract and eye inflammation.

UNIT - V:

PHARMACEUTICAL CHEMISTRY

1. Various Reaction Mechanisms:

- a. Substitution Reaction
- b. Elimination Reaction
- c. Addition Reaction
- d. Free Radical Reaction

2. Esterification reactions and ester hydrolysis.

3. Heterocyclic chemistry

4. Oxidation and reduction reactions

5. Modern synthetic methods:

a) Green Synthesis

b) Microwave assisted synthesis

UNIT - VI:

NOVEL DRUG DELIVERY SYSTEMS

1. Fundamentals of controlled release drug delivery systems
2. Oral novel drug delivery systems: Oral controlled drug delivery systems, dissolution and diffusion controlled delivery systems, gastro retentive, colon targeted and pulsatile drug delivery.
3. Parenteral controlled release system
4. Mucosal drug delivery models
5. Transdermal drug delivery system
6. Ocular Drug Delivery
7. Site specific drug delivery system
8. Protein & peptide drug delivery system
9. Regulatory consideration in controlled release

UNIT – VII

PHARMACOLOGY AND PHARMACOTHERAPEUTICS

1. Basic Principles of Clinical Pharmacology
2. Drug Therapy of Cardiovascular Disorders
3. Drug Therapy of Neurological Disorders
4. Drug Therapy of Psychiatric Disorders
5. Drug Therapy of Endocrine Disorders
6. Drug Therapy of Inflammatory Disorders
7. Drug Therapy of Respiratory Diseases
8. Drug Therapy of Gastrointestinal Diseases
9. Drug Therapy of Metabolic and Sexual Disorders
10. Pharmacology of Chemotherapeutic and Antimicrobial Agents
11. Pathophysiology of cancer and Antineoplastic Agents
12. Drug Therapy of Infectious Diseases

UNIT - VIII:

PHARMACOGNOSY AND PHYTOCHEMISTRY

1. Neutraceuticals
2. Study of herbal extracts
3. Extraction, isolation, purification and estimation of following phytoconstituents:
 - Alkaloids : Caffeine, Atropine, Berberine, Piperine
 - Glycosides :Sennosides, Digoxin
 - Flavonoids :Rutin, Hesperidin
 - Terpenoids :Taxol, Andrographolide
 - Saponins :Diosgenin, Glycyrrhizin
4. General aspects of cultivation and collection
5. Drug discovery from Natural Products.
6. Ethnobotany in Herbal Drug Evaluation.
7. Adverse reactions and safety in herbal medicine