Bpharm 6th Semester Syllabus

MEDICINAL CHEMISTRY– III

UNIT 1

Antibiotics
Historical background, Nomenclature, Stereochemistry, Structure-activity relationship, Chemical degradation, classification, and important products of the following classes:

β-Lactam antibiotics: Penicillin, Cephalosporins, β-Lactamase inhibitors, Monobactams
Aminoglycosides: Streptomycin, Neomycin, Kanamycin
Tetracyclines: Tetracycline, Oxytetracycline, Minocycline, Doxycycline

UNIT 2

Antibiotics
Historical background, Nomenclature, Stereochemistry, Structure-activity relationship, Chemical degradation, classification, and important products of the following classes:
Macrolide: Erythromycin, Clarithromycin, Azithromycin.
Miscellaneous: Chloramphenicol, Clindamycin.
Prodrugs: Basic concepts and applications of prodrug design.

Antimalarials: Etiology of malaria.
Quinolines: SAR, Quinine sulphate, Chloroquine, Amodiaquine, Primaquine phosphate, Pamaquine, Quinacrine hydrochloride, Mefloquine.
Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil.
Miscellaneous: Pyrimethamine, Artesunate, Artemether, Atovoquone.

UNIT 3

Anti-tubercular Agents
Synthetic anti-tubercular agents: Isoniazid, Ethionamide, Ethambutol, Pyrazinamide, Para-aminosalicylic acid.
Anti-tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine, Streptomycin, Capreomycin sulphate.

Urinary Tract Anti-Infective Agents
Quinolones: SAR of quinolones, Nalidixic Acid, Norfloxacin, Enoxacin, Ciprofloxacin,

Ofloxacin, Lomefloxacin, Sparfloxacin, Moxifloxacin.
Miscellaneous: Furazolidone, Nitrofurantoin, Methenamine.

Antiviral Agents
Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine, Trifluorothymidine, Acyclovir, Ganciclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirdine, Ribavirin, Saquinavir, Indinavir, Ritonavir.

UNIT 4

Antifungal Agents
Antifungal antibiotics: Amphotericin-B, Nystatin, Natamycin, Griseofulvin.
Synthetic antifungal agents: Clotrimazole, Econazole, Butoconazole, Oxiconazole, Tioconazole, Miconazole, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate.

Anti-Protozoal Agents
Metronidazole, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine isethionate, Atovaquone, Eflornithine.

Anthelmintics
Diethylcarbamazine citrate, Thiabendazole, Mebendazole, Albendazole, Niclosamide, Oxamniquine, Praziquantel, Ivermectin.

Sulphonamides and Sulfones
Historical development, chemistry, classification, and SAR of sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphapyridine, Sulphamethizine, Sulfacetamide, Sulfamethoxazole, Sulphadiazine, Mefenide acetate, Sulfasalazine.

Folate Reductase Inhibitors: Trimethoprim, Cotrimoxazole.

Sulfones: **Dapsone.**

UNIT 5

Introduction to Drug Design
Various approaches used in drug design.

Physicochemical parameters used in quantitative structure-activity relationship (QSAR) such as partition coefficient, Hammett's electronic parameter, Taft's steric parameter, and Hansch analysis.

Pharmacophore modeling and docking techniques.

Combinatorial Chemistry: Concept and applications.
Chemistry: solid-phase and solution-phase synthesis of combinatorial.

PHARMACOLOGY-III

UNIT 1

Pharmacology of drugs acting on Respiratory system
a. Anti-asthmatic drugs
b. Drugs used in the management of COPD
c. Expectorants and antitussives
d. Nasal decongestants
e. Respiratory stimulants

Pharmacology of drugs acting on the Gastrointestinal Tract
a. Antiulcer agents
b. Drugs for constipation and diarrhoea
c. Appetite stimulants and suppressants
d. Digestants and carminatives
e. Emetics and anti-emetics

UNIT 2

Chemotherapy
a. General principles of chemotherapy.
b. Sulfonamides and cotrimoxazole.
c. Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolins, tetracycline and aminoglycoside.

UNIT 3

Chemotherapy
a. Antitubercular agents
b. Antileprotic agents
c. Antifungal agents
d. Antiviral drugs
e. Anthelmintics
f. Antimalarial drugs
g. Antiamoebic agents

UNIT 4

Chemotherapy
Urinary tract infections and sexually transmitted diseases.
Chemotherapy of malignancy

Immunopharmacology
a. Immunostimulants
b. Immunosuppressants
Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

UNIT 5

Principles of toxicology
a. Definition and basic knowledge of acute, subacute and chronic toxicity.
b. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity
c. General principles of treatment of poisoning
d. Clinical symptoms and management of barbiturates, morphine, organophosphorus compound and lead, mercury and arsenic poisoning.

Chronopharmacology
a. Definition of rhythm and cycles.
b. Biological clock and their significance leading to chronotherapy.

HERBAL DRUG TECHNOLOGY

UNIT 1

Herbs as raw materials
Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation
Source of Herbs
Selection, identification and authentication of herbal materials
Processing of herbal raw material

Biodynamic Agriculture
Good agricultural practices in cultivation of medicinal plants including Organic farming.
Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.

Indian Systems of Medicine
a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy
b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika, Churna, Lehya and Bhasma.

UNIT 2

Nutraceuticals
General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastrointestinal diseases.
Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina

Herbal-Drug and Herb-Food Interactions: General introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.

UNIT 3

Herbal Cosmetics
Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums, colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products.

Herbal Excipients
Herbal Excipients– Significance of substances of natural origin as excipients– colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes.

Herbal Formulations
Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes.

UNIT 4

Evaluation of Drugs WHO & ICH guidelines for the assessment of herbal drugs.
Stability testing of herbal drugs.

Patenting and Regulatory Requirements of Natural Products
A. Definition of the terms: Patent, IPR, Farmers' rights, Breeder's rights, Bioprospecting, and Biopiracy.
B. Patenting aspects of Traditional Knowledge and Natural Products. Case study of **Curcuma** & **Neem**.

Regulatory Issues
A. Regulations in India (ASU DTAB, ASU DCC).
B. Regulation of manufacture of ASU drugs – Schedule Z of Drugs & Cosmetics Act for ASU drugs.

UNIT 5

General Introduction to Herbal Industry
Herbal drugs industry: Present scope and future prospects.
A brief account of plant-based industries and institutions involved in work on medicinal and aromatic plants in India.

Schedule T – Good Manufacturing Practice of Indian systems of medicine.
Components of GMP (Schedule-T) and its objectives.
Infrastructural requirements, working space, storage area, machinery and equipment, standard operating procedures, health and hygiene, documentation, and records.

BIOPHARMACEUTICS AND PHARMACOKINETICS

UNIT 1

Introduction to Biopharmaceutics

Absorption: Mechanisms of drug absorption through GIT, factors influencing drug absorption through GIT, absorption of drugs from non-peroral extra-vascular routes.
Distribution: Tissue permeability of drugs, binding of drugs, apparent volume of drug distribution, plasma, and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, clinical significance of protein binding of drugs.

UNIT 2

Elimination: Drug metabolism and basic understanding of metabolic pathways, renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, non-renal routes of drug excretion.
Bioavailability and Bioequivalence: Definition and objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, in-vitro drug dissolution models, in-vitro-in-vivo correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.

UNIT 3

Pharmacokinetics: Definition and introduction to pharmacokinetics, compartment models, non-compartment models, physiological models, one-compartment open model.
Intravenous injection (bolus), intravenous infusion, and extravascular administrations.

Pharmacokinetic parameters: KE, t1/2, Vd, AUC, Ka, Clt, and CLR – definitions, methods of elimination, understanding of their significance and application.

UNIT 4

Multicompartment models: Two-compartment open model. IV bolus.
Kinetics of multiple dosing: Steady-state drug levels, calculation of loading and maintenance doses and their significance in clinical settings.

UNIT 5

Nonlinear Pharmacokinetics:
A. Introduction
B. Factors causing Non-linearity
C. Michaelis-Menten method of estimating parameters, Explanation with example of drugs

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PHARMACEUTICAL BIOTECHNOLOGY

UNIT 1

A. Brief introduction to Biotechnology with reference to Pharmaceutical Sciences.
B. Enzyme Biotechnology – Methods of enzyme immobilization and applications.
C. Biosensors – Working and applications of biosensors in Pharmaceutical Industries.
D. Brief introduction to Protein Engineering.
E. Use of microbes in industry. Production of Enzymes – General consideration: Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase.
F. Basic principles of genetic engineering.

UNIT 2

A. Study of cloning vectors, restriction endonucleases, and DNA ligase.
B. Recombinant DNA technology. Application of genetic engineering in medicine.
C. Application of rDNA technology and genetic engineering in the production of:
i. Interferon
ii. Vaccines – hepatitis-B
iii. Hormones – Insulin
D. Brief introduction to PCR.

UNIT 3

Types of immunity- humoral immunity, cellular immunity

A. Structure of Immunoglobulins.
B. Structure and Function of MHC.
C. Hypersensitivity reactions, Immune stimulation, and Immune suppression.
D. General method of the preparation of bacterial vaccines, toxoids, viral vaccines, antitoxins, serum-immune blood derivatives, and other products relative to immunity.
E. Storage conditions and stability of official vaccines.
F. Hybridoma technology – Production, Purification, and Applications.
G. Blood products and Plasma Substitutes.

UNIT 4

A. Immuno blotting techniques – ELISA, Western blotting, Southern blotting.
B. Genetic organization of Eukaryotes and Prokaryotes.
C. Microbial genetics including transformation, transduction, conjugation, plasmids, and transposons.
D. Introduction to Microbial biotransformation and applications.
E. Mutation: Types of mutation/mutants.

UNIT 5

A. Fermentation methods and general requirements, study of media, equipment, sterilization methods, aeration process, stirring.
B. Large scale production fermenter design and its various controls.
C. Study of the production of penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin.
D. Blood Products: Collection, Processing, and Storage of whole human blood, dried human plasma, plasma substitutes.

PHARMACEUTICAL QUALITY ASSURANCE

UNIT 1

Quality Assurance and Quality Management Concepts: Definition and concept of Quality Control, Quality Assurance, and GMP.
Total Quality Management (TQM): Definition, elements, and philosophies.
ICH Guidelines: Purpose, participants, process of harmonization, brief overview of QSEM with special emphasis on Q-series guidelines, and ICH stability testing guidelines.
Quality by Design (QbD): Definition, overview, elements of QbD program, and tools.
ISO 9000 & ISO 14000: Overview, benefits, elements, and steps for registration.
NABL Accreditation: Principles and procedures.

UNIT 2

Organization and Personnel
Personnel responsibilities, training, hygiene, and personal records.

Premises
Design, construction, and plant layout. Maintenance, sanitation, environmental control, utilities, and maintenance of sterile areas. Control of contamination.

Equipment and Raw Materials
Equipment selection, purchase specifications, and maintenance. Purchase specifications and maintenance of stores for raw materials.

UNIT 3

Quality Control: Quality control tests for containers, rubber closures, and secondary packing materials.

Good Laboratory Practices (GLP): General provisions, organization, and personnel. Facilities, equipment, testing facilities operation, test and control articles, protocol for conducting a nonclinical laboratory study, records and reports, and disqualification of testing facilities.

UNIT 4

Complaints: Complaints and evaluation of complaints, Handling of return good, recalling and
waste disposal.
Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula
Record, SOP, Quality audit, Quality Review and Qualitydocumentation, Reports and documents, distribution records.

UNIT 5

Calibration and Validation:
Introduction, definition, and general principles of calibration, qualification, and validation. Importance and scope of validation, types of validation, and validation master plan. Calibration of pH meter and qualification of UV-Visible spectrophotometer. General principles of analytical method validation.

Warehousing:
Good warehousing practice and materials management.