

## SEMESTER - VI

BP601T. MEDICINAL CHEMISTRY — III (Theory)

### UNIT — I

#### 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, Chlortetracycline, Minocycline, Doxycycline

### UNIT — II

#### 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 application of prodrugs 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 — III

#### Anti-tubercular Agents

Synthetic anti tubercular agents: Isoniazid\*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic 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, Gatifloxacin, Moxifloxacin

Miscellaneous: Furazolidine, Nitrofurantoin\*, Methanamine.

Antiviral agents: Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir\*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirdine, Ribavirin, Saquinavir, Indinavir, Ritonavir.

### UNIT — IV

08 Hours

#### 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, Omidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine.

**Anthelmintics:** Diethylcarbamazine citrate\*, Thiabendazole, Mebendazole\*, Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin.

### **Sulphonamides and Sulfones**

Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide\*, Sulphapyridine, Sulfamethoxazole\*, Sulphadiazine, Mefenide acetate, Sulfasalazine.

**Folate reductase inhibitors:** Trimethoprim\*, Cotrimoxazole.

**Sulfones:** Dapsone\*.

## **UNIT — V**

### **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 of combinatorial chemistry: solid phase and solution phase synthesis.

## **BP607P. MEDICINAL CHEMISTRY- III (Practical)**

### **I Preparation of drugs and intermediates**

- 1 Sulphanilamide
- 2 7-Hydroxy, 4-methyl coumarin
- 3 Chlorobutanol
- 4 Triphenyl imidazole
- 5 Tolbutamide
- 6 Hexamine

### **II Assay of drugs**

- 1 Isonicotinic acid hydrazide
- 2 Chloroquine
- 3 Metronidazole
- 4 Dapsone
- 5 Chlorpheniramine maleate
- 6 Benzyl penicillin

### **III Preparation of medicinally important compounds or intermediates by Microwave irradiation technique**

### **IV Drawing structures and reactions using chem dra**

### **V Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinski's RO5)**

## **BP602 T. PHARMACOLOGY-III (Theory)**

### **UNIT-I**

#### **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

## **2. 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-II**

#### **3. Chemotherapy**

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

### **UNIT-III**

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

### **UNIT-IV**

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

#### **4. Immunopharmacology**

- a. Immunostimulants
- b. Immunosuppressant

Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

### **UNIT-V**

- a. Principles of toxicology 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.

#### **5. Chronopharmacology**

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

### **BP 608 P. PHARMACOLOGY-III (Practical)**

**4Hrs/Week**

1. Dose calculation in pharmacological experiments
2. Antiallergic activity by mast cell stabilization assay
3. Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.
4. Study of effect of drugs on gastrointestinal motility

5. Effect of agonist and antagonists on guinea pig ileum
6. Estimation of serum biochemical parameters by using semi- autoanalyser
7. Effect of saline purgative on frog intestine
8. Insulin hypoglycemic effect in rabbit
9. Test for pyrogens ( rabbit method)
10. Determination of acute oral toxicity (LD50) of a drug from a given data
11. Determination of acute skin irritation / corrosion of a test substance
12. Determination of acute eye irritation / corrosion of a test substance
13. Calculation of pharmacokinetic parameters from a given data
14. Biostatistics methods in experimental pharmacology( student's t test, ANOVA)
15. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)

## **BP 603 T. HERBAL DRUG TECHNOLOGY (Theory)**

### **UNIT-I**

**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-II**

#### **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 Gastro intestinal 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-III**

#### **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- IV

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 right, Breeder's right, Bioprospecting and Biopiracy
- b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.

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

## UNIT-V

### **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 equipments, standard operating procedures, health and hygiene, documentation and records.

## **BP 609 P. HERBAL DRUG TECHNOLOGY (Practical)**

1. To perform preliminary phytochemical screening of crude drugs.
2. Determination of the alcohol content of Asava and Arista
3. Evaluation of excipients of natural origin
4. Incorporation of prepared and standardized extract in cosmetic formulations like creams, lotions and shampoos and their evaluation.
5. Incorporation of prepared and standardized extract in formulations like syrups, mixtures and tablets and their evaluation as per Pharmacopoeial requirements.
6. Monograph analysis of herbal drugs from recent Pharmacopoeias
7. Determination of Aldehyde content
8. Determination of Phenol content
9. Determination of total alkaloids

## **BP 604 T. BIOPHARMACEUTICS AND PHARMACOKINETICS**

### **UNIT-I**

**Hours Introduction Biopharmaceutics Absorption;** Mechanisms of drug absorption through GIT, factors influencing drug absorption through GIT, absorption of drug from Non per oral 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- II**

**Elimination:** Drug metabolism and basic understanding metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug

excretion of drugs

**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- III

**Pharmacokinetics:** Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra vascular administrations. Pharmacokinetics parameters -  $KE$ ,  $t_{1/2}$ ,  $V_d$ ,  $AUC$ ,  $K_a$ ,  $Cl_t$  and  $CLR$ - definitions methods of eliminations, understanding of their significance

### UNIT- IV

**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- V

**Nonlinear Pharmacokinetics:**

- a. Introduction,
- b. Factors causing Non-linearity.
- c. Michaelis-menton method of estimating parameters, Explanation with example of drugs.

## BP 605 T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)

### Unit I

- 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 II

- a) Study of cloning vectors, restriction endonucleases and DNA ligase.
- b) Recombinant DNA technology. Application of genetic engineering in medicine.
- c) Application of r DNA technology and genetic engineering in the production of:
  - i) Interferon ii) Vaccines- hepatitis- B iii) Hormones-Insulin.
- d) Brief introduction to PCR

### Unit III

Types of immunity- humoral immunity, cellular immunity

- a) Structure of Immunoglobulins
- b) Structure and Function of MHC

- c) Hypersensitivity reactions, Immune stimulation and Immune suppressions.
- d) General method of the preparation of bacterial vaccines, toxoids, viral vaccine, 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 IV**

- 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 V**

- a) Fermentation methods and general requirements, study of media, equipments, 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.

### **BP606TPHARMACEUTICAL QUALITY ASSURANCE (Theory)**

#### **UNIT — 1**

**Quality Assurance and Quality Management concepts:** Definition and concept of Quality control, Quality assurance and GMP

**Total Quality Management (TQM):** Definition, elements, philosophies

**ICH Guidelines:** purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines

**Quality by design (QbD):** Definition, overview, elements of QbD program, tools **ISO 9000 &**

**ISO14000:** Overview, Benefits, Elements, steps for registration NABL accreditation : Principles and procedures

#### **UNIT - II**

**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.

**Equipments and raw materials:** Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

#### **UNIT — III**

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

**Good Laboratory Practices:** General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a

Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities

**UNIT — IV**

**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 Quality documentation, Reports and documents, distribution records.

**UNIT — V**

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

**Warehousing:** Good warehousing practice, materials management