

## **Syllabus for Bachelor of Pharmacy (B. Pharm.) Course**

## SEMESTER VI

Course code	Name of the course	No. of hours	Tutorial	Credit points	Evaluation Scheme		
					Internal	External	Total
BP601T	Medicinal Chemistry III – Theory	3	1	4	20	80	100
BP602T	Pharmacology III – Theory	3	1	4	20	80	100
BP603T	Herbal Drug Technology – Theory	3	1	4	20	80	100
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	3	1	4	20	80	100
BP605T	Pharmaceutical Jurisprudence-II – Theory	3	1	4	20	80	100
BP606P	Medicinal chemistry III – Practical	4	-	2	10	40	50
BP607P	Pharmacology III – Practical	4	-	2	10	40	50
BP608P	Herbal Drug Technology – Practical	4	-	2	10	40	50
<b>Total</b>		<b>27</b>	<b>5</b>	<b>26</b>	<b>130</b>	<b>520</b>	<b>650</b>

## BP601T: MEDICINAL CHEMISTRY – III (Theory)

45 Hours

**Scope:** This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasis on modern techniques of rational drug design like quantitative structure activity relationship (QSAR), Prodrug concept, combinatorial chemistry and Computer aided drug design (CADD). The subject also emphasizes on the chemistry, mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR), therapeutic uses and synthesis of important drugs.

**Objectives:** Upon completion of this course the student should be able to:

1. Understand the importance of drug design and different techniques of drug design.
2. Understand the chemistry of drugs with respect to their biological activity.
3. Know the metabolism, adverse effects and therapeutic value of drugs.
4. Know the importance of SAR of drugs.

### Course Content

**Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted by (\*)**

#### UNIT I

10 Hours

##### Antibiotics

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

**$\beta$ -Lactam antibiotics:** Penicillin, Cephalosporins,  $\beta$ -Lactamase inhibitors, Monobactams

**Aminoglycosides:** Streptomycin, Neomycin, Kanamycin

**Tetracyclines:** Tetracycline, Oxytetracycline Chlortetracycline, Minocycline, Doxycycline

#### UNIT II

10 Hours

##### 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, Atovaquone.

### UNIT III

**10 Hours**

#### Anti-tubercular Agents

**Synthetic anti tubercular agents:** Isoniazid\*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.\*

**Anti tubercular antibiotics:** Rifampicin, Rifabutin, Cycloserine Streptomycine, 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, Delavirding, 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, Ornidazole, 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, Sulfoxazole, Sulphamethizine, Sulfacetamide\*, Sulphapyridine, Sulfamethoxazole\*, Sulphadiazine, Mefenide acetate, Sulfasalazine.

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

**Sulfones:** Dapsone\*.

## **UNIT V**

**07 Hours**

**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.

## **BP606P: MEDICINAL CHEMISTRY- III (Practical)**

**4 Hours/week**

### **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 draw®

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 (Lipinskies RO5)

**Recommended Books (Latest Editions)**

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.
7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

## **BP602T: PHARMACOLOGY-III (Theory)**

**45 Hours**

**Scope:** This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on respiratory and gastrointestinal system, infectious diseases, immuno-pharmacology and in addition, emphasis on the principles of toxicology and chronopharmacology.

**Objectives:** Upon completion of the course student shall be able to

1. understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
2. comprehend the principles of toxicology and treatment of various poisonings and
3. appreciate correlation of pharmacology with related medical sciences.

### **Course Content**

#### **UNIT-I**

**10 Hours**

##### **Pharmacology of drugs acting on Respiratory system**

- a. Anti -asthmatic drugs
- b. Expectorants and antitussives
- c. Nasal decongestants
- d. Respiratory stimulants e. COPD

##### **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**

**10 Hours**

##### **Chemotherapy**

- a. General principles of chemotherapy.
- b. Sulfonamides and cotrimoxazole.

- c. Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolones, tetracycline and aminoglycosides

### **UNIT-III**

**10 Hours**

#### **Chemotherapy**

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

### **UNIT-IV**

**08 Hours**

#### **Chemotherapy**

- a. Urinary tract infections and sexually transmitted diseases.
- b. Chemotherapy of malignancy.

#### **Immunopharmacology**

- a. Immunostimulants
- b. Immunosuppressant Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

### **UNIT-V**

**07 Hours**

#### **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.

## BP607P: PHARMACOLOGY-III (Practical)

4 Hours/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)

*\*Experiments are demonstrated by simulated experiments/videos*

### **Recommended Books: (Latest Editions)**

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology
6. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.

7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert.
8. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
9. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan,
10. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

## **BP603T: HERBAL DRUG TECHNOLOGY (Theory)**

**45 Hours**

**Scope:** This subject gives the student the knowledge of basic understanding of herbal drug industry, the quality of raw material, guidelines for quality of herbal drugs, herbal cosmetics, natural sweeteners, nutraceutical etc. The subject also emphasizes on Good Manufacturing Practices (GMP), patenting and regulatory issues of herbal drugs.

**Objectives:** Upon completion of this course the student should be able to:

1. understand raw material as source of herbal drugs from cultivation to herbal drug product
2. know the WHO and ICH guidelines for evaluation of herbal drugs
3. know the herbal cosmetics, natural sweeteners, nutraceuticals
4. appreciate patenting of herbal drugs, GMP.

### **Course Content**

#### **UNIT-I**

**10 Hours**

##### **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.

#### **UNIT-II**

**10 Hours**

##### **Evaluation of Drugs**

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

##### **Natural sweeteners and bitters**

##### **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.

### **UNIT-III**

**10 Hours**

#### **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.

### **UNIT-IV**

**08 Hours**

#### **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.

### **UNIT-V**

**07 Hours**

#### **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.

#### **BP608P: HERBAL DRUG TECHNOLOGY (Practical)**

**4 Hours / week**

1. To perform preliminary phytochemical screening of crude drugs.
2. Determination of Ash value
3. Determination of moisture content of crude drugs
4. Determination of Extractive values of crude drugs
5. Determination of the alcohol content of Asava and Arista
6. Preparation of herbal cosmetics

7. Preparation and standardization of herbal formulation
8. Determination of swelling index and foaming index
9. Monograph analysis of herbal drugs from recent Pharmacopoeias

**Recommended Books: (Latest Editions)**

1. Textbook of Pharmacognosy by Trease & Evans.
2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
3. Pharmacognosy by Kokate, Purohit and Gokhale
4. Essential of Pharmacognosy by Dr.S.H.Ansari
5. Pharmacognosy & Phytochemistry by V.D.Rangari
6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
7. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

## **BP604T: BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)**

**45 Hours**

**Scope:** This subject is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply Biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of Biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

**Objectives:** Upon completion of course student shall be able to

1. Understand the basic concepts in biopharmaceutics and pharmacokinetics.
2. Use plasma data and derive the pharmacokinetic parameters to describe the process of drug absorption, distribution, metabolism and elimination.
3. Critically evaluate biopharmaceutic studies involving drug product equivalency
4. Design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
5. detect potential clinical pharmacokinetic problems and apply basic pharmacokinetic principles to solve them

### **Course Content**

#### **UNIT-I**

**10 Hours**

##### **Introduction to 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 of drugs Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein bin-drug binding

#### **UNIT-II**

**10 Hours**

**Drug Elimination** renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs

**Bioavailability and Bioequivalence:** Objectives of bioavailability studies, absolute and relative bioavailability, measurement of bioavailability, in-vitro drug dissolution models, in-vitro, in-vivo correlations, bioequivalence studies, methods to enhance the bioavailability.

**UNIT-III****10 Hours**

**Pharmacokinetics:** Introduction to Pharmacokinetics models, Compartment models, Non compartment models, physiological models, One compartment open model. a. Intravenous Injection (Bolus) b. Intravenous infusion, extra vascular administrations, calculations of  $K_a$ ,  $K_E$ . From plasma and urinary excretion data

**UNIT-IV****08 Hours**

**Multicompartment models:** Two compartment open model. IV bolus

**Multiple – Dosage Regimens:**

- a) Repetitive Intravenous injections – One Compartment Open Model
- b) Repetitive Extravascular dosing – One Compartment Open model

**UNIT-V****07 Hours**

**Nonlinear Pharmacokinetics:** a. Introduction, b. Factors causing Non-linearity.

- a) Michaelis-menton method of estimating parameters, Biotransformation of drugs

**Recommended Books (Latest Editions)**

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition,Prentice-Hall International edition,USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B. Jaiswal,Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: By Milo Gibaldi Donald, R. Merceel Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick
8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and
9. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
10. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company,Pennsylvania 1989.
11. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebert F Notari Marcel Dekker Inn, New York and Basel, 1987.
12. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania.

## **BP605T: PHARMACEUTICAL JURISPRUDENCE-II (Theory)**

**45 Hours**

**Scope:** This course is designed to impart basic knowledge on several important legislations related to the profession of pharmacy in India.

**Objectives:** Upon completion of course student shall be able to

1. The Pharmaceutical legislations and their implications in the development and marketing
2. Various Indian pharmaceutical Acts and Laws
3. The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
4. The code of ethics during the pharmaceutical practice

### **Course Content**

#### **UNIT-I**

**10 Hours**

**Medicinal and Toilet Preparation Act –1955:** Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.

#### **UNIT-II**

**10 Hours**

**Narcotic Drugs and Psychotropic substances Act-1985 and Rules:** Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties

#### **UNIT-III**

**10 Hours**

**Study of Salient Features of Drugs and magic remedies Act and its rules:** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties. Introduction to Intellectual Property Rights (IPR)

**Pharmaceutical Legislations** – A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee

**UNIT-IV**

**08 Hours**

**Prevention of Cruelty to animals Act-1960:** Objectives, Definitions, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties

**UNIT-V**

**07 Hours**

**National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO)-2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

**Recommended Books (Latest Editions)**

1. Forensic Pharmacy by B. Suresh
2. Text book of Forensic Pharmacy by B.M. Mithal
3. Hand book of drug law-by M.L. Mehra
4. A text book of Forensic Pharmacy by N.K. Jain
5. Drugs and Cosmetics Act/Rules by Govt. of India publications.
6. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
7. Narcotic drugs and psychotropic substances act by Govt. of India publications
8. Drugs and Magic Remedies act by Govt. of India publication
9. Bare Acts of the said laws published by Government. Reference books (Theory)