**DEPARTMENT OF PHARMACEUTICAL SCIENCES AND DRUG RESEARCH**

**PUNJABI UNIVERSITY, PATIALA**

**B. Pharm III year**

**(V and VI Sem)**

**(2019-20, 2020-21 and 2021-22)**

**Course of study for semester V**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Course Code** | **Name of the course** | **No. of hours** | **Tutorial** | **Credit points** |
| BP501T | Medicinal Chemistry II -Theory | 3 | 1 | 4 |
| BP502T | Industrial Pharmacy I Theory | 3 | 1 | 4 |
| BP503T | Pharmacology II Theory | 3 | 1 | 4 |
| BP504T | Pharmacognosy and Phytochemistry-II Theory | 3 | 1 | 4 |
| BP505T | Pharmaceutical Jurispudence-Theory | 3 | 1 | 4 |
| BP506P | Industrial Pharmacy I - Practical | 4 | - | 2 |
| BP507P | Pharmacology II- Practical | 4 | - | 2 |
| BP508P | Pharmacognosy and Phytochemistry II -Practical | 4 | - | 2 |
| Total | | 27 | 5 | 26 |

**Course of study for semester VI**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Course Code** | **Name of the course** | **No. of hours** | **Tutorial** | **Credit points** |
| BP601T | Medicinal Chemistry III -Theory | 3 | 1 | 4 |
| BP602T | Pharmacology IIITheory | 3 | 1 | 4 |
| BP603T | Herbal Drug Technology Theory | 3 | 1 | 4 |
| BP604T | Biopharmaceutics and Pharmacokinetics Theory | 3 | 1 | 4 |
| BP605T | Pharmaceutical Biotechnology Theory | 3 | 1 | 4 |
| BP606T | Quality assurance Theory | 3 | 1 | 4 |
| BP607P | Medicinal Chemistry III- Practical | 4 | - | 2 |
| BP608P | Pharmacology III- Practical | 4 | - | 2 |
| BP609P | Herbal Drug Technology -Practical | 4 | - | 2 |
| Total | | 30 | 6 | 30 |

**B PHARM III SEM**

**BP501T. MEDICINAL CHEMISTRY – II (Theory)**

**Max Marks: 75 Max Time: 3h**

**Internal Assessment: 25 Marks 3L +1T/Week (45 Hours)**

**Total Marks: 100 Credits: 04**

**INSTRUCTIONS FOR THE PAPER SETTERS**

All questions should be evenly distributed taken from the whole syllabus to discourage selective reading. The question paper will consist of three sections A, B and C. Sections A will have 3 long answer type questions of 10 marks each. Section B will have 9 short answer type questions of 5 marks each. Section C will comprise 20 Multiple Choice Questions (MCQs) of 1 mark each or ten short questions of 2 marks each.

**INSTRUCTIONS FOR THE CANDIDATES**

Candidates are required to attempt any Two questions from section A, any Seven questions from section B, and all MCQs/ very short questions from Section C.

**Scope**: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

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

1. Understand the chemistry of drugs with respect to their pharmacological activity

2. Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs

3. Know the Structural Activity Relationship of different class of drugs

4. Study the chemical synthesis of selected 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 (\*)

**UNIT- I 10 Hours**

**Antihistaminic agents:** Histamine, receptors and their distribution in the humanbody

**H1– antagonists:** Diphenhydramine hydrochloride\*, Dimenhydrinate, Doxylaminescuccinate, Clemastine fumarate, Diphenylphyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride\*, Phenidaminetartarate, Promethazine hydrochloride\*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, LevocetrazineCromolyn sodium

**H2-antagonists:** Cimetidine\*, Famotidine, Ranitidin.

**Gastric Proton pump inhibitors**: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole

**Anti-neoplastic agents**:

**Alkylating agents**: Meclorethamine\*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa, SAR of alkylating agents

**Antimetabolites**: Mercaptopurine\*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate\*, Azathioprine

**Antibiotics**: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin

**Plant products**: Etoposide, Vinblastinsulphate, Vincristinsulphate

**Miscellaneous**: Cisplatin, Mitotane.

**UNIT – II 10 Hours**

**Anti-anginal:**

**Vasodilators**: Amyl nitrite, Nitroglycerin\*, Pentaerythritoltetranitrate, Isosorbide dinitrite\*, Dipyridamole.

**Calcium channel blockers:** Verapamil, Bepridil hydrochloride, Diltiazem hydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine.

**Diuretics:**

Carbonic anhydrase inhibitors: Acetazolamide\*, Methazolamide, Dichlorphenamide.

Thiazides: Chlorthiazide\*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide,

Loop diuretics: Furosemide\*, Bumetanide, Ethacrynic acid.

Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride.

Osmotic Diuretics: Mannitol

**Anti-hypertensive Agents**: Timolol, Captopril, Lisinopril, Enalapril, Benazepril hydrochloride, Quinapril hydrochloride, Methyldopate hydrochloride,\* Clonidine hydrochloride, Guanethidinemonosulphate, Guanabenz acetate, Sodium nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.

**UNIT- III 10 Hours**

**Anti-arrhythmic Drugs**: Quinidine sulphate, Procainamide hydrochloride, Disopyramide phosphate\*, Phenytoin sodium, Lidocaine hydrochloride, Tocainide hydrochloride, Mexiletine hydrochloride, Lorcainide hydrochloride, Amiodarone, Sotalol.

**Anti-hyperlipidemic agents**: Clofibrate, Lovastatin, Cholesteramine and Cholestipol

**Coagulant & Anticoagulants**: Menadione, Acetomenadione, Warfarin\*, Anisindione, clopidogrel

**Drugs used in Congestive Heart Failure**: Digoxin, Digitoxin, Nesiritide, Bosentan, Tezosentan.

**UNIT- IV 08 Hours**

**Drugs acting on Endocrine system**

Nomenclature, Stereochemistry and metabolism of steroids

**Sex hormones**: Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol, Oestrione, Diethyl stilbestrol.

**Drugs for erectile dysfunction**: Sildenafil, Tadalafil.

**Oral contraceptives**: Mifepristone, Norgestril, Levonorgestrol

**Corticosteroids:** Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone , SAR

**Thyroid and antithyroid drugs:** L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole. SAR of thyroid hormones

**UNIT – V 07 Hours**

**Antidiabetic agents:**

Insulin and its preparations

Sulfonyl ureas: Tolbutamide\*, Chlorpropamide, Glipizide, Glimepiride.

Biguanides: Metformin.

Thiazolidinediones: Pioglitazone, Rosiglitazone.

Meglitinides: Repaglinide, Nateglinide.

Glucosidase inhibitors: Acrabose, Voglibose.

**Local Anesthetics**: SAR of Local anesthetics

**Benzoic Acid derivatives**; Cocaine, Hexylcaine, Meprylcaine, Cyclomethycaine, Piperocaine.

**Amino Benzoic acid derivatives**: Benzocaine\*, Butamben, Procaine\*, Butacaine, Propoxycaine, Tetracaine, Benoxinate.

Lidocaine/Anilide derivatives: Lignocaine, Mepivacaine, Prilocaine, Etidocaine.

Miscellaneous: Phenacaine, Diperodon, Dibucaine.\*

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. 1to 5.

9. Indian Pharmacopoeia.

10. Text book of practical organic chemistry- A.I.Vogel.

**BP 502 T. INDUSTRIAL PHARMACY I (Theory)**

**Max Marks: 75 Max Time: 3h**

**Internal Assessment: 25 Marks 3L +1T/Week (45 Hours)**

**Total Marks: 100 Credits: 04**

**INSTRUCTIONS FOR THE PAPER SETTERS**

All questions should be evenly distributed taken from the whole syllabus to discourage selective reading. The question paper will consist of three sections A, B and C. Sections A will have 3 long answer type questions of 10 marks each. Section B will have 9 short answer type questions of 5 marks each. Section C will comprise 20 Multiple Choice Questions (MCQs) of 1 mark each or ten short questions of 2 marks each.

**INSTRUCTIONS FOR THE CANDIDATES**

Candidates are required to attempt any Two questions from section A, any Seven questions from section B, and all MCQs/ very short questions from Section C.

**Scope**: Course enables the student to understand and appreciate the influence of pharmaceutical additives and various pharmaceutical dosage forms on the performance of the drug product.

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

1. Know the various pharmaceutical dosage forms and their manufacturing techniques.

2. Know various considerations in development of pharmaceutical dosage forms

3. Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality

**Course content:**

**UNIT-I 07 Hours**

**Preformulation Studies**: Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances.

a. Physical properties: Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism

b. Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization, BCS classification of drugs & its significant

Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.

**UNIT-II 10 Hours**

**Tablets**:

a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling.

b. Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating.

c. Quality control tests: In process and finished product tests

**Liquid orals**: Formulation and manufacturing consideration of syrups and elixirs suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia

**UNIT-III 08 Hours**

**Capsules**:

a. Hard gelatin capsules: Introduction, Production of hard gelatin capsule shells. size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules.

b. Soft gelatin capsules: Nature of shell and capsule content, size of capsules,importance of base adsorption and minim/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules and their applications.

**Pellets**: Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets

**UNIT-IV 10 Hours**

**Parenteral Products:**

a. Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity

b. Production procedure, production facilities and controls, aseptic processing

c. Formulation of injections, sterile powders, large volumeparenterals and lyophilized products.

d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests of parenteral products.

**Ophthalmic Preparations**: Introduction, formulation considerations; formulation of eye drops, eye ointments and eye lotions; methods of preparation; labeling, containers; evaluation of ophthalmic preparations

**UNIT-V 10 Hours**

**Cosmetics**: Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens.

Pharmaceutical Aerosols: Definition, propellants, containers, valves, types of aerosol systems; formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies.

**Packaging Materials Science**: Materials used for packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.

**BP 506 P. INDUSTRIAL PHARMACY I (PRACTICAL)**

**Max Marks: 35 Max Time: 4 h**

**Internal Assessment: 15 Marks 4h /Week**

**Total Marks: 50 Credits:02**

1. Preformulation studies on paracetamol/asparin/or any other drug

2. Preparation and evaluation of Paracetamol tablets

3. Preparation and evaluation of Aspirin tablets

4. Coating of tablets- film coating of tables/granules

5. Preparation and evaluation of Tetracycline capsules

6. Preparation of Calcium Gluconate injection

7. Preparation of Ascorbic Acid injection

8. Quality control test of (as per IP) marketed tablets and capsules

9. Preparation of Eye drops/ and Eye ointments

10. Preparation of Creams (cold / vanishing cream)

11. Evaluation of Glass containers (as per IP)

**Recommended Books: (Latest Editions)**

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman &J.B.Schwartz

2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman& Lachman

3. Pharmaceutical dosage form disperse system VOL-1 by Liberman& Lachman

4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition

5. Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science

6. Theory and Practice of Industrial Pharmacy by Liberman& Lachman

7. Pharmaceutics- The science of dosage form design by M.E.Aulton, Churchill livingstone, Latest edition

8. Introduction toPharmaceutical Dosage Forms by H. C.Ansel, Lea &Febiger, Philadelphia, 5thedition, 2005

9. Drug stability - Principles and practice by Cartensen& C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.

**BP503.T. PHARMACOLOGY-II (Theory)**

**Max Marks: 75 Max Time: 3h**

**Internal Assessment: 25 Marks 3L +1T/Week (45 Hours)**

**Total Marks: 100 Credits: 04**

**INSTRUCTIONS FOR THE PAPER SETTERS**

All questions should be evenly distributed taken from the whole syllabus to discourage selective reading. The question paper will consist of three sections A, B and C. Sections A will have 3 long answer type questions of 10 marks each. Section B will have 9 short answer type questions of 5 marks each. Section C will comprise 20 Multiple Choice Questions (MCQs) of 1 mark each or ten short questions of 2 marks each.

**INSTRUCTIONS FOR THE CANDIDATES**

Candidates are required to attempt any Two questions from section A, any Seven questions from section B, and all MCQs/ very short questions from Section C.

**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 different systems of body and in addition,emphasis on the basic concepts of bioassay.

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

1. Understand the mechanism of drug action and its relevance in the treatment of different diseases

2. Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments

3. Demonstrate the various receptor actions using isolated tissue preparation 4. Appreciate correlation of pharmacology with related medical sciences

**Course Content:**

**UNIT-I 10hours**

**1. Pharmacology of drugs acting on cardio vascular system**

a. Introduction to hemodynamic and electrophysiology of heart.

b. Drugs used in congestive heart failure

c. Anti-hypertensive drugs.

d. Anti-anginal drugs.

e. Anti-arrhythmic drugs.

f. Anti-hyperlipidemic drugs.

**UNIT-II 10hours**

**1. Pharmacology of drugs acting on cardio vascular system**

a. Drug used in the therapy of shock.

b. Hematinics, coagulants and anticoagulants.

c. Fibrinolytics and anti-platelet drugs

d. Plasma volume expanders

2. Pharmacology of drugs acting on urinary system

a. Diuretics

b. Anti-diuretics.

**UNIT-III 10hours**

**3. Autocoids and related drugs** a. Introduction to autacoids and classification b. Histamine,

5-HT and their antagonists. c. Prostaglandins, Thromboxanes and Leukotrienes. d. Angiotensin, Bradykinin and Substance P. e. Non-steroidal anti-inflammatory agents f. Anti-gout drugs g. Antirheumatic drugs

**UNIT-IV 08hours**

**4. Pharmacology of drugs acting on endocrine system**

a. Basic concepts in endocrine pharmacology. b. Anterior Pituitary hormones- analogues and their inhibitors. c. Thyroid hormones- analogues and their inhibitors. d. Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D. d. Insulin, Oral Hypoglycemic agents and glucagon. e. ACTH and corticosteroids.

**UNIT-V 07hours**

**5. Pharmacology of drugs acting on endocrine system** a. Androgens and Anabolic steroids. b. Estrogens, progesterone and oral contraceptives. c. Drugs acting on the uterus.

**6. Bioassay** a. Principles and applications of bioassay. b.Types of bioassay c. Bioassay of insulin, oxytocin, vasopressin, ACTH,d-tubocurarine,digitalis, histamine and 5-HT

**BP 507 P. PHARMACOLOGY-II (Practical)**

**Max Marks: 35 Max Time: 4 h**

**Internal Assessment: 15 Marks 4h /Week**

**Total Marks: 50 Credits:02**

1. Introduction to in-vitro pharmacology and physiological salt solutions.

2. Effect of drugs on isolated frog heart.

3. Effect of drugs on blood pressure and heart rate of dog.

4. Study of diuretic activity of drugs using rats/mice.

5. DRC of acetylcholine using frog rectus abdominis muscle.

6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively.

7. Bioassay of histamine using guinea pig ileum by matching method.

8. Bioassay of oxytocin using rat uterine horn by interpolation method.

9. Bioassay of serotonin using rat fundus strip by three point bioassay.

10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.

11. Determination of PA2 value of prazosin using rat anococcygeus muscle (by Schilds plot method).

12. Determination of PD2 value using guinea pig ileum.

13. Effect of spasmogens and spasmolytics using rabbit jejunum.

14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.

15. Analgesic activity of drug using central and peripheral methods

Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale’s Pharmacology, Churchil 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

8. Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert.

9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.

10. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan.

**BP504 T. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)**

**Max Marks: 75 Max Time: 3h**

**Internal Assessment: 25 Marks 3L +1T/Week (45 Hours)**

**Total Marks: 100 Credits: 04**

**INSTRUCTIONS FOR THE PAPER SETTERS**

All questions should be evenly distributed taken from the whole syllabus to discourage selective reading. The question paper will consist of three sections A, B and C. Sections A will have 3 long answer type questions of 10 marks each. Section B will have 9 short answer type questions of 5 marks each. Section C will comprise 20 Multiple Choice Questions (MCQs) of 1 mark each or ten short questions of 2 marks each.

**INSTRUCTIONS FOR THE CANDIDATES**

Candidates are required to attempt any Two questions from section A, any Seven questions from section B, and all MCQs/ very short questions from Section C.

**Scope**: The main purpose of subject is to impart the students the knowledge of how the secondary metabolites are produced in the crude drugs, how to isolate and identify and produce them industrially. Also this subject involves the study of producing the plants and phytochemicals through plant tissue culture, drug interactions and basic principles of traditional system of medicine

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

1. to know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents

2. to understand the preparation and development of herbal formulation.

3. to understand the herbal drug interactions 4. to carryout isolation and identification of phytoconstituents

**Course Content:**

**UNIT-I 7 HoursMetabolic pathways in higher plants and their determination**

a) Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway.

b) Study of utilization of radioactive isotopes in the investigation of Biogenetic studies.

**UNIT-II 14 Hours**

**General introduction**, composition, chemistry & chemical classes, biosources, therapeutic uses and commercial applications of following secondary metabolites:

**Alkaloids**: Vinca, Rauwolfia, Belladonna, Opium,

**Phenylpropanoids and Flavonoids**: Lignans, Tea, Ruta

**Steroids,** Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis

**Volatile oils**: Mentha, Clove, Cinnamon, Fennel, Coriander,

**Tannins**: Catechu, Pterocarpus Resins: Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony

**Glycosides**: Senna, Aloes, Bitter Almond

**Iridoids, Other terpenoids&Naphthaquinones**: Gentian, Artemisia, taxus, carotenoids

**UNIT-III 06 HoursIsolation, Identification and Analysis of Phytoconstituents**

a) Terpenoids: Menthol, Citral, Artemisin

b) Glycosides: Glycyrhetinic acid &Rutin

c) Alkaloids: Atropine,Quinine,Reserpine,Caffeine

d) Resins: Podophyllotoxin, Curcumin

**UNIT-IV 10 Hours**

Industrial production, estimation and utilization of the following phytoconstituents: Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine

**UNIT V 8 Hours**

Basics of Phytochemistry Modern methods of extraction, application of latest techniques like Spectroscopy, chromatography and electrophoresis in the isolation, purification and identification of crude drugs.

**BP 508 P. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)**

**Max Marks: 35 Max Time: 4 h**

**Internal Assessment: 15 Marks 4h /Week**

**Total Marks: 50 Credits:02**

1. Morphology, histology and powder characteristics & extraction & detection of: Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander

2. Exercise involving isolation & detection of active principles a. Caffeine - from tea dust. b. Diosgenin from Dioscorea c. Atropine from Belladonna d. Sennosides from Senna

3. Separation of sugars by Paper chromatography

4. TLC of herbal extract

5. Distillation of volatile oils and detection of phytoconstitutents by TLC

6. Analysis of crude drugs by chemical tests: (i) Asafoetida (ii) Benzoin (iii) Colophony (iv) Aloes (v) Myrrh

**Recommended Books: (Latest Editions)**

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.

2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.

3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, NiraliPrakashan, New Delhi.

4. Herbal drug industry by R.D. Choudhary (1996), IstEdn, Eastern Publisher, New Delhi.

5. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007

6. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.

7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.

8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.

9. Pharmacognosy&Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.

10. The formulation and preparation of cosmetic, fragrances and flavours.

11. Remington’s Pharmaceutical sciences.

12. Text Book of Biotechnology by Vyas and Dixit. 13. Text Book of Biotechnology by R.C. Dubey.

**BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)**

**Max Marks: 75 Max Time: 3h**

**Internal Assessment: 25 Marks 3L +1T/Week (45 Hours)**

**Total Marks: 100 Credits: 04**

**INSTRUCTIONS FOR THE PAPER SETTERS**

All questions should be evenly distributed taken from the whole syllabus to discourage selective reading. The question paper will consist of three sections A, B and C. Sections A will have 3 long answer type questions of 10 marks each. Section B will have 9 short answer type questions of 5 marks each. Section C will comprise 20 Multiple Choice Questions (MCQs) of 1 mark each or ten short questions of 2 marks each.

**INSTRUCTIONS FOR THE CANDIDATES**

Candidates are required to attempt any Two questions from section A, any Seven questions from section B, and all MCQs/ very short questions from Section C.

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

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

1. The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals. 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**

Drugs and Cosmetics Act, 1940 and its rules 1945:

Objectives, Definitions, Legal definitions of schedules to the Act and Rules

Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties.

Manufacture of drugs – Prohibition of manufacture and sale of certain drugs,

Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

**UNIT-II 10 Hours**

Drugs and Cosmetics Act, 1940 and its rules 1945.

Detailed study of Schedule G, H, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA) Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties.

Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors

**UNIT-III 10 Hours**

Pharmacy Act –1948: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and

Penalties

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.

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-IV 08 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

Prevention of Cruelty to animals Act-1960: Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for 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

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)

**UNIT-V 07 Hours**

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

Code of Pharmaceutical ethics D efinition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist’s oath

Medical Termination of Pregnancy Act

Right to Information Act

Introduction to Intellectual Property Rights (IPR)

Recommended books: (Latest Edition)

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)

**B PHARM VI SEM**

**BP601T. MEDICINAL CHEMISTRY – III (Theory)**

**Max Marks: 75 Max Time: 3h**

**Internal Assessment: 25 Marks 3L +1T/Week (45 Hours)**

**Total Marks: 100 Credits: 04**

**INSTRUCTIONS FOR THE PAPER SETTERS**

All questions should be evenly distributed taken from the whole syllabus to discourage selective reading. The question paper will consist of three sections A, B and C. Sections A will have 3 long answer type questions of 10 marks each. Section B will have 9 short answer type questions of 5 marks each. Section C will comprise 20 Multiple Choice Questions (MCQs) of 1 mark each or ten short questions of 2 marks each.

**INSTRUCTIONS FOR THE CANDIDATES**

Candidates are required to attempt any Two questions from section A, any Seven questions from section B, and all MCQs/ very short questions from Section C.

**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 the course student shall 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.

β-Lactam antibiotics: Penicillin, Cepholosporins, β- 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 dihydrotriazines: Cycloguanilpamoate, Proguanil.

Miscellaneous: Pyrimethamine, Artesunete, Artemether, Atovoquone.

**UNIT – III 10 Hours**

**Anti-tubercular Agents**

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

Anti tubercular antibiotics: Rifampicin, Rifabutin, CycloserineStreptomycine, Capreomycinsulphate.

**Urinary tract anti-infective agents**

Quinolones: SAR of quinolones, NalidixicAcid,Norfloxacin, Enoxacin, Ciprofloxacin\*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin

Miscellaneous: Furazolidine, Nitrofurantoin\*, Methanamine.

**Antiviral agents:**

Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridinetrifluoride, 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, OxiconazoleTioconozole, 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, Sulfisoxazole, Sulphamethizine, Sulfacetamide\*, Sulphapyridine, Sulfamethoxaole\*, 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, Hammet’s electronic parameter, Tafts steric parameter and Hansch analysis. Pharmacophore modeling and docking techniques.

Combinatorial Chemistry: Concept and applications chemistry: solid phase and solution phase synthesis.

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

**Max Marks: 35 Max Time: 4 h**

**Internal Assessment: 15 Marks 4h /Week**

**Total Marks: 50 Credits:02**

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.

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

**Max Marks: 75 Max Time: 3h**

**Internal Assessment: 25 Marks 3L +1T/Week (45 Hours)**

**Total Marks: 100 Credits: 04**

**INSTRUCTIONS FOR THE PAPER SETTERS**

All questions should be evenly distributed taken from the whole syllabus to discourage selective reading. The question paper will consist of three sections A, B and C. Sections A will have 3 long answer type questions of 10 marks each. Section B will have 9 short answer type questions of 5 marks each. Section C will comprise 20 Multiple Choice Questions (MCQs) of 1 mark each or ten short questions of 2 marks each.

**INSTRUCTIONS FOR THE CANDIDATES**

Candidates are required to attempt any Two questions from section A, any Seven questions from section B, and all MCQs/ very short questions from Section C.

**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 this course the student should 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 poisoningsand

3. appreciate correlation of pharmacology with related medical sciences.

**Course Content:**

**UNIT-I 10hours**

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 10hours**

3. Chemotherapy a. General principles of chemotherapy.

b. Sulfonamides and cotrimoxazole.

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

**UNIT-III 10hours**

3. Chemotherapy

a. Antitubercular agents

b. Antileprotic agents

c. Antifungal agents d. Antiviral drugs e.Anthelmintic f. Antimalarial drugs

g. Antiamoebic agents

**UNIT-IV 08hours**

3. Chemotherapy l. Urinary tract infections and sexually transmitted diseases. m. Chemotherapy of malignancy.

4. Immunopharmacology

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

**UNIT-V 07hours**

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, organophosphosphorus compound and lead, mercury and arsenic poisoning.

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

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

**Max Marks: 35 Max Time: 4 h**

**Internal Assessment: 15 Marks 4h /Week**

**Total Marks: 50 Credits:02**

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, Churchil 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. VallabhPrakashan,

10. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

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

**Max Marks: 75 Max Time: 3h**

**Internal Assessment: 25 Marks 3L +1T/Week (45 Hours)**

**Total Marks: 100 Credits: 04**

**INSTRUCTIONS FOR THE PAPER SETTERS**

All questions should be evenly distributed taken from the whole syllabus to discourage selective reading. The question paper will consist of three sections A, B and C. Sections A will have 3 long answer type questions of 10 marks each. Section B will have 9 short answer type questions of 5 marks each. Section C will comprise 20 Multiple Choice Questions (MCQs) of 1 mark each or ten short questions of 2 marks each.

**INSTRUCTIONS FOR THE CANDIDATES**

Candidates are required to attempt any Two questions from section A, any Seven questions from section B, and all MCQs/ very short questions from Section C.

**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 11 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.

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 7 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

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 10 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.

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 10 Hours** 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 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.

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

**Max Marks: 35 Max Time: 4 h**

**Internal Assessment: 15 Marks 4h /Week**

**Total Marks: 50 Credits:02**

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

**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.

**BP 604 T. BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)**

**Max Marks: 75 Max Time: 3h**

**Internal Assessment: 25 Marks 3L +1T/Week (45 Hours)**

**Total Marks: 100 Credits: 04**

**INSTRUCTIONS FOR THE PAPER SETTERS**

All questions should be evenly distributed taken from the whole syllabus to discourage selective reading. The question paper will consist of three sections A, B and C. Sections A will have 3 long answer type questions of 10 marks each. Section B will have 9 short answer type questions of 5 marks each. Section C will comprise 20 Multiple Choice Questions (MCQs) of 1 mark each or ten short questions of 2 marks each.

**INSTRUCTIONS FOR THE CANDIDATES**

Candidates are required to attempt any Two questions from section A, any Seven questions from section B, and all MCQs/ very short questions from Section C.

**Scope**:This subject is designed to impart knowledge and skills of Biopharmaceutics and pharmacokinetics and their applications in pharmaceutical development, design of dose and dosage regimen and in solving the problems arised therein.

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

1. Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.

2. Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.

3. To understand the concepts of bioavailability and bioequivalence of drug products and their significance.

4. Understand various pharmacokinetic parameters, their significance & applications.

**Course Content:**

**UNIT-I 10 Hours**

Introduction to Biopharmaceutics Absorption; Mechanisms of drug absorption through GIT, factors influencing drug absorption though 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 10 Hours**

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 10 Hours**

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 ,t1/2,Vd,AUC,Ka, Clt and CLR- definitions methods of eliminations, understanding of their significance and application

**UNIT- IV 08 Hours**

Multicompartment models: Two compartment open model. IV bolus Kinetics of multiple dosing, steady state drug levels, calculation of loading and mainetnance doses and their significance in clinical settins.

**UNIT- V 07 Hours**

Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity. c. Michaelis-menton method of estimating parameters, Explanation with example 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 Inernationaledition.USA

4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal,VallabhPrakashanPitampura, Delhi

5. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel 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 Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.

12. Remington’s Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia

**BP 605 T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)**

**Max Marks: 75 Max Time: 3h**

**Internal Assessment: 25 Marks 3L +1T/Week (45 Hours)**

**Total Marks: 100 Credits: 04**

**INSTRUCTIONS FOR THE PAPER SETTERS**

All questions should be evenly distributed taken from the whole syllabus to discourage selective reading. The question paper will consist of three sections A, B and C. Sections A will have 3 long answer type questions of 10 marks each. Section B will have 9 short answer type questions of 5 marks each. Section C will comprise 20 Multiple Choice Questions (MCQs) of 1 mark each or ten short questions of 2 marks each.

**INSTRUCTIONS FOR THE CANDIDATES**

Candidates are required to attempt any Two questions from section A, any Seven questions from section B, and all MCQs/ very short questions from Section C.

Biotechnology has a long promise to revolutionize the biological sciences and technology. Scientific application of biotechnology in the field of genetic engineering, medicine and fermentation technology makes the subject interesting.  Biotechnology is leading to new biological revolutions in diagnosis, prevention and cure of diseases, new and cheaper pharmaceutical drugs.

Biotechnology has already produced transgenic crops and animals and the future promises lot more.

It is basically a research-based subject.

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

1. Understanding the importance of Immobilized enzymes in Pharmaceutical Industries

2. Genetic engineering applications in relation to production of pharmaceuticals

3. Importance of Monoclonal antibodies in Industries

4. Appreciate the use of microorganisms in fermentation technology

**Unit I 10 Hours**

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 10 Hours**

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 10 Hours**

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 Substituties.

**Unit IV 08Hours**

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 07 Hours**

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 Substituties.

**Recommended Books (Latest edition):**

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.

2. RA Goldshyet. al., :Kuby Immunology.

3. J.W. Goding: Monoclonal Antibodies.

4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal

Society of Chemistry.

5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.

6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.

7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

**BP606T QUALITY ASSURANCE (Theory)**

**Max Marks: 75 Max Time: 3h**

**Internal Assessment: 25 Marks 3L +1T/Week (45 Hours)**

**Total Marks: 100 Credits: 04**

**INSTRUCTIONS FOR THE PAPER SETTERS**

All questions should be evenly distributed taken from the whole syllabus to discourage selective reading. The question paper will consist of three sections A, B and C. Sections A will have 3 long answer type questions of 10 marks each. Section B will have 9 short answer type questions of 5 marks each. Section C will comprise 20 Multiple Choice Questions (MCQs) of 1 mark each or ten short questions of 2 marks each.

**INSTRUCTIONS FOR THE CANDIDATES**

Candidates are required to attempt any Two questions from section A, any Seven questions from section B, and all MCQs/ very short questions from Section C.

**Scope**: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It deals with the important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.

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

 understand the cGMP aspects in a pharmaceutical industry

 appreciate the importance of documentation

 understand the scope of quality certifications applicable to pharmaceutical industries

 understand the responsibilities of QA & QC departments

**Course content**:

**UNIT – I 10 Hours**

**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 10 Hours** 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 10Hours**

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 08 Hours** 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 07 Hours** 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

**Recommended Books: (Latest Edition)**

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.

2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.

3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.

4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh

5. How to Practice GMP’s – P P Sharma.

6. ISO 9000 and Total Quality Management – Sadhank G Ghosh

7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms

8. Good laboratory Practices – Marcel Deckker Series

9. ICH guidelines, ISO 9000 and 14000 guidelines