EVALUATION SCHEME & SYLLABUS
FOR
B. PHARMA 3rd YEAR
ON
PCI Guidelines

(EFFECTIVE FROM THE SESSION: 2019-20)
### Scheme of Evaluation
#### Bachelor of Pharmacy (B. Pharm.)

**Semester V**

<table>
<thead>
<tr>
<th>Course code</th>
<th>Name of the course</th>
<th>Internal Assessment</th>
<th>End Semester Exams</th>
<th>Total Marks</th>
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<td>Marks</td>
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<tr>
<td>BP501T</td>
<td>Medicinal Chemistry II – Theory</td>
<td>10</td>
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<td>15</td>
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<tr>
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<td>Pharmaceutical Jurisprudence – Theory</td>
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<tr>
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Effective from the Session 2019-20
### Semester VI

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<td>Biopharmaceutics and Pharmacokinetics – Theory</td>
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SEMESTER V
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 human body.

H₁-antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines succinate, Clemastine fumarate, Diphenylphyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartrate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium.

H₂-antagonists: Cimetidine*, Famotidine, Ranitidine.

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

Anti-neoplastic agents:

Alkylating agents: Meclorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa


Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin.

Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate.

Miscellaneous: Cisplatin, Mitotane.
UNIT – II
10 Hours

Anti-anginal:


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

Diuretics:

Carbonic anhydrase inhibitors: Acetazolamide*, Methazolamide, Dichlorphenamidine.

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, Guanethidine monosulphate, 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, Lorcaainide hydrochloride, Amiodarone, Sotalol.

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


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.

**Thyroid and antithyroid drugs:** L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole.

**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)**
2. Foye’s Principles of Medicinal Chemistry.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington’s Pharmaceutical Sciences.
9. Indian Pharmacopoeia.
BP502T: Industrial Pharmacy I (Theory)  

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  

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  

Tablets:


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

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, equipment for manufacture of pellets

UNIT-IV

Parenteral Products:


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

c. Formulation of injections, sterile powders, large volume parenterals 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

**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.
BP506P: Industrial Pharmacy I (Practical)  

1. Preformulation studies on Paracetamol/Aspirin/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  
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  
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

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

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

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

5. 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

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 507P: PHARMACOLOGY-II (Practical)  
4Hrs/Week

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 abdominalis muscle and rat ileum respectively.
10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
12. Determination of PD₂ value using guinea pig ileum.
13. Effect of spasmodgens and spasmyltics using rabbit jejunum.
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)**

3. Goodman and Gilman’s, The Pharmacological Basis of Therapeutics
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
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 carry out isolation and identification of phytoconstituents

Course Content:

UNIT-I 07 Hours
Metabolic 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 Hours
Isolation, Identification and Analysis of Phytoconstituents

a) Terpenoids: Menthol, Citral, Artemisin
b) Glycosides: Glycyrrhetinic 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 08 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.
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)
10. The formulation and preparation of cosmetic, fragrances and flavours.
12. Text Book of Biotechnology by Vyas and Dixit.
BP505T: PHARMACEUTICAL JURISPRUDENCE (Theory)

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.
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

• **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** Definition, 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
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
SEMESTER VI
BP601T: MEDICINAL CHEMISTRY – III (Theory)

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

Antibiotics

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

β-Lactam antibiotics: Penicillin, Cephlosporins, 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: Isoniozid*, 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:


UNIT – IV  

Antifungal agents:

Antifungal antibiotics: Amphotericin-B, Nystatin, Natamycin, Griseofulvin.

Synthetic Antifungal agents: Clotrimazole, Econazole, Butoconazole, Oxiconazole Tinoconazole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*.


**Sulphonamides and Sulfones**

Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphonamethazine, Sulfacetamide*, Sulphapyridine, Sulfamethoxaole*, 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, Hammet’s electronic parameter, Tafts 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)  
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 (Lipinsky’s RO5)

Recommended Books (Latest Editions)
2. Foye’s Principles of Medicinal Chemistry.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington’s Pharmaceutical Sciences.
6. Martindale’s extra pharmacopoeia.
9. Indian Pharmacopoeia.
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 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 poisonings and
3. appreciate correlation of pharmacology with related medical sciences.

Course Content:

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 diarrhea.
   c. Appetite stimulants and suppressants.
   d. Digestants and carminatives.
   e. Emetics and anti-ematics.

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

UNIT-IV

3. Chemotherapy
   1. 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

5. Principles of toxicology
   a. Definition and basic knowledge of acute, sub acute 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.

6. Chronopharmacology
   a. Definition of rhythm and cycles.
   b. Biological clock and their significance leading to chronotherapy.
BP608P: PHARMACOLOGY-III (Practical)  
4Hrs/Week

1. Dose calculation in pharmacological experiments
2. Antiallergic activity by mast cell stabilization assay
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)**
3. Goodman and Gilman’s, The Pharmacological Basis of Therapeutics
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott’s Illustrated Reviews-Pharmacology
9. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,
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**  
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
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.
BP609P: HERBAL DRUG TECHNOLOGY (Practical)

4 hours/ week

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. Pharmacopoeial standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
BP604T: BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

45 Hours

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 arising 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

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 - $K_E$, $t_{1/2}$, $Vd$, $AUC$, $Ka$, $Cl_t$ and $CL_R$ - 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 mainenace 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
5. Pharmacokinetics: By Milo Gibaldi 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
BP605T: PHARMACEUTICAL BIOTECHNOLOGY (Theory)

45 Hours

Scope:
- 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

Blood products and Plasma Substitutes.

Unit IV 08 Hours
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 Substitutes.

Recommended Books (Latest edition):
2. RA Goldshy et. al.: Kuby Immunology.
45 Hours

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.

UNIT – III 10 Hours
Quality Control: Quality control test for containers, rubber closures and secondary packing
materials.


**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

**Recommended Books: (Latest Edition)**

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