DR. A.P.J ABDUL KALAM TECHNICAL UNIVERSITY, LUCKNOW

SYLLABUS & EVALUATION SCHEME

FOR

B. PHARM. III YEAR

(Effective from the Session: 2020-21)

Scheme of Evaluation
Bachelor of Pharmacy (B. Pharm.)

Semester V

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP501T	Medicinal Chemistry II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP502T	Industrial Pharmacy I– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP503T	Pharmacology II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP504T	Pharmacognosy II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP505T	Pharmaceutical Jurisprudence – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP506P	Industrial Pharmacy I– Practical	5	10	4 Hr	15	35	4 Hrs	50
BP507P	Pharmacology II – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP508P	Pharmacognosy II – Practical	5	10	4 Hr	15	35	4 Hrs	50
Total		**65**	**105**	**17 Hr**	**170**	**480**	**27 Hrs**	**650**

Semester VI

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP601T	Medicinal Chemistry III – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP602T	Pharmacology III – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP603T	Herbal Drug Technology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP605T	Pharmaceutical Biotechnology– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP606T	Quality Assurance– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP607P	Medicinal chemistry III – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP608P	Pharmacology III – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP609P	Herbal Drug Technology – Practical	5	10	4 Hrs	15	35	4 Hrs	50
Total		**75**	**120**	**18 Hrs**	**195**	**555**	**30 Hrs**	**750**

SEMESTER V

BP 501T. MEDICINAL CHEMISTRY-II (Theory)

45 Horus

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 valueof drugs
3. Know the Structural Activity Relationship of different class of drugs
4. Study the chemical synthesis of selected drugs

Course Outcomes

1. Students will be able to know the development of the Antihistaminic drugs, Proton pump inhibitors and antineoplastic drugs. Classification, mechanism of action of each class, Synthesis and structure activity relationship of representative drugs of the class.
2. Student will be able to know the use of Antianginal, antihypertensive and diuretic drugs. Classification, mechanism of action of each class, Synthesis and structure activity relationship of representative drugs of the class.
3. After completion of the module the student will be familiar with Anti-arrhythmic, Antihyperlipidemic, coagulant and anticoagulant drugs and drugs used in congestive heart failure. Classification, mechanism of action of each class, Synthesis and structure activity relationship of representative drugs of the class.
4. This module will assist the student to have a good understanding about the development of drugs acting on endocrine system, Sex hormones, drugs for erectile dysfunction, oral contraceptives, corticosteroids, thyroid and antithyroid drugs. Classification, mechanism of action of each class, Synthesis and structure activity relationship of representative drugs of the class.
5. This module summarizes the need and importance of antidiabetic agents and local anaesthetics. Classification, mechanism of action of each class, Synthesis and structure activity relationship of representative drugs of the class.

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

H_1–antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines cuccinate, Clemastine fumarate, Diphenylphyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolynsodium

H_2-antagonists: Cimetidine*, Famotidine, Ranitidine.

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

Anti-neoplastic agents:

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

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

Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleom ycin

Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate

Miscellaneous: Cisplatin, Mitotane.

UNIT – II **10 Hours**

Anti-anginal:

Vasodilators: Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, 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, 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, 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

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

UNIT – V **07 Hours**

Antidiabetic agents:

Insulin and its preparations

Sulfonylureas: 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 by 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 by A.I. Vogel.
11. Synthesis of Essential Drugs by Vardanyan and Hruby, Elsevier.
12. Medicinal and Pharmaceutical Chemistry by Singh and Kapoor.
13. Medicinal Chemistry- A Biochemical Approach by Nogrady
14. The Organic Chemistry of Drug Design and Drug Action by Silverman, Elsevier.

BP 502 T. Industrial Pharmacy I (Theory)

45 Hours

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 outcome:

1. To apply principle of pre formulation studies in development of solid, liquid oral and parental dosage form
2. The students will able to know about manufacturing of tablet, liquid orals and their evaluation
3. The students will able to know about manufacturing of capsule shells, there filling technique and their evaluation
4. The student will able to know about formulation of parental dosage forms
5. Student will able to know various key ingredients used in cosmetics and formulation of various cosmetic product and will aware of science of packaging and there legal requirement

Course content:

3 hours/ week

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 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 **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.

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 (RPS).
6. Theory and Practice of Industrial Pharmacy by Liberman & Lachman.
7. Pharmaceutics- The science of dosage form design by M. E. Aulton, Churchill

BP 506 P. Industrial Pharmacy I (Practical)

4 Hours/week

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. Qulaity 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. Livingstone, Latest edition.
2. Introduction to Pharmaceutical Dosage Forms by H. C.Ansel, Lea &Febiger, Philadelphia, 5thedition, 2005.
3. Drug stability- Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.
4. Tutorial Pharmacy, by Cooper and Gunn, Petman Books Ltd., London.
5. The Theory and Practice of Industrial Pharmacy by Khar R. K., Vyas S.P., Ahmad F., Jain G. K., 4th Edition, CBS Publishers and Distributors.
6. Drug Delivery Systems by Juliano, R.L., Oxford University Press, Oxford.
7. Turco S. J., Sterile Dosage Form-Their Preparation and Clinical Application, LWW.

BP503.T. PHARMACOLOGY-II (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 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 Outcome

1. Students would have understood the signal transduction mechanism of various receptors.
2. They would have understood mechanism of drug action at organ system/sub cellular/ macromolecular levels and its relevance in the treatment of different diseases.
3. They would have understood the drug metabolic pathways, adverse effect and therapeutic value of drugs.
4. They would have understood the pharmacological actions of different categories of drugs.
5. They would have understood the application of basic pharmacological knowledge in the prevention and treatment of various diseases.

Course Content:

UNIT-I **10 hours**

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 **10 hours**

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 **10 hours**

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 **08 hours**

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 **07 hours**

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, histamineand 5-HT

BP 507 P. 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 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 PA_2 value of prazosin using rat anococcygeus muscle (by Schilds plot method).
12. Determination of PD_2 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 and Dale's Pharmacology, Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Churchil Livingstone Elsevier
2. Basic and clinical pharmacologyby Katzung B. G., Masters S. B., Trevor A. J., Tata McGraw-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. Applied Therapeutics, The Clinical use of Drugs by K., Bradley R.W. The Point Lippincott Williams & Wilkins.
5. Lippincott's Illustrated Reviews- Pharmacologyby Mycek M.J, Gelnet S.B and Perper M.M..
6. Essentials of Medical Pharmacology by K.D.Tripathi. JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Principles of Pharmacology by Sharma H. L., Sharma K. K. Paras medical publisher
8. Modern Pharmacology with clinical Applications by Charles R.Craig& Robert.
9. Fundamentals of Experimental Pharmacology, Ghosh MN. Hilton & Company, Kolkata.
10. Handbook of experimental pharmacology by Kulkarni S.K. Vallabh Prakashan.
11. Text Book of Pharmacology, Barar F.S.K., Interprint.
12. Clinical Pharmacology, by Laurence, D.R. and Bannet P.N., Churchill Livingstone.
13. Modern Pharmacology by Craig C.R. and Stitzel, R.R., 4th Edition, Little Brown and Co.

BP504 T. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)

45Hours

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 theherbal 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 outcomes

1. Students will be understanding the basic knowledge of biosynthesis of secondary metabolites in plants. A radio tracer technique provides detail about the various step involved for the biosynthesis of secondary metabolites.
2. Students shall be able to understand the composition, chemistry, commercial applications of phytoconstituents of various chemical category like alkaloids, lignans, steroids, terpenes, resin etc.
3. After the completion of the module student will be able familiar with extraction, isolation and analysis of Glycosides, Terpenoids, alkaloids and resin containing drugs.
4. This module will assist the student to have a good understanding about Industrial production, estimation and utilization of Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine.
5. This module summaries the fundamental aspects and importance of modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents by Spectroscopy, chromatography and electrophoresis.

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 metabolitesthrough 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 usesand 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: 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 **0 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 crudedrugs.

BP 508 P. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)

4 Hours/Week

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, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, 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) 45 hours

Scope: This course is designed to impart basic knowledge on importantlegislations 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 Outcome: 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.
5. The salient features of different laws which have been prescribed by the PCI from time to time including International Laws.

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)

SEMESTER VI

BP601T. MEDICINAL CHEMISTRY – III (Theory)

45 Hours

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

Objectives: Upon completion of 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 Outcomes: Upon completion of course student shall be able to-

1. Understand & learn classification, nomenclature, SAR, MOA, synthesis & uses of various drugs of classes like β-Lactam antibiotics, Aminoglycosides, Tetracycline.
2. Understand & learn classification, nomenclature, SAR, MOA, synthesis & uses of various drugs of classes like Macrolide, Antimalarial drugs like Quinolines, Biguanides and dihydro triazines & miscellaneous with basic concept and application of prodrugs.
3. Understand & learn classification, nomenclature, SAR, MOA, synthesis & uses of various drugs of classes like Anti-Tubercular Agents, Urinary tract anti-infective agents, Antiviral agents.
4. Understand & learn classification, nomenclature, SAR, MOA, synthesis & uses of various drugs of classes like Antifungal antibiotics, Synthetic Antifungal agents, Anti-protozoal Agents, Anthelmintic, Sulphonamides and Sulfones.
5. Understand and learn different physicochemical parameters of QSAR & different approaches of drug design.

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 dihydro triazines: Cycloguanil pamoate, 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, Cycloserine Streptomycine, Capreomycin sulphate.

Urinary tract anti-infective agents

Quinolones: SAR of quinolones, Nalidixic Acid,Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin

Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine.

Antiviral agents:

Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirding, Ribavirin, Saquinavir, Indinavir, Ritonavir.

UNIT – IV **08 Hours**

Antifungal agents:

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

Synthetic Antifungal agents: Clotrimazole, Econazole, Butoconazole, Oxiconazole Tioconozole, 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 of combinatorial chemistry: solid phase and solution phase synthesis.

BP607P. MEDICINAL CHEMISTRY- III (Practical)

4 Horus/ week

I Preparation of drugs and intermediates

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

II Assay of drugs

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

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

IV Drawing structures and reactions using chem draw®

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

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic Medicinal and Pharmaceutical Chemistry.
2. Foyes Principles of Medicinal Chemistry, Lippincott Williams and Wilkins.
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.
11. Synthesis of Essential Drugs by Vardanyan and Hruby, Elsevier.
12. Medicinal and Pharmaceutical Chemistry by Singh and Kapoor, Vallabh Prakashan.
13. Medicinal Chemistry: A Biochemical Approach by Nogrady, Oxford University Press.
14. An Introduction to Medicinal Chemistry by Patrick Oxford University Press.
15. Comprehensive Medicinal Chemistry by Hansch, Pergamon Press.
16. Practical Organic Chemistry by Mann and Saunders, Orient Longman Limited.
17. Vogel's Textbook of Practical Organic Chemistry, Dorling Kindersley (India) Pvt. Ltd. (Pearson Education Ltd.).

BP602 T. 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 Outcomes: The learner should be able to understand:

1 basic knowledge about the disease of respiratory system / gastrointestinal system and drugs used in these problems.

2. Mechanism of action, adverse effect, drug interaction, contraindication arises due to use of Penicillin's, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolones, tetracycline and aminoglycosides drugs and their management.

3. Basic knowledge of drugs used in the treatment of tuberculosis, leprosy viral infection, worm infestation, fungal and amoebic infection

4. Area of medicine used in malignancy, sexually transmitted diseases, transplantation and immunity enhancer agents, knowledge about the anticancer drugs, drugs used in sexually transmitted diseases, immunostimulants and immunosuppressants drugs.

5. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity, General principles of treatment of poisoning, Clinical symptoms and management of barbiturates, morphine, organophosphosphorus compound and lead, mercury and arsenic poisoning. Definition of rhythm and cycles. Biological clock and their significance leading to chronotherapy.

Course Content:

UNIT-I **10 hours**

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 **10 hours**

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 **10 hours**

3. Chemotherapy

a. Antitubercular agents

b. Antileprotic agents

c. Antifungal agents

d. Antiviral drugs

e.Anthelmintics

f. Antimalarial drugs

g. Antiamoebic agents

UNIT-IV **08 hours**

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 **07 hours**

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)

4Hrs/Week

1. Dose calculation in pharmacological experiments
2. Antiallergic activity by mast cell stabilization assay
3. Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.
4. Study of effect of drugs on gastrointestinal motility
5. Effect of agonist and antagonists on guinea pig ileum
6. Estimation of serum biochemical parameters by using semi- autoanalyser
7. Effect of saline purgative on frog intestine
8. Insulin hypoglycemic effect in rabbit
9. Test for pyrogens (rabbit method)
10. Determination of acute oral toxicity (LD50) of a drug from a given data
11. Determination of acute skin irritation / corrosion of a test substance
12. Determination of acute eye irritation / corrosion of a test substance
13. Calculation of pharmacokinetic parameters from a given data
14. Biostatistics methods in experimental pharmacology(student's t test, ANOVA)
15. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)

**Experiments are demonstrated by simulated experiments/videos*

Recommended Books (Latest Editions)

1. Rang and Dale's Pharmacology, Churchil Livingstone Elsevier.
2. Basic and clinical pharmacologyby Katzung B. G., Masters S. B., Trevor A. J., Tata McGraw-Hill.
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics.
4. Applied Therapeutics, The Clinical use of Drugs by Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A.K., Bradley R.W. The Point Lippincott Williams & Wilkins.
5. Lippincott's Illustrated Reviews- Pharmacology by Mycek M.J, Gelnet S.B and Perper M.M.
6. Essentials of Medical Pharmacology by K.D.Tripathi, Jaypee Brothers Medical Publishers (P) Ltd.
7. Principles of Pharmacology by Sharma H. L., Sharma K. K., Paras Medical Publisher.
8. Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert,
9. Fundamentals of Experimental Pharmacologyby Ghosh, Hilton & Company.
10. Handbook of Experimental Pharmacology by Kulkarni S.K., Vallabh Prakashan.
11. Clinical Pharmacology by Laurene, D.R. & Bennet P.N., Churchill Livingstone.
12. Principles of Pharmacology by Paul, Chapman and Hall.
13. Concepts in Chronopharmacologyby N.Udupa and P.D. Gupta.
14. Text Book of Pharmacology by Barar, Interprint.

BP 603 T. 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 outcome

1. Students will be able to
   a) understand raw material as source of herbal drugs from cultivation to herbal drug product.
   b) Learn Good agricultural practices in cultivation of medicinal plants including Organic farming, Pest and Pest management in medicinal plants and Biopesticides/Bioinsecticides.
   c) understand basic principles involved in Ayurveda, Siddha, Unani and Homeopathy system of medicine and describe the processes of formulation and evaluation of various ayurvedic dosages form like Aristas and Asawas, Ghutika, Churna, Lehya and Bhasma.
2. a) Students will be able to describe Health benefits and role of Nutraceuticals and various herbs in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases.

   b) After study of this module student will be able to describe the various aspects of herbal drug and herbs-food interaction.
3. Students will be able to describe about sources and description of raw materials of herbal origin used in the preparation of herbal cosmetics and types of excipients like colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes used in the formulation of herbal syrups, mixtures and tablets.
4. Upon completion of this module student shall be able to know the patenting and regulatory requirements of natural products like Patent, IPR, Farmers right, Breeder's right and WHO and ICH guidelines for assessment and stability testing of herbal drugs.
5. After the completion of the course students will be able to know the present and future prospects of herbal drug industry, regulatory guidelines like GMP (Schedule T), SOPs, for the manufacturing of Ayurvedic formulations.

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)

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. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy).
7. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
8. Pharmacognosy by Tyler V.E., Lynnr B. and Robbers J.E., 8th Edition, Lea & Febiger, Philadelphia.
9. Harborne J.B., Phytochemical Methods, Chapman & Hall International Edition.
10. Medicinal Plants of India, Vol. I & II, Indian Council of Medical Research.
11. Indian Materia Medica by Nadkarni A.K.Vol- 1&2, Popular Prakashan (P) Ltd.
12. A Selection of Prime Ayurvedic Plant Drugs by Sukh Dev, Anamaya Publisher.
13. Indian Herbal Pharmacopoeia, Vol. I & II, ICMR & RRL, Jammu.
14. Indian Ayurvedic Pharmacopoeia, Govt. of India.
15. The Wealth of India, Raw Materials (All volumes), Council of Scientific & Industrial Research.
16. Rastogi R. P. and Mehrotra B.N., Compendium of Indian Medicinal Plants I-IV, Publications & Information Directorate/Central Drug Research Institute.
17. Wallis T.E., Analytical Microscopy, J&A Churchill Ltd.
18. Practical Pharmacognosy by Kokate C.K., Vallabh Prakashan.
19. Pharmacognosy of Powdered Crude Drugs by Iyengar M.A., PharmaMed Press.
20. Anatomy of Powdered Crude Drugsby Iyengar, M.A. and Nayak S.C.K., PharmaMed Press.

BP 604 T. 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 outcome: Upon completion of the syllabus the student shall be able to-

1. Explain about the basics of drug action with relevance to therapeutic action and side effects
2. Describe effects of Pharmacokinetic (ADME) parameters on the biological effects of the drug and body
3. Explain about distribution of drugs in various body site (Compartments) and their relevance to Protein binding.
4. Interpret dosage regime indicating loading dose, maintenance dose and clinical significance.
5. Justify non linearity in ADME profile, reasons and interpretation.

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 - K_E ,t1/2,Vd,AUC,Ka, Clt 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 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 International edition.
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal,Vallabh Prakashan Pitampura.
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 .
9. Thomas, N. Tozen, Lea and Febiger, 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 Robert F Notari Marcel Dekker Inn.
12. Remington's Pharmaceutical Sciences, Mack Publishing Company.
13. Drug Disposition & Pharmacokinetics by Curry, S. H., Pharma Book Syndicate.
14. Analytical Techniques for Biopharmaceuticals Development, by Robert, Rodriguezdiaz.
15. Clinical Pharmacokinetics, by Rowland M, and Tozer T.N. Lea and Febriger.
16. Fundamentals of Clinical Pharmacokinetics by Wagner J.G. Drugs Intelligence Publishers.
17. Pharmacokinetics for the Pharmaceutical Scientist by Wagner J.G. Technomic Publishing A.G.

BP 605 T. 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

Course outcomes

1. Understanding the importance of Immobilized enzymes in Pharmaceutical Industries.
2. Study the examples of biotechnology derived products and transgenic animals, cryopreservation and germplasm storage.
3. Understand basic Introduction of scope, Potential and achievements in biotechnology. Genetic engineering applications in relation to production of pharmaceuticals.
4. Understand and Study steps involved in monoclonal antibody production, enzyme technology and fermentation technology.
5. Understand the New concepts of Biotechnology, Genetic engineering techniques and recombinant DNA 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 Substitutes.

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 Substitutes.

Recommended Books (Latest edition):

1. Molecular Biotechnology: Principles and Applications of Recombinant DNA by B.R. Glick and J.J. Pasternak, ASM Press.
2. Kuby Immunologyby RA Goldshy et. al.
3. Monoclonal Antibodies by J.W. Goding.
4. Molecular Biology and Biotechnology by J.M. Walker and E.B. Gingold, Royal Society of Chemistry.
5. Immobilized Enzymes by Zaborsky, CRC Press.
6. Molecular Biotechnology (Second Edition) by S.B. Primrose, Blackwell Scientific Publication.
7. Principles of fermentation technology by Stanbury F., P., Whitakar A., and Hall J., S., 2nd edition, Aditya Books.
8. Prescott and Dunn's Industrial Microbiology, CBS Publishers and Distributors
9. Pharmaceutical Biotechnology by Vyas S.P. and Dixit V.K., CBS Publication.
10. Biotechnology by Kieslich K., Verleg Chernie.
11. Principles of Fermentation by Standury P.F.,Whitaker A. & Hall S.J., Aditya Book Private Limited.
12. Biotechnology- A Textbook of Industrial Microbiology by Crueger W. & CruegerA, Panima Publishing Corporation.

BP606T. PHARMACEUTICAL QUALITY ASSURANCE (Theory)

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 pharmaceuticalindustries
- understand the responsibilities of QA & QC departments

Course outcomes:

- The students can understand the principals of quality management system, responsibilities of QA & QC departments and cGMP aspects in a pharmaceutical industry. They will also analyze the problems associated with quality management system.
- The students can able to understand the specifications required in an organization. They can also build a communication link between pharmaceutical industry and society. They can be a leader in planning layouts of industry by lifelong learning and will establish their own identity.
- The students can able to justify the use of quality certifications applicable to society and pharmaceutical industry. They can also maintain the sustainability of environment by understanding the procedures related with laboratory practices in a pharmaceutical industry.
- The students will learn the importance of documentation necessary in a pharmaceutical industry by maintaining ethical standards in pharmacy.
- The students will be highly skilled in operating modern instruments and can able to plan the validation protocols.

Course content:

UNIT – I **10 Hours**

Quality Assurance and Quality Management concepts: Definition and concept of Qualitycontrol, 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 **10 Hours**

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, MasterFormula 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 andRelated 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.
10. Pharmacopoeia of India, Ministry of Health, Govt. of India.
11. WHO-Quality Assurance of Pharmaceuticals, Vol. I & II, AITBS Publisher &Distributors.
12. Validation of API by Berry I.R. and Harpaz, D., 2nd Edition, CRC Press.
13. Analytical Profile of Drug Substance, by Florey K., (All volume), Academic Press,Elsevier.