B. PHARM. III YEAR
SEMESTER – V

III B. PHARM SCHEME

SEMESTER – V

S. No.	Sub. Code	Subject	L	T	P	Th. Credit	Tu. Credit	Pr. Credit	Total Credit	Maximum Marks				
										TH	CW	SW	Pr.	Total
1.	PY3Y016	Medicinal Chemistry II	3	1	-	3	1	-	4	75	25	-	-	100
2.	PY3Y017	Industrial Pharmacy I	3	1	4	3	1	2	6	75	25	15	35	150
3.	PY3Y020	Pharmacology II	3	1	4	3	1	2	6	75	25	15	35	150
4.	PY3Y019	Pharmacognosy & Phytochemistry II	3	1	4	3	1	2	6	75	25	15	35	150
5.	PY3Y018	Pharmaceutical Jurisprudence	3	1	-	3	1	-	4	75	25	-	-	100
Total			**15**	**5**	**12**	**15**	**5**	**06**	**26**	**375**	**125**	**45**	**105**	**650**

PY3Y016: MEDICINAL CHEMISTRY–II

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Total Credit	Maximum Marks				
							TH	CW	SW	Pr.	Total
3	1	-	3	1	-	4	75	25	-	-	100

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

- Understand the chemistry of drugs with respect to their pharmacological activity.
- Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs.
- Know the Structural Activity Relationship of different class of drugs.
- Study the chemical synthesis of selected drugs.

Course Outcomes: Upon completion of the course, student shall be able to:

CO-1: Explain the principles of medicinal chemistry related with synthesis, SAR and MOA.

CO-2: Learn and extend the basic knowledge associated with chemical structure of drugs and their pharmacological actions.

CO-3: Understand the relationship of structure of medicinal compounds with their ADME properties and adverse drug reactions.

CO-4: Assess the quantum of lifestyle disorders and their treatment with modern therapeutic agents.

CO-5: Analyze and communicate the overall profile of a drug with health care professionals.

THEORY **DURATION (LECTURE)**

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**

Antihistaminic agents: Histamine, receptors and their distribution in the human body

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

H_2 -antagonists: Cimetidine*, Famotidine, Ranitidin.

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, Bleomycin
Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate
Miscellaneous: Cisplatin, Mitotane.

UNIT II **10**

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**

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**

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**

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.*

BOOKS AND REFERENCES RECOMMENDED:

Text books:

1. Block J. H., Beale J. M., "Wilson and Gisvold's Textbook of organic medicinal and pharmaceutical chemistry", 11th edition, 2004, Lippincott Williams and Wilkins-A WoltersKluwer Company.
2. Lemke T. L., Williams D. A.,"Foye's principles of medicinal chemistry", 6th edition, 2008,Lippincott Williams and Wilkins-A Wolters Kluwer Company.
3. Finar I. L., Organic Chemistry (2011) vol.2, Organic Chemistry: 6th Edition. Longman.
4. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1 to 5.

Reference books:

1. Wolff M. E.,"Burger's medicinal chemistry and drug discovery" 5th edition, 1995, Wiley-Interscience, New York.
2. Abraham D.J, Rotella D.P., "Burger's medicinal chemistry and drug discovery" 7th edition,2010, Wiley-Interscience, New York.
3. Hansch C., "Comprehensive medicinal chemistry" Vol. I-VI, 1990, Pergamon Press.
4. Indian Pharmacopoeia, (2014), published by Indian Pharmacopoeia Commission, Ghaziabad.
5. Loyd V. Allen., Remington's The science & Practice of pharmacy, 22nd edition, Pharmaceutical press, 2012.
6. Vogel, I. A., (1956) A Text Book of Practical Organic Chemistry Including Qualitative Organic Analysis: 3rd Edition. Longman
7. Smith H. J., Williams H., "Introduction to Principles of drug design" 4th edition (2005)CRC Press.

PY3Y017: INDUSTRIAL PHARMACY- I

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Total Credit	Maximum Marks				
							TH	CW	SW	Pr.	Total
3	1	4	3	1	2	6	75	25	15	35	150

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:

On completion of this subject, students should be able to:

- Understand the formulation principles, manufacturing, packaging and evaluation of tablet, capsule,liquid, ophthalmic, aerosol and cosmetic formulations.
- Familiarize with the formulation additives, their properties and appropriate use in above dosageforms.
- Develop skills related to production methods, formulation problems and their trouble shooting.
- Perform formulation and evaluation of cosmetics based on powders, creams, lotions, shampoo, haircolors, lipstick and sunscreen products.
- Identify the critical formulation requirements of ophthalmic products, and aerosols.

Course Outcomes: Upon completion of the course, student shall be able to:

CO-1: Describe the principles of formulation, manufacturing, packaging and evaluation of tablet, capsule, liquid, ophthalmic, aerosol and cosmetic formulations.

CO-2: Familiarize with the formulation additives, their properties and appropriate use in above dosage forms.

CO-3: Develop skills related to production methods, formulation problems and their trouble shooting.

CO-4: Identify the critical formulation requirements of ophthalmic products, and aerosols.

CO-5: Perform formulation and evaluation of cosmetics based on powders, creams, lotions, shampoo, hair colors, lipstick and sunscreen products.

THEORY **DURATION (LECTURE)**

UNIT I **7**

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**

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 **8**

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.

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

UNIT IV **10**

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 infusionfluids. 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; evaluationof ophthalmic preparations.

UNIT V **10**

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 & manufacture of aerosol; Evaluation of aerosol; Quality control & 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.

PRACTICALS:

Minimum 15 practicals covering following areas:

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 tablets/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
9. Quality control test of (as per IP) marketed capsules
10. Preparation of Eye drops
11. Preparation of Eye ointments
12. Preparation of Cold Creams
13. Preparation of Vanishing cream
14. Evaluation of Glass containers (as per IP)
15. Preparation of aqueous injection of poorly water soluble drug using mixed solvency concept.

BOOKS & REFERENCES RECOMMENDED:

Textbooks:

1. Theory and Practice of Industrial Pharmacy by Liberman & Lachman
2. Introduction to Pharmaceutical Dosage Forms by H. C. Ansel, Lea & Febiger, Philadelphia, 5th edition, 2005
3. Pharmaceutics- The science of dosage form design by M.E.Aulton, Churchil llivingstone, Latest edition
4. Mithal B.M., Saha R.N., A handbook of cosmetics, 1st Ed.,Vallabh Prakashan.
5. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition

Reference books:

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. Remington: The Science and Practice of Pharmacy, 20th edition, Pharmaceutical Science (RPS)
5. Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.
6. Ansel H.C., Pharmaceutical calculations, 14th ed. 2015, Lippincott Williams & Wilkins India
7. Sagarine Edward, Cosmetics: science & technology, 2nd Ed. 1972, John Wiley & Sons publisher
8. Harry's Cosmeticology, 8th Edition, 2000, Chemical Publishing Company, Inc.

PY3Y020: PHARMACOLOGY-II

L	T	P	Th. Credit	Tu. Credit	Pr. Credit	Total Credit	Maximum marks				
							TH	CW	SW	Pr	Total
3	1	4	3	1	2	6	75	25	15	35	150

Scope:

- To impart the fundamental knowledge on various aspects of pharmacology including classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications of drugs acting on given systems of body.
- To understand the basic concepts of bioassay and the way of demonstration of drug's effect in laboratory setup at suitable level i.e. *in-silico, in-vitro, ex-vivo* and *in-vivo*.

Objectives: After completion of course, student should be able to:

- Understand the drug treatment of cardiovascular disorders with mechanism of drug action.
- Understand various disorders due to imbalance of hormone system and their correction strategies.
- Understand ionotropic and chronotropic effect on heart and its subsequent effects.
- Develop understanding of demonstration of effect of various drugs on heart.
- Understand pharmacology of autocoids and drugs used in treatment of disorders of urinary system.
- Develop skills for demonstration of basic principles of pharmacology in laboratory setup.
- Understand *in-silico, in-vitro, ex-vivo* and *in-vivo* demonstration of principles of pharmacology.

Course Outcomes: Upon completion of the course, student shall be able to:

CO-1: Explain the classification, mechanism of action, interaction and adverse effects of drug assigned for cardiovascular disorders.

CO-2: Discuss the mechanism of action, interaction and adverse effects of drug used in Urinary track system.

CO-3: Classify autocoids, discuss the mechanism of action, interaction and adverse effects of autacoid related drugs.

CO-4: Enlist disorders related to imbalance in hormone system and discuss their drug treatment strategies**.**

CO-5: Learn, perform and interpret the bioassay and compare the various drug response to receptor using isolated tissue preparation

THEORY TOPICS DURATION (LECTURES)

UNIT I **10**

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

a) Pharmacology of drugs acting on cardio vascular system
   i. Drug used in the therapy of shock.
   ii. Hematinics, coagulants and anticoagulants.
   iii. Fibrinolytics and anti-platelet drugs
   iv. Plasma volume expanders
b) Pharmacology of drugs acting on urinary system
   i. Diuretics
   ii. Anti-diuretics.

10

UNIT III **10**

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

Pharmacology of drugs acting on endocrine system **8**

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.
e) Insulin, Oral Hypoglycemic agents and glucagon.
f) ACTH and corticosteroids.

UNIT V **7**

a) Pharmacology of drugs acting on endocrine system
   i. Androgens and Anabolic steroids.
   ii. Estrogens, progesterone and oral contraceptives.
   iii. Drugs acting on the uterus.
b) Bioassay
   i. Principles and applications of bioassay.
   ii. Types of bioassay
   iii. Bioassay of insulin, oxytocin, vasopressin, ACTH,d-tubocurarine,digitalis, histamine and 5-HT

PRACTICALS: Minimum 15 experiments based on the following:

1. Introduction to in-vitro pharmacology and physiological salt solutions.
2. Effect of drugs on isolated frog heart.
3. Effect of drugs on blood pressure and heart rate of dog.
4. Study of diuretic activity of drugs using rats/mice.
5. DRC of acetylcholine using frog rectus abdominis muscle.
6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively.
7. Bioassay of histamine using guinea pig ileum by matching method.

8. Bioassay of oxytocin using rat uterine horn by interpolation method.
9. Bioassay of serotonin using rat fundus strip by three point bioassay.
10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
11. Determination of PA2 value of prazosin using rat anococcygeus muscle (by Schilds plot method).
12. Determination of PD2 value using guinea pig ileum.
13. Effect of spasmogens and spasmolytics using rabbit jejunum.
14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
15. Analgesic activity of drug using central and peripheral methods

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

BOOKS AND REFERENCES RECOMMENDED

Text books:

1 Tripathi, K. D. Essentials of Medicinal Pharmacology, 7th edition 2013, Jaypee Brothers Medical Publishers (P) Ltd., New Delhi.
2 Satostkar, R.S., Rege, N.N., Bhandarkar, S.D. Pharmacology and Pharmacotherapeutics. Revised 23rd edition 2013, Popular Prakashan Pvt. Ltd., Mumbai,
3 Rang, H.P., Dale, M.M., Ritter, J.M., Flower, R.J., Henderson, G. Rang and Dale's Pharmacology. 8th edition 2015, Elsevier India.
4 Ghosh, M. N. Fundamentals of Experimental Pharmacology. 2nd edition 1984, Scientific Book Agency, Calcutta.
5 Kulkarni, S.K., Hand Book of Experimental Pharmacology, 3rd Edition, 1999, Vallabh Prakashan.
6 Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher.

Reference books:

1. Brunton, L., Chabner, B.A., Knollman, B. Goodman and Gillman's the Pharmacological Basis of Therapeutics. 12th edition 2011, McGraw Hill Education.
2. Katzung B. G., Trevor A.J. Basic and Clinical Pharmacology.13th edition 2015, McGraw-Hill Medical
3. Vogel, H. G. Drug Discovery and Evaluation. 2nd edition 2002, Springer Publication, Berlin.
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams &Wilkins.
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology.
6. Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert,

Software:

1 Ex-Pharm, Raveendran R. Department of pharmacology, JIPMER, Pandicherry, India, 2009.

Website:

1. http://www.indphar.org

Mobile Application:

1 Pharmacology by Apple Medical Group 2014.
2 ECG practical demo 2.84 by Kapelis Aristidis in 2014.

PY3Y019: PHARMACOGNOSY & PHYTOCHEMISTRY-II

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Total Credit	Maximum Marks				
							TH	CW	SW	Pr.	Total
3	1	4	3	1	2	6	75	25	15	35	150

Scope: The main purpose of subject is to impart the students 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:

After completion of course, student shall be able to:

- Understand the basic knowledge about traditional herbal drugs and their importance.
- Know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents.
- Understand biosynthetic pathways for production of secondary metabolites.
- Understand composition, chemistry, chemical classes, biosources and uses of secondary metabolites.
- Understand chromatographic techniques for isolation of phytoconstituents.
- To know about the production, applications and industrialization of phytoconstituents.

Course Outcomes: Upon completion of the course, student shall be able to:

CO-1: Understand biosynthetic pathways for production of secondary metabolites and their pharmaceutical and industrial applications.

CO-2: Describe utilization of radioactive isotopes in the investigation of Biogenetic studies

CO-3: Explain composition, chemical classes, biosources and uses of secondary metabolites.

CO-4: Apply the modern extraction techniques, characterization, analysis and identification of the herbal drugs and phytoconstituents.

CO-5: Develop skill of performing different chromatographic techniques for isolation of phytoconstituents.

THEORY **DURATION (LECTURES)**

UNIT I **7**

Metabolic pathways in higher plants and their determination:

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

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

UNIT II **14**

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 **6**

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**

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

UNIT V **8**

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.

PRACTICALS:

Minimum 15 experiments based on the following:

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: Caffeine - from tea dust.
3. Exercise involving isolation & detection of active principles:Diosgenin from Dioscorea.
4. Exercise involving isolation & detection of active principles:Atropine from Belladonna.
5. Exercise involving isolation & detection of active principles:Sennosides from Senna.
6. Separation of sugars by Paper chromatography
7. TLC of herbal extract
8. Distillation of volatile oils and detection of phytoconstitutents by TLC
9. Analysis of crude drugs by chemical tests: (i) Asafoetida (ii) Benzoin (iii) Colophony (iv) Aloes (v) Myrrh
10. Study the extraction efficiency by use of hydrotropic solubilization technique.

BOOKS & REFERENCES RECOMMENDED

Text books:

1. Mohammad Ali. Pharmacognosy and Phytochemistry, 1st edition, 2008, CBS Publishers & Distribution, New Delhi.
2. A.N. Kalia, Textbook of Industrial Pharmacognosy, 2005, CBS Publishers, New Delhi,
3. Ansari S.H.,Essentials of Pharmacognosy, 2nd edition, 2007, Birla publications, New Delhi.
4. Kokate C.K., Purohit A.P., Gokhale S.B., Pharmacognosy, 44th edition, 2009, Published by Nirali Prakashan, New Delhi.
5. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.
6. Dubey.R.C., Text Book of Biotechnology, 1993

Reference books:

1. Evans, W. C. "Trease and Evans Pharmacognosy", 16th edition, 2009, WB Saunders& Co, London.
2. Tyler VE., Brady LR and Robbers JE., Pharmacognosy, 9th edition, 1988, Lea and Febiger, Philadelphia
3. Choudhary R.D., Herbal drug industry, 1st edition, 1996, Eastern Publisher, New Delhi.
4. Vyas S.P., Dixit V.K., Pharmaceutical Biotechnology, 1st edition, reprint2007, CBS Publishers & Distribution, New Delhi.
5. R Endress, Plant cell Biotechnology, 1994, Springer-Verlag, Berlin.
6. Remington's Pharmaceutical sciences, 21st edition, 2006, Lippincott Williams & Wilkins.
7. The formulation and preparation of cosmetic, fragrances and flavours.

PY3Y018: PHARMACEUTICAL JURISPRUDENCE

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Total Credit	Maximum Marks				
							TH	CW	SW	Pr.	Total
3	1	-	3	1	-	4	75	25	-	-	100

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:

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

Course Outcomes: Upon completion of the course, student shall be able to:

CO-1: Describe the Pharmaceutical legislations and their implications in the development, Production and marketing of pharmaceuticals

CO-2: Explain various Indian pharmaceutical Acts and Laws

CO-3: Employ the guidelines of regulatory authorities and agencies governing the manufacture, sale and production of pharmaceuticals

CO-4: Identify the code of ethics during the pharmaceutical practice.

CO-5: Express the Pharmaceutical Legislations, code of ethics and IPR.

THEORY **DURATION (LECTURES)**

UNIT-I **10**

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 underlicense 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, loanlicense and repacking license.

UNIT-II **10**

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 fordrugs and cosmetics, List of permitted colors. Offences and penalties.

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

UNIT-III **10**

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**

Study of Salient Features of Drugs and Magic Remedies Act and itsrules: 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**

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)

BOOKS & REFERENCES RECOMMENDED

Text books:

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

Reference books:

1. Drugs and Cosmetics Act/Rules by Govt. of India publications.
2. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
3. Narcotic drugs and psychotropic substances act by Govt. of India publications
4. Drugs and Magic Remedies act by Govt. of India publication
5. Bare Acts of the said laws published by Government. Reference books (Theory)

Internet references:

1. http://indiacode.nic.in
2. http://india.gov.in/my-government/actrules
3. http://www.ipindia.nic.in

B. PHARM. III YEAR
SEMESTER - VI

III B.PHARM. SCHEME

SEMESTER - VI

S. No.	Sub. Code	Subject	L	T	P	Th. Credit	Tu. Credit	Pr. Credit	Total Credit	Maximum Marks				
										TH	CW	SW	Pr.	Total
1.	PY3Y517	Medicinal Chemistry III	3	1	4	3	1	2	6	75	25	15	35	150
2.	PY3Y518	Pharmacology III	3	1	4	3	1	2	6	75	25	15	35	150
3.	PY3Y519	Herbal Drug Technology	3	1	4	3	1	2	6	75	25	15	35	150
4.	PY3Y520	Biopharmaceutics & Pharmacokinetics	3	1	-	3	1	-	4	75	25	-	-	100
5.	PY3Y521	Pharmaceutical Biotechnology	3	1	-	3	1	-	4	75	25	-	-	100
6.	PY3Y542	Quality Assurance	3	1	-	3	1	-	4	75	25	-	-	100
Total			**18**	**6**	**12**	**18**	**6**	**6**	**30**	**450**	**150**	**45**	**105**	**750**

PY3Y517: MEDICINAL CHEMISTRY–III

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Total Credit	Maximum Marks				
							TH	CW	SW	Pr.	Total
3	1	4	3	1	2	6	75	25	15	35	150

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

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

Course Outcomes: Upon completion of the course, student shall be able to:

CO-1: Understand and describe the structures, classification, mode of action, stereochemistry, synthesis and uses of different classes of drugs.
CO-2: Articulate the importance of structure activity relationship in the field of drug design
CO-3: Summarize & interpret the results of ADMET of drugs to correlate with therapeutic efficacy.
CO-4: Comprehend, write reports, make presentations and documentation on a given drug molecule.
CO-5: Understand &analyze the results of drug profile in favour of health and safety of human being.

THEORY **DURATION (LECTURE)**

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**

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**

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**

Anti-tubercular Agents
Synthetic anti-tubercular agents: Isoniazid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.*
Anti-tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine, Streptomycine, Capreomycin sulphate.
Urinary tract anti-infective agents
Quinolones: SAR of quinolones, Nalidixic Acid, Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin
Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine.
Antiviral agents: Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirding, Ribavirin, Saquinavir, Indinavir, Ritonavir.

UNIT IV **08**

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**

Introduction to Drug Design
Various approaches used in drug design.
Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammet's electronic parameter, Tafts steric parameter and Hansch analysis.
Pharmacophore modeling and docking techniques
Combinatorial Chemistry: Concept and applications chemistry: solid phase and solution phase synthesis.

PRACTICALS: Minimum 15 experiments based on following:

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)

BOOKS AND REFERENCES RECOMMENDED:

Text books:

1. Block J. H., Beale J. M., "Wilson and Gisvold's Textbook of organic medicinal and pharmaceutical chemistry", 11th edition, 2004, Lippincott Williams and Wilkins-A WoltersKluwer Company.
2. Lemke T. L., Williams D. A.,"Foye's principles of medicinal chemistry", 6th edition, 2008, Lippincott Williams and Wilkins-A Wolters Kluwer Company.
3. Finar I. L., Organic Chemistry (2011) vol.2, Organic Chemistry: 6th Edition. Longman.
4. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1to 5.

Reference books:

1. Wolff M. E.,"Burger's medicinal chemistry and drug discovery" 5th edition, 1995, Wiley-Interscience, New York.
2. Abraham D.J, Rotella D.P., "Burger's medicinal chemistry and drug discovery" 7th edition, 2010, Wiley-Interscience, New York.
3. Hansch C., "Comprehensive medicinal chemistry" Vol. I-VI, 1990, Pergamon Press.
4. 4.Indian Pharmacopoeia, (2014), published by Indian Pharmacopoeia Commission, Ghaziabad.
5. Loyd V. Allen., Remington's The science & Practice of pharmacy, 22nd edition, Pharmaceutical press, 2012.
6. Vogel, I. A., (1956) A Text Book of Practical Organic Chemistry Including Qualitative Organic Analysis: 3rd Edition. Longman
7. Smith H. J., Williams H., "Introduction to Principles of drug design" 4th edition (2005) CRC Press.

PY3Y518: PHARMACOLOGY-III

L	T	P	Th. Credit	Tu. Credit	Pr. Credit	Total Credit	Maximum marks				
							TH	CW	SW	Pr	Total
3	1	4	3	1	2	6	75	25	15	35	150

Scope:

- 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, immune, gastrointestinal system, and drugs used in infectious diseases.
- To impart the knowledge of principles of toxicology and chronopharmacology.

Objectives: After completion of course, student should be able to:

- Understand treatment of disease related to respiratory system, GIT and infections.
- Understand the mechanism of drug action and its relevance in the treatment of different infectious diseases.
- Comprehend the principles of toxicology and treatment of various poisonings.
- Appreciate correlation of pharmacology with related medical sciences.
- Understand the fundamental principles of treatment of poisoning.

Course Outcomes: Upon completion of the course, student shall be able to:

CO-1: Discuss the mechanism of action, interaction and adverse effects of drugs used for the treatment of respiratory and gastrointestinal tract system.

CO-2: Discuss the mechanism of action, interaction and adverse effects of drugs used in treatment of chemotherapy.

CO-3: Describe the components of immunopharmacology and chronopharmacology

CO-4: Employ the principles of toxicology and outline the treatment of various poisonings.

CO-5: Learn, perform and interprete the advanced pharmacological experiments.

THEORY TOPICS **DURATION (LECTURES)**

UNIT I **10**

a. Pharmacology of drugs acting on Respiratory system
   i. Anti -asthmatic drugs.
   ii. Drugs used in the management of COPD.
   iii. Expectorants and antitussives.
   iv. Nasal decongestants.
   v. Respiratory stimulants.

b. Pharmacology of drugs acting on the Gastrointestinal Tract
   i. Antiulcer agents.
   ii. Drugs for constipation and diarrhoea.
   iii. Appetite stimulants and suppressants.
   iv. Digestants and carminatives.
   v. Emetics and anti-emetics.

UNIT II **10**

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**

Chemotherapy

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

UNIT IV **8**

a) Chemotherapy
   i. Urinary tract infections and sexually transmitted diseases.
   ii. Chemotherapy of malignancy.

b) Immunopharmacology
   i. Immunostimulants.
   ii. Immunosuppressant.

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

UNIT V **7**

a) Principles of toxicology
   i. Definition and basic knowledge of acute, subacute and chronic toxicity.
   ii. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity.
   iii. General principles of treatment of poisoning.
   iv. Clinical symptoms and management of barbiturates, morphine, organophosphosphorus compound and lead, mercury and arsenic poisoning.

b) Chronopharmacology
   i. Definition of rhythm and cycles.
   ii. Biological clock and their significance leading to chronotherapy.

PRACTICALS: Minimum 15 experiments based on the following:

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, WilcoxonSigned Rank test)

*Experiments are demonstrated by simulated experiments/videos

BOOKS AND REFERENCES RECOMMENDED

Text books:

1. Tripathi, K. D. Essentials of Medicinal Pharmacology, 7th edition 2013, Jaypee Brothers Medical Publishers (P) Ltd., New Delhi.
2. Satostkar, R.S., Rege, N.N., Bhandarkar, S.D. Pharmacology and Pharmacotherapeutics. Revised 23rd edition 2013, Popular Prakashan Pvt. Ltd., Mumbai,
3. Rang, H.P., Dale, M.M., Ritter, J.M., Flower, R.J., Henderson, G. Rang and Dale's Pharmacology. 8th edition 2015, Elsevier India.
4. Ghosh, M. N. Fundamentals of Experimental Pharmacology. 2nd edition 1984, Scientific Book Agency, Calcutta.
5. Kulkarni, S.K., Hand Book of Experimental Pharmacology, 3rd Edition, 1999, Vallabh Prakashan.
6. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher.

Reference books:

1. Brunton, L., Chabner, B.A., Knollman, B. Goodman and Gillman's the Pharmacological Basis of Therapeutics. 12th edition 2011, McGraw Hill Education.
2. Katzung B. G., Trevor A.J. Basic and Clinical Pharmacology.13th edition 2015, McGraw-Hill Medical
3. Vogel, H. G. Drug Discovery and Evaluation. 2nd edition 2002, Springer Publication, Berlin.
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams &Wilkins.
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology.
6. Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert,
7. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

Software:

1. Ex-Pharm, Raveendran R. Department of pharmacology, JIPMER, Pandicherry, India, 2009.

Website:

1. http://www.indphar.org

Mobile Application:

1. Pharmacology by Apple Medical Group 2014.

PY3Y519: HERBAL DRUG TECHNOLOGY

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Total Credit	Maximum Marks				
							TH	CW	SW	Pr.	Total
3	1	4	3	1	2	6	75	25	15	35	150

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:

After completion of course, student shall be able to:

- Knowledge about the Indian system of medicines and ayurvedic formulations
- Understand raw material as source of herbal drugs from cultivation to herbal drug product.
- Know the WHO and ICH guidelines for evaluation of herbal drugs.
- Know the herbal cosmetics, herb-food interaction and nutraceuticals.
- Appreciate patenting of herbal drugs and GMP.
- Understand the preparation and development of herbal formulation.

Course Outcomes: Upon completion of the course, student shall be able to:

CO-1: Describe and identify the sources of herbal drugs, processing of raw materials for herbal drug products and Implement the good agricultural practices.

CO-2: Explain the herb-food interaction and nutraceuticals.

CO-3: Examine the sources and applications of herbal cosmetics, herbal excipients and herbal formulations.

CO-4: Implementing the WHO and ICH guidelines for evaluation of herbal drugs, justifying the patenting of herbal drugs and GMP.

CO-5: Describe the requirements of herbal drug industries for the preparation and development of medicinal and aromatic plants in India.

THEORY **DURATION (LECTURES)**

UNIT I **11**

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**

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 andclassification. Study of following drugs and their possible side effects and interactions:Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.

UNIT III **10**

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**

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 **7**

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.

PRACTICALS

Minimum 15 experiments based on the following:

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.

BOOKS & REFERENCES RECOMMENDED

Text books:

1. Kokate C.K., Purohit A.P., Gokhale S.B., Pharmacognosy, 44th edition, 2009, Publishedby Nirali Prakashan, New Delhi.
2. Kokate C. K., *Practical Pharmacognosy*, 4th edition, 2006, Vallabh Prakashan, NewDelhi.
3. Mohammad Ali. Pharmacognosy and Phytochemistry, 1st edition, 2008, CBS Publishers& Distribution, New Delhi.
4. Ansari S.H.,Essentials of Pharmacognosy, 2nd edition, 2007, Birla publications, NewDelhi.
5. *Rangari V. D.*, Pharmacognosy and Phytochemistry, Vol-I, 2st edition, 2008, CareerPublications.

Reference books:

1. Evans, W. C. "Trease and Evans Pharmacognosy", 16th edition, 2009, WB Saunders&Co, London.
2. Tyler VE., Brady LR and Robbers JE., Pharmacognosy, 9th edition, 1988, Lea and Febiger, Philadelphia.
3. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy).
4. Mukherjee P. K., Quality Control of Herbal drugs. An Approach to Evaluation of Botanicals, 2002, Business Horizons.

PY3Y520: BIOPHARMACEUTICS & PHARMACOKINETICS

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Total Credit	Maximum Marks				
							TH	CW	SW	Pr.	Total
3	1	-	3	1	-	4	75	25	-	-	100

Scope:

- To provide basic knowledge of biopharmaceutics and pharmacokinetic and the parameters that describes the fate of drug in the body after its administration.
- To create understanding of factors affecting drug absorption from different dosage forms and factors that can cause pharmacokinetic variability among different individuals.
- To provide a general understanding of pharmacokinetic models, model equations, and pharmacokinetic calculations.
- To study concepts of bioavailability and bioequivalence

Objectives: On completion of this subject, students would be able to

- Understand the basic concepts and significance of biopharmaceutics and pharmacokinetics.
- Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
- Correlate physicochemical properties of drug molecule with their permeability across biological membrane.
- Identify the physiological, physicochemical and dosage form-related factors that affect drug absorption from different dosage forms.
- Perform calculation of pharmacokinetic parameters and understand compartment modeling in pharmacokinetics.
- Understand the concept of bioavailability and bioequivalence of drug products and significance & application of various pharmaceutical parameter.
- Assess absolute and relative bioavailability of drugs from different dosage forms using plasma drug concentration and urinary drug excretion data.

Course Outcomes: Upon completion of the course, student shall be able to:

CO-1: Describe the basic concepts and significance of biopharmaceutics and pharmacokinetics.

CO-2: Identify the physiological, physicochemical and dosage form-related factors that affect drug absorption from different dosage forms.

CO-3: Use the plasma drug concentration-time data to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.

CO-4: Calculate of pharmacokinetic parameters and understand compartment modeling in pharmacokinetics.

CO-5: Assess absolute and relative bioavailability of drugs from different dosage forms and understand the concept of bioavailability and bioequivalence of drug products.

THEORY TOPICS	DURATION (LECTURE)

UNIT-I **10**

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**

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**

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, Clt and CLR- definitions methods of eliminations, understanding of their significance and application

UNIT IV **8**

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

UNIT V **7**

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

BOOKS & REFERENCES RECOMMENDED

Text books:

1. Gibaldi, M., 2005. Biopharmaceutics and Clinical Pharmacokinetics. Pharma Book Syndicate..
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal,Vallabh Prakashan Pitampura, Delhi
4. Milo Glbaldi Donald, Pharmacokinetics R. Mercel Dekker Inc.
5. Shargel L., Yu A., Wu-Pong S. 2012. Applied Biopharmaceutics & Pharmacokinetics, 6th Edition. McGraw Hill Education.

Reference books:

1. Troy, D.B., Beringer, P., 2006. Remington: The Science and Practice of Pharmacy. Lippincott Williams & Wilkins.
2. Aulton, M.E., 2001. Pharmaceutics: the science of dosage form design, II Edition, Churchill Livingstone.
3. Lachman, L., Herbert A., 1991. The Theory and Practice of Industrial Pharmacy, III edition, Verghese publishing house.
4. Milo Gibaldi and Laurie Prescott, Hand Book of Clinical Pharmacokinetics by ADIS Health Science Press.
5. Biopharmaceutics; By Swarbrick
6. Clinical Pharmacokinetics, Concepts and Applications: ByMalcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
7. Abdou H.M, Mack,Dissolution, Bioavailability and Bioequivalence Publishing Company,Pennsylvania 1989.
8. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.

Internet references

1. www.who.int
2. www.fda.gov
3. www.cdsco.nic.in

PY3Y521: PHARMACEUTICAL BIOTECHNOLOGY

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Total Credit	Maximum Marks				
							TH	CW	SW	Pr.	Total
3	1	-	3	1	-	4	75	25	-	-	100

Scope: This subject is designed to provide a balanced and comprehensive knowledge of the basic as well as applied aspects related to Pharmaceutical Biotechnology. It also impart knowledge regarding application of biotechnology in the field of genetic engineering, medicine, drug discovery, disease diagnosis and fermentation technology.

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

- Understand and recall the historical development in Pharmaceutical biotechnology.
- Understand the importance of Immobilized enzymes in Pharmaceutical Industries.
- Understand various applications of genetic engineering in relation to production of pharmaceuticals.
- Importance of Monoclonal antibodies in Industries.
- Understand the basic principle of antigen antibody reaction mechanism related to immunity of human body.
- Gain knowledge of genetic engineering and recombination technology.
- Gain knowledge of microbial transformation in industrial biotechnology.

Course Outcomes: Upon completion of the course, student shall be able to:

CO-1: Recall the historical development in Pharmaceutical biotechnology and relating their application in pharmaceutical industry.

CO-2: Summarize the latest development in the field of Pharmaceutical biotechnology.

CO-3: Explain various applications of r-DNA technology, genetic engineering, fermentation technology and Protein Engineering in relation to production of pharmaceuticals.

CO-4: Analyze the application of MABs and antigen antibody reactions in the field of medical science.

CO-5: Recommend the needs of implementing biotechnological techniques for sustainable development in pharmaceutical science on an ongoing basis.

THEORY **DURATION (LECTURES)**

UNIT I **10**

(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**

(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:
(d) Interferon
(e) Vaccines- Hepatitis- B
(f) Hormones-Insulin.

(g) Brief introduction to PCR

UNIT III **10**

Types of immunity- humoral immunity, cellular immunity

(a) Structure of Immunoglobulins
(b) Structure and Function of MHC
(c) Hypersensitivity reactions, Immune stimulation and Immune suppressions.
(d) General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity.
(e) Storage conditions and stability of official vaccines
(f) Hybridoma technology- Production, Purification and Applications
(g) Blood products and Plasma Substituties.

UNIT IV **08**

(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**

(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.

BOOKS & REFERENCES RECOMMENDED

Text books:

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
2. RA Goldshy et. al., : Kuby Immunology.
3. J.W. Goding: Monoclonal Antibodies.
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.
5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

Reference books:

1. Zito S.W., Pharmaceutical Biotechnology : A Programmed Text, Second Edition 1998, CRC Press.
2. Dodds J. H. and Roberts L. W., Experiment in Plant Tissue Culture, second edition Cambridge University Press.
3. Trevan M. D., Boffey S. and Goulding K. H., Biotechnology (The Biological Principles),
4. Peppler, Microbial Technology: Microbial Processes Volume 1-2, Elsevier.

PY3Y542: QUALITY ASSURANCE

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Total Credit	Maximum Marks				
							TH	CW	SW	Pr.	Total
3	1	-	3	1	-	4	75	25	-	-	100

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:

On completion of this subject, students should be able to:

- Differentiate between the concept/scope of quality control and quality assurance.
- Understand the significance of quality and tools of ensuring quality in pharmaceutical products.
- Indentify the requirements related to GMP (as per schedule-M), GLP & pharmaceutical documents
- Familiarize with requirements of international regulatory agencies and their quality audit process.
- Prepare and interpret various types of pharmaceutical documents related to pharmaceutical R&D and production plant.

Course Outcomes: Upon completion of the course, student shall be able to:

CO-1: Compare concept/scope of quality control and quality assurance.

CO-2: Understand the significance of quality and tools to ensure the quality of pharmaceutical products.

CO-3: Identify the regulatory requirements related to GMP (as per schedule-M), GLP & pharmaceutical documents

CO-4: Familiarize with requirements of national/international regulatory agencies and their quality audit process.

CO-5: Prepare and interpret various types of pharmaceutical regulatory documents related to pharmaceutical R&D and production plant.

THEORY **DURATION (LECTURE)**

UNIT I **10**

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**

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**

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 **8**

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 **7**

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.

BOOKS AND REFERENCES RECOMMENDED

Text books:

1. "Quality Assurance of Pharmaceuticals" - WHO guideline, 4th Ed. Vol- I & II, Pharma Book Syndicate.
2. Potdar M. A. Pharmaceutical Quality Assurance, 2nd Ed., 2010, Nirali Prakashan.
3. Sarker D.K., Quality System & Control for Pharmaceuticals, 2008, John Wiley & Sons. Ltd.
4. L.Lachman, H.A.Lieberman and J.L.Kanig, The theory and practice of industrial pharmacy. Varghese publishing house.
5. Quality Assurance Guide by organization of Pharmaceutical Products of India.

Reference books:

1. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.
2. Quality Assurance of Pharmaceuticals- A compendium of Guidelines and Related materials Vol I, WHO Publications.
3. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
4. How to Practice GMP's – P P Sharma.

5. ISO 9000 and Total Quality Management – Sadhank G Ghosh
6. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms.
7. Good laboratory Practices – Marcel Deckker Series
8. ICH guidelines, ISO 9000 and 14000 guidelines
9. Nash R.A. and Wachter A.H., Pharmaceutical Process Validation, 3rd ed, 2003, Marcel Dekker Inc.
10. Schedule M- Drug and cosmetic Act and Rules, Govt. of India.