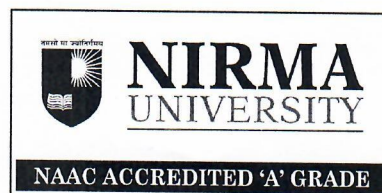


NU/AC/AC-180419/4(A)/19-54

Date: 08.05.2019



NOTIFICATION

- Read: 1. Regulation No. 44 of Academic Regulations for Admission to University, etc published vide notification No. NU-442 dated 27.01.2004 – empowering Academic Council to approve teaching & examination scheme, syllabi, etc
2. Notification No. NU-69 dated 05.06.2018 - Introduction of TES and Syllabus of Semester-III & IV of B. Pharm.
3. Notification No. NU-70 dated 05.06.2018 - Introduction of Programme/Course Structure of B. Pharm. in pursuance to B.Pharm. Course Regulations, 2014 as prescribed by PCI
4. Resolution Nos. 3 to 7 – Faculty of Pharmacy meeting – 01.03.2019
5. Resolution No. 4(A) – Academic Council meeting – 18.04.2019

Sub: Introduction of Teaching & Examination Scheme and Syllabi of Semester-V and VI of B.Pharm programme

It is hereby notified for information of all concerned that the Academic Council in its meeting held on 18.04.2019 under resolution No. 4(A) taking into consideration the recommendation of the Faculty of Pharmacy, has resolved to approve the introduction of Teaching & Examination Scheme and Syllabi of Semester-V and VI of B.Pharm programme in pursuance to new PCI guidelines in supersession of existing curricula, to be made effective for the students admitted in academic year 2017-18 onwards, as per Appendix-A attached herewith.


Executive Registrar

Encl.: Appendix-A [Pages 1 to 38]


To,

1. Dean, Faculty of Pharmacy
2. Dy. Registrar (Exam)

Copy to,

1. All Heads, Academic Area
2. Exam Section (IP)
3. OS (IP)
4. P.A. to ER

c.f.w.cs for kind information to: Director General

Nirma University
Institute of Pharmacy
Teaching & Examination Scheme (B.Pharm)

Semester - V

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/PW	T	C	Duration		Component Weightage		
							SEE	LPW/PW	CE	LPW/PW	SEE
1	BP501T	Medicinal Chemistry II – Theory	3	-	1	4	3.0	-	0.25	-	0.75
2	BP502T	Industrial Pharmacy I – Theory	3	-	1	4	3.0	-	0.25	-	0.75
3	BP506P	Industrial Pharmacy I – Practical	-	4	-	2	-	4.0	0.30	0.70	-
4	BP503T	Pharmacology II – Theory	3	-	1	4	3.0	-	0.25	-	0.75
5	BP507P	Pharmacology II – Practical	-	4	-	2	-	4.0	0.30	0.70	-
6	BP504T	Pharmacognosy and Phytochemistry II – Theory	3	-	1	4	3.0	-	0.25	-	0.75
7	BP508P	Pharmacognosy and Phytochemistry II – Practical	-	4	-	2	-	4.0	0.30	0.70	-
8	BP505T	Pharmaceutical Jurisprudence - Theory	3	-	1	4	3.0	-	0.25	-	0.75
Total			15	12	5	26					
			32								

L: Lectures, P/T: Practicals/Tutorial, C: Credits
LPW: Laboratory / Project Work

SEE: Semester End Examination
CE: Continuous Evaluation

w.e.f. academic year 2019-2020 and onwards

Appendix-A
Noti. No. NY-54
Ac Mtg. - 15.04.19

NIRMA UNIVERSITY
Institute of Pharmacy
(B. Pharm)
(Semester - V)

L	T	P	C
3	1	-	4

Course Code	BP501T
Course Title	Medicinal Chemistry II – Theory

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.

Objective: At the end of the course, the student shall be able to -

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

Course Learning Outcomes (CLO):

After successful completion of the course, student will be able to -

1. Understand chemistry, biology and functions of histamine, insulin and steroids.
2. Describe chemical classification of different therapeutic classes.
3. Discuss mechanism of action, uses and adverse effects of various classes of drugs.
4. Explain structure activity relationship studies of different classes of drugs.
5. Report synthetic protocol of some drugs.

Syllabus:

Teaching hours: 45 Hours

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

UNIT I

10 Hours

Antihistaminic Agents

- Histamine, receptors and their distribution in the human body
- **H₁-antagonists** : Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamine succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenindamine tartrate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine

hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetirizine
Cromolyn sodium

- **H₂-antagonists:** Cimetidine*, Famotidine, Ranitidine

Gastric Proton Pump Inhibitors

- Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole

Anti-neoplastic Agents

- **Alkylating agents:** Mecllorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepe
- **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 Hours

Anti-anginal Agents

- **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, Lorcaïnide 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, Nandrolone, Progesterones, Oestriol, Oestradiol, Oestrone, Diethyl stilbestrol
- **Drugs for Erectile Dysfunction:** Sildenafil, Tadalafil
- **Oral Contraceptives:** Mifepristone, Norgestrel, Levonorgestrel
- **Corticosteroids:** Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone
- **Thyroid and Antithyroid Drugs:** L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole

UNIT V

07 Hours

Antidiabetic Agents

- **Insulin and its preparations**
- **Sulfonyl ureas:** Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride
- **Biguanides:** Metformin
- **Thiazolidinediones:** Pioglitazone, Rosiglitazone
- **Meglitinides:** Repaglinide, Nateglinide
- **Glucosidase inhibitors:** Acarbose, Voglibose

Local Anesthetics

- **SAR of Local anesthetics**
- **Benzoic Acid derivatives:** Cocaine, Hexylcaine, Mepylcaine, Cyclomethycaine, Piperocaine
- **Amino Benzoic acid derivatives:** Benzocaine*, Butamben, Procaine*, Butacaine, Propoxycaine, Tetracaine, Benoxinate
- **Lidocaine/Anilide derivatives:** Lignocaine, Mepivacaine, Prilocaine, Etidocaine
- **Miscellaneous:** Phenacaine, Dipreron, Dibucaine.*

Tutorials

15 Hours

Tutorials will be based on above syllabus.

Suggested Readings^: (Latest edition)

1. Wilson, C. O., Beale, J. M., & Block, J. H. *Wilson and Gisvold's textbook of organic medicinal and pharmaceutical chemistry*. Lippincott Williams & Wilkins.
2. Foye, W. O. *Foye's principles of medicinal chemistry*. Lippincott Williams & Wilkins.
3. Burger, A., & Abraham, D. J. *Burger's medicinal chemistry and drug discovery* (Vol. I-IV). Wiley.
4. Smith, H. J., & Williams, H. *Introduction to the principles of Drug design*. Elsevier.
5. Remington, J. P. *Remington: the science and practice of pharmacy* (Vol. 1 & 2). Lippincott Williams & Wilkins.
6. Reynolds, J. E. F., *Martindale: the extra pharmacopoeia*. Pharmaceutical Press, London.
7. Finar, I. L. *Organic Chemistry, Volume 2: Stereochemistry And The Chemistry Natural Product.*, Pearson Education India.
8. Lednicher, D. *The organic chemistry of drug synthesis* (Vol. 1-5). John Wiley & Sons.
9. Indian pharmacopoeia, Indian Pharmacopoeial Commission.
10. Furniss, B. S. *Vogel's textbook of practical organic chemistry*. Pearson Education India.

L= Lecture, T= Tutorial, P= Practical, C= Credit

^this is not an exhaustive list

NIRMA UNIVERSITY
Institute of Pharmacy
(B. Pharm)
(Semester - V)

L	T	P	C
3	1	-	4

Course Code	BP502T
Course Title	Industrial Pharmacy I -Theory

Scope:

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

Objectives:

Upon completion of the course the student should be able to:

1. Understand 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 Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Understand the importance of preformulation and factors influencing in the designing of the dosage forms.
2. Describe formulation and evaluation of tablets and liquid orals.
3. Discuss manufacturing and quality control of sterile products.
4. Explain formulation development of hard gelatin capsule, soft gelatin capsule and pellets.
5. Practice solid and liquid oral formulations, with its labelling and packaging.
6. Develop and evaluate cosmetic and aerosol preparations.

Syllabus:

Teaching hours: 45 Hours

UNIT I

07 Hours

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

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

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:

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

Equipments and tablet tooling.

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

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 Hours

Capsules:

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.

Soft gelatin capsules: Nature of shell and capsule content, size of capsules, importance of base adsorption and min/mg 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:

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

Production procedure, production facilities and controls, aseptic processing

Formulation of injections, sterile powders, large volume parenterals and lyophilized products.

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.

Tutorials

Teaching Hours: 15 Hours

Tutorials will be based on above syllabus.

Suggested Readings[^]: (Latest edition)

1. Banker, G. S. & Rhodes, C. T, *Modern pharmaceuticals*, New York: Marcel Dekkar Inc.
2. Lieberman, H.A., Lachman, L., & Schwartz, J.B. *Pharmaceutical Dosage forms - Tablets*, volume 1 to 3. New York: Marcel Dekkar Inc.

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3. Lieberman, H.A, Rieger, M.M., & Banker, G.S. *Pharmaceutical dosage forms - Disperse systems*, volume 1 to 3. New York: Marcel Dekkar Inc.
4. Lieberman, H.A, Lachman, L., & Avis, K. E.. *Pharmaceutical dosage forms - Parenteral medications*, volume 1 to 3. New York: Marcel Dekkar Inc.
5. Aulton, M. E., *Pharmaceutics: The science of dosage form design*. London: Churchill livingstone,
6. Alfonso R., Gennaro, A. M., *Remington: The science and practice of pharmacy*, volume 1 & 2. Newyork: Lippincott Williams & Wilkins.

L= Lecture, T= Tutorial, P= Practical, C= Credit

^ this is not an exhaustive list

I

(B. Pharm.)
(Semester - V)

L	T	P	C
-	-	4	2

Course Code	BP506P
Course Title	Industrial Pharmacy I - Practical

Syllabus:

Total hours: 60 Hours

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 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)

L= Lecture, T= Tutorial, P= Practical, C= Credit

I

(B. Pharm)
(Semester -V)

L	T	P	C
3	1	-	4

Course Code	BP503T
Course Title	Pharmacology II - Theory

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.

Objective: 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 Learning Outcomes (CLO):

After successful completion of the course, student will be able to -

1. Outline the effects of drugs used in cardiovascular disorders.
2. Explain about drugs acting on blood and in renal disorders
3. Illustrate pharmacology of autacoids, drugs related to autacoids and those used for pain, gout and rheumatoid diseases
4. List detailed pharmacology of drugs useful for treatment of endocrine disorders
5. Assess potency of different drugs using different bioassay techniques.

Syllabus:

Teaching hours: 45 Hours

UNIT I

10 Hours

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

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

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Pharmacology of drugs acting on urinary system

- a. Diuretics
- b. Anti-diuretics.

UNIT III

10 Hours

Autocoids and related drugs

- a. Introduction to autocoids 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

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 Hypoglycaemic agents and glucagon.
- e. ACTH and corticosteroids.

UNIT V

07 Hours

Pharmacology of drugs acting on endocrine system

- a. Androgens and Anabolic steroids.
- b. Estrogens, progesterone and oral contraceptives.
- c. Drugs acting on the uterus.

Bioassay

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

Recommended Books (Latest Editions)

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

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6. K. D.Tripathi. Essentials of Medical Pharmacology; JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R. Craig & Robert.
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.

(B. Pharm)
(Semester - V)

L	T	P	C
-	-	4	2

Course Code	BP507P
Course Title	Pharmacology II – Practical

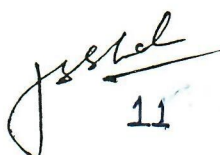
Syllabus:

Total Hours: 60 Hours

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 Schild's 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-oedema 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

L= Lecture, T= Tutorial, P= Practical, C= Credit


11

NIRMA UNIVERSITY

Institute of Pharmacy

(B. Pharm)

(Semester - V)

L	T	P	C
3	1	-	4

Course Code	BP504 T
Course Title	Pharmacognosy and Phytochemistry II-Theory

Scope:

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

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

1. To know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents
2. To understand the preparation and development of herbal formulation.
3. To understand the herbal drug interactions
4. To carryout isolation and identification of phytoconstituents

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Understand various types of metabolic pathways of medicinal plants
2. Describe Pharmacognosy of different secondary metabolites along with its therapeutic and commercial applications
3. Discuss methods for isolation and estimation of various classes of phytoconstituents
4. Explain industrial application and utilization of phytoconstituents.
5. Relate the applications of various chromatographic and spectroscopic techniques for standardization of herbal extracts/formulations
6. Develop hands on experience for isolation and estimation of some phytoconstituents

Syllabus:

Teaching hours: 45 Hours

UNIT-I

07 Hours

Metabolic pathways in higher plants and their determination

- a) Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway.
- b) Study of utilization of radioactive isotopes in the investigation of Biogenetic studies.

UNIT-II

14 Hours

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

Alkaloids: Vinca, Rauwolfia, Belladonna, Opium,
 Phenylpropanoids and Flavonoids: Lignans, Tea, Ruta
 Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis
 Volatile oils: Mentha, Clove, Cinnamon, Fennel, Coriander,
 Tannins: Catechu, Pterocarpus
 Resins: Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony
 Glycosides: Senna, Aloes, Bitter Almond
 Iridoids, Other terpenoids & Naphthaquinones: Gentian, Artemisia, taxus, carotenoids

UNIT-III

06 Hours

Isolation, Identification and Analysis of Phytoconstituents

- a) Terpenoids: Menthol, Citral, Artemisin
- b) Glycosides: Glycyrrhetic acid & Rutin
- c) Alkaloids: Atropine, Quinine, Reserpine, Caffeine
- d) Resins: Podophyllotoxin, Curcumin

UNIT-IV

10 Hours

Industrial production, estimation and utilization of the following phytoconstituents:

Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine

UNIT V

08 Hours

Basics of Phytochemistry

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

Recommended Books: (Latest Editions)

1. Evans, W.C. *Trease and Evans Pharmacognosy*. London, W.B. Saunders & Co.
2. Ali, M. *Pharmacognosy and phytochemistry*, CBS Publication & Distributors, New Delhi.
3. Kokate, C.K. *Text Book of Pharmacognosy*. New Delhi, Nirali Prakashan.
4. Choudhary R.D. *Herbal drug industry*, New Delhi, Eastern Publisher.
5. Ansari, S. H. *Essentials of Pharmacognosy*. New Delhi, Birla Publication.
6. Pande, H. *The Complete Technology Book on Herbal Perfumes & Cosmetics*. National Institute of Industrial Research.
7. Kalia, A. N. *Textbook of Industrial Pharmacognosy*. CBS Publishers & Distributors.
8. Endress, R., & Endress, R. *Plant Cell biotechnology*, Berlin, Springer-Verlag.
9. Remington, J. P., *pharmaceutical sciences*.
10. James Bobbers, Marilyn KS, VE Tylor. *Pharmacognosy & Pharmacobiotechnology*.
11. The formulation and preparation of cosmetic, fragrances and flavours.
12. Vyas, S. P., & Dixit, V. K. *Pharmaceutical biotechnology*. CBS Publishers & Distributors.
13. Dubey, R. C. *A textbook of Biotechnology*. S. Chand Publishing.

L= Lecture, T= Tutorial, P= Practical, C= Credit

^ this is not an exhaustive list

NIRMA UNIVERSITY
Institute of Pharmacy

(B. Pharm)
(Semester - V)

L	T	P	C
-	-	4	2

Course Code	BP508 P
Course Title	Pharmacognosy and Phytochemistry II- Practicals

Syllabus:

Teaching hours: 60 Hours

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

L= Lecture, T= Tutorial, P= Practical, C= Credit

^ this is not an exhaustive list

(B. Pharm.)
(Semester - V)

L	T	P	C
3	1	-	4

Course Code	BP505T
Course Title	Pharmaceutical Jurisprudence - Theory

Scope:

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

Objectives:

Upon completion of this course the student should 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 Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Explain importance of Pharmaceutical laws in India
2. Describe regulations related to import and manufacturing of drugs as per Drug & Cosmetic Act.
3. Discuss schedules, sale, labeling & packing of drugs and related regulations as per Drug & Cosmetic Act.
4. Identify functions of state and central pharmacy council
5. Discuss laws related to manufacturing of Narcotic and Alcoholic preparations
6. Understand Indian pharmaceutical Acts and Intellectual Property Rights

Syllabus:

Teaching hours: 45 Hours

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 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)

Tutorials

Tutorials will be based on above syllabus

Teaching hours: 15 Hours

Suggested Readings[^]: (Latest Edition)

1. Suresh, B. *Forensic Pharmacy: Pharmaceutical Jurisprudence*. Delhi, Birla Publications.
2. Mithal, B.M. *A Text book of Forensic Pharmacy*. Delhi, Vallabh Prakashan.
3. Mehra, M.L. *The Handbook of Drug Laws*. Allahbad, The University Book Agency.
4. Jain N.K. *A text book of Forensic Pharmacy*. Delhi, Vallabh Prakashan.
5. *Drugs and Cosmetics Act/Rules*. Govt. of India publications.
6. *Medicinal and Toilet preparations act 1955*. Govt. of India publications.
7. *Narcotic drugs and psychotropic substances act*. Govt. of India publications.
8. *Drugs and Magic Remedies act*. Govt. of India publications.
9. *Bare Acts of the said laws*. Government of India publications.

L= Lecture, T= Tutorial, P= Practical, C= Credit

[^] this is not an exhaustive list

Nirma University
Institute of Pharmacy
Teaching & Examination Scheme (B.Pharm)

Semester - VI

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/PW	T	C	Duration		Component Weightage		
							SEE	LPW/PW	CE	LPW/PW	SEE
1	BP601T	Medicinal Chemistry III – Theory	3	-	1	4	3.0	-	0.25	-	0.75
2	BP607P	Medicinal Chemistry III – Practical	-	4	-	2	-	4.0	0.30	0.70	-
3	BP602T	Pharmacology III – Theory	3	-	1	4	3.0	-	0.25	-	0.75
4	BP608P	Pharmacology III – Practical	-	4	-	2	-	4.0	0.30	0.70	-
5	BP603T	Herbal Drug Technology - Theory	3	-	1	4	3.0	-	0.25	-	0.75
6	BP609P	Herbal Drug Technology - Practical	-	4	-	2	-	4.0	0.30	0.70	-
7	BP604T	Biopharmaceutics and Pharmacokinetics - Theory	3	-	1	4	3.0	-	0.25	-	0.75
8	BP605T	Pharmaceutical Biotechnology - Theory	3	-	1	4	3.0	-	0.25	-	0.75
9	BP606T	Pharmaceutical Quality Assurance - Theory	3	-	1	4	3.0	-	0.25	-	0.75
		Total	18	12	6	30					
			36								

L: Lectures, P/T: Practicals/Tutorial, C: Credits
 LPW: Laboratory / Project Work

SEE: Semester End Examination
 CE: Continuous Evaluation

QW

(B. Pharm)
(Semester - VI)

L	T	P	C
3	1	-	4

Course Code	BP601T
Course Title	Medicinal Chemistry III –Theory

Scope:

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

Objectives:

Upon completion of the course, the 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 Learning Outcomes (CLO):

After successful completion of the course, student will be able to -

1. Understand basic concepts of prodrug, combinatorial chemistry and drug design
2. Describe history, chemical classification, mechanism of action, uses and degradation of different classes of chemotherapeutic agents
3. Explain stereochemistry and/or structure activity relationship studies of different classes of drugs
4. Report synthetic protocol of some drugs
5. Draw structures and reactions using software and determine physicochemical parameters of some drugs
6. Synthesize and/or analyze drugs and drug intermediates

Syllabus:

Teaching hours: 45 Hours

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

UNIT I

Antibiotics

10 Hours

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

- Nomenclature, Stereochemistry and metabolism of steroids
- **Sex Hormones:** Testosterone, Nandrolone, Progesterones, Oestriol, Oestradiol, Oestrione, Diethyl stilbestrol
- **Drugs for Erectile Dysfunction:** Sildenafil, Tadalafil
- **Oral Contraceptives:** Mifepristone, Norgestrel, Levonorgestrel
- **Corticosteroids:** Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone
- **Thyroid and Antithyroid Drugs:** L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole

UNIT V

07 Hours

Antidiabetic Agents

- **Insulin and its preparations**
- **Sulfonyl ureas:** Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride
- **Biguanides:** Metformin
- **Thiazolidinediones:** Pioglitazone, Rosiglitazone
- **Meglitinides:** Repaglinide, Nateglinide
- **Glucosidase inhibitors:** Acarbose, Voglibose

Local Anesthetics

- **SAR of Local anesthetics**
- **Benzoic Acid derivatives:** Cocaine, Hexylcaine, Meperylaine, Cyclomethycaine, Piperocaine
- **Amino Benzoic acid derivatives:** Benzocaine*, Butamben, Procaine*, Butacaine, Propoxycaine, Tetracaine, Benoxinate
- **Lidocaine/Anilide derivatives:** Lignocaine, Mepivacaine, Prilocaine, Etidocaine
- **Miscellaneous:** Phenacaine, Diperodon, Dibucaine.*

Tutorials

15 Hours

Tutorials will be based on above syllabus.

Suggested Readings^: (Latest edition)

1. Wilson, C. O., Beale, J. M., & Block, J. H. *Wilson and Gisvold's textbook of organic medicinal and pharmaceutical chemistry*. Lippincott Williams & Wilkins.
2. Foye, W. O. *Foye's principles of medicinal chemistry*. Lippincott Williams & Wilkins.
3. Burger, A., & Abraham, D. J. *Burger's medicinal chemistry and drug discovery* (Vol. I-IV). Wiley.
4. Smith, H. J., & Williams, H. *Introduction to the principles of Drug design*. Elsevier.
5. Remington, J. P. *Remington: the science and practice of pharmacy* (Vol. 1 & 2). Lippincott Williams & Wilkins.
6. Reynolds, J. E. F., *Martindale: the extra pharmacopoeia*. Pharmaceutical Press, London.
7. Finar, I. L. *Organic Chemistry, Volume 2: Stereochemistry And The Chemistry Natural Product.*, Pearson Education India.
8. Lednicer, D. *The organic chemistry of drug synthesis* (Vol. 1-5). John Wiley & Sons.
9. Indian pharmacopoeia, Indian Pharmacopoeial Commission.
10. Furniss, B. S. *Vogel's textbook of practical organic chemistry*. Pearson Education India.

L= Lecture, T= Tutorial, P= Practical, C= Credit

^ this is not an exhaustive list

(B. Pharm)
(Semester - VI)

L	T	P	C
-	-	4	2

Course Code	BP607P
Course Title	Medicinal Chemistry III - Practical

Syllabus:

Teaching hours: 60 Hours

I. Preparation of drugs/ 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 ChemDraw®

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 (Lipinski RO5)

NIRMA UNIVERSITY
Institute of Pharmacy
(B. Pharm.)
(Semester - VI)

L	T	P	C
3	1	-	4

Course Code	BP602T
Course Title	Pharmacology-III - Theory

Scope:

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

Objectives:

Upon completion of the course 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 Learning Outcomes (CLO):

At the end of the course, students will be able to –

1. Outline the mechanism of drug action and its relevance in the treatment of respiratory system and gastrointestinal disorders.
2. Illustrate mechanism of action of various drugs with their pharmacological actions and therapeutic applications of anti-infectives and chemotherapeutic agents.
3. Relate mechanism of action, pharmacological actions and applications of immunotherapeutic agents and biosimilars.
4. Explain principles of toxicology and treatment of various poisoning
5. Discuss significance of chronopharmacology in various disease treatments.
6. Improve their skills of handling of instruments, animals and softwares for studying pharmacological effects of the drugs.

Syllabus:

Teaching hours: 45 Hours

UNIT I

10 Hours

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

Pharmacology of drugs acting on the Gastrointestinal Tract

- a. Antiulcer agents.
- b. Drugs for constipation and diarrhoea.
- c. Appetite stimulants and suppressants.
- d. Digestants and carminatives.
- e. Emetics and anti-emetics.

UNIT II

10 Hours

Chemotherapy

- a. General principles of chemotherapy.
- b. Sulfonamides and cotrimoxazole
- c. Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolide, quinolones and fluoroquinolones, tetracycline and aminoglycosides

UNIT III

10 Hours

Chemotherapy

- d. Antitubercular agents
- e. Antileprotic agents
- f. Antifungal agents
- g. Antiviral drugs
- h. Anthelmintics
- i. Antimalarial drugs
- j. Antiamoebic agents

UNIT IV

08 Hours

Chemotherapy

- k. Urinary tract infections and sexually transmitted diseases.
- l. Chemotherapy of malignancy.

Immunopharmacology

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

UNIT V

07 Hours

Principles of toxicology

- a. Definition and basic knowledge of acute, subacute and chronic toxicity.
- b. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity
- c. General principles of treatment of poisoning
- d. Clinical symptoms and management of barbiturates, morphine, organophosphorus compound and lead, mercury and arsenic poisoning.

Chronopharmacology

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

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Tutorials

Tutorials will be based on above syllabus

Teaching hours: 15 Hours

Recommended books ^: (Latest Edition)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams & Wilkins
5. Mycek M.J., Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology
6. K.D. Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
- Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert,
8. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
9. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,
10. N. Udupa and P.D. Gupta, Concepts in Chronopharmacology.

L= Lecture, T= Tutorial, P= Practical, C= Credit

^ this is not an exhaustive list

(B. Pharm) (Semester - VI)

L	T	P	C
-	-	4	2

Course Code	BP608P
Course Title	Pharmacology III – Practical

Syllabus:

Teaching hours: 60 Hours

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) and LAL test

10. Determination of acute oral toxicity (LD50 and MTD) of a drug from a given data as per OECD guidelines.
11. Determination of acute skin irritation / corrosion of a test substance as per OECD guidelines.
12. Determination of acute eye irritation / corrosion of a test substance as per OECD guidelines.
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)
16. Demonstration of cell based efficacy and toxicity study and cell free assay.

**Experiments are demonstrated by simulated experiments/videos*

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc-Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology
6. K.D. Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
- Modern Pharmacology with clinical Applications, by Charles R. Craig & Robert,
8. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
9. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,
10. N. Udupa and P.D. Gupta, Concepts in Chronopharmacology. proportion

NIRMA UNIVERSITY
Institute of Pharmacy

(B. Pharm)
(Semester - VI)

L	T	P	C
3	1	-	4

Course Code	BP603T
Course Title	Herbal Drug Technology - Theory

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 the course the student shall 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 Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Understand the processing of herbal raw materials and good agricultural practices
2. Describe the principles and applications of various complementary and alternative system of medicine
3. Discuss health benefits of nutraceuticals and herb interactions
4. Explain the use of herbal raw materials in herbal cosmetics and formulations
5. Demonstrate the scope of herbal drug industry, various regulatory guidelines for evaluation of herbal drugs & natural products
6. Formulate and analyze various Ayurvedic dosage forms, herbal cosmetics and herbal formulations

Syllabus:

Teaching hours: 45 Hours

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

07 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:

Hypericum, 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.

Suggested Readings[^]: (Latest Edition)

1. Evans, W.C. *Trease and Evans Pharmacognosy*. London, W.B. Saunders & Co.
2. Tyler, V.E., Brady, L.R. and Robbers, J.E. *Pharmacognosy*. Philadelphia, Lea and Febiger.
3. Kokate, C.K. *Text Book of Pharmacognosy*. New Delhi, Nirali Prakashan.
4. Ansari, S.H. *Essentials of Pharmacognosy*. New Delhi. Birla Publications.
5. Rangari V.D. *Pharmacognosy & Phytochemistry*. Career Publications.
6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
7. Mukherjee, P.W. *Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals*. New Delhi, Business Horizons Publishers.

L= Lecture, T= Tutorial, P= Practical, C= Credit

[^] this is not an exhaustive list

NIRMA UNIVERSITY
Institute of Pharmacy

(B. Pharm)
(Semester - VI)

L	T	P	C
-	-	4	2

Course Code	BP609P
Course Title	Herbal Drug Technology - Practical

Syllabus:

Teaching hours: 60 Hours

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
10. To perform preliminary phytochemical screening of crude drugs.

L= Lecture, T= Tutorial, P= Practical, C= Credit

(B. Pharm.)
(Semester - VI)

L	T	P	C
3	1	-	4

Course Code	BP604T
Course Title	Biopharmaceutics and Pharmacokinetics - Theory

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 this course the student should be able to:

1. Understand 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 concepts of bioavailability & bioequivalence of drug products and significance.
4. Understand various pharmacokinetic parameters, their significance & applications.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Understand the concept of Absorption, Distribution & Elimination of drug in human body
2. Discuss factors influencing ADME of drugs
3. Describe pharmacokinetics of drug following one compartment model
4. Demonstrate use of multi-compartment model, multiple dosing and non-linear kinetics.
5. Explain development of BA-BE study protocol for various formulations
6. Calculate pharmacokinetic parameters of drug in clinical situations.

Syllabus:

Teaching hours: 45

Hours

UNIT I

10

Hours

Introduction to Biopharmaceutics - Absorption: Mechanisms of drug absorption through GIT, factors influencing drug absorption through GIT, absorption of drug from non-peroral extra-vascular routes.

Introduction to Biopharmaceutics - 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

Introduction to Biopharmaceutics – 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 (IVIVC), bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.

UNIT – III

10

Hours

Introduction to Pharmacokinetics: Definition and introduction to Pharmacokinetics. Compartment models, non-compartment models, physiological models.

One compartment open model: Intravenous injection (Bolus), Intravenous infusion and extra vascular administrations. Pharmacokinetics parameters (i.e. elimination rate constant, half-life, volume of distribution, area under the curve, total clearance, and renal clearance) definitions, methods of estimations, understanding of their significance and applications.

UNIT – IV

08

Hours

Multi-compartment model: Two compartment open model for Intravenous-Injection (Bolus).

Pharmacokinetics of multiple dosing: steady state drug levels, calculation of loading and maintenance doses and their significance in clinical settings.

UNIT – V

07

Hours

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

Tutorials

Teaching hours: 15

Hours

Tutorials will be based on above syllabus

Suggested Readings^: (Latest edition)

1. Gibaldi M. *Biopharmaceutics and Clinical Pharmacokinetics*, Pharmamed Press.
2. Notari R.F. *Biopharmaceutics and Pharmacokinetics – An Introduction*, Marcel Dekker.
3. Shargel L., *Applied Biopharmaceutics and Pharmacokinetics*. New York: Mc-Graw Hill.
4. Brahmankar M., D., Jaiswal B., S., *Biopharmaceutics and Pharmacokinetics A Treatise*, Delhi: Vallabh Prakashan.
5. Gibaldi M., Perrier D. *Pharmacokinetics*, Taylor & Francis
6. Gibaldi M., Prescott L.F. *Hand Book of Clinical Pharmacokinetics*, ADIS Health Science Press.
7. Rowland M., Tozer T.N., *Clinical Pharmacokinetics : Concepts and Applications*, Lippincott Williams & Wilkins
8. Abdou H.M. *Dissolution, Bioavailability and Bioequivalence*, Mack Publishing Company.
9. Notari R.F. *Biopharmaceutics and Clinical Pharmacokinetics-An introduction*, Marcel Dekker.
10. Remington: *The Science and Practice of Pharmacy*, Lippincott Williams and Wilkins.
11. Madan P.L. *Biopharmaceutics and Pharmacokinetics*, Jaypee Brothers Medical Publishers.
12. Venkateswarlu, V., *Biopharmaceutics and Pharmacokinetics*, India: Nirali Prakashan.

13. Jambhekar S.S., Breen P.J. *Basic Pharmacokinetics*, Pharmacutical Press.

L= Lecture, T= Tutorial, P= Practical, C= Credit

^ this is not an exhaustive list

NIRMA UNIVERSITY
Institute of Pharmacy

(B. Pharm)
(Semester - VI)

L	T	P	C
3	1	-	4

Course Code	BP605T
Course Title	Pharmaceutical Biotechnology – Theory

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 this course the student should 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 Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Relate microbial genetics with its applications
2. Understand importance of pharmaceutical biotechnology with its applications
3. Describe recombinant DNA technology with its applications
4. Discuss enzyme immobilization, biosensors, protein and genetic engineering
5. Explain fundamentals of immunology and preparation of immunological products
6. Recognize concepts of fermentation process, equipment and products

Syllabus:

Teaching hours: 45 Hours

UNIT I

10 Hours

Introduction to Pharmaceutical Biotechnology and its Applications:

Brief introduction to Biotechnology with reference to Pharmaceutical Sciences.
Enzyme Biotechnology- Methods of enzyme immobilization and applications.
Biosensors- Working and applications of biosensors in Pharmaceutical Industries.
Brief introduction to Protein Engineering.
Use of microbes in industry. Production of Enzymes- General consideration - Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase.
Basic principles of genetic engineering

UNIT II

10 Hours

Recombinant DNA Technology and its Applications:

Study of cloning vectors, restriction endonucleases and DNA ligase.
Recombinant DNA technology. Application of genetic engineering in medicine.
Application of r DNA technology and genetic engineering in the production of: i) Interferon ii) Vaccines- hepatitis- B iii) Hormones-Insulin.
Brief introduction to PCR

UNIT III

10 Hours

Immunology:

Types of immunity- humoral immunity, cellular immunity
Structure of Immunoglobulins
Structure and Function of MHC
Hypersensitivity reactions, Immune stimulation and Immune suppressions.
General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity.
Storage conditions and stability of official vaccines
Hybridoma technology- Production, Purification and Applications
Blood products and Plasma Substitutes.

UNIT IV

08 Hours

Microbial Genetics and Biotransformation:

Immuno blotting techniques- ELISA, Western blotting, Southern blotting.
Genetic organization of Eukaryotes and Prokaryotes
Microbial genetics including transformation, transduction, conjugation, plasmids and transposons.
Introduction to Microbial biotransformation and applications.
Mutation: Types of mutation/mutants.

UNIT V

07 Hours

Fermentation Technology:

Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring.

Large scale production fermenter design and its various controls.

Study of the production of - Penicillins, Citric acid, Vitamin B12, Glutamic acid, Griseofulvin.

Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substitutes.

Tutorials

Teaching hours: 15 Hours

Tutorials will be based on above syllabus

Suggested Readings[^]: (Latest Edition)

1. Tortora, Gerard J; Funke, Berdell R; Case, Christine L., *Microbiology: An Introduction*, USA: Pearson Education Inc.
2. Carter, S. J., *Cooper and Gunn's Tutorial Pharmacy*, India: C. B. S. Publishers & Distributors.
3. Prescott and Dunn., *Industrial Microbiology*, India: CBS Publishers & Distributors.
4. Vyas, S. P., *Pharmaceutical Biotechnology*, India: CBS Publishers & Distributors.
5. El-Mansi, Mansi, *Fermentation Microbiology and Biotechnology*, USA: Taylor & Francis.
6. Stanbury F., P., Whitakar A., and Hall J., S., *Principles of fermentation technology*, India: Aditya books Ltd.
7. Glick B.R. and Pasternak J.J., *Molecular Biotechnology: Principles and Applications of Recombinant DNA*, USA: ASM Press.
8. Goding J.W., *Monoclonal Antibodies*, London: Academic Press Limited.
9. Walker J.M. and Rapley R., *Molecular Biology and Biotechnology*, UK: RSC Publication.
10. Zaborsky, *Immobilized Enzymes*, USA: CRC Press.
11. Primrose S.B., *Molecular Biotechnology*, USA: Blackwell Scientific Publication.

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NIRMA UNIVERSITY
Institute of Pharmacy

(B. Pharm)
(Semester - VI)

L	T	P	C
3	1	-	4

Course Code	BP606T
Course Title	Pharmaceutical Quality Assurance – Theory

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, the student shall be able to-

1. Understand the cGMP aspects in a pharmaceutical industry
2. Appreciate the importance of documentation
3. Understand the scope of quality certifications applicable to pharmaceutical industries
4. Understand the responsibilities of QA & QC departments

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Understand the aspects of quality assurance, total quality Management, ICH guidelines, QbD, relevant ISO and accreditation process in a pharmaceutical industry
2. Describe the importance of organization, personnel, premises, equipment and raw material as per cGMP guideline
3. Explain the quality control and GLP practices
4. Appreciate the importance of documentation and complaint procedure
5. Apply the principles of calibration and validation and follow good warehousing practices

Syllabus:

Teaching hours: 45 Hours

UNIT I

10 Hours

- **Quality Assurance and Quality Management concepts:** Definition and concept of Quality control, Quality assurance and GMP
- **Total Quality Management (TQM):** Definition, elements, philosophies

CH

- **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, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

UNIT V

07 Hours

- **Calibration and Validation:** Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation.
- **Warehousing:** Good warehousing practice, materials management

Suggested Readings[^]: (Latest edition)

1. Quality Assurance Guide by Organisation of Pharmaceutical Producers of India.
2. Weinberg, S. (Ed.). Good laboratory practice regulations. CRC Press.
3. World Health Organization. Quality assurance of pharmaceuticals: A compendium of guidelines and related materials. Good manufacturing practices and inspection (Vol. 2). World Health Organization.
4. Maitra, K. and Ghosh, S.K. A guide to total quality management. Oxford Publishing House.
5. Sharma, P. P. How to practice GMPs. Vandana publications.
6. Ghosh, S.K. Introduction to ISO 9000 and Total Quality Management. Oxford Publishing House.
7. World Health Organization.. International Pharmacopoeia. Vol. 1-4.
8. Good laboratory Practices – Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines

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- **β -Lactam antibiotics:** Penicillin, Cephalosporins, 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

Anti-malarials

- Etiology of malaria.
- **Quinolines:** SAR, Quinine sulphate, Chloroquine*, Amodiaquine, Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine
- **Biguanides and dihydro triazines:** Cycloguanil pamoate, Proguanil
- **Miscellaneous:** Pyrimethamine, Artesunate, Artemether, Atovaquone

UNIT III

10 Hours

Anti-tubercular Agents

- **Synthetic anti tubercular agents:** Isoniazid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid*
- **Anti-tubercular antibiotics:** Rifampicin, Rifabutin, Cycloserine, Streptomycin, 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, Delavirdine, Ribavirin, Saquinavir, Indinavir, Ritonavir

UNIT IV

08 Hours

Antifungal Agents:

- **Antifungal antibiotics:** Amphotericin-B, Nystatin, Natamycin, Griseofulvin
- **Synthetic Antifungal agents:** Clotrimazole, Econazole, Butoconazole, Oxiconazole, Tioconazole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*

Anti-protozoal Agents

- Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine

B. Bhatt

Anthelmintics

- Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*, Albendazole, Niclosamide, Oxamniquine, Praziquantel, Ivermectin

Sulphonamides and Sulfones

- Historical development, Chemistry, Classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxazole*, Sulphadiazine, Mefenide acetate, Sulfasalazine
- Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole
- Sulfones: Dapsone*

UNIT V

07 Hours

Introduction to Drug Design

- Various approaches used in drug design
- Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammett's electronic parameter, Taft's steric parameter and Hansch analysis
- Pharmacophore modeling and docking techniques

Combinatorial Chemistry:

- Concept and applications of Combinatorial chemistry
- Solid phase and solution phase synthesis

Tutorials

Teaching hours: 15 Hours

Tutorials will be based on above syllabus.

Suggested Readings[^]: (Latest edition)

1. Wilson, C. O., Beale, J. M., & Block, J. H. *Wilson and Gisvold's textbook of organic medicinal and pharmaceutical chemistry*. Lippincott Williams & Wilkins.
2. Foye, W. O. *Foye's principles of medicinal chemistry*. Lippincott Williams & Wilkins.
3. Burger, A., & Abraham, D. J. *Burger's medicinal chemistry and drug discovery* (Vol. I-IV). Wiley.
4. Smith, H. J., & Williams, H. *Introduction to the principles of Drug design*. Elsevier.
5. Remington, J. P. *Remington: the science and practice of pharmacy* (Vol. 1 & 2). Lippincott Williams & Wilkins.
6. Reynolds, J. E. F., *Martindale: the extra pharmacopoeia*. Pharmaceutical Press, London.
7. Finar, I. L. *Organic Chemistry, Volume 2: Stereochemistry And The Chemistry Natural Product*, Pearson Education India.
8. Lednicher, D. *The organic chemistry of drug synthesis* (Vol. 1-5). John Wiley & Sons.
9. Indian pharmacopoeia, Indian Pharmacopoeial Commission.
10. Furniss, B. S. *Vogel's textbook of practical organic chemistry*. Pearson Education India.

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J. Bhatt