



C. U. SHAH UNIVERSITY

Wadhwan City

FACULTY OF: Pharmaceutical Sciences

DEPARTMENT OF: Pharmaceutical Chemistry

SEMESTER: V

CODE: BP501T

NAME: Medicinal chemistry – II (Theory)

Teaching & Evaluation Scheme:

Subject Code	Name of the Subject	Teaching Scheme(Hours)				Credits	Evaluation Scheme								
		Th	Tu	Pr	Total		Theory				Practical				Total
							Internal Exam		End Semester Exams		Internal Exam		End Semester Exams		
							Marks	Hrs	Marks	Hrs	Marks	Hrs	Marks	Hrs	
BP501T	Medicinal chemistry – II (Theory)	3	1	0	4	4	15	1	75	3	--	--	---	--	100
							10 (CM)	--							

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

UNIT	COURSE CONTENT (45 Hours)	HR.
I	<p>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 (*)</p> <ul style="list-style-type: none"> • Antihistaminic agents: Histamine, receptors and their distribution in the human body • H₁-antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetrizine, Levocetrizine, Cromolyn sodium • H₂-antagonists: Cimetidine*, Famotidine, Ranitidine. 	10



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	<ul style="list-style-type: none"> • Gastric Proton pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole • Anti-neoplastic agents: Alkylating agents: Meclroethamine*, 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. 	
II	<p>Anti-anginal:</p> <ul style="list-style-type: none"> • Vasodilators: Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, Isosorbidedinitrite*, Dipyridamole. • Calcium channel blockers: Verapamil, Bepridil hydrochloride, Diltiazemhydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine. <p>Diuretics: Carbonic anhydrase inhibitors: Acetazolamide*, Methazolamide, Dichlorphenamide.</p> <ul style="list-style-type: none"> • Thiazides: Chlorthiazide*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide, • Loop diuretics: Furosemide*, Bumetanide, Ethacrynic acid. • Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride. • Osmotic Diuretics: Mannitol <p>Anti-hypertensive Agents: Timolol, Captopril, Lisinopril, Enalapril, Benazepril hydrochloride, Quinapril hydrochloride, Methyldopate hydrochloride,* Clonidine hydrochloride, Guanethidine monosulphate, Guanabenz acetate, Sodiumnitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.</p>	10
III	<ul style="list-style-type: none"> • 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. 	10
IV	<p>Drugs acting on Endocrine system Nomenclature, Stereochemistry and metabolism of steroids</p> <ul style="list-style-type: none"> • Sex hormones: Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol, Oestrione, Diethyl stilbestrol. 	08



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	<ul style="list-style-type: none">• Drugs for erectile dysfunction: Sildenafil, Tadalafil.• Oral contraceptives: Mifepristone, Norgestrel, Levonorgestrol• Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone• Thyroid and antithyroid drugs: L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole.	
V	<p>Antidiabetic agents: Insulin and its preparations</p> <ul style="list-style-type: none">• Sulfonyl ureas: Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride.• Biguanides: Metformin.• Thiazolidinediones: Pioglitazone, Rosiglitazone.• Meglitinides: Repaglinide, Nateglinide.• Glucosidase inhibitors: Acarbose, Voglibose. <p>Local Anesthetics: SAR of Local anesthetics</p> <ul style="list-style-type: none">• 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, Dipiperodon, Dibucaine.*	07

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.
7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1 to 5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I. Vogel.



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FACULTY OF: Pharmaceutical Sciences

DEPARTMENT OF: Pharmaceutics

SEMESTER: V

CODE: BP 502 T

NAME: Industrial Pharmacy I (Theory)

Teaching & Evaluation Scheme:

Subject Code	Name of the Subject	Teaching Scheme(Hours)				Credits	Evaluation Scheme								
		Th	Tu	Pr	Total		Theory				Practical				Total
							Internal Exam		End Semester Exams		Internal Exam		End Semester Exams		
							Marks	Hrs	Marks	Hrs	Marks	Hrs	Marks	Hrs	
BP502T	Industrial Pharmacy I (Theory)	3	1	0	4	4	15	1	75	3	--	--	---	--	100
							10 (CM)	--							

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

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

- Know the various pharmaceutical dosage forms and their manufacturing techniques.
- Know various considerations in development of pharmaceutical dosage forms
- Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality

UNIT	COURSE CONTENT (45 Hours)	HR.
I	<p>Preformulation Studies: Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances.</p> <ul style="list-style-type: none"> • 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. 	07
II	<p>Tablets:</p> <ul style="list-style-type: none"> • 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 	10



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	<p>Liquid orals: Formulation and manufacturing consideration of syrups and elixirs suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia.</p>	
III	<p>Capsules:</p> <ul style="list-style-type: none"> • 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 minim/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules and their applications. <p>Pellets: Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets</p>	08
IV	<p>Parenteral Products:</p> <ul style="list-style-type: none"> • 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. <p>Ophthalmic Preparations: Introduction, formulation considerations; formulation of eye drops, eye ointments and eye lotions; methods of preparation; labeling, containers; evaluation of ophthalmic preparations</p>	10
V	<ul style="list-style-type: none"> • 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. 	10



C. U. SHAH UNIVERSITY
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FACULTY OF: Pharmaceutical Sciences

DEPARTMENT OF: Pharmaceutics

SEMESTER: V

CODE: BP 506 P

NAME: Industrial Pharmacy I (Practical)

Teaching & Evaluation Scheme:-

Subject Code	Name of the Subject	Teaching Scheme (Hours)				Credits	Evaluation Scheme										
		Th	Tu	Pr	Total		Theory				Practical				Total		
							Internal Exam		End Semester Exam		Internal Exam		End Semester Exam				
							Marks	Hrs	Marks	Hrs	Marks	Hrs	Marks	Hrs			
BP506P	Industrial Pharmacy I – Practical	--	--	4	4	2	--	--	--	--	10	4	5 (CM)	--	35	4	50

1. Preformulation studies on paracetamol/aspirin/or any other drug
2. Preparation and evaluation of Paracetamol tablets
3. Preparation and evaluation of Aspirin tablets
4. Coating of tablets- film coating of tables/granules
5. Preparation and evaluation of Tetracycline capsules
6. Preparation of Calcium Gluconate injection
7. Preparation of Ascorbic Acid injection
8. Quality control test of (as per IP) marketed tablets and capsules
9. Preparation of Eye drops/ and Eye ointments
10. Preparation of Creams (cold / vanishing cream)
11. Evaluation of Glass containers (as per IP)



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Recommended Books: (Latest Editions)

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman & J.B.Schwartz
2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman
3. Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman
4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition
5. Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS)
6. Theory and Practice of Industrial Pharmacy by Liberman & Lachman
7. Pharmaceutics- The science of dosage form design by M.E.Aulton, Churchill livingstone, Latest edition
8. Introduction to Pharmaceutical Dosage Forms by H. C.Ansel, Lea &Febiger, Philadelphia, 5thedition, 2005
9. Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition,Marcel Dekker Series, Vol 107.



C. U. SHAH UNIVERSITY
Wadhwan City

FACULTY OF: Pharmaceutical Sciences

DEPARTMENT OF: Pharmacology

SEMESTER: V

CODE: BP503T

NAME: Pharmacology II-Theory

Teaching & Evaluation Scheme:-

Subject Code	Name of the Subject	Teaching Scheme (Hours)				Credits	Evaluation Scheme								
		Th	Tu	Pr	Total		Theory				Practical				Total
							Internal Exam		End Semester Exam		Internal Exam		End Semester Exam		
							Marks	Hrs	Marks	Hrs	Marks	Hrs	Marks	Hrs	
BP503T	Pharmacology II – Theory	3	1	--	4	4	15	1	75	3	--	--	--	--	100
							10 (CM)	--							

Scope: This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on different systems of body and in addition, emphasis on the basic concepts of bioassay.

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

- Understand the mechanism of drug action and its relevance in the treatment of different diseases
- Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments
- Demonstrate the various receptor actions using isolated tissue preparation
- Appreciate correlation of pharmacology with related medical sciences

UNIT	COURSE CONTENT (45 Hours)	HR.
I	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.	10
II	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	10



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	d. Plasma volume expanders Pharmacology of drugs acting on urinary system a. Diuretics b. Anti-diuretics	
III	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	10
IV	Pharmacology of drugs acting on endocrine system a. Basic concepts in endocrine pharmacology. b. Anterior Pituitary hormones- analogues and their inhibitors. c. Thyroid hormones- analogues and their inhibitors. d. Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D. d. Insulin, Oral hypoglycemic agents and glucagon. e. ACTH and corticosteroids.	08
V	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	07



C. U. SHAH UNIVERSITY
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FACULTY OF: Pharmaceutical Sciences

DEPARTMENT OF: Pharmacology

SEMESTER: V

CODE: BP507 P

NAME: Pharmacology II– Practical

Teaching & Evaluation Scheme:-

Subject Code	Name of the Subject	Teaching Scheme (Hours)				Credits	Evaluation Scheme								
		Th	Tu	P r	Total		Theory				Practical				Total
							Internal Exam		End Semester Exam		Internal Exam		End Semester Exam		
							Marks	Hrs	Marks	Hrs	Marks	Hrs	Marks	Hrs	
BP507P	Pharmacology II – Practical	--	--	4	4	2	--	--	--	--	10	4	35	4	50
											5 (CM)	--			

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



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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
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.



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	<ul style="list-style-type: none">• 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	
III	Isolation, Identification and Analysis of Phytoconstituents <ul style="list-style-type: none">• Terpenoids: Menthol, Citral, Artemisin• Glycosides: Glycyrrhetic acid & Rutin• Alkaloids: Atropine, Quinine, Reserpine, Caffeine• Resins: Podophyllotoxin, Curcumin	06
IV	Industrial production, estimation and utilization of the following phytoconstituents: Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine	10
V	Basics of Phytochemistry <ul style="list-style-type: none">• Modern methods of extraction, application of latest techniques like Spectroscopy, Chromatography and electrophoresis in the isolation, purification and identification of crude drugs.	08



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FACULTY OF: Pharmaceutical Sciences

DEPARTMENT OF: Pharmacognosy

SEMESTER: V

CODE: BP508P

NAME: Pharmacognosy and Phytochemistry II – Practical

Teaching & Evaluation Scheme:-

Subject Code	Name of the Subject	Teaching Scheme (Hours)				Credits	Evaluation Scheme								
		Th	Tu	Pr	Total		Theory				Practical				Total
							Internal Exam		End Semester Exam		Internal Exam		End Semester Exam		
							Marks	Hrs	Marks	Hrs	Marks	Hrs	Marks	Hrs	
BP508P	Pharmacognosy and Phytochemistry II – Practical	--	--	4	4	2	--	--	--	--	10	4 Hrs	35	4 Hrs	50
										5 (CM)	--				

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



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Recommended Books: (Latest Edition)

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Saunders & Co., London, 2009.
2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), 1stEdn, Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
6. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.
7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
10. The formulation and preparation of cosmetic, fragrances and flavours.
11. Remington's Pharmaceutical sciences.
12. Text Book of Biotechnology by Vyas and Dixit.
13. Text Book of Biotechnology by R.C. Dubey.



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FACULTY OF: Pharmaceutical Sciences

DEPARTMENT OF: Pharmaceutics

SEMESTER: V

CODE: BP505T

NAME: Pharmaceutical Jurisprudence – Theory

Teaching & Evaluation Scheme:-

Subject Code	Name of the Subject	Teaching Scheme (Hours)				Credits	Evaluation Scheme								
		Th	Tu	Pr	Total		Theory				Practical				Total
							Internal Exam		End Semester Exam		Internal Exam		End Semester Exam		
							Marks	Hrs	Marks	Hrs	Marks	Hrs	Marks	Hrs	
BP505T	Pharmaceutical Jurisprudence – Theory	3	1	--	4	4	15	1	75	3	--	--	--	--	100
							10 (CM)	--							

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 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

UNIT	COURSE CONTENT (45 Hours)	HR.
I	<p>Drugs and Cosmetics Act, 1940 and its rules 1945:</p> <ul style="list-style-type: none"> • 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. 	10
II	<p>Drugs and Cosmetics Act, 1940 and its rules 1945.</p> <ul style="list-style-type: none"> • 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. 	10



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	<ul style="list-style-type: none">• 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	
III	<ul style="list-style-type: none">• 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	10
IV	<ul style="list-style-type: none">• 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)	08
V	<ul style="list-style-type: none">• 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)	07



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Recommended books: (Latest Edition)

1. Forensic Pharmacy by B. Suresh
2. Text book of Forensic Pharmacy by B.M. Mithal
3. Hand book of drug law-by M.L. Mehra
4. A text book of Forensic Pharmacy by N.K. Jain
5. Drugs and Cosmetics Act/Rules by Govt. of India publications.
6. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
7. Narcotic drugs and psychotropic substances act by Govt. of India publications
8. Drugs and Magic Remedies act by Govt. of India publication
9. Bare Acts of the said laws published by Government. Reference books (Theory)