Shri Shankaracharya Technical Campus (An Autonomous Institution)

Scheme of Teaching and Examination

Faculty of Pharmaceutical Sciences

Bachelor of Pharmacy (B. Pharmacy) V Semester

S. No	Board of Study	Subject Code	Name of the course with PCI code	Internal Assessment				End Semester Exams		Total Marks	Credit
				Continuous Mode	Sessional Exams		Total	Marks	Duration		
					Marks	Duration					
1	Pharmacy	PH108501	Formulative Pharmacy – Theory (BP502T)	10	15	1 Hr	25	75	3 Hrs	100	4
2	Pharmacy	PH108502	Pharmacology – II – Theory (BP503T)	10	15	1 Hr	25	75	3 Hrs	100	4
3	Pharmacy	PH108503	Pharmacognosy – II – Theory (BP504T)	10	15	1 Hr	25	75	3 Hrs	100	4
4	Pharmacy	PH108504	Medicinal Chemistry – II – Theory (BP501T)	10	15	1 Hr	25	75	3 Hrs	100	4
5	Pharmacy	PH108505	Pharmaceutical Jurisprudence – Theory (BP505T)	10	15	1 Hr	25	75	3 Hrs	100	4
6	Pharmacy	PH108591	Formulative Pharmacy – Practical (BP506P)	5	10	4 Hr	15	35	4 Hrs	50	2
7	Pharmacy	PH108592	Pharmacology – II – Practical (BP507P)	5	10	4 Hr	15	35	4 Hrs	50	2
8	Pharmacy	PH108593	Pharmacognosy – II – Practical (BP508P)	5	10	4 Hr	15	35	4 Hrs	50	2
Total				**65**	**105**	**17 Hr**	**170**	**480**	**27 Hrs**	**650**	**26**

Subject Code PH108501	Formulative Pharmacy	L=3	T =1	P =0	Credits= 4
Evaluation Scheme	ESE	CT	TA	Total	ESE Duration
	75	15	10	100	3 Hours

Course Objective	Course Outcomes
After completion of course student is able to know, 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.	On successful completion of the course, the student will be able to: **CO1:-** To differentiate various pharmaceutical dosage forms and compare its quality and efficiency. (BL-4) **CO2:-** To examine manufacturing techniques of various pharmaceutical dosage forms. (BL-1) **CO3:-** To test or analyse pharmaceutical dosage form and interpret results. (BL-4) **CO4:-** To analyse preformulation factors of different dosage forms and study its effect on quality and efficacy of dosage forms. (BL-4)

UNIT I (CO4) **7 hours**

Preformulation studies: introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances.

a. **Physical properties**: physical form (crystal and amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism

b. **chemical properties:** hydrolysis, oxidation, reduction, racemisation, polymerization BCS classificationof drug application of pre formulation consideration in the development of solid, liquid, oral and parenteral dosage forms and its impact on the stability of the dosage form.

UNIT–II (CO1, CO2) **10 hours**

a. Tablet ideal characteristics of tablets, classification of tablets. Excipients introduction, ideal characteristic of tablets, classification of tablet, excipients, formulation of tablets, granulation method, compression and processing problems, equipment and tablet tooling.

b. Tablet coating: types of coating, coating materials, formulation of the coating.

c. quality control tests: in process and finished product test

liquid orals: formulation and manufacturing consideration of solutions, suspension and emulsions, filling and packaging, evaluation of liquid orals official in pharmacopeia

UNIT – III (CO2, CO3) **8 hours**

Capsules:

a. **Hard gelatin capsule:** introduction, extraction of gelatin and production of hard gelatin capsule shells, size of capsules, filling, finishing and special techniques of the hard gelatin capsules. in the process and final product quality control test for capsules.

b. **Soft gelatin capsules:** nature of shell and capsule content, size of capsule, importance of base adsorption and minimum/ gram factor, production, in process and final product quality control test, packing, storage and stability testing of soft gelatin capsule

Pellets: introduction, formulation requirements, pelletization process, equipments for manufacture of pellet

UNIT – IV (CO2, CO3) **10 hours**

Parenteral products:

a. definition, type, advantages and limitations, preformulation factor and essential requirements, vehicles, additives, importance of tonicity

b. production procedure, production facilities and control

c. formulation of injection, sterile powders, emulsion, suspensions, large volume parenterals and lyophilized products, sterilization product.

d. container closures selection, filling and sealing of ampoules, vials and infusion fluid. quality controltest

Ophthalmic preparation: introduction, formulation consideration, formulation of eye drops, eye ointments and eye lotions, method of preparation, labeling, containers, evaluation of ophthalmic preparation.

UNIT – V (CO2, CO4) **10 hours**

Cosmetics: formulation and preparation of the following cosmetic preparations lipstick, shampoos, cold cream and vanishing cream, tooth paste, hair dyes and sunscreens.

Pharmaceutical aerosol: definition, propellant, containers, valves, types of aerosol system, formulation and manufacture of aerosols, evaluation of aerosols, quality control and stability studies.

Packaging material science: material used for packaging of pharmaceutical products, factor influencing the choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.

Text Books:

S.No.	Title	Authors	Edition	Publisher
1	Industrial Pharmacy	D.K. Tripathi	1st	Pharmamed Press
2	Pharmaceutics II	R. M. Mehta	4th	Vallabh Prakashan
3	Cosmetic Technology	Sanju Nanda	1st	Birla Publication

Reference books:

S. No.	Title	Authors	Edition	Publisher
1	Industrial pharmacy	Leon Lachman	Special	CBS Publisher
2	Practice of Pharmacy	Remington	21st	Elsevier

Subject Code PH108591	Formulative Pharmacy- Practical	L=3	T =1	P =0	Credits= 4
Evaluation Scheme	ESE	CT	TA	Total	ESE Duration
	75	15	10	100	3 Hours

Course Objective	Course Outcomes
After completion of course student is able to know, know the various Pharmaceutical dosage forms and their manufacturing techniques. know various considerations in development of Pharmaceuticaldosage forms. formulate solid, liquid and semisolid dosage forms and evaluate them for their quality.	On successful completion of the course, the student will be able to: **CO1:-** To differentiate various pharmaceutical dosage forms and compare its quality and efficiency. (BL-4) **CO2:-** To examine manufacturing techniques of various pharmaceutical dosage forms. (BL-4) **CO3:-** To test or analyse Pharmaceutical dosage form and interpret results. (BL-4) **CO4:-** To analyse preformulation factors of different dosage forms and study its effect on quality and efficacy of dosage forms. (BL-4)

1. Preformulation study for prepared granules
2. Preparation and evaluation of Paracetamol tablets
3. Preparation and evaluation of Aspirin tablets
4. Coating of tablets
5. Preparation and evaluation of Tetracycline capsules
6. Preparation of Calcium Gluconate injection
7. Preparation of Ascorbic Acid injection
8. Preparation of Paracetamol Syrup
9. Preparation of Eye drops
10. Preparation of Pellets by extrusion spheronization technique
11. Preparation of Creams (cold / vanishing cream)
12. Evaluation of Glass containers

Text Books:

S.No.	Title	Authors	Edition	Publisher
1	Pharmaceutical Formulation	Swarnali Das Paul	1st	Birla Publication

Reference books:

S. No.	Title	Authors	Edition	Publisher
1	Practical Pharmaceutics	R.S. Gaud	1st	CBS Publisher

Subject Code PH108502	Pharmacology – II	L=3	T =1	P =0	Credits= 4
Evaluation Scheme	ESE	CT	TA	Total	ESE Duration
	75	15	10	100	3 Hours

Course Objective	Course Outcomes
Objectives: Upon completion of this course the student should be able to 1. Understand the mechanism of drug action and its relevance in the treatment of different diseases 2. Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments 3. Demonstrate the various receptor actions using isolated tissue preparation 4. Appreciate correlation of pharmacology with related medical sciences	**CO1**-Understand the Pharmacology of different drugs acted on cardiovascular and urinary system (BL-2) **CO2**-Exaplain the Pharmacology and significance of autocoids and related drugs (BL-2) **CO3**- Describe the Pharmacological importence of various hormones and related drugs (BL-2) **CO4**- To undestand the basic principle of bioassay (BL-2)

UNIT-I (CO1)	**10hours**
1. Pharmacology of drugs acting on cardio vascular system	
a. Introduction to hemodynamic and electrophysiology of the 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 (CO1)	**10hours**
1. Pharmacology of drugs acting on cardio vascular system	
a. Drug used in the therapy of shock.	
b. Hematinics, coagulants and anticoagulants.	
c. Fibrinolytic and anti-platelet drugs	
d. Plasma volume expanders	
2. Pharmacology of drugs acting on urinary system	
a. Diuretics	
b. Anti-diuretics	
UNIT-III (CO2)	**10hours**
1.Autocoids and related drugs	
a. Introduction to autacoids and classification	
b. Histamine, 5-HT and their antagonists.	
c. Prostaglandins, Thromboxanes and Leukotrienes.	
d. Angiotensin, Bradykinin and Substance P.	
e. Non-steroidal anti-inflammatory agents	
f. Anti-gout drugs	
g. Antirheumatic drugs	
UNIT-IV (CO3)	**08hours**
1. Pharmacology of drugs acting on endocrine system	
a. Basic concepts in endocrine pharmacology.	
b. Anterior Pituitary hormones- analogues and their inhibitors.	
c. Thyroid hormones- analogues and their inhibitors.	
d. Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D.	
d. Insulin, Oral Hypoglycemic agents and glucagon.	
e. ACTH and corticosteroids.	
UNIT-V (CO3)	**07hours**
1. Pharmacology of drugs acting on endocrine system	
a. Androgens and Anabolic steroids.	

b. Estrogens, progesterone and oral contraceptives.
c. Drugs acting on the uterus.
2. Bioassay (CO4)
a. Principles and applications of thebioassay.
b.Types of bioassay
c. Bioassay of insulin, oxytocin, vasopressin, ACTH,d-tubocurarine, digitalis, histamine and 5-HT

Text Books:

S.No.	Title	Authors	Edition	Publisher
1	Essential of medicinal Pharmacology	K.D. Tripathi	6th	Jaypee brother medical publisher
2	Basic and clinical Pharmacolgy	Bentham and Susan B.Mastene	11th	Tata mcgnaw education pvt limited

Reference books:

S. No.	Title	Authors	Edition	Publisher
1	Pharmacological basis of therapeutic	Goodman & Gill man	2nd	Mcjraw Hill
2	Elements of Pharmacolgy	Dr. Ramesh K. Goyal	18th	B.S Shah Prakashan

Subject Code PH108592	Pharmacology – II- Practical	L=3	T =1	P =0	Credits= 4
Evaluation Scheme	ESE	CT	TA	Total	ESE Duration
	75	15	10	100	3 Hours

Course Objective	Course Outcomes
Objectives: Upon completion of this course the student should be able to 1. Understand the mechanism of drug action and its relevance in the treatment of different diseases 2. Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments 3. Demonstrate the various receptor actions using isolated tissue preparation 4. Appreciate correlation of pharmacology with related medical sciences	**CO1**-Understand the pharmacology of different drugs acted on cardiovascular and urinary system **CO2**-Exaplain the pharmacology and significance of autocoids and related drugs **CO3**- Describe the pharmacological importance of various hormones and related drugs **CO4**- To understand the basic principle of bioassay

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 the matching method.
8. Bioassay of oxytocin using rat uterine horn by an 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 inducedpaw-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 software and videos

Text Books:

S.No.	Title	Authors	Edition	Publisher
1	Experiment and Pharmacolgy	S.K. Kulkarni	4th	Vallabh Prakashan

Subject Code PH108503	Pharmacognosy – II – Theory	L=3	T =1	P =0	Credits= 4
Evaluation Scheme	ESE	CT	TA	Total	ESE Duration
	75	15	10	100	3 Hours

Course Objective	Course Outcomes
The main purpose of the 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 photochemical through plant tissue culture, drug interactions and basic principles of traditional system of medicine	**CO1**.To know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents (BL-3) **CO2**. To understand the preparation and development of herbal formulation. (BL-3) **CO3**. To understand the herbal drug interactions (BL-4) **CO4**.To carryout isolation and identification of phytoconstituents (BL-3)

UNIT-I **7 Hours**

Metabolic pathways in higher plants and their determination

a) 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 **20 Hours**

General introduction, composition, chemistry & chemical classes, general methods of extraction & analysis, biosources, therapeutic uses and commercial applications of following secondary metabolites:

Alkaloids: Vinca, Rauwolfia, Belladonna, Opium,

Phenylpropanoids and Flavonoids: Lignans, Tea, Ruta

Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis

Volatile oils: Mentha, Clove, Cinnamon, Fennel, Coriander,

Tannins: Catechu, Pterocarpus

Resins: Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony

Glycosides: Senna, Aloes, Bitter Almond

Iridoids, Other terpenoids &Naphthoquinones: Gentian, Artemisia, taxus, carotenoids

UNIT-III **10 Hours**

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

UNIT- IV **8 Hours**

Basics of Phytochemistry

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

Text Books:

S.No.	Title	Authors	Edition	Publisher
1	Text book of Pharmacognosy	T. E. Walis	5th edition	CBS Publisher and distributor
2.	Pharmacognosy	C.K. Kokate	48th edition	Nirali Prakashan

Reference books:

S. No.	Title	Authors	Edition	Publisher
1	Text book of Pharmacognosy	S. S. Handa	2nd edition	Vallabh Prakashan

Subject Code PH108593	Pharmacognosy – II Practical	L=3	T =1	P =0	Credits= 4
Evaluation Scheme	ESE	CT	TA	Total	ESE Duration
	75	15	10	100	3 Hours

Course Objective	Course Outcomes
The main purpose of the 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 photochemical through plant tissue culture, drug interactions and basic principles of traditional system of medicine	**CO1**.To know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents **CO2**. To understand the preparation and development of herbal formulation. **CO3**. To understand the herbal drug interactions **CO4**.To carryout isolation and identification of phytoconstituents

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

Text Books:

S.No.	Title	Authors	Edition	Publisher
1	Practical Pharmacognosy	Rasheeduz Zafar	1st	CBS Publisher

Reference books:

S. No.	Title	Authors	Edition	Publisher
1	Practical Pharmacognosy	C. K. Kokate	5th	Vallabh Prakashan

Subject Code PH108504	Medicinal Chemistry – II	L=3	T =1	P =0	Credits= 4
Evaluation Scheme	ESE	CT	TA	Total	ESE Duration
	75	15	10	100	3 Hours

Course Objective	Course Outcomes
Objectives: Upon completion of the course the student shall be able to 1. Understand the chemistry of drugs with respect to their pharmacological activity 2. Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs 3. Know the Structural Activity Relationship of different class of drugs 4. Study the chemical synthesis of selected drugs	**CO1**- Describe the chemistry of drugs with respect to their pharmacological activity (BL-4,BL-5) **CO2**- State the drug metabolic pathways, adverse effect and therapeutic value of drugs.(BL-2,BL-3) **CO3**-Compute the Structural Activity Relationship of different class of drugs (BL-4) **CO4**- Discuss the chemical synthesis of selected drugs (BL-2,BL-3)

UNIT- I (CO1) **10 Hours**

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

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

H2-antagonists: Cimetidine*, Famotidine, Ranitidin.

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

Anti-neoplastic agents:

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

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

Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin

Plant products: Etoposide, Vinblastin sulphate, Vincristine sulphate

Miscellaneous: Cisplatin, Mitotane.

UNIT – II (CO1,CO4) **10 Hours**

Anti-anginal:

Vasodilators: Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate,Isosorbidedinitrite*, Dipyridamole.

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

Diuretics:

Carbonic anhydrase inhibitors: Acetazolamide*, Methazolamide,Dichlorphenamide.

Thiazides: Chlorothiazide*, 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, Benazeprilhydrochloride, Quinapril hydrochloride, Methyldopate hydrochloride,* Clonidine hydrochloride, Guanethidine monosulphate, Guanabenz acetate, Sodium nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.

UNIT- III (CO1,CO4) **10 Hours**

Anti-arrhythmic Drugs: Quinidine sulphate, Procainamide hydrochloride,Disopyramide phosphate*, Phenytoin sodium, Lidocaine hydrochloride, Tocainide hydrochloride, Mexiletine hydrochloride, Lorcainide hydrochloride, Amiodarone, Sotalol.

Anti-hyperlipidemic agents: Clofibrate, Lovastatin, Cholesteramine andCholestipol

Coagulant & Anticoagulants: Menadione, Acetomenadione, Warfarin*,Anisindione, clopidogrel

Drugs used in Congestive Heart Failure: Digoxin, Digitoxin, Nesiritide, Bosentan, Tezosentan

UNIT- IV (CO1,CO3) **08 Hours**

Drugs acting on Endocrine system

Nomenclature, Stereochemistry and metabolism of steroids

Sex hormones: Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol,Oestrione, Diethyl stilbestrol.

Drugs for erectile dysfunction: Sildenafil, Tadalafil.

Oral contraceptives: Mifepristone, Norgestril, Levonorgestrol

Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone,Dexamethasone

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

UNIT – V (CO3,CO4) **07 Hours**

Antidiabetic agents:

Insulin and its preparations

Sulfonyl ureas: Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride. Biguanides: Metformin.

Thiazolidinediones: Pioglitazone, Rosiglitazone.Meglitinides: Repaglinide, Nateglinide.

Glucosidase inhibitors: Acrabose, Voglibose.

Local Anesthetics: SAR of Local anaesthetics

Benzoic Acid derivatives; Cocaine, Hexylcaine, Meprylcaine, Cyclomethycaine,Piperocaine.

Amino Benzoic acid derivatives: Benzocaine*, Butamben, Procaine*, Butacaine,Propoxycaine, Tetracaine, Benoxinate.

Lidocaine/Anilide derivatives: Lignocaine, Mepivacaine, Prilocaine, Etidocaine.

Miscellaneous: Phenacaine, Diperodon, Dibucaine.*

Text Books:

S.No.	Title	Authors	Edition	Publisher
1	Principal of Medicinal Chemistry	Dr. S.S. Kadam Dr. K.R. Mahadik	1st	Nirali Prakashan
2	Medicinal Chemistry	Ashutos Kar	1st	New age international limited publisher

Reference books:

S. No.	Title	Authors	Edition	Publisher
1	Text book of medicinalchemistry	Prof Surendra Nath Pandey	3rd	S.G. Publisher

Subject Code PH108505	Pharmaceutical Jurisprudence	L=3	T =1	P =0	Credits= 4
Evaluation Scheme	ESE	CT	TA	Total	ESE Duration
	75	15	10	100	3 Hours

Course Objective	Course Outcomes
After completion of course student is able to know, 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.	On successful completion of the course, the student will be able to: **CO1:-** To understand fundamental concepts of law, methodology, judicial organization and functioning of pharmaceutical legislation. (BL-2,BL-3) **CO2:-** To develop awareness of integrity, justice and ethics.(BL-3,BL-4) **CO3:-** To make a critical evaluation of basic concepts and problems of law. (BL-5) **CO4:-** To know the regulatory authorities and agencies governing the Import, manufacture and sale of Pharmaceuticals. (BL-2,BL-4)

UNIT I (CO1,CO4) **10Hrs**

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 (CO1,CO4) **10Hrs**

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, Listof 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 (CO2,CO3) **10Hrs**

- **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 122 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 (CO2,CO4) **8Hrs**

- **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 **7Hrs**

- **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)**

Text Books:

S.No.	Title	Authors	Edition	Publisher
1	A text book of Forensic Pharmacy	N.K. Jain	First	Vallabh Prakashan
2	Text book of Forensic Pharmacy	B.M. Mithal	Third	Mithal

Reference books:

S. No.	Title	Authors	Edition	Publisher
1	Bare Acts of the said laws published	by Government	1st	
2	Drugs and Cosmetics Act/Rules	Govt. of India publications.	1st	