(Formerly West Bengal University of Technology)

**B.PHARM Syllabus** 

#### (Effective from 2020-2021 Admission Session)

### Semester-V

#### PT 513A. MEDICINAL CHEMISTRY – I (Theory)

#### **45 Hours**

**Scope:** This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

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

- 1. understand the chemistry of drugs with respect to their pharmacological activity
- 2. understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
- 3. know the Structural Activity Relationship (SAR) of different class of drugs
- 4. write the chemical synthesis of some drugs

#### Course Content:

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

Only structure and Chemical name of the highlighted compounds need to be discussed.

### UNIT-I

#### **10 Hours**

Introduction to Medicinal Chemistry

History and development of medicinal chemistry

#### Physicochemical properties in relation to biological action

Ionization, Solubility, Partition Coefficient, Hydrogen bonding, Protein binding, Chelation, Bioisosterism, Optical and Geometrical isomerism.

#### Drug metabolism

Drug metabolism principles- Phase I and Phase II.

Factors affecting drug metabolism including stereo chemical aspects.

#### UNIT-II

**10 Hours** 

**Drugs acting on Autonomic Nervous** 

System Adrenergic

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#### **Neurotransmitters:**

Biosynthesis and catabolism of catecholamine.

Adrenergic receptors (Alpha & Beta) and their distribution.

#### Sympathomimetic agents: SAR of Sympathomimetic agents

Direct acting: Nor-epinephrine, Epinephrine, Phenylephrine\*, Dopamine, Methyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline, Salbutamol\*, Bitolterol, Naphazoline, Oxymetazoline and Xylometazoline.

- Indirect acting agents: Hydroxyamphetamine, Pseudoephedrine, Propylhexedrine.
- Agents with mixed mechanism: Ephedrine, Metaraminol.

#### Adrenergic Antagonists:

Alpha adrenergic blockers: Tolazoline\*, Phentolamine, Phenoxybenzamine, Prazosin, Dihydroergotamine, Methysergide.

**Beta adrenergic blockers:** SAR of beta blockers, Propranolol\*, Atenolol, Esmolol, Metoprolol, Labetolol, Carvedilol.

#### **UNIT-III**

#### **10 Hours**

#### Cholinergic neurotransmitters:

Biosynthesis and catabolism of acetylcholine.

Cholinergic receptors (Muscarinic & Nicotinic) and their distribution.

Parasympathomimetic agents: SAR of Parasympathomimetic agents

**Direct acting agents:** Acetylcholine, Carbachol\*, Bethanechol, Methacholine, Pilocarpine.

Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible): Physostigmine, Neostigmine\*, Pyridostigmine, Edrophonium chloride, Tacrine hydrochloride, Ambenonium chloride, Isofluorphate, Echothiophate iodide, Parathione, Malathion.

Cholinesterase reactivator: Pralidoxime chloride.

**Cholinergic Blocking agents: SAR of cholinolytic agents** 

**Solanaceous alkaloids and analogues:** Atropine sulphate, Hyoscyamine sulphate, Scopolamine hydrobromide, Homatropine hydrobromide, Ipratropium bromide\*.

Synthetic cholinergic blocking agents: Tropicamide, Cyclopentolate hydrochloride, Clidinium bromide, Dicyclomine hydrochloride\*,

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Glycopyrrolate, Methantheline bromide, Benztropine mesylate, Orphenadrine citrate, Biperidine hydrochloride, Procyclidine hydrochloride\*, Tridihexethyl chloride, Ethopropazine hydrochloride.

#### **UNIT-IV**

**08 Hours** 

#### **Drugs acting on Central Nervous System**

A. Sedatives and Hypnotics:

**Benzodiazepines:** SAR of Benzodiazepines, Chlordiazepoxide, Diazepam\*, Oxazepam, Lorazepam, Alprazolam, Zolpidem

**Barbiturtes:** SAR of barbiturates, Barbital\*, Phenobarbital, Mephobarbital, Amobarbital, Pentobarbital, Secobarbital

**Miscelleneous:** 

Amides & imides: Glutethmide.

Alcohol & their carbamate derivatives: Meprobomate, Ethchlorvynol.

Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

#### **B.** Antipsychotics

**Phenothiazines:** SAR of Phenothiazeines - Chlorpromazine hydrochloride\*, Triflupromazine, Thioridazine hydrochloride, Trifluoperazine hydrochloride.

**Ring Analogues of Phenothiazines:** Chlorprothixene, Thiothixene, Loxapine succinate, Clozapine.

Fluro buterophenones: Haloperidol, Droperidol, Risperidone.

Beta amino ketones: Molindone hydrochloride.

Benzamides: Sulpieride.

C. Anticonvulsants: SAR of Anticonvulsants, mechanism of anticonvulsant action

Barbiturates: Phenobarbitone, Methabarbital.

Hydantoins: Phenytoin\*, Mephenytoin, Ethotoin

Oxazolidine diones: Trimethadione, Paramethadione

Succinimides: Phensuximide, Methsuximide,

Ethosuximide\*

Urea and monoacylureas: Phenacemide,

Carbamazepine\* Benzodiazepines: Clonazepam

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Miscellaneous: Primidone, Valproic acid, Gabapentin, Felbamate

#### UNIT – V

**07 Hours** 

Drugs acting on Central Nervous System General anesthetics:

Inhalation anesthetics: Halothane\*, Methoxyflurane, Enflurane, Isoflurane, Desflurane.

**Ultra short acting barbitutrates:** Methohexital sodium\*, Thiamylal sodium, Thiopental sodium.

Dissociative anesthetics: Ketamine hydrochloride.\*

#### Narcotic and non-narcotic analgesics

**Morphine and related drugs:** SAR of Morphine analogues, Morphine sulphate, Codeine, Meperidine hydrochloride, Loperamide hydrochloride, Fentanyl citrate\*, Methadone hydrochloride\*, Pentazocine, Levorphanol tartarate.

Narcotic antagonists: Nalorphine hydrochloride, Naloxone hydrochloride.

Anti-inflammatory agents: Sodium salicylate, Aspirin, Mefenamic acid\*, Meclofenamate, Indomethacin, Sulindac, Tolmetin, Zomepriac, Diclofenac, Ketorolac, Ibuprofen\*, Naproxen, Piroxicam, Phenacetin, Acetaminophen, Antipyrine, Phenylbutazone.

#### **PT593 MEDICINAL CHEMISTRY - I (Practical)**

4 Hours/Week

- I Preparation of drugs/intermediates
- 1 1,3-pyrazole
- 2 1,3-oxazole
- 3 Benzimidazole
- 4 Benztriazole
- 5 2,3- diphenyl quinoxaline
- 6 Benzocaine
- 7 Phenytoin
- 8 Phenothiazine
- 9 Barbiturate

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- II Assay of drugs
- 1 Chlorpromazine
- 2 Phenobarbitone
- 3 Atropine
- 4 Ibuprofen
- 5 Aspirin
- 6 Furosemide
- III Determination of Partition coefficient for any two drugs

#### **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. 1-5.
- 9. Indian Pharmacopoeia.
- 10. Text book of practical organic chemistry- A.I.Vogel.

#### PT 513B. MEDICINAL CHEMISTRY – II (Theory)

#### **45 Hours**

**Scope:** This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

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

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

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#### (Effective from 2020-2021 Admission Session)

#### 4. Study the chemical synthesis of selected drugs

#### **Course Content:**

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (\*).<u>Only structure and Chemical name of the highlighted compounds need to be discussed.</u>

# UNIT- I

#### Hours

10

Antihistaminic agents: Histamine, receptors and their distribution in the humanbody

H<sub>1</sub>–antagonists: antagonists, SAR of classical H1 Diphenhydramine hydrochloride\*. Doxylamines cuccinate, Clemastine fumarate, Tripelenamine hydrochloride, hydrochloride, hvdrochloride. Meclizine Buclizine Chlorpheniramine maleate, Triprolidine hydrochloride\*, 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, Vincristin sulphate

Miscellaneous: Cisplatin, Mitotane.

#### UNIT – II

#### **10 Hours**

### Anti-anginal:

**Vasodilators:** Amyl nitrite, Nitroglycerin\*, Pentaerythritol tetranitrate, Isosorbide dinitrite\*, Dipyridamole.

**Calcium channel blockers: SAR of 1,4-dihydropyridines,** Verapamil, Bepridil hydrochloride, Diltiazem hydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine.

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#### **Diuretics**:

Carbonic anhydrase inhibitors: Acetazolamide\*, Methazolamide.

Thiazides: SAR of thiazide diuretics, Chlorthiazide\*, Hydrochlorothiazide,

Loop diuretics: Furosemide\*, Bumetanide, Ethacrynic acid. Potassium

sparing Diuretics: Spironolactone, Triamterene, Amiloride. Osmotic

Diuretics: Mannitol

Anti-hypertensive Agents: Timolol, Captopril, Lisinopril, Enalapril, Methyldopate hydrochloride,\* Clonidine hydrochloride, Guanethidine monosulphate, Guanabenz acetate, Sodium nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.

# UNIT-III

# **10 Hours**

**08 Hours** 

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

Anti-hyperlipidemic agents: Clofibrate, Lovastatin, Cholesteramine and Cholestipol

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

Drugs used in Congestive Heart Failure: Digoxin, Digitoxin, Tezosentan.

UNIT-IV

# Drugs acting on Endocrine system

Nomenclature, Stereochemistry and metabolism of steroids

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

Drugs for erectile dysfunction: Sildenafil, Tadalafil.

Oral contraceptives: Mifepristone, levo-Norgestrel, Levonorgestrol

Corticosteroids: SAR of 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: SAR of Sulfonyl ureas, Tolbutamide\*, Chlorpropamide, Glipizide, Glimepiride.

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Biguanides: Metformin.

Thiazolidinediones: Pioglitazone, Rosiglitazone. Meglitinides:

Repaglinide, Nateglinide.

Glucosidase inhibitors: Acrabose, Voglibose.

Local Anesthetics: SAR of Local anesthetics

Benzoic Acid derivatives; Cocaine, Meprylcaine, Piperocaine.

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

Anilide derivatives: Lignocaine (lidocaine), Mepivacaine, Ropivacaine.

Miscellaneous: Diperodon, Dibucaine.\*

### **Recommended Books (Latest Editions)**

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

# PT 518 PHARMACOLOGY-II (Theory)

# **45 Hours**

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

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

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

### **Course Content:**

# UNIT-I

#### 10hours

# 1. Pharmacology of drugs acting on cardio vascular system

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#### (Effective from 2020-2021 Admission Session)

- a. Introduction to hemodynamic and electrophysiology ofheart.
- 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**

#### 1. Pharmacology of drugs acting on cardio vascular system

- a. Drug used in the therapy of shock.
- b. Hematinics, coagulants and anticoagulants.
- c. Fibrinolytics and anti-platelet drugs
- d. Plasma volume expanders

#### 2. Pharmacology of drugs acting on urinary system

- a. Diuretics
- b. Anti-diuretics.

#### **UNIT-III**

#### 3. Autocoids and related drugs

- a. Introduction to autacoids and classification
- b. Histamine, 5-HT and their antagonists.
- c. Prostaglandins, Thromboxanes and Leukotrienes.
- d. Angiotensin, Bradykinin and Substance P.
- e. Non-steroidal anti-inflammatory agents
- f. Anti-gout drugs
- g. Antirheumatic drugs

#### **UNIT-IV**

### 5. 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

#### 5. Pharmacology of drugs acting on endocrine system

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

#### 6. Bioassay

a. Principles and applications of bioassay. b.

#### **10hours**

#### **10hours**

#### 10 hours

#### **05hours**

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#### (Effective from 2020-2021 Admission Session)

Types of bioassay c. Bioassay of insulin, oxytocin, vasopressin

#### PT 598 PHARMACOLOGY-II (Practical)

4Hrs/Week

- 1. Introduction to *in-vitro* pharmacology and physiological salt solutions.
- 2. Effect of drugs on isolated frog heart.
- 3. Effect of drugs on blood pressure and heart rate of dog.
- 4. Study of diuretic activity of drugs using rats/mice.
- 5. DRC of acetylcholine using frog rectus abdominis muscle.
- 6. Effect of physostigmine and atropine on DRC of acetylcholine using frogrectus abdominis muscle and rat ileum respectively.
- 7. Bioassay of histamine using guinea pig ileum bymatching method.
- 8. Bioassay of oxytocin using rat uterine horn by interpolationmethod.
- 9. Bioassay of serotonin using rat fundus strip by three point bioassay.
- 10. Bioassay of acetylcholine using rat ileum/colon by four pointbioassay.
- 11. Determination of PA<sub>2</sub> value of prazosin using rat anococcygeus muscle (by Schilds plot method).
- 12. Determination of PD<sub>2</sub> value using guinea pigileum.
- 13. Effect of spasmogens and spasmolytics using rabbit jejunum.
- 14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
- 15. Analgesic activity of drug using central and peripheral methods

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

**Recommended Books (Latest Editions)** 

- 1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil 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
- 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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# **B.PHARM Syllabus** (Effective from 2020-2021 Admission Session)

# PT 512 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 Content:**

# UNIT-I

# 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, mevalonic pathways.

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

# UNIT-II

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

Alkaloids: Vinca, Rauwolfia, Belladonna, Opium,

Phenylpropanoids and Flavonoids: Lignans, Tea, Ruta

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

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

Tannins: Catechu, Pterocarpus

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

Glycosides: Senna, Aloes, Bitter Almond

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

# **UNIT-III**

Isolation, Identification and Analysis of Phytoconstituents

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

# **UNIT IV**

# **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.

# **06 Hours**

# 9 Hours

# **17 Hours**

**10 Hours** 

**45Hours** 

PT 592 PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical) 4 Hours/Week

- 1. Morphology, histology and powder characteristics & extraction & detection of: Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander
- 2. Exercise involving isolation & detection of active principles
  - a. Caffeine from tea dust.
  - b. Starch from Potato
  - c. Atropine from Belladonna
  - d. Sennosides from Senna
- 3. Separation of sugars by Paper chromatography
- 4. TLC of herbal extract
- 5. Analysis of crude drugs by chemical tests: (i) Asafoetida (ii) Benzoin (iii) Colophony (iv) Aloes (v) Myrrh

### **Recommended Books: (Latest Editions)**

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

#### PT 516 PHARMACEUTICAL JURISPRUDENCE (Theory)

45 Hours

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:

- 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 Content:**

### **UNIT-I**

#### 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**

#### Drugs and Cosmetics Act, 1940 and its rules 1945.

Detailed study of Schedule G, H and H1, M, N, P,T,U, V, X, Y, Part XII B, Sch F

A) 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

#### **10 Hours**

# **10 Hours**

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, 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 Stocking of Animals, Performance of Experiments, Records, 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 of Health survey and development committee, Brief note on 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 a brief review
- Introduction to Intellectual Property Rights (IPR) a brief review

# **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)