TECHNO INDIA UNIVERSITY

WEST BENGAL

**B.PHARM SYLLABUS**

**SEMESTER-V**

**Medicinal Chemistry II- Theory (TIU-UBP-501T)**

**Credit points-4**

## Course Outcomes

Upon completion of the course, the student shall be able

| | | |
|---|---|---|
| **CO1** | **Classify** different drugs according to their chemical and pharmacological outcome including H1 and H2 antagonists, proton pump inhibitors and anti-neoplastic agents | K2 |
| **CO2** | **Identify** structure and pharmacology of anti-anginal drugs, diuretics and anti-hypertensive agents | K3 |
| **CO3** | **Summarize** structure and pharmacology of anti-arrythmic drugs, anti-hyperlipidemic drugs, anti-coagulants and drugs used in congestive heart failure | K2 |
| **CO4** | **Compare** chemical and pharmacological advances of drugs acting on endocrine system | K4 |
| **CO5** | **Illustrate** structure and pharmacological response of antidiabetic drugs and others | K2 |

## 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 (*)

**UNIT- I**

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

**H1–antagonists:** Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamine scuccinate, Clemastine fumarate, Diphenylphyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizinehydrochloride, 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, Vincristin sulphate

**Miscellaneous:** Cisplatin, Mitotane.

**UNIT – II**

**Anti-anginal**:

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

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

**Diuretics:**

Carbonic anhydrase inhibitors: Acetazolamide*, Methazolamide, Dichlorphenamide.

Thiazides: Chlorthiazide*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide,

Loop diuretics: Furosemide*, Bumetanide, Ethacrynic acid.

Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride.

Osmotic Diuretics: Mannitol

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

**UNIT- III**

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

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

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

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

**UNIT- IV**

**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**

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

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

**Industrial Pharmacy I- Theory (TIU-UBP-502T)**
**Credit points-4**

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

| | | |
|---|---|---|
| **CO1** | **Explain** the role of physico-chemical factors in preformulation of pharmaceutical dosage form. | K2 |
| **CO2** | **Illustrate** the formulation development of tablets and liquid oral preparations. | K2 |
| **CO3** | **Describe** the formulation development of capsule dosage forms and pellets | K2 |
| **CO4** | **Explicate** the concepts of dosage form design & formulation strategies of pharmaceutical parenteral products, ophthalmic preparations | K3 |
| **CO5** | **Elucidate** about the legal and official requirements of pharmaceutical packaging & formulation strategies of pharmaceutical aerosols and cosmetics | K2 |

**Course Content**

**UNIT-I**
**Preformulation Studies:** Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances.
**a. Physical properties:** Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism
**b. Chemical Properties:** Hydrolysis, oxidation, reduction, racemisation, polymerization
BCS classification of drugs & its significance

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**
**Tablets:**

a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling.
b. Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating.
c. Quality control tests: In process and finished product tests
**Liquid orals:** Formulation and manufacturing consideration of syrups and elixirs suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia

**UNIT-III**
**Capsules:**
a. **Hard gelatin capsules:** Introduction, Production of hard gelatin capsule shells. Size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules.

b. **Soft gelatin capsules:** Nature of shell and capsule content, size of capsules, importance of base adsorption and minim/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules and their applications.
**Pellets:** Introduction, formulation requirements, palletization process, equipments for manufacture of pellets

**UNIT IV**
**Parenteral Products:**
a. Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity
b. Production procedure, production facilities and controls, aseptic processing
c. Formulation of injections, sterile powders, large volume parenterals and lyophilized products.
d. Containers and closures selection, filling and sealing of ampoules, vials and 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**
**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.

**Industrial Pharmacy I– Practical (TIU-UBP-506P)**

**Credit points-2**

**Course Outcomes:**

After successful completion of this course, students will be able to:

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|---|---|---|
| **CO1** | **Describe** the correct use of various equipments in Pharmaceutics laboratory relevant to tablets, capsules & coating | K2 |
| **CO2** | **Explain** preformulation of drug and formulation, evaluation, labelling of tablets & capsules | K2 |
| **CO3** | **Understand** rationale behind use of formulation ingredients while preparing cream, ophthalmic and parenteral products | K2 |
| **CO4** | **Develop** labels to suit regulatory requirements along with conduct survey and report its finding | K3 |
| **CO5** | **Describe** the evaluation of packaging materials | K2 |

**Course Content**

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)

**Pharmacology II- Theory (TIU-UBP-503T)**
**Credit points-4**

**Course Outcomes**

Upon completion of the course, the student shall be able

| | | |
|---|---|---|
| **CO1** | **Describe** the mechanism of drug action and its relevance in the treatment of different diseases related to cardiovascular system including anti-hypertensive, anti-anginal drugs, etc. | K2 |
| **CO2** | **Illustrate** the mechanism of drug action in the treatment of different diseases related to cardiovascular system and urinary system including anticoagulants, antiplatelets and diuretics | K2 |
| **CO3** | **Summarize** the mechanism of autocoids and related drugs | K2 |
| **CO4** | **Explain** the therapeutic effects, clinical uses, side effects and contraindication of drugs acting on endocrine system | K2 |

| | | |
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| **CO5** | **Summarize** principles and methods related to bioassay. | K2 |

**Course Content**

**UNIT-I**

Pharmacology of drugs acting on cardio vascular system
Introduction to hemodynamic and electrophysiology of heart.
Drugs used in congestive heart failure
Anti-hypertensive drugs.
Anti-anginal drugs.
Anti-arrhythmic drugs.
Anti-hyperlipidemic drugs.

**UNIT-II**

**Pharmacology of drugs acting on cardio vascular system**

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

**Pharmacology of drugs acting on urinary system**

Diuretics
Anti-diuretics.

**UNIT-III**

**Autocoids and related drugs**

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

**UNIT IV**

**Pharmacology of drugs acting on endocrine system**

Basic concepts in endocrine pharmacology.
Anterior Pituitary hormones- analogues and their inhibitors.
Thyroid hormones- analogues and their inhibitors.
Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D.
Insulin, Oral Hypoglycemic agents and glucagon.
ACTH and corticosteroids.

**UNIT V**

**Pharmacology of drugs acting on endocrine system**

Androgens and Anabolic steroids.
Estrogens, progesterone and oral contraceptives.
Drugs acting on the uterus.

**Bioassay**

Principles and applications of bioassay.

Types of bioassay

Bioassay of insulin, oxytocin, vasopressin, ACTH, d-tubocurarine, digitalis, histamine and 5-HT

## Pharmacology II–Practical (TIU-UBP-507P)
## Credit points-2

**Course Outcomes:**

After successful completion of this course, students will be able to:

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| **CO1** | **Demonstrate** *in vitro* pharmacology. | K2 |
| **CO2** | **Identify** the action of drugs on different isolated organs. | K3 |
| **CO3** | **Demonstrate** bioassay by using different isolated organs from the laboratory animals by simulated experiments. | K2 |
| **CO4** | **Distinguish** the drugs by using different animal models. | K4 |
| **CO5** | **Demonstrate** *ex-vivo* studies | K2 |

**Course Content**

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

## Pharmacognosy and Phytochemistry II- Theory (TIU-UBP-504T)
## Credit points-4

**Course Outcomes**

Upon completion of the course, the student shall be able to

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|---|---|---|
| **CO1** | Demonstrate metabolic pathways in order to understand the mechanism of secondary metabolites formation in plants. | K2 |
| **CO2** | **Classify** the composition, chemistry & chemical classes, biosources, therapeutic uses and commercial applications of secondary metabolites | K2 |
| **CO3** | **Illustrate** the isolation, identification and analysis of phytoconstituents | K2 |
| **CO4** | **Illustrate** industrial productions of phytoconstituents | K2 |
| **CO5** | **Demonstrate** the role of spectroscopy and chromatographic techniques in isolation, purification and identification of phytoconstituents. | K2 |

**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, Acetate pathways and Amino acid pathway.

b) Study of utilization of radioactive isotopes in the investigation of Biogenetic 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**

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

**UNIT V**

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.

**Pharmacognosy and Phytochemistry II- Practical (TIU-UBP-508P)**

**Credit points-2**

**Course Outcomes:**

After successful completion of this course, students will be able to:

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| **CO1** | **Demonstrate** chemical tests for unorganized crude drugs and its analysis | K2 |
| **CO2** | **Evaluate** the quality and purity of crude drugs | K4 |
| **CO3** | **Describe** linear measurements for crude drug identification using microscopical techniques | K2 |
| **CO4** | **Develop** quality control methods for standardisation of herbal drug | K3 |
| **CO5** | **Examine** swelling, foaming and moisture characteristics | K4 |

**Course Content**

1. Analysis of crude drugs by chemical tests: **(** i)Tragaccanth (ii) Acacia (iii)Agar (iv) Gelatin (v) starch (vi) Honey (vii) Castor oil
2. Determination of stomatal number and index
3. Determination of vein islet number, vein islet termination and palisade ratio.
4. Determination of Ash value
5. Determination of size of starch grains, calcium oxalate crystals by eye piece micrometer
6. Determination of Fiber length and width
7. Determination of number of starch grains by Lycopodium spore method
8. Determination of Extractive values of crude drugs
9. Determination of moisture content of crude drugs
10. Determination of swelling index and foaming

**Pharmaceutical Jurisprudence –Theory (TIU-UBP-505T)**

**Credit points-4**

**Course Outcomes**

Upon completion of the course, the student shall be able

| | | |
|---|---|---|
| **CO1** | **Recognize** the various Pharmaceutical jurisprudence and global regulations related to Drugs and Cosmetics Act 1940 and its rules 1945 with respect to import and manufacture of drugs | K2 |
| **CO2** | **Recognize** the various Pharmaceutical jurisprudence and global regulations related to Drugs and Cosmetics Act 1940 and its rules 1945 with respect to labeling, packing and sale of drugs | K2 |
| **CO3** | **Demonstrate** regarding different regulations of various acts applied in pharma industry like Pharmacy Act 1948, etc | K2 |
| **CO4** | **Illustrate** regulations of various acts applied in pharma industry like Drugs and Magic Remedies Act and understand the regulations of NPPA | K2 |
| **CO5** | **Describe** pharmaceutical ethics and laws related to pharmaceutical industry and | K2 |

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|---|---|---|
| | recognize IPR and RTA guidelines | |

**Course Content**

**Unit – 1:-**

**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 -2:-**

**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 penaltiesLabelling& 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- 3:-**

**Pharmacy Act –1948:** Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, Describe and Joint Describe 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- 4:-**

**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, Describeance 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 -5:-**

**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