TECHNO INDIA UNIVERSITY
WESTBENGAL

B.PHARM SYLLABUS

SEMESTER-VI

Medicinal Chemistry III- Theory (TIU-UBP-601T)

Credit points-4

Course Outcomes

Upon completion of the course, the student shall be able

CO1	**Classify** and understand the structure activity relationship of different classes of antibiotics including lactams, aminoglycosides, tetracyclines	K2
CO2	**Identify** the structure activity relationship of different classes of antibiotics including macrolides, prodrugs, antimalarials, quinolines, biguanides, etc.	K3
CO3	**Summarize** the classification, chemistry, structure activity relationship of anti-tubercular agents, anti-viral agents and urinary tract anti-infective agents	K2
CO4	**Illustrate** the classification, chemistry, structure activity relationship of anti-fungal agents, anti-protozoal agents, anthelmintics	K2
CO5	**Summarize** the techniques to implement different computational techniques to calculate and visualise molecules and their activity properties quantitatively using a computer aided tool for effective drug design and understand the concept of combinatorial chemistry	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 by (*)

UNIT – I

Antibiotics

Historical background, Nomenclature, Stereochemistry, Structure activityrelationship, Chemical degradation classification and important products ofthe following classes.

β-Lactam antibiotics: Penicillin, Cepholosporins, β- Lactamase inhibitors,Monobactams

Aminoglycosides: Streptomycin, Neomycin, Kanamycin

Tetracyclines: Tetracycline,Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

UNIT – II

Antibiotics

Historical background, Nomenclature, Stereochemistry, Structure activityrelationship, Chemical degradation classification and important products ofthe following classes.

Macrolide: Erythromycin Clarithromycin, Azithromycin.

Miscellaneous: Chloramphenicol*, Clindamycin.

Prodrugs: Basic concepts and application of prodrugs design.

Antimalarials: Etiology of malaria. Quinolines: SAR, Quinine sulphate, Chloroquine*, Amodiaquine, Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine.

Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil.

Miscellaneous: Pyrimethamine, Artesunete, Artemether, Atovoquone.

UNIT – III

Anti-tubercular Agents

Synthetic anti tubercular agents: Isoniozid*, Ethionamide, Ethambutol,Pyrazinamide, Para amino salicylic acid. *

Anti-tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine,Streptomycine, Capreomycin sulphate.

Urinary tract anti-infective agents

Quinolones: SAR of quinolones, Nalidixic Acid,Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin,Moxifloxacin

Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine.

Antiviral agents:

Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridinetrifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine,Lamivudine, Loviride, Delavirding, Ribavirin, Saquinavir, Indinavir,Ritonavir.

UNIT – IV

- Antifungal agents:
- Antifungal antibiotics: Amphotericin-B, Nystatin, Natamycin, Griseofulvin.

  Synthetic Antifungal agents: Clotrimazole, Econazole, Butoconazole,Oxiconazole, Tioconozole, Miconazole*, Ketoconazole, Terconazole,Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*.
- Anti-protozoal Agents: Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine.
- Anthelmintics: Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*,Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin.
- Sulphonamides and Sulfones

- Historical development, chemistry, classification and SAR of Sulfonamides:Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*,Sulphapyridine, Sulfamethoxaole*, Sulphadiazine, Mefenide acetate, Sulfasalazine.

  Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.
- Sulfones: DaPEOne*

UNIT – V

- Introduction to Drug Design
- Various approaches used in drug design.
- Physicochemical parameters used in quantitative structure activityrelationship (QSAR) such as partition coefficient, Hammet'selectronicparameter, Tafts steric parameter and Hansch analysis.
- Pharmacophore modeling and docking techniques.
- Combinatorial Chemistry: Concept and applicationschemistry: solid phase and solution phase synthesis

Medicinal Chemistry III- Practical (TIU-UBP-607P)
Credit points-2

Course Outcomes:

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

CO1	**Demonstrate** synthesis methods of a drug	K2
CO2	**Evaluate** the quality and purity of synthetic drugs	K4
CO3	**Describe** linear measurements for drugs using computational tools	K2
CO4	**Demonstrate** the use of softwares for structure generation	K2
CO5	**Examine** physicochemical properties of drugs	K4

Course Content

I Preparation of drugs and intermediates

1. Sulphanilamide
2. 7-Hydroxy, 4-methyl coumarin
3. Chlorobutanol
4. Triphenyl imidazole
5. Tolbutamide
6. Hexamine

II Assay of drugs

7. Isonicotinic acid hydrazide
8. Chloroquine
9. Metronidazole
10. DaPEOne
11. Chlorpheniramine maleate
12. Benzyl penicillin
13. Preparation of medicinally important compounds or intermediates by Microwave irradiation technique
14. Drawing structures and reactions using chem draw®
15. Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinskies RO5)

Pharmacology III –Theory (TIU-UBP-602T)
Credit points-4

Course Outcomes

Upon completion of the course, the student shall be able

CO1	**Classify** the drugs acting on respiratory and gastrointestinal system	K2
CO2	**Describe** the mechanism of action and pharmacological actions of the drugs used in chemotherapy including antibiotics, sulphonamides, etc	K2
CO3	**Analyze** the mechanism of action and pharmacological actions of the drugs used in chemotherapy including antitubercular agents, antileprotic agents, antimalarial drugs, etc.	K4
CO4	**Illustrate** the concept of immunopharmacology	K2
CO5	**Apply** the concept of toxicology and chronopharmacology to prevent adverse effects and toxic reactions.	K3

Course Content

UNIT-I

1. Pharmacology of drugs acting on Respiratory system

a. Anti -asthmatic drugs
b. Drugs used in the management of COPD
c. Expectorants and antitussives
d. Nasal decongestants
e. Respiratory stimulants

2. Pharmacology of drugs acting on the Gastrointestinal Tract

a. Antiulcer agents.

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

UNIT-II
1.Chemotherapy
a. General principles of chemotherapy.
b. Sulfonamides and cotrimoxazole.
c. Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolins, tetracycline and aminoglycosides

UNIT-III
1.Chemotherapy
a. Antitubercular agents
b. Antileprotic agents
c. Antifungal agents
d. Antiviral drugs
e.Anthelmintics
f. Antimalarial drugs
g. Antiamoebic agents

UNIT-IV
1.Chemotherapy
l. Urinary tract infections and sexually transmitted diseases.
m. Chemotherapy of malignancy.
2.Immunopharmacology
a. Immunostimulants
b. Immunosuppressant
Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

UNIT-V
1.Principles of toxicology
a. Definition and basic knowledge of acute, subacute and chronic toxicity.
b. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity
c. General principles of treatment of poisoning
d. Clinical symptoms and management of barbiturates, morphine, organophosphosphorus compound and lead, mercury and arsenic poisoning.
2.Chronopharmacology
a. Definition of rhythm and cycles.
b. Biological clock and their significance leading to chronotherapy.

Pharmacology III- Practical (TIU-UBP-608P)
Credit points-2

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

CO1	**Demonstrate**the effect of drugs from different therapeutic classes using pharmacological software.	K2
CO2	**Explain** the results using suitable statistical analysis software.	K2
CO3	**Estimate** the dose calculation and pharmacokinetic calculations from experimental data.	K3
CO4	**Demonstrate** the correlation of pharmacodynamics and pharmacokinetics concept of theory with experimental data.	K2
CO5	**Examine** Biostatistics methods in experimental pharmacology	K4

Course Content

1. Dose calculation in pharmacological experiments
2. Antiallergic activity by mast cell stabilization assay
3. Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.
4. Study of effect of drugs on gastrointestinal motility
5. Effect of agonist and antagonists on guinea pig ileum
6. Estimation of serum biochemical parameters by using semi- autoanalyser
7. Effect of saline purgative on frog intestine
8. Insulin hypoglycemic effect in rabbit
9. Test for pyrogens (rabbit method)
10. Determination of acute oral toxicity (LD50) of a drug from a given data
11. Determination of acute skin irritation / corrosion of a test substance
12. Determination of acute eye irritation / corrosion of a test substance
13. Calculation of pharmacokinetic parameters from a given data
14. Biostatistics methods in experimental pharmacology(student's t test, ANOVA)
15. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)

Herbal Drug Technology- Theory (TIU-UBP-603T)

Credit points-4

Course Outcomes

Upon completion of the course, the student shall be able

CO1	**Describe** the various aspects of herbal drugs as raw materials and good agricultural practices related to their cultivation and understand Indian systems of medicine	K2
CO2	**Identify** the diverse array of nutraceuticals in the treatment of various diseases and the different drug and food interactions arising with respect to herbal drugs.	K3
CO3	**Discuss** various herbal cosmetics and their raw materials as well as different herbal formulations and excipients used for preparing the same.	K2
CO4	**Identify** the various evaluation parameters for herbal drugs with respect to WHO and ICH guidelines as well as different patenting and regulatory requirements of the same.	K3
CO5	**Apply** the knowledge based on herbals and Good Manufacturing Practice in herbal drug industry	K3

Course Content

UNIT-I

Herbs as raw materials:

Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation

Source of Herbs

Selection, identification and authentication of herbal materials

Processing of herbal raw material

Biodynamic Agriculture:

Good agricultural practices in cultivation of medicinal plants including Organic farming

Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides

Indian Systems of Medicine:

a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy

b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika,Churna, Lehyaand Bhasma.

UNIT-II

Nutraceuticals:

General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases

Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina

Herbal-Drug and Herb-Food Interactions:

General introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra

UNIT-III

Herbal Cosmetics:

Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products

Herbal excipients:

Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes

Herbal formulations:

Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes

UNIT IV

Evaluation of Drugs:

WHO & ICH guidelines for the assessment of herbal drugs Stability testing of herbal drugs

Patenting and Regulatory requirements of natural products:

a) Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy
b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem
Regulatory Issues:
Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.

UNIT V
General Introduction to Herbal Industry:
Herbal drugs industry: Present scope and future prospects
A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India
S**chedule T – Good Manufacturing Practice of Indian systems of medicine:**
Components of GMP (Schedule – T) and its objectives
Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records

Herbal Drug Technology- Practical (TIU-UBP-609P)

Credit points-2

Course Outcomes:

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

CO1	Describe the various methods of preliminary phytochemical screening of crude drugs as a means of their identification.	K2
CO2	Demonstrate the various procedures for finding out the content of different phytochemicals present in medicinal herbs.	K2
CO3	Describe the various methods of evaluating excipients of natural origin.	K2
CO4	Demonstrate the incorporation of standardized extracts in various liquid and solid formulations of herbal origin as well as herbal cosmetics and Describe their evaluation.	K2
CO5	Execute the monograph analysis of herbal drugs from pharmacopoeias.	K4

Course Content

1. To Describe preliminary phytochemical screening of crude drugs.
2. Determination of the alcohol content of Asava and Arista
3. Evaluation of excipients of natural origin
4. Incorporation of prepared and standardized extract in cosmetic formulations like creams, lotions and shampoos and their evaluation.

5. Incorporation of prepared and standardized extract in formulations like syrups, mixtures and tablets and their evaluation as per Pharmacopoeial requirements.
6. Monograph analysis of herbal drugs from recent Pharmacopoeias
7. Determination of Aldehyde content
8. Determination of Phenol content
9. Determination of total alkaloids

Biopharmaceutics and pharmacokinetics - Theory (TIU-UBP-604T)

Credit points-4

Course Outcomes:

Upon Completion of the Course, the student shall be able to

CO1	**Identify** various factors affecting drug absorption and protein-drug binding.	K3
CO2	**Explain** the concept of bioavailability and bioequivalence and factors affecting elimination	K2
CO3	**Analyze** the concept of Pharmacokinetics and its applications.	K4
CO4	**Summarize** compartmental models, their significance and application.	K2
CO5	**Apply** concept of non-linear Pharmacokinetics and biopharmaceutics in in-vivo drug analysis	K3

Course Content:

UNIT-I

Absorption; Mechanisms of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from Non per oral extra-vascular routes.

Distribution: Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs.

UNIT-II

Elimination: Drug metabolism and basic understanding metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs

Bioavailability and Bioequivalence: Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, *in-vitro* drug dissolution models, *in-vitro-in-vivo* correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.

UNIT-III

Pharmacokinetics: Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b) Intravenous infusion and (c) Extra vascular administrations. Pharmacokinetics parameters - KE, t1/2, Vd, AUC, Ka, Clt and CLR- definitions methods of eliminations, understanding of their significance and application.

UNIT-IV

Multi-compartment models: Two compartment open model. IV bolus Kinetics of multiple dosing, steady Describe drug levels, calculation of loading and mainetnance doses and their significance in clinical settings.

UNIT-IV

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

Pharmaceutical Biotechnology- Theory (TIU-UBP-605T)
Credit points-4

Course Outcomes

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

CO1	**Summarize** the use of immobilized enzymes, Biosensors and microbes in pharmaceutical industry.	K2
CO2	**Demonstrate** the application of genetic engineering	K2
CO3	**Illustrate** the concept of Immunity and **classify** various hypersensitivity reactions	K2
CO4	**Analyze** Immuno-blotting techniques and **Demonstrate** different types of mutations	K4
CO5	**Apply** biotechnology methods in biotech industry and **Identify** the production of bio-products through the fermentation method	K3

Course Content:

UNIT I

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

UNIT II

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

UNIT III

Types of immunity- humoral immunity, cellular immunity

a) Structure of Immunoglobulins
b) Structure and Function of MHC
c) Hypersensitivity reactions, Immune stimulation and Immune suppressions.
d) General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity.
e) Storage conditions and stability of official vaccines
f) Hybridoma technology- Production, Purification and Applications
g) Blood products and Plasma Substituties.

UNIT IV

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

UNIT V

a) Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring.
b) Large scale production fermenter design and its various controls.
c) Study of the production of - penicillins, citric acid, Vitamin B 12, Glutamic acid, Griseofulvin,
d) Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substituties.

Pharmaceutical Quality Assurance –Theory (TIU-UBP 606T)

Credit points-4

Course Outcomes:

Upon completion of the course, the student shall be able

CO1	**Demonstrate** the concept of Quality Assurance and management.	K2

CO2	**Identify** the responsibilities of personnel and memorize the design and construction of plant layout	K3
CO3	**Analyze** the quality control tests and **Explain** the provisions of Good Laboratory practices	K4
CO4	**Summarize** the documents that are to be maintained in a Pharmaceutical Industry	K2
CO5	**Apply** the principles of calibration and validation in pharmaceutical practice	K3

Course content:

UNIT-I

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP

Total Quality Management (TQM): Definition, elements, philosophies.

ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines

Quality by design (QbD): Definition, overview, elements of QbD program, tools. **ISO 9000 & ISO14000**: Overview, Benefits, Elements, steps for registration.

NABL accreditation: Principles and procedures.

UNIT-II

Organization and personnel: Personnel responsibilities, training, hygiene and personal records.

Premises: Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

Equipments and raw materials: Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

UNIT-III

Quality Control: Quality control test for containers, rubber closures and secondary packing materials.

Good Laboratory Practices: General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities.

UNIT-IV

Complaints: Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.

Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

UNIT – V

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

Warehousing: Good warehousing practice, materials management