4-Year Bachelor of Pharmacy (B.Pharm) Curriculum and Syllabus

Course Structure

Sixth Semester

Course Code	Name of the course	No.of hours	Tutorial	Credit points
TIU-UBP-601T	Medicinal Chemistry III–Theory	3	1	4
TIU-UBP-602T	Pharmacology III– Theory	3	1	4
TIU-UBP-603T	Herbal Drug Technology- Theory	3	1	4
TIU-UBP-604T	Biopharmaceutics and Pharmacokinetics- Theory	3	1	4
TIU-UBP-605T	Pharmaceutical Biotechnology- Theory	3	1	4
TIU-UBP-606T	Quality Assurance–Theory	3	1	4
TIU-UBP-607P	Medicinal Chemistry III– Practical	4	-	2
TIU-UBP-608P	Pharmacology III– Practical	4	-	2
TIU-UBP-609P	Herbal Drug Technology- Practical	4	-	2
	Total	**30**	**6**	**30**

B.PHARM SYLLABUS

SEMESTER-VI

SEMESTER-VI

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

Contact hour -45hrs

Course Objectives

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

1. Understand the importance of drug design and different techniques of drug design.
2. Understand the chemistry of drugs with respect to their biological activity.
3. Know the metabolism, adverse effects and therapeutic value of drugs.
4. Know the importance of SAR of drugs.

Course Outcomes

Upon completion of the course, the student shall be able

CO1.**Classify**different drug according to their activity on various parasites

CO2.**Identify**the factors affecting the activity of different drugs

CO3.**Summarize** the chemistry behind activity and synthetic scheme of different drugs

CO4.**Summerize** the techniques to implement different computational techniques to calculate and visualise molecules and their activity properties quantitatively using a computer aided tool

Course Content 45 Hours

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 **10 Hours**

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 **10 Hours**

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 **10 Hours**

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 **08 Hours**

Antifungal agents:
Antifungal antibiotics: Amphotericin-B, Nystatin, Natamycin, Griseofulvin.
Synthetic Antifungal agents: Clotrimazole, Econazole, Butoconazole,OxiconazoleTioconozole, 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 **07 Hours**

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

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.

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Mapping between COs and POs		
	Course Outcomes (COs)	**Mapped Program Outcomes**
CO1	**Classify** different drug according to their activity on various parasites	PO1, PO2, PO5, PEO1, PEO2, PEO3
CO2	**Identify** the factors affecting the activity of different drugs	PO1, PO2, PO5, PEO1, PEO2, PEO3
CO3	**Summarize**the chemistry behind activity and synthetic scheme of different drugs	PO1, PO2, PO5, PO11, PEO1, PEO2, PEO3
CO4	**Summerize** the techniques to implement different computational techniques to calculate and visualise molecules and their activity properties quantitatively using a computer aided tool	PO1, PO2, PO11, PEO1, PEO2, PEO3

		Pharmaceutical Knowledge	Problem solving	Conduct, analyze and interpret data	Ability to design and formulating a process	Ability to understand mechanism	Demonstrate skills in problem solving	Professional and ethical responsibilities	Communication to present a technical report	Impact on society and responsibilities	Leadership qualities	Self educating and Life-long Learning	Preparation for competitive examinations	Building a theoretical knowledge base along with necessary practical skills	To build a strong foundation as per the requirements of pharmaceutical Industries, Community and Hospital Pharmacy	Training students to achieve expertise
Course Code	**Course Title**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PEO1**	**PEO2**	**PEO3**
TIU-UBP-601T	Medicinal Chemistry III - Theory	3	3	-	-	3	-	-	-	-	-	3	-	3	3	3

1=weakly mapped
2= moderately mapped
3=strongly mapped

Medicinal Chemistry III- Practical (TIU-UBP-607P)

Contact hours: 4 hrs/week

Course Objectives

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

1. Implement theoretical knowledge on synthesis of drugs in laboratory
2. Analysis different drugs for its purity
3. Compute different molecular properties with respect to its biological activity.

Course Outcomes:

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

CO1. **Demonstrate** synthesis methods of a drug

CO2. **Evaluate** the quality and purity of synthetic drugs

CO3.**Describe** linear measurements for drugs using computational tools

Course Content 4 Hours/Week

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)

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.

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Mapping between COs and POs		
	Course Outcomes (COs)	**Mapped Program Outcomes**
CO1	**Demonstrate** synthesis methods of a drug	PO1, PO3, PO5, PO2, PO6, PEO1

CO2	**Evaluate** the quality and purity of synthetic drugs	PO1, PO5, PO7,PO12, PO4, PO6, PEO3
CO3	**Describe** linear measurements for drugs using computational tools	PO1, PO8, PO11,PO10, PO9, PO5, PEO2

		Pharmaceutical Knowledge	Problem solving	Conduct, analyze and interpret data	Ability to design and formulating a process	Ability to understand mechanism	Demonstrate skills in problem solving	Professional and ethical responsibilities	Communication to present a technical report	Impact on society and responsibilities	Leadership qualities	Self educating and Life-long Learning	Preparation for competitive examinations	Building a theoretical knowledge base along with necessary practical skills	To build a strong foundation as per the requirements of pharmaceutical Industries, Community and Hospital Pharmacy	Training students to achieve expertise
Course Code	**Course Title**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PEO1**	**PEO2**	**PEO3**
TIU-UBP-607P	MEDICINAL CHEMISTRY III- Practical	3	2	3	3	3	3	2	2	2	2	3	3	3	3	3

1=weakly mapped
2= moderately mapped
3=strongly mapped

Pharmacology III –Theory (TIU-UBP-602T)
Contact hours: 45 hrs

Course Objectives
1. To know the fundamentals of pharmacology on various aspects of drug action on physiological system of human beings.
2. To understand the mechanism of drug action and its relevance in the treatment of different infectious diseases.
3. To comprehend the principles of toxicology and treatment of various poisonings.
4. To correlate the concept of pharmacology with related medical sciences

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

CO1.Classify the drugs acting on respiratory and gastrointestinal system, infectious diseases, and immuno-pharmacology.

CO2. **Describe** the mechanism of action and pharmacological actions of the drugs working on these systems.
CO3. **Analyze** the side effects and contraindications of these drugs.
CO4. **Apply** the pharmacological knowledge in the prevention and treatment of different infectious diseases.
CO5. **Demonstrate** the concept of toxicology and chronopharmacology.

Course Content — 45 Hours

UNIT-I — **10hours**

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 — **10hours**

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

UNIT-III — **10hours**

3. Chemotherapy
a. Antitubercular agents
b. Antileprotic agents
c. Antifungal agents
d. Antiviral drugs
e.Anthelmintics
f. Antimalarial drugs
g. Antiamoebic agents

UNIT-IV — **08hours**

3. Chemotherapy
l. Urinary tract infections and sexually transmitted diseases.
m. Chemotherapy of malignancy.

4. Immunopharmacology
a. Immunostimulants
b. Immunosuppressant
Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

UNIT-V — **07hours**

5. 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.
6. Chronopharmacology
a. Definition of rhythm and cycles.
b. Biological clock and their significance leading to chronotherapy.

Reference 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
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams &Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology
6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert,
8. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
9. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,
10. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Mapping between COs and POs		
	Course Outcomes (COs)	**Mapped Program Outcomes**
CO1	Classify the drugs acting on respiratory and gastrointestinal system, infectious diseases, immuno-pharmacology.	PO1, PO12
CO2	Describe the mechanism of action and pharmacological actions of the drugs working on these systems.	PO1, PO2, PO3,PO5, PEO1
CO3	Analyze the side effects and contraindications of these drugs.	PO1,PO3, PO5,PO7, PO9, PO11, PO12,PEO2, PEO3
CO4	Apply the pharmacological knowledge in the prevention and treatment of different infectious diseases	PO1,PO2, PO6, PO7, PO9, PO11, PEO1, PEO2
CO5	Demonstrate the concept of toxicology and chronopharmacology.	PO1,PO11, PO12,PEO1

		Pharmaceutical Knowledge	Problem solving	Conduct, analyze and interpret data	Ability to design and formulating a process	Ability to understand mechanism	Demonstrate skills in problem solving	Professional and ethical responsibilities	Communication to present a technical report	Impact on society and responsibilities	Leadership qualities	Self educating and Life-long Learning	Preparation for competitive examinations	Building a theoretical knowledge base along with necessary practical skills	To build a strong foundation as per the requirements of pharmaceutical Industries, Community and Hospital Pharmacy	Training students to achieve expertise
Course Code	**Course Title**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PEO1**	**PEO2**	**PEO3**
TIU-UBP-602T	Pharmacology III -Theory	3	2	3	-	3	2	2	-	2	-	3	3	2	3	2

1=weakly mapped
2= moderately mapped
3=strongly mapped

Pharmacology III- Practical (TIU-UBP-608P)
Contact hours: 4 hr/week

Course Objectives

1. To know the fundamentals of animal models and techniques involved in experimental pharmacology.
2. To learn the skills of dose calculations and animal handling techniques.
3. To understand the concept of pharmacodynamics and pharmacokinetics and biostatistical methods.

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.
CO2. **Explain** the results using suitable statistical analysis software.
CO3. **Estimate** the dose calculation and pharmacokinetic calculations from experimental data.
CO4. **Demonstrate** the correlation of pharmacodynamics and pharmacokinetics concept of theory with experimental data.

Course Content 4 Hours/Week

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)

Reference Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier
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Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Mapping between COs and POs		
	Course Outcomes (COs)	**Mapped Program Outcomes**
CO1	**Demonstrate**the effect of drugs from different therapeutic classes using pharmacological software.	PO1,PO3,PO6,PEO1
CO2	**Explain** the results using suitable statistical analysis software.	PO1, PO2, PO3, PO6, PEO1, PEO3
CO3	**Estimate** the dose calculation and pharmacokinetic calculations from experimental data.	PO1,PO2,PO3, PO4,PO6,PO12, PEO1
CO4	**Demonstrate** the correlation of pharmacodynamics and pharmacokinetics concept of theory with experimental data.	PO1, PO5, PO8, PO12, PEO1,PEO2, PEO3

		Pharmaceutical Knowledge	Problem solving	Conduct, analyze and interpret data	Ability to design and formulating a process	Ability to understand mechanism	Demonstrate skills in problem solving	Professional and ethical responsibilities	Communication to present a technical report	Impact on society and responsibilities	Leadership qualities	Self educating and Life-long Learning	Preparation for competitive examinations	Building a theoretical knowledge base along with necessary practical skills	To build a strong foundation as per the requirements of pharmaceutical Industries, Community and Hospital Pharmacy	Training students to achieve expertise
Course Code	**Course Title**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PEO1**	**PEO2**	**PEO3**
TIU-UBP-608P	Pharmacology III -Practical	3	2	2	2	2	3	-	2	-	-	-	2	3	2	2

1=weakly mapped
2= moderately mapped
3=strongly mapped

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

Contact hour: 45 hrs

Course Objectives

1. To administer the knowledge regarding the basic understanding of herbal drug industry.
2. To understand raw materials as the source of herbal drugs starting from cultivation to final drug product.
3. To knowWHO and ICH guidelines with respect to evaluation of herbal drugs.
4. To gain knowledge related to nutraceuticals, herbal excipients and cosmetics.
5. To have a detailed understanding of patenting and Good Manufacturing Practices of natural products.

Course Outcomes

Upon completion of the course, the student shall be able

CO1.**ReDescribe**the various aspects of herbal drugs as raw materials and good agricultural practices related to their cultivation.

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.

C03. **Discuss** various herbal cosmetics and their raw materials as well as different herbal formulations and excipients used for preparing the same.

CO4.**Classify** 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.

CO5.**Describe** the opportunities and future perspective ofherbal drug industry alongwith Good

Manufacturing Practices with respect to the same.

Course Content **45 Hours**

UNIT-I **11 Hours**

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 **7 Hours**

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 **10 Hours**

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 **10 Hours**

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 **7 Hours**

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
Schedule 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

Reference Books (Latest Editions)
1. Textbook of Pharmacognosy by Trease& Evans.
2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
3. Pharmacognosy by Kokate, Purohit and Gokhale
4. Essential of Pharmacognosy by Dr. S .H.Ansari
5. Pharmacognosy & Phytochemistry by V.D.Rangari
6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
7. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Mapping between COs and POs		
	Course Outcomes (COs)	**Mapped Program Outcomes**
CO1	ReDescribethe various aspects of herbal drugs as raw materials and good agricultural practices related to their cultivation.	PO1, PO8, PO9, PO11, PO12, PEO1, PEO2
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.	PO1, PO5, PO7, PO8, PO9, PO11, PO12, PEO1, PEO2
CO3	Discuss various herbal cosmetics and their raw materials as well as different herbal formulations and excipients used for preparing the same.	PO1, PO2, PO3,PO8, PO9, PO11, PO12, PEO1, PEO2, PEO3
CO4	Classify 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.	PO1, PO2, PO3, PO6, PO7, PO8, PO9, PO11, PO12, PEO1, PEO2

CO5	Describe the opportunities and future perspective of herbal drug industry alongwith Good Manufacturing Practices with respect to the same.	PO1,PO2, PO7, PO8, PO9, PO11, PO12, PEO1, PEO2

		Pharmaceutical Knowledge	Problem solving	Conduct, analyze and interpret data	Ability to design and formulating a process	Ability to understand mechanism	Demonstrate skills in problem solving	Professional and ethical responsibilities	Communication to present a technical report	Impact on society and responsibilities	Leadership qualities	Self educating and Life-long Learning	Preparation for competitive examinations	Building a theoretical knowledge base along with necessary practical skills	To build a strong foundation as per the requirements of pharmaceutical Industries, Community and Hospital Pharmacy	Training students to achieve expertise
Course Code	**Course Title**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PEO1**	**PEO2**	**PEO3**
TIU-UBP-603T	Herbal Drug Technology-Theory	3	2	2	-	2	2	2	3	3	-	3	3	3	3	2

1=weakly mapped
2= moderately mapped
3=strongly mapped

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

Contact Hours: 4 hrs/wk

Course Objectives

1. To understand the different methods of phytochemical screening of herbal drugs.
2. To recognize and administer the different techniques for determination of various phytochemicals in herbal drugs.
3. To know the various methods for preparation of herbal formulations.

Course Outcomes:

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

CO1. **Implement** the various methods of preliminary phytochemical screening of crude drugs as a means of their identification.

CO2.**Demonstrate** the various procedures for finding out the content of different phytochemicals present inmedicinal herbs.

CO3. **Implement** the various methods of evaluating excipients of natural origin.

C04.**Demonstrate** the incorporation of standardized extracts in various liquid and solid formulations of herbal origin as well as herbal cosmetics and Describe their evaluation.

CO5. **Execute** the monograph analysis of herbal drugs from pharmacopoeias.

Course Content **4 Hours/Week**

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

Reference Books (Latest Editions)

1. Textbook of Pharmacognosy by Trease& Evans.

2. Textbook of Pharmacognosy by Tyler, Brady & Robber.

3. Pharmacognosy by Kokate, Purohit and Gokhale

4. Essential of Pharmacognosy by Dr. S .H.Ansari

5. Pharmacognosy & Phytochemistry by V.D.Rangari

6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)

7. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Mapping between COs and POs		
	Course Outcomes (COs)	**Mapped Program Outcomes**
CO1	Implement the various methods of preliminary phytochemical screening of crude drugs as a means of their identification.	PO1,PO8,PO11, PO12, PEO1, PEO2
CO2	Demonstrate the various procedures for finding out the content of different phytochemicals present in medicinal herbs.	PO1,PO3, PO6,PO8,PO11, PO12, PEO1, PEO2
CO3	Implement the various methods of evaluating excipients of natural origin.	PO1,PO3, PO6, PO7,PO8, PO9,PO11, PO12, PEO1,

		PEO2, PEO3
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.	PO1,PO3,PO6, PO7,PO8, PO9,PO11, PO12, PEO1, PEO2, PEO3
CO5	Execute the monograph analysis of herbal drugs from pharmacopoeias.	PO1,PO3,PO8,PO9,PO11, PO12, PEO1, PEO2

		Pharmaceutical Knowledge	Problem solving	Conduct, analyze and interpret data	Ability to design and formulating a process	Ability to understand mechanism	Demonstrate skills in problem solving	Professional and ethical responsibilities	Communication to present a technical report	Impact on society and responsibilities	Leadership qualities	Self educating and Life-long Learning	Preparation for competitive examinations	Building a theoretical knowledge base along with necessary practical skills	To build a strong foundation as per the requirements of pharmaceutical Industries, Community and Hospital Pharmacy	Training students to achieve expertise
Course Code	**Course Title**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PEO1**	**PEO2**	**PEO3**
TIU-UBP-609P	Herbal drug technology -Practical	3	-	3	-	-	2	2	3	2	-	3	3	3	3	2

1=weakly mapped
2= moderately mapped
3=strongly mapped

BIOPHARMACEUTICS AND PHARMACOKINETICS - Theory (TIU-UBP-604T)

Contact hours: **45 hours**

Coruse Objectives:

1. To understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
2. To administer the plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
3. To understand the concepts of bioavailability and bioequivalence of drug

products and their significance.

4. To understand various pharmacokinetic parameters, their significance &applications.

Course Outcomes:

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

CO1. **Identify** various factors affecting drug absorption and protein-drug binding.

CO2. **Explain** the concept of bioavailability and bioequivalence.

CO3. **Demonstrate** the concept of Pharmacokinetics and its applications.

CO4. **Summarize** compartmental models, their significance and application.

CO5. **Elucidate** non-linear Pharmacokinetics.

Course Content: 45 Hours

UNIT-I 10 Hours

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 10 Hours

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 10 Hours

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 08 Hours

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 **07 Hours**

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

Recommended Books: (Latest Editions)

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition,Prentice-Hall Inernationaledition.USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal,VallabhPrakashan Pitampura, Delhi
5. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick
8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and
9. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
10. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company,Pennsylvania 1989.
11. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
12. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsy

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Mapping between COs and POs		
	Course Outcomes (COs)	Mapped Program Outcomes
CO1	**Identify** various factors affecting Drug absorption in GIT and various factors affecting protein-drug binding.	PO1, PO4, PO12. PEO2
CO2	**Explain** the concept of bioavailability and bioequivalence.	PO1, PO2, PO6, PEO1, PEO2, PEO3
CO3	**Demonstrate** the concept of Pharmacokinetics and its applications	PO1, PO2,PO3, PO4, PO5, PO6, PO11, PO12, PEO1,PEO2, PEO3
CO4	**Summarize** compartmental models, their significance and application.	PO1, PO4, PO11,PO12,PEO1, PEO3

CO5	**Identify** the factors of Non-linearity.	PO1,PO3, PO5, PO6, PO11, PO12,PEO1,PEO2

		Pharmaceutical Knowledge	Problem solving	Conduct, analyze and interpret data	Ability to design and formulating a process	Ability to understand mechanism	Demonstrate skills in problem solving	Professional and ethical responsibilities	Communication to present a technical report	Impact on society and responsibilities	Leadership qualities	Self educating and Life-long Learning	Preparation for competitive examinations	Building a theoretical knowledge base along with necessary practical skills	To build a strong foundation as per the requirements of pharmaceutical Industries, Community and Hospital Pharmacy	Training students to achieve expertise
Course Code-	**Course Title**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PEO1**	**PEO2**	**PEO3**
TIU-UBP-604T	Biopharmaceutics and Pharmacokinetics-Theory	3	2	2	2	2	2	-	-	2	-	2	3	3	3	2

1=weakly mapped
2= moderately mapped
3=strongly mapped

Pharmaceutical Biotechnology- Theory (TIU-UBP-605T)
Contact Hours: 45 hours

Course Objectives

1. To know the fundamentals about various immobilized enzymes used in the field of Pharmaceuticals.
2. To understand the importance enzymes in Pharmaceutical Industries.
3. To gain knowledge about the applications of genetic engineering and its relation with the Pharmaceutical Technology.
4. To understand the importance of Monoclonal Antibodies in Industries.
5. To know the use of micro-organisms in fermentation technology.

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.
CO2. **Demonstrate** the application of genetic engineering.
CO3. **Demonstrate** the concept of Immunity and various hypersensitivity reactions.
CO4. **Summarize** Immuno-blotting techniques and Demonstrate different types of mutations
CO5. **Identify** the production of different things through the fermentation method.

Course Content: 45 Hours

UNIT I 10 Hours

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 10 Hours

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 10 Hours

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 08 Hours

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 **07 Hours**

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.

Recommended Books (Latest edition):

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.
2. RA Goldshy et. al., :Kuby Immunology.
3. J.W. Goding: Monoclonal Antibodies.
4. ___ J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.
5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Mapping between COs and POs		
	Course Outcomes (COs)	Mapped Program Outcomes
CO1	Summarize the use of immobilized enzymes, Biosensors and microbes in pharmaceutical industry.	PO1, PO4, PO5, PO9, PO11, PO12, PEO1
CO2	Demonstrate the application of genetic engineering.	PO1, PO2, PO5, PO9, PO11,PO12, PEO2
CO3	Demonstrate the concept of Immunity and various hypersensitivity reactions.	PO1, PO3, PO11, PO12,PEO1,PEO2, PEO3
CO4	Summarize Immuno-blotting techniques and Demonstrate different types of mutations	PO1, PO3, PO11,PO12,PEO1

CO5	Identify the production of different things through the fermentation method.	PO1,PO3,PO11, PO12,PEO1,PEO2,PEO3

		Pharmaceutical Knowledge	Problem solving	Conduct, analyze and interpret data	Ability to design and formulating a process	Ability to understand mechanism	Demonstrate skills in problem solving	Professional and ethical responsibilities	Communication to present a technical report	Impact on society and responsibilities	Leadership qualities	Self educating and Life-long Learning	Preparation for competitive examinations	Building a theoretical knowledge base along with necessary practical skills	To build a strong foundation as per the requirements of pharmaceutical Industries, Community and Hospital Pharmacy	Training students to achieve expertise
Course Code	Course Title	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PEO1	PEO2	PEO3
TIU-UBP-605T	Pharmaceutical Biotechnology-Theory	3	1	2	2	3	-	-	-	2	-	3	3	3	3	2

1=weakly mapped
2= moderately mapped
3=strongly mapped

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

Contact Hours- 45 hours

Course Objectives:

1. To understand the cGMP aspects in a pharmaceutical industry.
2. To appreciate the importance of documentation.
3. To understand the scope of quality certifications applicable to pharmaceutical industries.
4. To understand the responsibilities of QA & QC departments.
5. To Understand the responsibilities of QA and QC departments.

Course Outcomes:

Upon completion of the course, the student shall be able

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

CO2. **Identify** the responsibilities of personnel and memorize the design and construction of plant layout
CO3. **Explain**the provisions of Good Laboratory practices
CO4. **List**the Documents that are to be maintained for a Pharmaceutical Industry.
CO5. **Summarize** the general Principles of calibration and validation

Course content:

UNIT-I **10 Hours**

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 **10 Hours**

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 **10 Hours**

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 **08 Hours**

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 **07 Hours**

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 managemen

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Mapping between COs and POs		
	Course Outcomes (COs)	**Mapped Program Outcomes**
CO1	**Demonstrate**the concept of Quality Assurance and management.	PO1, PO12
CO2	**Identify** the responsibilities of personnel and memorize the design and construction of plant layout	PO1, PO3, PO4, PO11, PO8, PEO2
CO3	**Identify** the provisions of Good Laboratory practices	PO1, PO3, PO8, PO11, PO12,PEO1,PEO2, PEO3
CO4	**List** the Documents that are to be maintained for a Pharmaceutical Industry.	PO1,PO11,PO12,PEO1
CO5	**Summarize** the General Principles of calibration and validation	PO1,PO2, PO3,PO11, PO12,PEO1,PEO2,PEO3

		Pharmaceutical Knowledge	Problem solving	Conduct, analyze and interpret data	Ability to design and formulating a process	Ability to understand mechanism	Demonstrate skills in problem solving	Professional and ethical responsibilities	Communication to present a technical report	Impact on society and responsibilities	Leadership qualities	Self educating and Life-long Learning	Preparation for competitive examinations	Building a theoretical knowledge base along with necessary practical skills	To build a strong foundation as per the requirements of pharmaceutical Industries, Community and Hospital Pharmacy	Training students to achieve expertise
Course Code	**Course Title**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PEO1**	**PEO2**	**PEO3**
TIU-UBP-606T	Pharmaceutical Quality Assurance - Theory	3	2	3	2	-	-	-	2	-	-	3	2	3	3	3

1=weakly mapped
2= moderately mapped
3=strongly mapped