# JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR (Established by Govt. of A.P., Act. No. 30 of 2008) ANANTHAPURAMU – 515 002 (A.P.) INDIA.

### Course Structure for B.Pharmacy-R15 Regulations

# **B.Pharmacy**

#### B.Pharm III-I Semester

S.	Course	Subject	L	Т	Ρ	С
No.	Code	-				
1.	15R00501	Medicinal Chemistry-I	3	1	-	3
2.	15R00502	Pharmacology-I	3	1	-	3
3.	15R00503	Pharmaceutical Technology-II	3	1	-	3
4.	15R00504	Pharmaceutical Biotechnology	3	1	-	3
5.	15R00505	MOOCS - I	3	1	-	3
		(Application of spectroscopic methods in				
		molecular structure Determination) /				
		Conventional/ Self study				
6.	15R00506	Medicinal Chemistry-I Laboratory	-	-	4	2
7.	15R00507	Pharmacology-I Laboratory	-	-	4	2
8.	15R00508	Pharmaceutical Technology-II Laboratory		-	4	2
9.	15R00509	Pharmaceutical Biotechnology Laboratory	-	-	4	2
10.	15A99501	Audit course – Social Values & Ethics	2	0	2	
		Total:	17	5	18	23

Note: MOOC-I- NPTEL (http://nptel.ac.in) Chemistry & Biochemistry and Biotechnology

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# B.Pharm III-II Semester

S.	Course	Subject	L	Т	Р	С
No.	Code					
1.	15R00601	Pharmacology-II	3	1	-	3
2.	15R00602	Pharmaceutical Analysis-II	3	1	-	3
3.	15R00603	Biopharmaceutics & Pharmacokinetics	3	1	-	3
4.	15R00604	Pharmaceutical Jurisprudence	3	1	-	3
5.		CBCC-I	3	1	-	3
	15R00605	1. Pharmacy Administration				
	15R00606	2. Clinical Trials				
	15R00607	3. Cosmetic Technology				
6.	15R00608	Pharmacology-II Laboratory	-	-	4	2
7.	15R00609	Pharmaceutical Analysis-II Laboratory	-	-	4	2
8.	15R00610	Biopharmaceutics & Pharmacokinetics		-	4	2
		Laboratory				
9.	15A52602	Advanced English Language	-	-	2	-
		Communication Skills (AELCS)				
		Laboratory (Audit Course)				
10.	15R00611	Comprehensive Online Exam - II	-	-	-	1
		Total:	15	5	16	22

# **B.Pharm IV-I Semester**

S.	Course	Subject	L	Т	Р	С
No.	Code	-				
1.	15R00701	Novel Drug Delivery Systems	3	1	-	3
2.	15R00702	Pharmacology -III	3	1	-	3
3.	15R00703	Clinical and Hospital Pharmacy	3	1	-	3
4.	15R00704	Medicinal Chemistry-II	3	1	-	3
5.		CBCC-II	3	1	-	3
	15R00705	1.Chemistry of Natural Products				
	15R00706	2. Computer Aided Drug Design				
	15R00707	3. Pharmacovigilance.				
6.	15R00708	Novel Drug Delivery Systems Laboratory	-	-	4	2
7.	15R00709	Clinical and Hospital Pharmacy	-	-	4	2
		Laboratory				
8.	15R00710	Medicinal Chemistry-II Laboratory		-	4	2
		Total:	15	5	12	21

# B.Pharm IV-II Semester

S.	Course	Subject	L	Т	Р	С
No.	Code					
1.	15R00801	MOOCS -II	3	1	-	3
		(Biostatistics and Design of Experiments)				
		/ Conventional/ Self study				
2.	15R00802	MOOCS - III	3	1	-	3
		(Intellectual Property Rights) /				
		/Conventional/ Self study				
3.	15R00803	Comprehensive viva voice	-	-	4	2
4.	15R00804	Technical Seminar	-	-	4	2
5.	15R00805	Project Work	-	-	24	13
		Total:	06	02	32	23

Subject	MEDICINAL CHEMISTRY – I	Code	15R00501
Course year	B. Pharm III year	Semester	Ι
Theory	3 hrs/week	Tutorial	1 hr / week
End Exam	70 Marks	Internal	30 Marks
		marks	
Credits	3		

**Scope:** This subject will provide an opportunity for the student to learn medicinal chemistry information about the drugs. In this subject student will be able to understand the properties and its biological activity of the drugs.

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

- 1. Understand various drugs structure, their properties and biological activities.
- 2. Correlate and apply the knowledge.
- 3. Influence of chemical structure on biological activities.

## Outcomes:

- 1. Acquire skill in the structure of drugs and their biological activities.
- 2. Acquire the knowledge of synthesis of chemical compounds.
- 3. Assay of some official compounds.

## UNIT I

**Physico chemical properties of drug molecules in relation to biological activity** – Solubility, partition-coefficient, Ionization, hydrogen bonding, Chelation, redox potential and surface activity, Bioisosterism and steric features of drugs, drug distribution and protein binding. Types of receptor and its relation with biological activity.

Enzyme stimulation, Enzyme inhibition. Theories of drug action (Ferguson's, Dale's, perturbation and occupation). Drug metabolism: Introduction to Biotransformation, concept of soft and hard drug, phase I & II (With one drug example). Introduction, basic concepts and clinical importance of Prodrug.

## UNIT II

## Drugs acting on ANS

Adrenergic and antiadrenergic agents: Adrenergic agonist: Chemistry and metabolism of neurotransmitters, Dopamine, Ephedrine\*, Isoprenaline\*, Oxymetazoline\*, Salbutamol, Adrenergic antagonist: Classification, Phenoxybenzamine\*, Prazosin\*, Propranolol, Atenolol, Metaprolol. SAR Sympathomimetics (Catecholamines)

Cholinergic and anti-cholinergic agents: Cholinergic receptor and neuro chemistry and concept of neuromuscular blocking agents. Succinylcholine\*, pilocarpine,

Physostigmine, Malathion, Pralidoxime, Nicotine, Dicyclomine\*, Biperiden\*. SAR-Cholinergic agonists, Anti-cholinergics, Neuro muscular blockers.

## UNIT III

## Drugs acting on CNS

Depressants and Central dopaminergic signalling agents

Anxiolytics, Sedatives and Hypnotics: Benzodiazepines (Diazepam\*, Oxazepam, ,Midozolam, Alprazolam), Barbiturates (Phenobarbital\*),Glutethimide\*, Meprobamate\*, SAR-Benzodiazepines, Barbiturates.

Anti-Psychotics: Phenothiazines (Chlorpromazine\*, Thioridazine), thioxanthines (Thiothixene\*), Butyrophenones (Haloperidol\*, Droperidol), Miscellaneous-

Lithium salts, Clozapine and Olanzapine. SAR- Phenothiazines, Butyrophenones.

**Anti-convulsants:** Phenytoin\*, Valproic acid, Carbamazepine\*, Ethosuximide. SAR-Hydantoins, Oxazolidinediones, Succinimides.

**Anti-parkinsonism**: Levodopa\*-Carbidopa, Amantidine\*, Selegiline, Apomorphine, Ropinirole, Entacapone, Tolcapone.

## UNIT IV

**Analeptics:**Picrotoxin, Doxapram\*, Methyl xanthines (Caffeine, Theophylline, Theobromine) Psychomotorstimulant: Dextro amphetamine\*, Methamphetamine, Phenfluramine, Sibutramine, Methylphenidate.

**Anti-depressants:** Types, Phenelzine, Tranylcypromine\*, Tricyclic anti-depressants: Imipramine\*, Desipramine, Fluoxetine\*, Newer agents: Venlafaxine, Buspironeand Bupropion. SAR- Tricyclic antidepressants, MAOIs.

Miscellaneous: Psilocybin, Dimethyltryptamine, Mescaline, Lysergic acid and Tetrahydro cannabinol.

# UNIT V

## Anaesthetics:

**General anaesthetics**: Chemical classification, Inhaled and Injectable, Meyer-Overton theory, Halothane\*, Propofol, Ketamine, Thiopental sodium\*.

Local anaesthetics: Cocaine, Lignocaine\*. Adjuvant to localanaesthetics. SAR- Esters and amides.

**NOTE:** Introduction, definition, chemical classification with structure, nomenclature, synthesis (only for \*marked drugs), mechanism of action, SAR including stereo chemical aspects, metabolites (including its ADR)and therapeutic uses of the following classes of drugs from UNIT II to UNIT V.

- 1. William O. Foye, Textbook of Medicinal Chemistry, Lea Febiger, Philadelphia.
- JH Block & JM Beale (Eds), Wilson & Giswold "s Text book of organic Medicinal Chemistryand pharmaceutical chemistry, 11th Ed, Lipcolt, Raven, Philadelphia, 2004

# Reference Books:

- 1. Hansch, Comprehensive medicinal chemistry, Vol 1 6 Elsevier pergmon press, Oxford
- 2. D. Abraham (Ed), Burger Medicinal chemistry ad Drug discovery, Vol. 1 & 2. John Wiley &Sons, New York 2003, 6th Ed.
- 3. M. Atherden, Bentley and Driver''s Textbook of Pharmaceutical Chemistry Ed: I.OxfordUniversity Press, Delhi.

Subject	PHARMACOLOGY - I	Code	15R00502
Course Year	B.Pharmacy III year	Sem	Ι
Theory	3hrs/week	Tutorial	1hr/week
End exam	70 Marks	Internal	30Marks
		exam	
Credits	3		

### Scope:

This subject provides an insight to know the class and mode of action of drugs, their unwanted effects and therapeutic actions.

Objectives: Upon completion of the subject student shall be able to

- 1. Understand various pharmacological aspects like pharmacokinetics, side effects, drug interactions, contraindications and indications of drugs falling under below mentioned chapters.
- 2. Correlate and apply the knowledge.

### Outcomes:

- 1. Acquire the knowledge in basic mechanism of action of drugs.
- 2. Therapeutic uses of drugs of the following chapters.

## UNIT I

### General Pharmacology:

### a. Introduction

Definition, historical development and scope of pharmacology. Sources of drugs and routes of administration. Principles of discovery and development of new drugs, phases of clinical trials.

### b. Pharmacodynamics

Mechanism of action with special emphasis on receptors, drug-receptor interaction theories, factorsmodifying drug action.

## c. Pharmacokinetics

Drug absorption, distribution, metabolism and excretion. Factors affecting/modifying Pharmacokinetic parameters.

## UNIT II

## Pharmacology of Peripheral Nervous System

a. Neurohumoral transmission (autonomic and somatic), cholinergic receptors and adrenergicreceptors.

b. Parasympathomimetics, parasympatholytics ,sympathomimetics and sympatholytics.

- c. Ganglionic stimulants and blocking agents.
- d. Neuromuscular blocking agents and local anesthetic agents.

## UNIT III

# Pharmacology of Central Nervous System: I

a. Neurohumoral transmission in the C.N.S with special emphasis on dopamine, GABA and 5-HTneurotransmission.

- b. General anesthetics, sleep cycle, sedatives, hypnotics and anti-anxiety agents.
- c. CNS stimulants and centrally acting muscle relaxants.
- d. Alcohols and disulfiram. Drug addiction, abuse, tolerance and dependence.

# UNIT IV

## Pharmacology of Central Nervous System: II

a. Pharmacology of drugs used in affective/mood disorders like depression and mania andbehavioral disorders like psychosis.

b. Pharmacology of drugs used in neurodegenerative disorders like Parkinsonism and Alzheimer'sdisease.

c. Pharmacology of drugs used in epilepsy

## UNIT V

a. Analgesics, Antipyretics, and Anti-inflammatory drugs.

b. Narcotic analgesics and antagonists.

## Text Books:

- 1. H.P Rang, M. M. dale & J.M. Ritter, Pharmacology, Churchill living stone, 4th Ed.
- J.G. Hardman and Lee E. Limbard, Good Mann & Gilmann, The Pharmacological basis of the rapeutics, Mc Grawhill, Health Professions Dvn.

## **Reference Books**

- 1. Bertram. G. Katzung, Basic and clinical pharmacology, 9th Edn; Prentice Hall International
- 2. Sathoskar, Pharmacology and pharmaco therapeutics Vol. 1 & 2, Publ by PopularPrakashan, Mumbai.
- 3. Tripathi, Essentials of Medical Pharmacology, Jaypee Brother"s, Latest Edition

Subject	PHARMACEUTICAL TECHNOLOGY –II	Code	15R00503
Course Year	B.Pharmacy III year	Sem	I
Theory	3hrs/week	Tutorial	1hr/week
End exam	70 Marks	Internal	30Marks
		exam	
Credits	3		

**Scope:** This subject will provide an opportunity for the student to learn about the formulation, evaluation and manufacturing of various types of tablets, capsules and also provide insights about aseptic area and parenteral.

Objectives: Upon completion of the subject student shall be able to

- 1. Understand various formulation aspects of tablets and capsules and also provide knowledge about selection of excipients in the preparation of same.
- 2. Provide knowledge on packaging materials used in pharmaceutical products.

### Outcomes:

- 1. Acquire skill in preparation of different types of tablets.
- 2. Demonstrate the handling of equipment for evaluation of various dosage forms.
- 3. Acquire the knowledge of processing of dosage form on large scale that suit pharma industry.
- 4.

## UNIT I

**Tablets:** Introduction to different types of tablets, Formulation of tablets, direct compression, Granulation technology on large-scale by various techniques and equipments. Tablet processing problems and their remedy. Types of tablet compression machinery and the equipments employed and evaluation of tablets.

**Coating of Tablets:** Types of coating, coating materials and their selection, formulation of coating solution, equipment for coating, coating processes, evaluation of coated tablets. Tablet coating defects and their remedy.

## UNIT II

**Capsules:** Advantages and disadvantages of capsule dosage forms, material for production of hardand soft gelatin capsules, sizes of capsules, capsule filling, soft processing problems in capsulemanufacturing, importance of base absorption and minimum/gm factors in soft capsules, qualitycontrol, stability testing and storage of capsule dosage forms.

**Microencapsulation:** Types of microencapsulation and importance of microencapsulation in

Pharmacy, microcapsulation by coacervation phase seperation, multi orifice centrifugal separation. Spray drying, spray congealing, polymerization complex emulsion, air suspension technique, and pancoating techniques, evaluation of microcapsules.

# UNIT IV

## **Parenteral Products**

a. Preformulation factors, routes of administration, water for injection, treatment of apyrogenicity, non-aqueous vehicles, isotonicity and methods of its adjustment.

b. Formulation details, containers, closures and their selection.

c. Prefilling treatment, washing and sterilization of containers and closures, preparation of solutionsand suspensions, filling and closing of ampoules, vials, infusion fluids, lyophillization & preparation of sterile powders, equipment for large-scale manufacture and evaluation of parenteralproducts.

d. Aseptic techniques, sources of contamination and methods of prevention. Design of aseptic area, laminar flow benches, Environmental control monitoring.

# UNIT V

## Packaging of Pharmaceutical products:

Packaging components, types, specifications and methods of evaluation as per I.P. Factors influencingchoice of containers, package testing, legal and other official requirements for containers, packingtesting. Methods of packing of solid, liquid and semi-solid dosage forms, Factors influencing packingmaterial, stability aspects of packaging.

# Text Books:

- 1. L. Lachman, H.A, Lieberman and J.L. Kanig, Theory & Practice of industrial pharmacy, Lea & Febieger, Philadelphia Latest Edn.
- L. V. Allen Jr., N. G. Popovich, H. C. Ansel. Ansel's pharmaceutical dosage forms and drugdelivery systems. Lippincott Williams & Wilkins, 2005.

# Reference Books:

- 1. M. E. Aulton Pharmaceutics. The science of dosage form design. 2nd ed. Churchill-Livingstone, 2002
- 2. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences.
- 3. E.A.Rawlkins, Bentley"s Text Book of Pharmaceutics, Elbspubl

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Subject	PHARMACEUTICAL BIOTECHNOLOGY	Code	15R00504
Course Year	B.Pharmacy III year	Sem	1
Theory	3hrs/week	Tutorial	1hr/week
End exam	70 Marks	Internal	30Marks
		exam	
Credits	3		

**Scope:** To study the Fermentation, Recombinant and Enzyme Technology **Objective:** To know the various technologies types, design, preparation and operation **Outcome:** The Student has to know the Application of below mentioned technologies and uses of immunological preparations.

### UNIT I

**Fermentation Technology:** Isolation, Selection, Screening of Industrially important microbes, Strain improvement. Types, design & operation of Bioreactor. Types of fermentations, optimization of fermentation process, Principle and Procedure involving in downstream process and effluent treatment. **Specific Fermentations:** Selection of organism, fermentation & purification of antibiotics (penicillin, streptomycin, tetracycline, and erythromycin), vitamins (riboflavin and cyanocobalamine), lactic acid, alcohol and acetone.

### UNIT II

**Recombinant DNA Technology:** Introduction to r-DNA technology and genetic engineering, steps involved in isolation of enzymes, vectors, recombination and cloning of genes. Production of bio technology derived therapeutic proteins like humulin, humatrop, activase, intron a, monoclonal antibodies by hybridoma technique, recombivax HB (hepatitis b). Stem cells and their applications.

### UNIT III

**Immunology & Immunological Preparations:** Principles of Immunity, Humoral immunity, cell mediated immunity, antigen – antiboby reactions, hypersensitivity and its applications. Active & passive immunizations vaccine preparation, standardization & storage of BCG, cholera, smallpox, polio, typhus, tetanus toxoid, immuno serum & diagnostic agents.

### UNIT IV

Enzyme Technology: Techniques of immobilization of enzymes, factors affecting enzyme kinetics, advantages of immobilization over isolated enzymes. Study of

enzymes such as hyaluronidase, penicillinase, streptokinase, streptodornase, amylase, protease etc. immobilization of bacteria & plant cells.

## UNIT V

Introductory study & applications of bioinformatics, proteomics and genomics, Nanobiotechnology, Gene therapy.

## Text Books:

- 1. Wulf Crueger and Anneliese Crueger, Biotechnology, 2 nd Ed, Publ- Panima publication cooperation, New Delhi.
- P. F. Stanbury & A. Whitaker, Principles of fermentation technology, Pergamon Press. J. D. Watson, Recombinant DNA technology. 2 nd Edition, W.H. Freemann1992.
- 3. S.P.Vyas and Dixit, Pharmaceutical Biotechnology, CBS Publishers New Delhi.

## **Reference Books:**

- 1. Prescott and Dunne, "Industrial Microbiology" MC Graw Hill Book Company.
- 2. K. Kielsliched "Biotechnology" Vol 6, Verlegchemic, Switzerland.
- PF Standury& A. Whitaker, "Principles of fermentation Technology" Pergamon Press, Oxford. Wiseman, Handbook of enzyme biotechnology. A. 3rdEdition Elis Horwood.
- 4. Alexande M Moo-young, Comprehensive Biotechnology, Pergamon Press, New York.

Subject	(MOOCS-I) APPLICATION OF SPECTROSCOPIC METHODS IN MOLECULAR STRUCTURE DETERMINATION	Code	15R00505
Course Year	B.Pharmacy III year	Sem	Ι
Theory	3hrs/week	Tutorial	1hr/week
End exam	70 Marks	Internal	30 Marks
		exam	
Credits	3		

#### **Objectives:**

- 1. Introduction, Modern approaches in Bioanalysis and Bioassays.
- Spectroscopic techniques: UV-Visible spectroscopy, Fluorescence spectroscopy, IR spectroscopy, CD spectroscopy, and Mass spectroscopy.

#### Out comes:

- 1. Chemists are molecule makers; whenever a new molecule is synthesized it is essential to determine its structure using spectroscopic techniques.
- 2. This course is all about practical applications of spectroscopic methods for the determination of organic molecules.

#### UNIT-I

**UV-Vis spectroscopy** - Electronic transitions in organic molecules, selection rules, application of Beer Lambert law, qualitative and quantitative analysis by UV-Vis spectroscopy.

### UNIT-II

#### Electrophoresis Techniques

Electrophoresis; Principle, Design of horizontal and vertical gel electrophoresis apparatus, performing electrophoresis techniques, application of electrophoresis in analyzing macromolecules.

#### UNIT-III

**NMR spectroscopy** – Nuclear magnetic resonance spectroscopy (NMR), spin ½ nuclei, 1H and 13C-NMR spectroscopy. Chemical shifts, spin-spin coupling, spin-spin splitting pattern recognition for structure elucidation, coupling constants.

## UNIT-IV

**Mass Spectrometry** – various ionization methods – EI, CI, ESI and MALDI methods, fragmentation patterns of simple organic molecules, Use of HRMS. Infra-red spectroscopy – basic concepts, experimental methods, functional group analysis and identification using IR spectroscopy, structural effects on vibrational frequency.

## UNIT-V

## Introduction & Bioanalytical Spectroscopic techniques

Introduction, Modern approaches in Bioanalysis and Bioassays, Spectroscopic techniques: UV-Visible spectroscopy and IR spectroscopy.

## Sources: NPTEL

- 1. <u>http://nptel.iitm.ac.in</u> Biotechnology (Bioanalytical Techniques and Bioinformatics)
- 2. <u>http://nptel.ac.in</u> Chemistry and Biochemistry ( Application of Spectroscopic methods in molecular structure determination)

## Text Books

- 1. Spectroscopy, D. L. Pavia, G. M. Lampman, G. S. Kriz, J. R. Vyvyan, Cengage Learning (Indian Edition), 2007.
- 2. Organic Spectroscopy, William Kemp, 3<sup>rd</sup> Edition, 1991, Macmillan (Indian Edition).
- 3. NMR Spectroscopy, H. Gnther, second edition, John Wiley and sons, 1998

## **References:**

- 1. GA. Manz, N. Pamme and D. Iossifidis, Bioanalytical Chemistry, World Scientific
- 2. Publishing Company, 2004
- Baxevanis, B. F. F. Ouellette, Bioinformatics -A practical Guide to the analysis of Genes and Proteins, 2nd Ed, John Wiley and Sons Inc., 2001.
- 4. T. Lengauer; Bioinformatics From Genomes to Drugs, Vols 1 & 2, Wiley-VCH, 2002.
- 5. Live Cell Imaging: A Laboratory Manual R. D. Goldman, J. R. Swedlow and D. L. Spector Cold Spring.

Subject	MEDICINAL CHEMISTRY – I LABORATORY	Code	15R00506
Course year	B. Pharm III year	Semester	1
Practical	4hrs/week	Tutorial	Nil
End Exam	70Marks	Internal marks	30Marks
Credits	2		

**Scope:** This subject will provide an opportunity for the student on synthesis of various compounds.

Objectives: Upon completion of the subject student shall be able to

- a. Synthesis various chemical compounds.
- b. Provide knowledge on monograph analysis of some chemical compounds.

### Outcomes:

- 1. Acquire skills in synthesis various chemical compounds.
- 2. Demonstrate of stereo models of some drugs relevant to theory.
- 3. Acquire skills of extraction of drugs from different dosage forms.

## I. EXPERIMENTS

- 1. Synthesis of Barbituric acid from Diethyl Malonate
- 2. Synthesis of Phenytion from Benzoin or Benzil
- 3. Synthesis of Diphenyl quinaoxaline from o-phenylene diamine and benzil
- 4. Synthesis of phenothiazine from o-phenylene diamine
- 5. Synthesis of Benzocaine from Para amino benzoic acid
- 6. Synthesis of Dibromo succinic acid from malic acid
- 7. Synthesis of Benzoxazine from Anthranilic acid
- 8. Monograph analysis of Caffeine
- 9. Monograph analysis of Phenytoin
- 10. Monograph analysis of Barbituric acid
- 11. Monograph analysis of Benzocaine
- 12. Monograph analysis of carbamazine citrate

(Literature, Journal reported lead compounds synthesis relevant to theory can also be Included)

## II Demo/Workshop

- 1. Stereo models of some drugs relevant to theory.
- 2. Extraction of drugs from different dosage forms

## III Seminar/Assignment/Group discussion

Photochemistry as a green synthetic method, novel methods for the separation of optical isomers, highly selective metalation reactions, QSAR, high throughput screening, combinatorial chemistry, In silico drug design.

### References:

- 1. A.I. Vogel, Text Book of Practical Organic Chemistry, 5th Edition. Pearson Prentice Hall.
- 2. F.G. Mann & B.C. Saunders, Pratical Organic Chemistry, 4th Edition. Pearson Publishers.

## LIST OF MINIMUM EQUIPMENTS REQUIRED

- 1. Water bath
- 2. Suction pumps
- 3. Analytical/physical balance
- 4. Triple beam balance
- 5. Reflux flask with condenser
- 6. Hot plates
- 7. Refrigerator
- 8. Mechanical and magnetic stirrer with thermostat
- 9. Distillation unit
- 10. Oven
- 11. Adequate glass wares

Subject	PHARMACOLOGY - I LABORATORY	Code	15R00507
Course Year	B.Pharmacy III year	Sem	I
Practical	4hrs/week	Tutorial	NIL
End exam	70 Marks	Internal	30 Marks
		exam	
Credits	2		

#### Scope:

- To find out the agents suitable for clinical use.
- Study the toxicity and mechanism of Action and Site of action
- Study the actions of drugs in Preclinical

### **Objectives:**

To know and understand pharmacological investigation techniques applied in the research

## Outcomes:

- Knows to administration of drugs to experiments rats by various routes.
- Have insight fundamental difference between agonists and antagonists
- Englighted with basic equipments, anesthetics, lab animals that are to be handled in the pharmacology lab

# **1.EXPERIMENTAL PART**

## (To use appropriate softwares for animal experimentation)

- 1. Introduction to Experimental Pharmacology
  - Preparation of different solutions for experiments.
  - Drug dilutions, use of molar and % w/v solutions in experimental Pharmacology.
  - Common laboratory animals and anaesthetics used in animal studies.
  - Commonly used instruments in experimental pharmacology.
  - Different routes of administration in animals
  - Collection of blood samples from animals
  - 2. Study the effect of autonomic drugs on rabbit's eye
  - 3. Record the concentration response curve (CRC) of acetylcholine using rectus abdominus muscle preparation of frog.
  - 4. Record the CRC of 5-HT on rat fundus preparation.
  - 5. Record the CRC of histamine on guinea pig ileum preparation.

- 6. To study the inotropic and chronotropic effects of drugs on isolated frog heart.
- To study the effects of various agonists and antagonists and their characterisation using isolated preparations like frog's rectus abdominus muscle and isolated ileum preparation of rat& guinea pig.

# II. DEMO/ WORK SHOP

Arterial and venous cannulations, organ isolation and its application in research.

# III. SEMINAR/ ASSIGNMENT/ GROUP DISCUSSION

- 1. Isolation, characterization and nomenclature of receptors.
- 2. Metabolic disorders and their complications
- 3. Novel targets for the treatment of various disorders

# References:

- 1. Practicals in pharmacology By Dr.R.K.Goyal
- 2. Handbook of experimental pharmacology By S.K.Kulakarni
- 3. Experimental pharmacology By M.N.Ghosh
- 4. EXPO Experimental pharmacology software.

Subject	PHARMACEUTICAL TECHNOLOGY – II LABORATORY	Code	15R00508
Course Year	B.Pharmacy III year	Sem	I
Practical	4hrs/week	Tutorial	NIL
End exam	70 Marks	Internal	30 Marks
		exam	
Credits	2		

**Scope:** This subject will provide an opportunity for the student to learn manufacturing of dosage forms such as tablets, capsules and parenteral.

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

- Manufacture the various types of tablets.
- Evaluate the finished pharmaceutical products.

### Outcomes:

- 1. Acquire skills in manufacture the various types of tablets.
- 2. Learn how to evaluate the tablets.
- 3. Acquire skills of manufacturing and evaluation of parental dosage forms.

## I. EXPERIMENTS:

- 1. Manfacturing of tablets:
  - a. Ordinary compressed tablets by wet granulation.
  - b. Tablets prepared by direct compression
  - c. Soluble tablets/dispersible granules
  - d. Chewable tablets
  - e. Effervescent tablets.

2. Evaluation of tablets (Weight variation, hardness, friability, disintegration and dissolution)

- 3. Formulation and filling of hard gelatin capsules.
- 4. Parenteral:
  - a. Manufacturing of parenterals (Ampoule sealing (Pull sealing and tip sealing)
  - b. Evaluation of parenterals (Clarity test, and leaking test).

#### II. DEMO/ WORKSHOP

Coating of tablets (sugar/film/enteric)

## III. SEMINAR/ASSIGNMENT/GROUP DISCUSSION

- 1. Advances in granulation technology.
- 2. Multifunctional excipients.
- 3. Excipients and their commercial names.

# Text Books:

- 1. L. Lachman, H.A, Lieberman and J.L. Kanig, Theory & Practice of industrial pharmacy, Lea & Febieger, Philadelphia Latest Edn.
- 2. L. V. Allen Jr., N. G. Popovich, H. C. Ansel. Ansel's pharmaceutical dosage forms and drugdelivery systems. Lippincott Williams & Wilkins, 2005.

# Reference Books:

- 1. M. E. Aulton Pharmaceutics. The science of dosage form design. 2nd ed. Churchill-Livingstone, 2002
- 2. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences.
- 3. E.A.Rawlkins, Bentley's Text Book of Pharmaceutics, Elbspubl

Subject	PHARMACEUTICAL BIOTECHNOLOGY LABORATORY	Code	15R00509
Course Year	B.Pharmacy III year	Sem	Ι
Practical	4hrs/week	Tutorial	Nil
End exam	70 Marks	Internal	30Marks
		exam	
Credits	2		

### I.EXPERIMENTS:

- 1. Isolation of antibiotic producing microorganism from soil.
- 2. Enzyme immobilization by Ca-alginate method.
- 3. Determination of minimum inhibitory concentration of the given antibiotic.
- 4. Standardization of Cultures.
- 5. Microbiological assay of Antibiotics / Vitamins.
- 6. Production of alcohol by fermentation techniques.
- 7. Comparison of efficacy of immobilized cells.
- 8. Isolation of mutants by gradient plate technique.
- 9. Preparation of bacterial vaccine.
- 10. Preparation of blood products / Human normal immunoglobulin injection
- 11. Extraction of DNA and RNA and their estimations by colorimetry.
- 12. Separation techniques: Various types of Gel Electro Phoresis, Centrifugation.

### II.DEMO/WORKSHOP:

Production of Antibiotics by Fermentation, Development of a Simple Biosensor.

### III.ASSIGNEMENT/SEMINAR/GROUP DISCUSSION:

Monoclonal antibodies and Diagnosis, New Drug Targets and Vaccine Development, Stem cells and

their applications.

### LIST OF MINIMUM EQUIPMENTS REQUIRED

- 1. Micropipettes
- 2. Eppendorf's tubes
- 3. Ultra centrifuge
- 4. Dessicators
- 5. Gel electrophoresis unit
- 6. Small scale bioreactor
- 7. Syringes
- 8. laminar flow bench
- 9. Autoclave

- 10. Hot air oven
- 11. BOD incubator
- Rotary shaker
  Anerobic jar
- 14. Colorimeter
- 15. Adequate glassware

B. Pharmacy III-I Sem.

L T P C 2 0 2 0

15A99501 SOCIAL VALUES & ETHICS (AUDIT COURSE) (Common to all Branches)

#### UNIT - I

**Introduction and Basic Concepts of Society: Family and Society:** Concept of family, community, PRIs and other community based organizations and society, growing up in the family – dynamics and impact, Human values, Gender Justice.

Channels of Youth Moments for National Building: NSS & NCC: History, philosophy, aims & objectives; Emblems, flags, mottos, songs, badge etc.; Organizational structure, roles and responsibilities of various NSS functionaries. Nehru Yuva Kendra (NYK): Activities – Socio Cultural and Sports.

#### UNIT – II

Activities of NSS, NCC, NYK:

**Citizenship:** Basic Features Constitution of India, Fundamental Rights and Fundamental Duties, Human Rights, Consumer awareness and the legal rights of the consumer, RTI.

**Youth and Crime:** Sociological and psychological Factors influencing youth crime, Peer Mentoring in preventing crimes, Awareness about Anti-Ragging, Cyber Crime and its prevention, Juvenile Justice

**Social Harmony and National Integration:** Indian history and culture, Role of youth in peace-building and conflict resolution, Role of youth in Nation building.

### UNIT – III

**Environment Issues:** Environment conservation, enrichment and Sustainability, Climate change, Waste management, Natural resource management (Rain water harvesting, energy conservation, waste land development, soil conservations and afforestation).

**Health, Hygiene & Sanitation:** Definition, needs and scope of health education, Food and Nutrition, Safe drinking water, Sanitation, Swachh Bharat Abhiyan.

**Disaster Management:** Introduction to Disaster Management, classification of disasters, Role of youth in Disaster Management. Home Nursing, First Aid.

**Civil/ Self Defense:** Civil defense services, aims and objectives of civil defense, Need for self defense training – Teakwondo, Judo, karate etc.,

### UNIT – IV

**Gender Sensitization:** Understanding Gender – Gender inequality – Role of Family, Society and State; Challenges – Declining Sex Ratio – Sexual Harassment – Domestic

#### R15

Violence; Gender Equality – Initiatives of Government – Schemes, Law; Initiates of NGOs – Awareness, Movements;

## UNIT - V

**Physical Education :** Games & Sports: Health and Recreation – Biolagical basis of Physical activity – benefiets of exercise – Physical, Psychological, Social; Physiology of Musucular Activity, Respiration, Blood Circulation.

**Yoga:** Basics of Yoga – Yoga Protocol, Postures, Asanas, Pranayama: Introduction of Kriyas, Bandhas and Mudras.

## TEXT BOOKS:

- 1. NSS MANUAL
- 2. SOCIETY AND ENVIRONMENT: A.S.Chauha, Jain Brothers Publications, 6th Edition,
- 3. 2006
- 4. INDIAN SOCIAL PROBLEM: G.R.Madan, Asian Publisher House
- 5. INDIAN SOCIAL PROBLEM: Ram Ahuja, Rawat Publications
- 6. HUMAN SOCIETY: Kingsley Davis, Macmillan
- 7. SOCIETY: Mac Iver D Page, Macmillan
- SOCIOLOGY THEMES AND PERSPECTIVES: Michael Honalambos, Oxford University Press
- 9. CONSTITUTION OF INDIA: D.D.Basu, Lexis Nexis Butterworth Publishers
- 10. National Youth Policy 2014 (available on www.yas.nic.in)
- 11. TOWARS A WORLD OF EQUALS: A.Suneetha, Uma Bhrugudanda, Duggirala Vasantha, Rama Melkote, Vasudha Nagraj, Asma Rasheed, Gogu Shyamala, Deepa Streenivas and Susie Tharu
- 12. LIGHT ON YOGA : B.K.S.Iyengar, Penguin Random House Publishers

www.un.org www.india.gov.in www.yas.nic.in http://www.who.int/countries/ind/en/ http://www.ndma.gov.in http://ayush.gov.in/event/common-yoga-protocol-2016-0

Subject	PHARMACOLOGY – II	Code	15R00601
Course Year	B.Pharmacy III year	Sem	II
Theory	3hrs/week	Tutorial	1hr/week
End exam	70 Marks	Internal	30Marks
		exam	
Credits	3		

**Scope:** This subject will provide an opportunity for the student to learn pharmacological information about the drugs. In this subject drugs acting on cardiovascular system, drugs acting on hematopoietic system, drugs acting on renal system, drugs acting on respiratory system and drugs acting on autacoids will be taught.

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

- a. Understand various pharmacological aspects like mechanism of action, pharmacokinetics, side effects, drug interactions, contraindications and indications of drugs falling under below mentioned chapters.
- b. Correlate and apply the knowledge.
- c. Handle the animals and carry out the experiments on animals

#### Outcomes:

- 1. Acquire the knowledge in basic mechanism of action of drugs.
- 2. Therapeutic uses of drugs of the following chapters.

### UNIT I

#### Drugs acting on cardiovascular System

a. Pharmacology of drugs used in hypertension and CHF

b. Pharmacology of drugs used in coronary artery diseases (Atherosclerosis, Angina and MI)

c. Pharmacology of drugs used in arrhythmias

d. Shock and treatment of different types of shock

### UNIT II Drugs acting on hematopoietic system

- a. Coagulants, anticoagulants
- b. Fibrinolytics, antifibrinolytics, antiplatelet drugs
- c. Hematinics and plasma expanders

## UNIT III

### a. Drugs acting on urinary system

i) Diuretics and antidiuretics

## b. Drugs acting on respiratory system

- i) Antiasthmatics
- ii) Antitussives, expectorants and respiratoty stimulants

## UNIT IV

## Autacoids

- a. Amine autacoids- Histamine and 5-HT
- b. Lipid derived autacoids-Prostaglandins, thromboxanes and leukotrienes.
- c. Peptide autacoids- Angiotensin, bradykinin

## UNIT V

## Hormones and hormone antagonists

- a. Insulin, Oral hypoglaceamics agents
- b. Thyroid and antithyroid drugs
- c. Adrenocortical steroids and their analogues
- d. Uterine stimulants and relaxants

## Text Books:

- 1. H.P Rang, M. M. dale & J.M. Ritter, Pharmacology, Churchill living stone, 4<sup>th</sup> Ed.
- 2. J.G. Hardman and Lee E. Limbard, Good Mann & Gilmann, The Pharmacological basis of therapeutics, Mc Grawhill, Health Professions Dvn.
- 3. Illiterated Pharmacology by Lippincotts

### **References:**

- 1. Tripathi, Essentials of Medical Pharmacology, Jaypee Brother's, Latest Edition
- 2. Sathoskar, Pharmacology and pharmaco therapeutics Vol. 1 & 2, Publ by Popular Prakashan, Mumbai.

Subject	PHARMACEUTICAL ANALYSIS- II	Code	15R00602
CourseYear	B.Pharmacy III year	Sem	
Theory	3hrs/week	Tutorial	1hr/week
End exam	70 Marks	Internal	30Marks
		exam	
Credits	3		

**Scope:** This subject will provide an opportunity for the student to learn about the spectroscopic and chromatographic techniques.

### Objective:

- The course is designed to explore the knowledge in modern analytical instrumental techniques i.e., both spectroscopy and chromatography.
- The course helps to assess the process for identification, determination, quantification and purification of a substance and separation of the components of a solution or mixture.

### Outcome:

- 1. To gain knowledge on basic fundamentals of modern analytical instrumental techniques.
- 2. Analyze the drug structure, identification, purity determination, and quantification of the drug substance.

## UNIT I

a) Study of separations, introduction to chromatography, classifications, types, various stationary and mobile phase in the following techniques and their applications in pharmacy (IP 2010 and 2014).

b) **Column chromatography**: Adsorption and partition theory, concept of theoretical plates, HETP, adsorbents used, preparation, procedure and methods of detection.

c) **Paper Chromatography:** Theory, different techniques employed, filter papers used, qualitative and quantitative detection.

e) **Thin layer chromatography:** Principle, 1D and 2D techniques, preparation of plates, Rf, Rx, Rm values and detection techniques. Concept of HPTLC.

f) **Ion Pair Chromatography**, Ion suppression and Ion Exchange Chromatography, Introduction to Theory and Principle, Instrumentation. Advantages and limitations. Pharmaceutical and other Applications.

g) **Size exclusion chromatography:** Introduction, principle, instrument. Column packing, Applications.

### UNIT-II

**Gas Chromatography:** Principle, adsorption isotherm and its relation to tailing and fronting, Instrumentation - carrier gas, flow regulators, injectors columns, detectors. Various parameters used in GC analysis. Brief note on GC-MS.

## UNIT III

a) Basic Principles (exothermic and endothermic reactions), Instrumentation and applications of the following: Differential Scanning Colorimetry (DSC), DTA, & TGA in analysis of Pharmaceuticals,

## b) Quality Assurance

Concept of Quality control and Quality Assurance, ISO 9000, TQM, QC, Vs QA, Concepts of ICH, GMP and GLP, Calibration of UV and IR, Validation of analytical methods as per ICH guidelines.

## UNIT IV

**HPLC:** Principle, Instrumentation- mobile phase, degassing, pumps, injectors, columns, detectors. Normal Phase Vs Reverse Phase HPLC, Isocratic and gradient elution in RP-HPLC. Various parameters in chromatogram of HPLC.

## UNIT V

**Optical Rotatory dispersion:** Principle of optical activity, optical purity, concept of Optical Rotatory dispersion (ORD).

**XRD:** Production X-ray, types of X-rays, Braggs law, Octant rule, Cotton effect, XRD pattern in identification and comparison of polymorphs with examples.

**Radio Immuno Assay & Enzyme Linked Immuno Sorbate Assay:** Principle and procedure of RIA, Principle, Types, Procedures of ELISA and application of RIA and ELISA in various diagnosis.

# Text books:

- 1. Willard HH, Merritt LL, Dean JA and Settle FA. (2001). Instrumental Methods of Analysis, 7thed., CBS Publishers and Distributors, Delhi, ISBN: 9788123909431.
- 2. Douglas A. Skoog, F. James Holler and Stanley R. Crouch. (2006). Principles of Instrumental Analysis, Cengage Learning; 6th edition, ISBN-10: 0495012017

# References:

- 1. Settle, Handbook of Instrumental Techniques for Analytical Chemistry. Prentice Hall.
- 2. Robert M Silverstein. Spectrometric Identification of Organic compounds. Sixth edition, John Wiley & Sons, 2004.
- 3. B.K. Sharma, Instrumental Chemical Analysis, Goel Publishers.

Subject	BIOPHARMACEUTICS AND PHARMACOKINETICS	Code	15R00603
Course Year	B. Pharmacy III year	Sem	II
Theory	3hrs/week	Tutorial	1hr/week
End exam	70 Marks	Internal	30Marks
		exam	
Credits	3		

**Scope:** This subject will provide an opportunity for the student to learn about the Biopharmaceutics and pharmacokinetic.

### Objective:

- The course is designed to explore the knowledge in ADME.
- The course helps to learn ssignificance of plasma drug concentration measurement.

#### Outcomes:

- 1. Graduate will acquire knowledge on the factors influencing absorption, distribution, protein binding and also on pharmacokinetic models.
- 2. Able to calculate the pharmacokinetic parameters based on plasma level-time data & urine data.
- 3. Understand the importance of clinical pharmacokinetics and the bioavailability and bio equivalence studies.

### UNIT – I

Biopharmaceutics, Pharmacokinetics and Pharmacodynamics. Structure of GI membrane. Routes of drug administration and absorption from different routes.

**Drug Absorption**. Mechanisms of GI absorption, physico-chemical, biological and dosage form factors influencing absorption.

**Drug distribution**. Factors affecting drug distribution, physiological barriers of drug diffusion, apparent volume of distribution, drug binding to blood, tissues, protein binding – factors affecting, significance and kinetics of protein binding.

## UNIT – II

**Drug Metabolism**: Pathways of drug metabolism. Phase-I (oxidative, reductive and hydrolytic reactions). Phase II reactions (conjugation) Enzyme induction and inhibition, hepatic clearance, pharmacological activity of metabolites, first pass effect.

**Drug excretion**. Glomerular filtration, tubular secretion and reabsorption, effect of pH and other drugs. Clearance concept, excretion through bile, feces, lungs and skin in brief.

## UNIT – III

**Bioavailability and bioequivalence:** concept of equivalents, Definitions of various types of equivalents, types of Bioavailability studies, measurement of Bioavailability, plasma level and urinary excretion studies. Bioequivalence study design, IVIVC.

# UNIT – IV

**Pharmacokinetics**. Basic considerations, compartment modeling, one compartment open model - i.v. bolus and extra vascular administration, urinary excretion studies. Apparent volume of distribution, elimination rate constant, biological half life, area under the curve and clearance. Calculation of pharmacokinetic parameters. Method of residuals, Wagner and Nelson method , excretion rate method, sigma minus method. Solving of simple problems

## UNIT – V

Nonlinear kinetics. Non compartmental models, reasons for non linearity, concepts of linearity and non linearity, <u>Michaelis- Menten</u> equation and its significance.

## Text Books:

- 1. L. Shargel and ABC Yu, textbook of applied biopharmaceutics & Pharmacokinetics, 4th edn, Appleton centuary crofts, Connecticut, 2004.
- 2. Milo Gibaldi, Biopharmaceutics and clinical pharmacokinetics 4/Edn. Pharma Book
- 3. Syndicate.Hyderabad.
- 4. DM Brahmankar and SB Jaiswal, biophamaceutics and pharmacokinetics- a treatise, vallabh prakasham, Delhi.

## Reference Books:

- 1. Ronald & trouser. Clinical pharmacokinetics concepts & applications. 3rd ed, wolterskluwer Pvt Ltd., 2007.
- 2. Robert E notary, Biopharmaceutics and pharmacokinetics an introduction, marcel dekker inc., NY
- 3. Basic pharmacokinetics by Hedaya, CRC press.

Subject	PHARMACEUTICAL JURISPRUDENCE	Code	15R00604
Course Year	B.Pharmacy III year	Sem	I
Theory	3hrs/week	Tutorial	1hr/week
End exam	70 Marks	Internal	30Marks
		exam	
Credits	3		

**Scope:** This subject will provide an opportunity for the student to review Pharmaceutical Legislations, Pharmaceutical ethics & policy.

#### Objectives:

- The course is designed to explore the knowledge Pharmaceutical Education.
- The course helps to learn various laws and acts in pharmacy.

#### Outcomes:

- 1. Graduate will acquire knowledge on Pharmaceutical Education.
- 2. Able to understand drugs & pharmaceutical industry.
- 3. Understand the importance of Pharmacy Acts.

## UNIT I

### Introduction

- a. Pharmaceutical Legislations A brief review
- b. Drugs & Pharmaceutical Industry A brief review
- c. Pharmaceutical Education A brief review.
- d. Pharmaceutical ethics & policy
- e. Pharmacy Act 1948

### UNIT II

Drugs and Cosmetics Act 1940 and Rules 1945

### UNIT III

Narcotic Drugs & Psychotropic Substances Act 1985

### UNIT IV

Drugs (Prices Control) Order 1995. Medicinal & Toilet Preparations (Excise Duties) Act 1955 Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 and Rules 1955.

# UNIT V

Study of the salient features of the following.

- a.Prevention of Cruelty to animals Act 1960.
- b.Medical termination of pregnancy act 1970 and rules 1975

c.Factories Act 1948.

d.WTO, GATT and The Indian Patents Act 1970

# Text Books:

- 1. B.M.Mithal, Text book of Forensic Pharmacy, publ by Vallabh Prakashan
- 2. Suresh.B, Text book of Forensic Pharmacy
- 3. C.K.Kokate&S.B.Gokhale, Textbook of Forensic Pharmacy, Pharmabook, Syndicate.
- 4. N.k.jain. Textbook of Forensic Pharmacy. 7<sup>th</sup>ed, Vallabh prakashan, 2007.

# Reference Books:

- 1. Bare Acts and Rules Publ by Govt of India/state Govt from time to time.
- 2. Pharmaceutical policy of India
- 3. Notification from NPPA
- 4. Vijay Malik, Drugs & Cosmetics act 1940 and Rules, Eastern Law House Co. Delhi, Kolkata.
- 5. K.Sampath, Pharmaceutical Jurisprudence (Forensic Pharmacy) Jai Publishers.

Subject	PHARMACY ADMINISTRATION (CBCC-I)	Code	15R00605
Course Year	B.Pharmacy III year	Sem	II
Theory	3hrs/week	Tutorial	1hr/week
End exam	70 Marks	Internal	30Marks
		exam	
Credits	3		

**Scope:** This subject will provide an opportunity for the student to learn about the Organization of Distribution and Marketing, Principles of drug store and community pharmacy administration.

#### Objectives:

- To learn Manufacturing Management, work study insurance in pharma industry.
- To gain knowledge on drug store planning and layout.

#### Outcome:

- 1. To gain knowledge on basic fundamentals of management and administration in pharma industry.
- 2. To acquire knowledge on organization of distribution and marketing. (organization =correct spelling)

#### UNIT – I

#### Features of Business Organizations & New Economic Environment:

Characteristic features of Business, Features and evaluation of Sole Proprietorship, Partnership, Joint Stock Company, Public Enterprises and their types, Changing Business Environment in Post-Liberalisation scenario.

**Manufacturing Management:** Goals of Production Management and Organization– Production, Planning and Control – Plant location - Principles and Types of Plant Layout-Methods of production (Job, batch and Mass Production).

#### UNIT – II

**Work Study** -Basic procedure involved in Method Study and Work Measurement-Statistical Quality Control: X chart, R chart, c chart, p chart, (simple Problems), Acceptance Sampling, Deming's contribution to quality.

**Organization of Distribution and Marketing**: Functions of Marketing, Marketing Strategies based on Product Life Cycle., Channels of distribution – Factors influencing channels of distribution, sales organization and sales promotion.

# UNIT - III

**Pharma Industry:** Growth of Pharma Industry in India – current status and its role in building national economi and national health – Structure of Pharma Industry in India – PSUs in Pharma Industry –Progress in the manufacture of basic drugs, synthetic and drugs of vegetable origin. Export and import of drugs and pharmaceuticals – Export and import Trade.

# UNIT – IV

**Insurance and Pharma:** Various types of insurance including marine and health insurance.

# UNIT – V

# Principles of drug store and community pharmacy administration:

Drug store planning and layout, sales promotion and salesmanship in drug store. Accounting records in drug stores.

# Text Books

- 1. Aryasri and Subbarao, Pharmaceutical Administration, TMH.
- 2. Smarta, Strategic Pharma Marketing
- 3. G.Vidya Sagar, Pharmaceutical Industrial Management. PBS/BS Publication 2005.

# References

- 1. Subbarao Chaganti, Pharmaceutal Marketing in India Concepts and Strategy Cases, Pharma Book Syndicate.
- 2. O.P.Khanna, Industrial Management, Dhanpatrai, New Delhi.

Subject	CLINICAL TRIALS (CBCC-I)	Code	15R00606
Course year	B. Pharmacy III year	Semester	Ш
Theory	3 hrs/week	Tutorial	1 hr / week
End Exam	70 Marks	Internal	30 Marks
		marks	
Credits	3		

**Scope:** This subject will provide an opportunity for the student to learn about the Introduction to clinical trials.

#### Objective:

- To learn Phase I, II and III levels of clinical trials.
- To gain knowledge on statistical approaches for various endpoints.

### Outcome:

- 1. To gain knowledge on clinical trials.
- 2. To acquire knowledge on Phase I, II, III toxicity studies and dosage calculations.
- 3. To learn the selection of volunteers for clinical trials.

## UNIT –I

### Overview of clinical trials

Introduction to clinical trials, Issues in modern clinical trials, Study population.

### UNIT –II

### Phase I trials:

Up-and-down design, Single patient per cohort design, Titration design.

### Phase II trials:

Randomized dose ranging design, Randomized titration design, Two-stage phase II designs, Multistage design, Bayesian design, Randomized phase II design, Multiple outcomes design.

### UNIT –III

### Phase III trials:

Randomized controlled clinical trials, Uncontrolled trials, Historical controls, Crossover designs, Withdrawal studies, Factorial designs, Group allocation designs, Studies of equivalency.

**Randomization methods:** Simple randomization, Replacement randomization, Random permuted blocks, Blinded studies.

### UNIT –IV

Baseline assessment, subgroup analysis, recruitment, multicenter trials: Use of baseline data, Analysis of baseline comparability, Balance and imbalance, Difficulties of subgroup analysis, Recruitment of study subjects, Multicenter trials

### UNIT –V

Statistical approaches for various endpoints: t-test, chisquare test, Fisher's exact test, analysis of variance, regression analysis, longitudinal analysis, nonparametric statistics

### Text Books

- 1. Chow SC, Liu JP. Design and Analysis of Clinical Trials: Concepts and Methodologies. New York, NY: Wiley; 1998.
- Geller N, Chow SC. Advances in Clinical Trial Biostatistics. New York, NY: Marcel Dekker; 2004.

### Reference Books

- 1. Interdisciplinary Statistics. New York, NY: Chapman & Hall; 1997.
- 2. Jennison C, Turnbull BW. Group Sequential Methods with Applications to Clinical Trials. New York, NY: Chapman & Hall; 2000.
- 3. Machin D, Day S, Green S, Everitt B, George S. *Textbook of Clinical Trials*. New York, NY: Wiley; 2004.

Subject	COSMETIC TECHNOLOGY (CBCC-I)	Code	15R00607
Course year	B. Pharmacy III year	Semester	Π
Theory	3 hrs/week	Tutorial	1 hr / week
End Exam	70 Marks	Internal	30 Marks
		marks	
Credits	3		

**Scope:** This subject will provide an opportunity for the student to learn about Cosmetics, scientific background technology and its future.

Objectives: Upon completion of the subject student shall be able to

- a. Understand various formulation aspects of cosmetic preparations.
- b. Provide knowledge on excipients & its applications in cosmetics.

### Outcomes:

1. Acquire skill in preparation of different types of cosmetics.

2. Demonstrate the handling of equipment for evaluation of various cosmetics.

3. Acquire the knowledge of processing of cosmetic, selection of materials for containers.

#### UNIT – I

**Introduction of Cosmetics:** Purposes of Cosmetics meaning of Cosmetics and cosmeceuticals. Classification of Cosmetics Quality characteristics and Quality Assurance Development Process of Cosmetics. Scientific background technology and its future.

### UNIT – II

### Excipients & its applications in cosmetics.

**a. Oily Materials:** Introduction, Oils and Fats, Wax, Hydrocarbons, Higher Fatty Acids, Higher Alcohols, Esters, Silicones.

**b. Surface Active Agents:** Introduction Anionic Surfactant, Cationic, Surfactants, Amphoteric Surfactant, Non-ionic, Surfactant. Other Surfactants.

**c. Humectants:** Introduction, Choice of Humectants Unusual Humectants, Special Uses of Humectants.

**d. Antioxidants:** Introduction, General Oxidative theory, Measurement of Oxidation and Assessment of Oxidant efficiency, Choice of Antioxidant.

### UNIT – III

Safety of Cosmetics: Basic Concept of Cosmetic Safety, Safety test items & Evaluation method: Skin irritation, sensitization, Testing on Human (Patch test, Usage test)

### UNIT – IV

**Cosmetics Containers:** Introduction, Characteristics required by Cosmetic Containers-Quality Maintenance functional Design, Optimum Packaging.

Types of Cosmetic Containers:- Narrow Mouth bottles, Wide Mouth Bottles (Containers), Tubes, tubular Containers, Powders Containers, Compact containers, Stick containers, pencil containers Applicator containers.

### UNIT – V

**Material of construction for containers:** Types of Material Forming and processing methods. Container design procedure. Material test methods & Specifications. Trends in Container materials

### Text Books

1) New Cosmetic Science by Takeo Mitsui

2) Harry's Cosmetology.

### **Reference Books**

1) Cosmetic Science & Technology by Sagarin C.B.

2) Hand book of Cosmetic science & Technology by Marc paye, Andre O. Barel.

3) Cooper & Gunn Dispensing for Pharmaceutical Students.

Subject	PHARMACOLOGY - II LABORATORY	Code	15R00608
CourseYear	B. Pharmacy III year	Sem	Π
Lab	4hrs/week	Tutorial	Nill
End exam	70 Marks	Internal	30Marks
		exam	
Credits	2		

### Scope:

- a. To find out the drugs that is beneficial in clinics.
- b. Study the mechanism of Action and Site of action and their toxicities.
- c. Study the actions of drugs existing in Preclinicals

### **Objectives:**

To know and understand pharmacological investigation techniques applied in the research

### Outcomes:

- 1. Acquires ability to apply experimental approaches in characterization of drugs.
- 2. Able to use the knowledge to screen novel drugs in different animal models.

### A. EXPERIMENTAL PART

- 1. Experiments on Isolated Preparations:
  - a. Calculate the PA<sub>2</sub> value of atropine using acetylcholine as an agonist on rat ileum preparation.
  - b. Calculate the PA<sub>2</sub> value of chlorpheniramine using histamine as an agonist on guinea pig ileum preparation.
  - c. Find out the strength of the given sample (e.g. Acetylcholine, Histamine, 5-HT. Oxytocin etc.) using a suitable isolated muscle preparation by
    - i. Interpolation bioassay
    - i. Matching or bracketing bioassay
    - iii. Three point bioassay
    - iii. Four point bioassay

- 2. Experiments on intact animals like
  - a. Study of drug induced catatonia in rats
  - b. Study of muscle relaxant activity (rotarod apparatus)
  - c. Study of antipsychotic activity (pole climb response apparatus)
  - d. Study of antianxiety activity (elevated plus maze)
  - e. Study of analgesic activity (analgesiometer)
  - f. Study of anti-inflammatory activity (plethysmometer)
  - g. Study of antidepressant activity (swim test & tail suspension test)
  - h. Study of anticonvulsant activity (electroconvulso meter)
- i. Study of spontaneous motor activity and locomotor activity (actophotometer)

# B. DEMO/ WORK SHOP

- a. Screening of antiulcer activity
- b. Invitro antioxidant activity
- c. Screening of antihistaminic activity (histamine chamber)

# C. SEMINAR/ ASSIGNMENT/ GROUP DISCUSSION

- a. BABE studies
- b. Invitro-invivo correlation studies
- c. Pharmacovigilance
- d. Biostatistics and its application

### REFERENCES

- 1. Practicals in pharmacology By Dr.R.K.Goyal
- 2. Handbook of experimental pharmacology By S.K.Kulakarni
- 3. Experimental pharmacology By M.N.Ghosh
- 4. Experimental Pharamcology and Toxicology By Dr.B.M.VrushabendraSwamy and Prof.K.N.Jayaveera, S.Chand& Co.,

Subject	PHARMACEUTICAL ANALYSIS-II LABORATORY	Course Code	15R00609
Course Year	B. Pharmacy III Year	Semester	II
Lab	4 Hrs/ Week	Tutorial	NIL
End Exam	70 Marks	Internal Exam	30 marks
Credits	2		

### Scope:

This subject will provide an opportunity for the student on handling of modern analytical instruments or equipment.

### Objective:

- The course is designed to explore the knowledge in handling of modern analytical instruments or equipment.
- The course helps to understand the instrumental or equipment operational procedures

### Outcomes:

- Analyze the drug compound independently by using the instrument.
- Design and deepen their practical skills so as to be capable of performing the analysis in a good manner.
- Compare the results in determination of percent purity of drug performed by self with monographs.

### I. Experiments

- 1. Determination of  $\lambda$  max of KMnO<sub>4</sub>
- 2. Determination of  $\lambda$  max of any one drug
- 3. Determination of isobestic point of any 2 drugs.
- 4. Estimate the unknown concentration of Paracetamol by UV Spectrophotometric method.
- 5. Estimate the unknown concentration of ciprofloxacin in the ciprofloxacin injection by colorimetric method.
- 6. Estimate the unknown concentration of Riboflavin by fluorimetric method.
- 7. Assay of Ibuprofen (any one drug) by UV-spectrophotometric method using calibrative curve method.
- Assay of Paracetamol (any one drug) by UV-spectrophotometry-A (1%, 1 cm) method.

- 9. Assay of Pheniramine Maleate by UV-spectrophotometry-A (1%, 1 cm) method.
- 10. Study of quenching effect of quinine by Fluorimetry.
- 11. Determination of Na/K ions by Flame photometry.
- 12. Interpretation of UV Spectra.
- 13. Interpretation of IR Spectra
- 14. Interpretation of Mass Spectra
- 15. Interpretation of NMR Spectra

# II. Demo/ Work Shop

- 1. Demonstration of UV instrumentation of single and double beam spectrophotometer.
- 2. Demonstration of IR instrumentation including KBr pressed pellet technique, ATR, liquid film technique.

# III. Seminar/Assignment/Group Discussion

- 1. Determination of two drugs simultaneously by using UV spectrophotometer.
- 2. Reagent mechanisms: Ninhydrin, FC, MBTH, PDAC, PDAB (at least two)

# LIST OF MINIMUM INSTRUMENTS/EQUIPMENTS REQUIRED

- 1. Fluorimeter
- 2. UV-Spectrophotometer
- 3. Digital balance
- 4. IR Spectrometer
- 5. Digital Colorimeter
- 6. Flame photometry
- 7. Hot air oven
- 8. Adequate glassware

# **REFERENCES:**

- 1. Monographs: Indian Pharmacopoeia, British Pharmacopoeia, United States of Pharmacopoeia, European Pharmacopoeia, Japanese Pharmacopoeia.
- 2. AH Beckett & Stenlake, Text book of Practical Pharmaceutical chemistry, Vol. II Continum International Publishing Group, Althone.
- 3. Martindale: The Complete Drug Reference. 34<sup>th</sup> and 35<sup>th</sup> editions.

Subject	BIOPHARMACEUTICS AND PHARMACOKINETICS LABORAOTORY	Code	15R00610
Course Year	B. Pharmacy III year	Sem	II
Lab	4hrs/week	Tutorial	Nil
End exam	70 Marks	Internal	30Marks
		exam	
Credits	2		

**Scope:** This subject will provide an opportunity for the student to learn about the Biopharmaceutics and pharmacokinetic.

### Objective:

- The course is designed to analysis of biological samples for drug content.
- The course helps to estimation of the pharmacokinetic parameters.

### Outcomes:

- 1. Graduate will acquire knowledge on analysis of biological samples for drug content.
- 2. Able to calculate the pharmacokinetic parameters based on plasma level-time data & urine data.
- 3. Understand the statistical treatment of pharmaceutical data.

### I. EXPERIMENTS

- 1. Analysis of biological samples for drug content and estimation of the pharmacokinetic parameters.
- 2. In vitro evaluation of tablet/capsule for drug release
- 3. Drug-protein binding studies.
- 4. Statistical treatment of pharmaceutical data.
- 5. Problems related to pharmacokinetics determination of PK Parameters
- 6. Problems related to bioavailability and bioequivalence.

### II. DEMO/ WORKSHOP

- 1. Absorption studies *in vitro*.
- 2. Experiments designed for the estimation of various pharmacokinetic parameters.

### III. SEMINAR/ASSIGNMENT/GROUP DISCUSSION

Chronopharmacokinetics.

### Text Books:

- 1. L. Shargel and ABC Yu, textbook of applied biopharmaceutics & Pharmacokinetics, 4th edn, Appleton centuary crofts, Connecticut, 2004.
- 2. Milo Gibaldi, Biopharmaceutics and clinical pharmacokinetics 4/Edn. Pharma BookSyndicate.Hyderabad.
- 3. DM Brahmankar and SB Jaiswal, biophamaceutics and pharmacokinetics- a treatise, vallabh prakasham, Delhi.

# Reference Books:

- Ronald & trouser. Clinical pharmacokinetics concepts & applications. 3rd ed, wolterskluwer Pvt Ltd., 2007.
- 2. Robert E notary, Biopharmaceutics and pharmacokinetics an introduction, marcel dekker inc., NY
- 3. Basic pharmacokinetics by Hedaya, CRC press.

B. Pharmacy III-II Sem.

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### 15A52602 ADVANCED ENGLISH LANGUAGE COMMUNICATION SKILLS (AELCS) LAB (Audit Course)

### 1. INTRODUCTION

With increased globalization and rapidly changing industry expectations, employers are looking for the wide cluster of skills to cater to the changing demand. The introduction of the Advanced Communication Skills Lab is considered essential at 3<sup>rd</sup> year level. At this stage, the students need to prepare themselves for their careers which may require them to listen to, read, speak and write in English both for their professional and interpersonal communication in the globalised context.

The proposed course should be a laboratory course to enable students to use 'good' English and perform the following:

- Gathering ideas and information and to organise ideas relevantly and coherently.
- Engaging in debates.
- Participating in group discussions.
- Facing interviews.
- Writing project/research reports/technical reports.
- Making oral presentations.
- Taking part in social and professional communication.

# 2. OBJECTIVES:

This Lab focuses on using multi-media instruction for language development to meet the following targets:

- To improve the students' fluency in English, through a well-developed vocabulary and enable them to listen to English spoken at normal conversational speed by educated English speakers and respond appropriately in different socio-cultural and professional contexts.
- Further, they would be required to communicate their ideas relevantly and coherently in writing.
- To prepare all the students for their placements.

# 3. SYLLABUS:

The following course content to conduct the activities is prescribed for the Advanced English Communication Skills (AECS) Lab:

### UNIT-I: COMMUNICATION SKILLS

- 1. Reading Comprehension
- 2. Listening comprehension
- 3. Vocabulary Development
- 4. Common Errors

# UNIT-II: WRITING SKILLS

- 1. Report writing
- 2. Resume Preparation
- 3. E-mail Writing

### UNIT-III: PRESENTATION SKILLS

- 1. Oral presentation
- 2. Power point presentation
- 3. Poster presentation

# UNIT-IV: GETTING READY FOR JOB

- 1. Debates
- 2. Group discussions
- 3. Job Interviews

# UNIT-V: INTERPERSONAL SKILLS

- 1. Time Management
- 2. Problem Solving & Decision Making
- 3. Etiquettes

### 4. LEARNING OUTCOMES:

- Accomplishment of sound vocabulary and its proper use contextually
- Flair in Writing and felicity in written expression.
- Enhanced job prospects.
- Effective Speaking Abilities
- 5. MINIMUM REQUIREMENT:

The Advanced English Communication Skills (AECS) Laboratory shall have the following infra-structural facilities to accommodate at least 60 students in the lab:

- Spacious room with appropriate acoustics.
- Round Tables with movable chairs
- Audio-visual aids
- LCD Projector
- Public Address system

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- P IV Processor, Hard Disk 80 GB, RAM–512 MB Minimum, Speed – 2.8 GHZ
- T. V, a digital stereo & Camcorder
- Headphones of High quality

# 6. SUGGESTED SOFTWARE:

The software consisting of the prescribed topics elaborated above should be procured and G

- 1. Walden Infotech: Advanced English Communication Skills Lab
- 2. K-VAN SOLUTIONS-Advanced English Language Communication Skills lab
- 3. DELTA's key to the Next Generation TOEFL Test: Advanced Skills Practice.
- 4. TOEFL & GRE( KAPLAN, AARCO & BARRONS, USA, Cracking GRE by CLIFFS)
- 5. Train2success.com

# 7. BOOKS RECOMMENDED:

- 1. **Objective English for Competitive Exams**, Hari Mohana Prasad, 4<sup>th</sup> edition, Tata Mc Graw Hill.
- Technical Communication by Meenakshi Raman & Sangeeta Sharma, O U Press 3<sup>rd</sup> Edn. 2015.
- 3. Essay Writing for Exams, Audrone Raskauskiene, Irena Ragaisience & Ramute Zemaitience, OUP, 2016
- 4. Soft Skills for Everyone, Butterfield Jeff, Cengage Publications, 2011.
- 5. **Management Shapers Series** by Universities Press (India) Pvt Ltd., Himayatnagar, Hyderabad 2008.
- 6. Campus to Corporate, Gangadhar Joshi, Sage Publications, 2015
- 7. Communicative English, E Suresh Kumar & P.Sreehari, Orient Blackswan, 2009.
- 8. English for Success in Competitive Exams, Philip Sunil Solomon OUP, 2015

Subject	NOVEL DRUG DELIVERYSYSTEMS	Code	15R00701
Course year	B. Pharm IV year	Semester	I
Theory	3 hrs/week	Tutorial	1hr/week
End exam	70 marks	Internal	30 marks
		exam	
Credits	3		

**Scope**:The novel drug delivery systems course provide the knowledge about various novel and targeted systems- formulation, evaluation and applications

**Objectives:** To learn the novel technologies in drug delivery systems **Outcomes:** Student must able to formulate the drug delivery systems for drugs.

### UNIT I

Concepts of controlled release, sustained release, extended release, timed release and delayed release.Rationale behind the design of above delivery systems. Factors influencing the design and performance of sustained and controlled release dosage forms.

### UNIT II

**Oral Control Drug Delivery Systems:** Fundamentals, Dissolution Controlled, Diffusion Controlled, Ion Exchange Resins, Osmotic based systems, pH Independent Systems, altered density systems and use of polymers in controlled drug delivery.

### UNIT III

**Targeted Drug Delivery Systems:** Fundamentals and applications, formulation and evaluation of nano particles, resealed erythrocytes and liposomes and niosomes.

### UNIT IV

**Transdermal Drug Delivery Systems:** Fundamentals, permeation of drugs across the skin, types ofTDDS, Materials employed and Evaluation of TDDS.

### UNIT V

**Mucoadhesive Delivery Systems**: Mechanism of bioadhesion, mucoadhesive materials, formulationand evaluation of Buccal and Nasal drug delivery systems.

- 1. Robinson JR and Vincent HL lee. Controlled drug delivery fundamentals and applications, 2ed, marcel dekker 2005.
- 2. YiewChien, Novel drug delivery systems, 2<sup>nd</sup>ed, marcel dekker 2003.

# Reference Books:

- 1. N.K. Jain, Advances in Control & Novel drug delivery, CBS Publishers.
- 2. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences
- 3. E.ARawlkins, Bentley"s Text Book of Pharmaceutics, Elbspubl

Subject	PHARMACOLOGY – III	Code	15R00702
Course Year	B.Pharmacy IVyear	Sem	Ι
Theory	3hrs/week	Tutorial	1hr/week
End exam	70 Marks	Internal	30Marks
		exam	
Credits	3		

**Scope:** This subject will provide an opportunity for the student to learn pharmacological information about the drugs. In this subject drugs acting on gastrointestinal system, chemotherapeutic agents, principles of toxicology and bioassays will be taught.

**Objectives:** Upon completion of the subject student shall be able to Understand various pharmacological aspects like mechanism of action, pharmacokinetics, sideeffects,druginteractions,contraindications and indications of drugs falling under below mentioned chapters.

### Outcomes:

- a. Correlate and apply the knowledge.
- b. Handle the animals and carry out the experiments on animals
- d. Understand the chemotherapy of various diseases

### UNIT I.Drugs acting on the gastrointestinal tract

- a. Anti-ulcers Drugs
- b. Laxatives and anti-diarrhoeal drugs
- c. Emetics and anti-emetics
- d. Appetite Stimulants and Suppressants

### UNIT II. Chemotherapeutic agents and their applications

- a. General principles of chemotherapy.
- b. Sulphonamides, co-trimoxazole and  $\beta$ -lactam antibiotics
- c.Tetracyclines, aminoglycosides, chloramphenicol, macrolides, quinolones,

fluoroquinolones and polypeptide antibiotics

### UNITIII.

- a. Chemotherapy of tuberculosis & leprosy
- b. Chemotherapy of malignancy and immunosuppressive agents.

### UNIT IV.

- a. Chemotherapy of fungal and viral diseases
- b. Chemotherapy of protozoal diseases and helminticinfections

### UNITV. Principles of toxicology & Principles of bioassays.

- a. Definition of poison, general principles of treatment of poisoning
- b. Treatment of barbiturate, opiod, organophosphorous and atropine poisoning. Heavy metals and heavy metal antagonisits. LD<sub>50</sub>,ED<sub>50</sub> and therapeutic index
- c. Principles of bioassays and errors in bioassys.
- d. Study of bioassay methods for the following drugs
  i. Digitalis ii. d-tubocurarine, iii. Oxytocin iv. Insulin v. HCV

# Text Books:

- 1. H.P Rang, M. M. dale & J.M. Ritter, Pharmacology, Churchill living stone, 4<sup>th</sup> Ed.
- 2. J.G. Hardman and Lee E. Limbard, Good Mann & Gilmann, The Pharmacological basis of therapeutics, Mc Grawhill, Health Professions Dvn.
- 3. Illiterated Pharmacology by Lippincotts

# REFERENCES

- 1. Tripathi, Essentials of Medical Pharmacology, Jaypee Brother's, Latest Edition
- 2. Sathoskar, Pharmacology and pharmaco therapeutics Vol. 1 & 2, Publ by Popular Prakashan, Mumbai.

Subject	CLINICAL AND PHARMACY	HOSPITAL	Code	15R00703
CourseYear	B.Pharmacy IV year		Sem	1
Theory	3hrs/week		Tutorial	1hr/week
End exam	70 Marks		Internal	30Marks
			exam	
Credits	3			

Scope: To acquire the Knowledge about Clinical Procedures and study of case reports.

**Objectives:**Patient counseling and Dispensing of Drugs and identification of drug interactions in Prescriptions.

Outcomes: To council the patients about usage of drugs and drug interactions

### UNIT I

### Introduction to clinical pharmacy:

- a. Prospects and perspectives of clinical pharmacy in national and international scenario, scopeof clinical pharmacy
- b. Therapeutic Drug Monitoring.
- c. Clinical Pharmacokinetics and individualization of Drug Therapy.
- d. Concept of Essential Drugs and Rational Drug use.

### UNIT II

### Introduction to daily activities of Clinical pharmacist

- a. Drug therapy monitoring (Medication chart review)
- b. Adverse Drug Reactions & Drug Interactions
- c. Patient counseling
- d. Drug and poison information.
- e. Ward round participation.

### UNIT III

### Clinical laboratory tests and interpretation of test results.

- a. Hematological (complete blood picture)
- b. Pulmonary function tests
- c. Tests associated with cardiac disorders
- d. Liver, Renal function tests

### UNIT IV

### Hospital Management

Organization of a hospital and hospital pharmacy (drug store), responsibilities of a hospital pharmacist, pharmacy and therapeutic committee. Hospital formulary,

purchase and inventory control, role of Pharmacist in community health care and education.

### UNIT V

### Drug distribution and records

Procedural manual, drug distribution, dispensing to out-patients, in-patients and ambulatory patient dispensing of ancillary and controlled substances. Prescription filling, drug profile.

### Text Books:

- a. A Textbook of clinical pharmacy practice: Essential concepts and skills. Dr G Parthasarathiet al. Orient Longmannpvt Itd. ISSBN: 8125026
- b. Leon shargel, comprenhesive pharmacy review, Latest Edition
- c. Health Education and Community Pharmacy, Gupta AK, CBS, Publ. and Distributors New Delhi (2010).

### Reference Books:

- 1. J.G. Hardman and Lee E. Limbard, Good Mann & Gilmann, The Pharmacological basis of the rapeutics, Mc Grawhill, Health Professions Dvn.
- 2. Health Education and Community Pharmacy, NK Jain, CBS, Publ. and Distributors New Delhi.
- 3. Hospital pharmacy by Hassan.

Subject	MEDICINAL CHEMISTRY-II	Code	15R00704
CourseYear	B.Pharmacy IV year	Sem	I
Theory	3hrs/week	Tutorial	1hr/week
End exam	70 Marks	Internal	30Marks
		exam	
Credits	3		

**Scope:** This subject will provide an opportunity for the student to learn medicinal chemistry information about the drugs. In this subject student will be able to understand the properties and its biological activity of the drugs.

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

- 1. Understand various drugs structure, their properties and biological activities.
- 2. Correlate and apply the knowledge.
- 3. Influence of chemical structure on biological activities.

### Outcomes:

- 1. Acquire skill in the structure of drugs and their biological activities.
- 2. Acquire the knowledge of synthesis of chemical compounds.
- 3. Assay of some official compounds.

### UNIT I

**Drugs acting on renal system Renin-Angiotensin system inhibitors:** Captopril\*, Enalapril\*, Losartan\*.

**Diuretics:** Acetazolamide, Hydrochlorthiazide\*, Furosemide\*, Ethacrynic acid\*, Spironolactone, Amiloride, Triamterene and Mannitol. SAR- Carbonic anhydrase inhibitors, Thiazides, Loop diuretics.

### UNIT II

### Drugs acting on CVS

Anti anginal agents & vasodilators: Nitroglycerin\*, Isosorbide dinitrate\*. Ion channel blockers- Verapamil, Diltiazem, Nifedipine, Amlodipine\*.

Antithrombotic agents- Aspirin, Dipyridamole, Clopidogrel\*

**Antiarrhythmic drugs:** Quinidine, Procainamide\*, Lidocaine, Mexiletine\*, Amiodarone, Sotalol.

**Antihypertensive agents**: classification, Reserpine, Prazosin, Clonidine, Hydralazine, Sildenafil citrate, Minoxidil, Amrinone, SAR- beta-blockers.

Antihyperlipidemic agents: Fenofibrate\*, Dextrothyroxine, Colestipol, Nicotinic acid, ß-Sitosterol, Probucol, Ezetimibe, Simvastatin, Atorvastatin, Rosuvastatin. SAR-HMG CO-A inhibitors

# UNIT III

Drugs acting on Blood, hypoglycemic agents and thyroid.

Anticoagulants: Factors, Warfarin sodium\*, Dicumarol

**Synthetic hypoglycemic agents:**Tolbutamide\*, Tolazamide, Glipizide, Glimepiride, Gliclazide, Pioglitazone, Metformin\*, Miglitol.

Thyroid and antithyroid drugs: Levothyroxine, Liothyronine, Propylthiouracil.

# UNIT IV

# Analgesic, antipyretic and anti-inflammatory agents

**Opioids**:Morphine, Levorphanol, Pentazocine, Meperidine\*, Methadone, Tramadol\*, Buprenorphine. Opioid antagonist: Naltrexone, Naloxane, Methylnaltrexone.

**NSAIDs**: A note on prostaglandins and leukotrienes. Aspirin, Indomethacin, Sulindac\*, Ketorolac, Ibuprofen, Naproxen, Mefenamic acid, Diclofenac\*, Piroxicam, Celecoxib, Paracetamol\*.

Management of Gout and Hyperuricemia:, Allopurinol\*, Sulfinpyrazole.

Antimigraine drugs: Sumatriptan, SAR – Salicylates, Aryl propionic acids.

# UNIT V

**Antibiotics β- Lactams:** Penicillin G, Ampicillin\*, Amoxicillin. β- Lactamase inhibitors: Clavulanate potassium, Sulbactam.

**Cephalosporins:** Cephalexin\*, Cefixime. SAR-Penicillins and Cephalosporin **Aminoglycosides and Tetracyclines**: Streptomycin, Gentamicin, Tobramycin, Tetracycline, Doxycycline. SAR- Aminoglycosides and tetracyclines

**Macrolides and Lincomycins:** Erythromycin, Azithromycin, Clindamycin. **Miscellaneous:** Chloramphenicol,

**NOTE:** Introduction, definition, chemical classification with structure, nomenclature, synthesis (only for \* marked drugs), mechanism of action, SAR including stereo chemical aspects, metabolites (including its ADR) and therapeutic uses of the following classes of drugs from UNIT I to UNIT V.

# Text Books

- 1. William O. Foye, Textbook of Medicinal Chemistry, Lea Febiger, Philadelphia.
- 2. An Introduction to Medicinal Chemistry by Graham. L. Patrick, Oxford University publishers.

- JH Block & JM Beale (Eds), Wilson & Giswold stress took of organic Medicinal Chemistry and pharmaceutical chemistry, 11th Ed, Lipcolt, Raven, Philadelphia, 2004
- 4. Rama Rao Nadendla, Medicinal Chemistry; Mc Millan Publishers.

### **Reference Books:**

- 1. Hansch, Comprehensive medicinal chemistry, Vol 1 6 Elsevier pergmon press, Oxford
- 2. Abraham (Ed), Burger Medicinal chemistry and Drug discovery, Vol. 1 & 2. John Wiley & Sons, New York 2003, 6th Ed.
- 3. M. Atherden, Bentley and Driver<sup>\*\*</sup>s Textbook of Pharmaceutical Chemistry Ed: I.Oxford University Press, Delhi.
- Daniel lednicer, Strategies for Organic Drug Synthesis and Design, John Wiley, N. Y. 1998. 5. D. Lednicer, Organic drug synthesis, Vol, 1 – 6, J.Wiley N.Y.

Subject	CHEMISTRY OF NATURAL PRODUCTS (CBCC-II)	Code	15R00705
Courseyear	B. PharmIV year	Semest er	I
Theory	3 hrs/week	Tutorial	1hr/week
End exam	70 marks	Internal exam	30 marks
Credits	3		

Scope: To Study the Phytochemical evaluation and Synthesis of natural Products

**Objectives:** To identify the structure and screening of the natural products

**Outcomes:**Acquire the skills in determination of structure, mechanism of action and uses of Natural products.

### UNIT I

**Phytochemical Screening:** Preparation of extracts, screening of alkaloids, saponins, cardiac

glycosides,flavonoids,tanninsandanthraquinonesinplantextracts.ldentificationandesti mationof various phytoconstituents.

**Planttissueculture:** History, types, media requirements, methodology forestablishmentofcell cultures; growthmeasurements, viabilitymeasurementsandapplications. Micropropagation, immobilization, hairy root culture.

### Cosmeceuticals:

General introduction to cosmeceuticals, role of herbs in cosmetics. Study of the followingcosmeceuticals-Amla, Henna, Cyperus, SoapNut, AloeVera, Turmeric, SandalWood and Bitter Orange Peel.

**Neutraceuticals**:Definition, introduction and study ofGarlic, Spirulina, Soya and Royaljelly.

Introduction and importance of trade in herbal medicine, herbal cosmetics and Indian herbal drug industry.

### UNIT II

### General structural elucidation of natural products

Chemical methods for determination of active hydrogen, methoxy, hydroxyl, N-methyl and degradation (Hoffmann, Edmannetc) techniques for the determination of ring size. Structural elucidation ofEphedrine, Atropine,Morphine, Papaverine.

# UNIT III

# Alkaloids

Definitionofalkaloids, pseudoalkaloids and protoalkaloids. General methods of extraction, i solation, Properties and tests for alkaloids.

**Opiumalkaloids:** Structuralfeatures of Morphinemolecule – Peripheralgroups. Modification of structureand effecton analgesic activity– SAR of morphineand morphine-like analgesics.

**Narcotic antagonists:** Nalorphine, Levallorphan. Anti-tussiveagents: Noscapine, Dextromethorphan.

Smoothmusclerelaxants:Papaverineandrelatedcompoundslikeethaverine,Dioxyline. Structures and usesof thesecompounds.

**Tropanealkaloids:**Structures of Atropine/hyoscyamine, Hyoscine, Hydrolytic products of these–Tropine and Scopine. Relationship between tropine&pseudotropine. Biological actions and usesof tropanealkaloids.Homatropine.

Rauwolfiaalkaloids:Structures and uses of Reserpine, Rescinnamine, Deserpidine,<br/>ajmaline, syrosingapine.Hydrolysisofreserpineandrescinnamine.Mechanismofaction of reserpine.Hechanismofaction of reserpine.HechanismofactionHechanismofaction

**Ergotalkaloids:**Classification,structures,hydrolyticproducts,pharmacologicalactions,t herapeutic uses andtoxicity. Synthetic derivatives: Methyl ergonovine(Methyl ergometrine), LSD, Ethysergide.

# UNIT IV

# Terpenes&Terpenoids:

Introduction to Volatile oils, terpene vs terpenoids, Classification, isoprene, special isoprene and gem- dialkyl rules. Sources and structures, general extraction procedure for Citral, citral-a (Geranial), citral-b (Neral). Alpha-terpeniol, Carvone, Menthol, Menthone, 1,8- Cineole, Camphor. Chemical transformation and interconversion of citral to citronellal, citronellol, geraniol, nerol, geranicacid, p-cymene, alfa-terpeneolandionones.Conversionandinterconversion ofcamphorintocamphoricacid,camphoronicacids, p-cymene, Borneol,isoborneol.

# UNIT V

**Steroids:** Introduction, nomenculature and classification of steroids. Stereochemistry of Cholesterol. Uses of Bile acids, steroidal hormones. Different Sources of steroidal drugs like diosgenin, cholesterol, stigmasterol and ergosterol.

Synthetic oestrogens like diethylstilbosterol, hexosterol,17-alphaethinyloestradiol, Interconversions of Estrone, Estriol,Estradiol.Chemistryofketoandnonketoadrenocorticoids.Anoteonanabolic steroids (Structures and uses).

**Cardiac glycosides:** Structures of glycosides from Digitalis, Strophanthus, SquillandBufa. Enzymatic andacid hydrolytic reactions of the glycosides. Mechanismofaction, SAR,therapeutic usesand toxicity.

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### TextBooks:

- 1. IL Finar, Organicchemistry, Vol. 1 &2, the Englishlanguagebooksociety, London, NewDelhi.
- 2. O.P. Agarwal, Naturalproductsby. Vol.1 &2, Goelpublications- Meerut.
- 3. Kokate CK, PurohitA.P. &Gokhale;PharmacognosyNiraliPrakashan, New Delhi.

# ReferenceBooks:

- 1. RTMorrison and R.NBoyd, Organic chemistry, AllynandBacon, inc., boston
- 2. Me-Wolf,ed., Burger"smedicinalchemistry, J. Wiley&sons, NY.
- 3. F.G. Mann &B. Saunders, Practical Organic chemistry Longmansgreen & Co. Ltd., UK.

Subject	COMPUTER AIDED DRUG DESIGN (CBCC- II)	Code	15R00706
CourseYear	B.Pharmacy IV year	Sem	1
Theory	3hrs/week	Tutorial	1hr/week
End exam	70 Marks	Internal	30Marks
		exam	
Credits	3		

#### **Objectives:**

- 1. CADD course covers the key areas of computational chemistry methods as applied to the modelling of biological processes and to rational drug design, building on students' knowledge of theoretical chemistry.
- 2. This course also deals with cheminformatics, relations between thermodynamic properties and protein-ligand binding by structure.

### Outcomes:

- 1. Describe the use of lead candidates and database representations
- 2. Explain the drug development pipeline and understand where computational chemistry fits in chemistry
- 3. Apply how to use software in structure prediction, ligand design methods, docking programs etc.,

### UNITI

Introduction to computer aided drug design: Introduction, types of enzyme inhibition, how drugs are discovered, and the basics of mechanistic drug design, important techniques UNITII

**Uses of computer graphics in computer aided drug design:** Computer graphics displays, Computed molecular models, Molecular modeling systems for drug design, uses of computer-assisted drug design, extending molecular modeling.

### UNITIII

**Molecular mechanics and molecular dynamics:**Potential energy function,Nonbonded energy terms, electrostatic energy, hydrogen bonds, energy minimization, applications of theoretical techniques to drug design.

### UNITIV

### Computer-Aided Drug Design

EARLY METHODS: Statistical Prediction of Pharmacological Activity, Molecular descriptors based on lipophilicity (Partition coefficient 'logP', substituent hydrophobicity

constant ' $\pi$ '), polarizability (Molar refractivity, Molar volume), steric (Taft's Steric Factor 'Es', Charton's steric parameter r<sub>v</sub>, Verloopparameters), electrostatics (Hammet substitution constant ' $\sigma$ ', ionization 'pKa') and quantum mechanical (Partial atomic charges, dipolemoment, HOMO/LUMO)

NEWER METHODS: Forces Involved with Drug–Receptor Interactions, Optical Isomerism and Biological Activity, conformational analysis, Comparative/Homology modeling, Molecular Docking, Pharmacophore modeling, Quantitative Structure–Activity Relationships, Structural alerts, Database Searching and Mining, Isosterism.

# UNITV

Inhibitors of Dihydrofolate Reductase: The enzyme, enzyme – inhibitor interactions, inhibitor design. Approaches to antiviral drug design: Rhinovirus as a drug receptor, Designing Antiviral drugs. Conformational Biological activity relationships for Receptor-selective, conformationally constrained Opoid peptides: Design of conformationally constrained Delta and  $\mu$  Opoid Receptor-selective peptides, Problems and prospects for rational design of Receptor-selective peptides.

### Text Books:

- 1. **Computer aided drug design** Methods and Applications by Thomas J.Perun, C.L. Propst; Marcel Dekker, 2010.
- Wilson and Gisvold'sText book of Organic Medical and Pharmaceutical Chemistry by John M. Beale, John H. Block; Lippincott Williams & Wilkins, 12<sup>th</sup> Edition, 2011.
- 3. **Molecular Modelling: Principles and Applications** by Andrew R. Leach, Published by Pearson Education EMA, January 2001.

Subject	PHARMACOVIGILANCE (CBCC- II)	Code	15R00707
CourseYear	B.Pharmacy IV year	Sem	1
Theory	3hrs/week	Tutorial	1hr/week
End exam	70 Marks	Internal	30Marks
		exam	
Credits	3		

**Scope:** To study Adverse effects and monitoring of adverse Drug Reactions **Objectives:** To Identify the Adverse drug reactions and surveillance of Reports. **Outcomes:** Should have the Knowledge about the terminology of adverse medication related events, roles and responsibilities in Pharmacovigilance.

### UNIT –I

### Introduction to Pharmacovigilance

- History and development of Pharmacovigilance
- Importance of safety monitoring / Why Pharmacovigilance

### National and international scenario

- Pharmacovigilance in India
- Pharmacovigilance global perspective
- WHO international drug monitoring programme

### UNIT –II

### Basic terminologies used in Pharmacovigilance

- Terminologies of adverse medication related events
- Information resources in Pharmacovigilance

### Establishing Pharmacovigilance programme

- Establishing in a hospital
- Establishment & operation of drug safety department in industry
- Establishing a national programme
- SOPs Types, designing, maintenance and training
- Roles and responsibilities in Pharmacovigilance
- Licence Partners, Contract Research Organisations (CROs) and Market Authorisation Holders (MAH)

### UNIT –III

- Pharmacovigilance methods
- Passive surveillance Spontaneous reports and case series
- Stimulated reporting
- Active surveillance Sentinel sites, drug event monitoring and registries
- Comparative observational studies Cross sectional study, case control study and cohort study

### UNIT –IV

- Adverse drug reaction reporting
- Introduction to reporting systems
- Spontaneous reporting system
- Reporting to regulatory authorities
- Guidelines for reporting ADRs in biomedical literature

### UNIT –V

- Communication in Pharmacovigilance
- Effective communication in Pharmacovigilance
- Communication in Drug Safety Crisis management
- Communicating with Regulatory Agencies, Business Partners, Healthcare facilities &Media, Doctor Letters to Healthcare Professionals

### TEXTBOOKS

- 1. Textbook of Pharmacovigilance by S.K. Gupta, Jaypee brothers.
- 2. Pharmacovigilance by Ronald D. Mann, Elizabeth B.Andrews, 2<sup>nd</sup> edition.

Subject	NOVEL DRUG DELIVERY SYSTEMS LABORATORY	Code	15R00708
Course year	B. Pharm IV year	Semester	1
Lab	4 hrs/week	Tutorial	NIL
End exam	70 marks	Internal	30 marks
		exam	
Credits	2		

**Scope:** This subject will provide an opportunity for the student to learn about preparation and evaluation of Novel Drug Delivery Systems.

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

- a. Understand various Novel Drug delivery systems and their preparations.
- b. Provide knowledge on filing of various regulatory agencies.

#### Outcomes:

- 1. Acquire skil, l in preparation and evaluation of variousNovel formulations.
- 2. Acquire the knowledge of Product development and filing to various regulatory agencies.

### I. EXPERIMENTS:

- 1. Preparation and evaluation of Matrix Tablets
- 2. Prepartion and evaluation of Transdermal Drug Delivery Systems.
- 3. Formulation and evaluation of Mucoadhesive Delivery Systems.
- 4. Evaluation of Market Sustained Release Formulations.
- 5. Preparation and evaluation of microspheres.
- 6. Assignment on Product development and filing to various regulatory agencies, FDA, TGA.Etc (Ref.: www.fda.gov)

### II. Demo/ Workshop

Floating drug delivery system.

### III. SEMINAR/ASSIGNMENT/GROUP DISCUSSION

Advances in novel drug delivery.

# Text Books:

- 1. N.K. Jain, Advances in Control & Novel drug delivery, CBS Publishers.
- 2. NK Jain, Pharmaceutical product development, CBS publishers.
- 3. L. Lachman, H.A, Lieberman and J.L. Kanig, Theory & Practice of industrial pharmacy by, Lea & Febieger, Philadelphia Latest Edn.

# Reference Books:

- 1. Gilbert S. Banker and Christopher T Rhodes, Modern Pharmaceutics, IVthed, marcel dekker, usa, 2005.
- 2. Controlled drug delivery systems by Robinson.
- 3. YiewChien, novel drug delivery systems, 2<sup>nd</sup>ed, marcel dekker 2003.

Subject	CLINICAL AND HOSPITAL PHARMACY LABORATORY	Code	15R00709
Course year	B. Pharm IV year	Semester	1
Lab	4 hrs/week	Tutorial	NIL
End exam	70 marks	Internal	30 marks
		exam	
Credits	2		

**Scope:** This subject will provide an opportunity for the student to learn about various parental preparations.

**Objectives:** Upon completion of the subject student shall be able to Underst and various Sterilization techniques and parenteral preparations. Provide knowledge on Role of Pharmacist in patient counseling.

### Outcomes:

- 1. Acquire skill in preparation parenteral Preparations.
- 2. Acquire the knowledge on First Aid treatment and improving patient Compliance.

### I. EXPERIMENTS:

- 1. Preparation of water for injection IP
- 2. Test for pyrogens on water for injection IP
- 3. Determination of suitability of NaCl for preparation of transfusion fluid by flame photometer
- 4. Hydrolytic resistance test on glass used for transfusion fluids
- 5. Preparation of 5% W/V dextrose IV infusion IP
- 6. Preparation of 0.9% W/V NaCl IV infusion IP
- 7. Preparation of Compound NaCl injection (Ringers solution) IP
- 8. Preparation of NaCl& dextrose injection IP
- 9. Preparation of sodium bicarbonate intravenous infusion BP
- 10. Determination of sinking time and water holding capacity of absorbent cotton wool IP
- 11. Demonstration: Sterilization of surgical instruments, syringes, needles, rubber gloves, hospital fabrics and surgical dressings

### II. ASSIGNMENT

- 1. Assignment 1: Study of role of pharmacist in first aid treatment
- 2. Assignment 2: Study of role of pharmacist in improving patient compliance

Subject	MEDICINAL CHEMISTRY-II LABORATORY	Code	15R00710
Course Year	B.Pharmacy IV year	Sem	1
Lab	4hrs/week	Tutorial	NIL
End exam	70 Marks	Internal	30 Marks
		exam	
Credits	2		

**Scope:** This subject will provide an opportunity for the student on synthesis of various compounds.

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

- c. Synthesis various chemical compounds.
- d. Provide knowledge on monograph analysis of some chemical compounds.

### Outcomes:

- 1. Acquire skills in synthesis various chemical compounds.
- 2. Demonstrate of stereo models of some drugs relevant to theory.
- 3. Acquire skills of extraction of drugs from different dosage forms.

### EXPERIMENTS:

- 1. Synthesis of Paracetamol from p-amino phenol
- 2. Synthesis of Cinnamic acid from benzaldehyde
- 3. Synthesis of Benzotriazole from o-phenylene diamine
- 4. Synthesis of 1-phenyl-3-methyl-5-pyrazolone from hydrazine hydrate
- 5. Synthesis of 7-Hydroxy-4-methyl coumarin from resorcinol and ethyl acetoacetate
- 6. Synthesis of Salicylaldehyde from phenol
- 7. Identification and test for purity for Aspirin tablet as per IP
- 8. Identification and test for purity for Acetazolamide tablet as per IP
- 9. Identification and test for purity for propranolol tablet as per IP
- 10. Identification and test for purity for Diclofenac sodium tablet as per IP
- 11. Identification and test for purity for Paracetamol tablet as per IP

**II. DEMO/WORKSHOP**: Microwave assisted organic synthesis, Purification of synthesized compounds (Column chromatography), Demo on Thin layer chromatography.

III. SEMINAR/ASSIGNMENT/GROUP DISCUSSION Antibiotic discovery in the twentyfirst century: Current trends and future perspectives, Current Trends in  $\beta$ -Lactam based  $\beta$ -Lactamase inhibitors and CVS agents.

# References:

1. A.I. Vogel, Text Book of Practical Organic Chemistry, 5th Edition. Pearson, Prentice Hall.

2. F.G. Mann & B.C. Saunders, Practical Organic Chemistry, 4th Edition, Pearson Publishers.

# LIST OF MINIMUM EQUIPMENTS REQUIRED

- 1. Water bath
- 2. Suction pumps
- 3. Analytical/physical balance
- 4. Triple beam balance
- 5. Reflux flask with condenser
- 6. Hot plates
- 7. Refrigerator
- 8. Mechanical and magnetic stirrer with thermostat
- 9. Distillation unit
- 10. Oven
- 11. Adequate glass wares

Subject	MOOCS -II (Biostatistics and Design of Experiments) / Conventional/ Self study	Code	15R00801
Course Year	B.Pharmacy IV year	Sem	Ш
Lab	3hrs/week	Tutorial	1hr/week
End exam	70 Marks	Internal exam	30 Marks
Credits	3		

**SCOPE:** Biostatistics is the application of statistics to different topics in biology including medicine, pharmacy, public health science, agriculture and fishery. It involves the analysis of data from experiments; its interpretation and drawing conclusion from the results. It involves the application of statistical theory to real-world problems, the practice of designing and conducting biomedical experiments and clinical trials. Design of experiments is planning experimental strategy, screening a large number of parameters and selecting the important ones, determining the minimum number of experiments and deciding on the mode and manner in which experiment have to be conducted. The course encompasses topics such as distribution of data, sample size, tests of significance, data reduction, regression analysis, comparison of performance of drugs in clinical trials, design of experiments, screening and second order designs.

#### UNIT I

Introduction to Statistics

Various Distributions: Normal Distribution, sample and Population, Z distribution.

#### UNIT II

Test of Significance, t- test, F test, ANOVA.

#### UNIT III

2 test/odds ratio, Non-Parametric test, other tests.

#### UNIT IV

Design of Experiments: Introduction to design of experiments, screening designs – Data Analysis.

#### UNIT V

Higher order Designs - Data analysis Regression Analysis – Data reduction

### **REFERENCES**:

- 1. 'Biostatistics', KS Negi, AITB Publishers, Delhi.
- 2. 'Fundamentals of Biostatistics', Irfan Ali Khan, Ukaaz Publications
- 3. 'Biostatistics for Pharmacy', Khan and Khanum, Ukaaz Publications
- 4. 'Basic statistics and Pharmaceutical applications', J.E, Demuth, Mercel & Dekker.
- 5. 'Applied statistics' by S.C.Gupta &V.K.Kapoor
- 6. 'Fundamentals of mathematical statistics' by S.C.Gupta & V.K.Kapoor

NPTEL: http://nptel.ac.in/courses/102106051/

Subject	MOOCS – III (Intellectual Property Rights) / /Conventional/ Self study	Code	15R00802
Course Year	B.Pharmacy IV year	Sem	II
Lab	3hrs/week	Tutorial	1 hr/week
End exam	70 Marks	Internal	30 Marks
		exam	
Credits	3		

**SCOPE:** The course is designed to introduce fundamental aspects of Intellectual property Rights to students who are going to play a major role in development and management of innovative projects in industries. The course introduces all aspects of the IPR Acts. It also includes case studies to demonstrate the application of the legal concepts in Science, Engineering, Technology and Creative Design.

### UNIT I

### OVERVIEW OF INTELLECTUAL PROPERTY

Introduction and the need for intellectual property right (IPR), IPR in India – Genesis and Development, IPR in abroad, Some important examples of IPR

### UNIT II

### PATENTS AND UTILITY MODELS

**PATENTS:** Patent document, searching a patent, Drafting of a patent, Filing of a patent Macro-economic impact of the patent system, Patent and kind of inventions protected by a patent, Granting of patent, Rights of a patent Protecting your inventions – extension in patent protection The different layers of the international patent system (national, regional and international options)

**UTILITY MODELS:** Differences between a utility model and a patent, Trade secrets and know-how agreements.

### UNIT III

### COPYRIGHTS, TRADEMARKS AND GEOGRAPHICAL INDICATIONS

**COPYRIGHTS:** Copyright, things covered by copyright, period of copyright, Rights covered by copyrights and protection of copyrights.

**RELATED RIGHTS:** Related rights, Distinction between related rights and copyright **TRADEMARKS:** Trademark –Rights, kind of signs, types and function of trademarks Registration, period, extension and protection of trademark.Well-known marks and their protection, Domain name and its relation to trademarks.

### **GEOGRAPHICAL INDICATIONS**

Geographical indication - its protection, reasons for protection

### UNIT IV

### INDUSTRIAL DESIGNS AND NEW PLANT VARIETIES

**INDUSTRIAL DESIGNS**: Protection, kinds of protection, needs for protection **NEW PLANT VARIETIES**: New varieties of plants – protection and extension Breeder – Rights and protection

### UNIT V

**UNFAIR COMPETITION AND ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS UNFAIR COMPETITION:** Unfair competition, Relationship between unfair competition and intellectual property laws.

**ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS:** Infringement of intellectual property rights, Enforcement Measures and Emerging Issues in Science and technologies.

Overview of Biotechnology and Intellectual Property Rights in Biotechnology Research. Management - Licensing and Enforcing Intellectual Property, Commercializing Biotechnology Invention and Case studies of Biotechnology. Case studies of patents in other areas – Pharmaceutical Research

# TEXT BOOKS

1. T. M Murray and M.J. Mehlman, Encyclopedia of Ethical, Legal and Policy issues in Biotechnology, John Wiley & Sons 2000

# REFERENCES

- 1. P.N. Cheremisinoff, R.P. Ouellette and R.M. Bartholomew, Biotechnology Applications and Research, Technomic Publishing Co., Inc. USA, 1985
- 2. D. Balasubramaniam, C.F.A. Bryce, K. Dharmalingam, J. Green and K. Jayaraman, Concepts in Biotechnology, University Press (Orient Longman Ltd.), 2002
- 3. Bourgagaize, Jewell and Buiser, Biotechnology: Demystifying the Concepts, Wesley Longman, USA, 2000.
- 4. AjitParulekar and Sarita D' Souza, Indian Patents Law Legal & Business Implications; Macmillan India Ltd , 2006.
- 5. B.L.Wadehra; Law Relating to Patents, Trade Marks, Copyright, Designs & Geographical Indications; Universal law Publishing Pvt. Ltd., India 2000
- 6. P. Narayanan; Law of Copyright and Industrial Designs; Eastern law House, Delhi , 2010

NPTEL: http://nptel.ac.in/syllabus/syllabus.php?subjectId=110999906