

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**  
**B.PHARM. IV YEAR COURSE STRUCTURE & SYLLABUS (R16)**

**Applicable From 2016-17 Admitted Batch**

**IV Year I Semester**

S. No.	Course Code	Course Title	L	T	P	Credits
1	PS701	Pharmaceutical Analysis – II	4	1	0	4
2	PS702	Biopharmaceutics and Pharmacokinetics	4	1	0	4
3	PS703	Pharmacology - III	3	1	0	3
4	PS704	Medicinal Chemistry – II	4	1	0	4
5	HS705	Pharmacy Administration	3	1	0	3
6	PS706	Pharmaceutical Analysis – II Lab	0	0	3	2
7	PS707	Biopharmaceutics and Pharmacokinetics Lab	0	0	3	2
8	PS708	Medicinal Chemistry – II Lab	0	0	3	2
9	PS709	Seminar and Industrial visit	0	0	2	1
		<b>Total</b>	<b>18</b>	<b>5</b>	<b>11</b>	<b>25</b>

**IV Year II Semester**

S. No.	Course Code	Course Title	L	T	P	Credits
1	PS801	Novel Drug Delivery Systems	3	1	0	3
2	PS802	Clinical Pharmacy	3	1	0	3
3	PS803	Pharmaceutical Biotechnology	3	1	0	3
4	PS804	Pharmacognosy – III	3	1	0	3
5	PS805 PS806 PS807	<b>Open Elective - III</b> 1. Nano Technology 2. Pharmacoepidemiology, Pharmacoeconomics and pharmacovigilance 3. Medicinal Plant Biotechnology	3	1	0	3
6	PS808	Novel Drug Delivery Systems and Regulatory Affairs Lab	0	0	3	2
7	PS809	Pharmacognosy – III Lab	0	0	3	2
8	PS810	Major Project	0	0	10	5
		<b>Total</b>	<b>15</b>	<b>5</b>	<b>16</b>	<b>24</b>

**PS701: PHARMACEUTICAL ANALYSIS - II****B. Pharm IV Year I sem**

L	T	P	C
4	1	0	4

**Course Objectives:** The principles involved in the determination of various bulk drugs and formulations are discussed. Modern methods and instrumental techniques are applied in the study and analysis of pharmaceutical substances.

**Course Outcome:** The students are exposed to the modern instrumental techniques for the study of pharmaceuticals to a high level which would be useful for their future in academia and industry.

**UNIT - I**

- a. UV & Visible Spectrophotometry:** Introduction to Spectroscopy, Basic terminology – Chromophore, Auxochrome, Bathochromic shift, Hypsochromic shift, hyperchromic and hypochromic shift. UV & Visible Spectrophotometry: Principle, Theory, Beer-Lamberts Law & Deviations, Instrumentation – Single Beam and Double Beam Spectrophotometers, Applications, Woodward –Feiser rule.
- b. Fluorimetry:** Principle, Theory, Quenching, Instrumentation and applications.

**UNIT - II**

- a. Infrared Spectrophotometry (IR):** Introduction, principle, theory, types of vibrations, Instrumentation, Single and double beam spectrophotometer, sampling techniques, applications, basic principles in the interpretation of IR Spectra.
- b. Atomic Absorption Spectroscopy:** Principle, Theory, Instrumentation and applications.

**UNIT - III**

**Nuclear Magnetic Resonance Spectrophotometry (NMR) :** Basic Principle, theory, instrumentation, chemical shift, shielding and deshielding, relaxation processes, spin-spin splitting, applications, basic principles in the interpretation of NMR spectra.

**UNIT - IV**

**Mass Spectrometry:** Basic principle, theory, instrumentation and applications, basic principles in the interpretation of Mass Spectra.

**UNIT - V**

An Elementary study of the following:

- GC: Columns, Carrier gas and detectors used
- HPLC & HPTLC: Basic Principles
- Electrophoresis: Various types of Electrohoresis
- ORD Curves, RIA & ELISA: Basic principles

**TEXT BOOKS**

- R.M. Silvesterin and G.C. Bassler. Spectrometric Identification of Organic Compounds.
- AH Beckett & Stenlake, Text book of Practical Pharmaceutical chemistry, Vol.I&II
- AI Vogel, Quantitative Chemical Analysis.

**REFERENCES**

- Settle, Handbook of Instrumental Techniques for Analytical Chemistry.
- Y.Anjaneyulu & Maraiah, Quality Assurance & Quality Management in Pharmaceutical Industry.

**PS702: BIOPHARMACEUTICS AND PHARMACOKINETICS****B. Pharm IV Year I sem**

<b>L</b>	<b>T</b>	<b>P</b>	<b>C</b>
<b>4</b>	<b>1</b>	<b>0</b>	<b>4</b>

**Course Objectives:** This course is designed to impart fundamental knowledge of Biopharmaceutics and Pharmacokinetics. It also helps to know how the absorption distribution, metabolism, excretion takes place and bioavailability and bioequivalence parameters.

**Course Outcome:** The students shall be able to understand Bioavailability, Bioequivalence, Biopharmaceutical parameters, Pharmacodynamic and Pharmacokinetics of the drug. It also explains the ADME of the drug besides non-linear pharmacokinetics.

**UNIT - I**

- a) Introduction:** Definitions of Biopharmaceutics, Pharmacokinetics and Pharmacodynamics.  
**b) Drug Absorption.** Mechanisms of GI absorption, physico-chemical, biological and dosage form factors influencing absorption.

**UNIT - II**

**Drug distribution:** Factors of drug distribution, volume of distribution, protein binding – factors affecting and significance and kinetics of protein binding.

**UNIT - III**

- a) Drug Metabolism:** Pathways of drug metabolism. Phase-I (oxidative, reductive and hydrolytic reactions). Phase II reactions (conjugation) Enzyme induction and inhibition  
**b) 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 - IV****Bioavailability and bioequivalence**

Definitions, concept of equivalence, Definitions of various types of equivalence, types of Bioavailability studies, measurement of Bioavailability, plasma level and urinary excretion studies. Bioequivalence study design. Bioavailability testing procedure and protocol (CDSCO), Invitro – Invivo correlation of data

**UNIT - V**

**Pharmacokinetics:** Basic considerations, compartment modeling, one compartment open model - i.v. bolus and extra vascular administration, urinary excretion studies. Calculation of pharmacokinetic parameters, brief over view of nonlinear kinetics, noncompartmental models

**TEXT BOOKS**

1. Venkateshwarlu, Fundamentals of Biopharmaceutics and Pharmacokinetics, Pharma Book Syndicate.
2. Milo Gibaldi, Biopharmaceutics and clinical pharmacokinetics 4/Edn. Pharma Book Syndicate.Hyderabad
3. DM Brahmanekar and SB Jaiswal, biopharmaceutics and pharmacokinetics- a treatise, vallabh prakasham, Delhi.

**REFERENCES**

1. Remington's pharmaceutical sciences, Mac Pub. Co., Easton Pennsylvania.
2. Modern pharmaceuticals by banker Marcel Dekker Inc., NY

**PS703: PHARMACOLOGY – III****B. Pharm IV Year I sem**

<b>L</b>	<b>T</b>	<b>P</b>	<b>C</b>
<b>3</b>	<b>1</b>	<b>0</b>	<b>3</b>

**Course Objectives:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. The basic practical knowledge relevant to therapeutics will be imparted. This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

**Course Outcome :** Understand the pharmacological aspects of drugs, importance of pharmacology subject as a basis of therapeutics and correlate the knowledge therapeutically. Knowledge on experimental methodologies on various animal models is carried out. The pathophysiology of selected disease states and the rationale for drug therapy and the therapeutic approach to management of these diseases.

**UNIT - I****Drugs Acting on the Gastrointestinal Tract**

- a. Antacids, Antisecretory and Anti-ulcer Drugs
- b. Laxatives and antidiarrhoeal drugs
- c. Appetite Stimulants and Suppressants.
- d. Emetics and anti-emetics
- e. Miscellaneous; Carminatives, demulcents, protectives, adsorbents, astringents, digestants, enzymes and mucolytics.

**UNIT - II****Chemotherapeutic agents and their applications:**

- a. General principles of chemotherapy.
- b. Sulphonamides and co-trimoxazole.
- c. Antibiotics: Penicillins, cephalosporins, betalactams,
- d. Tetracyclines aminoglycosides, chloramphenicol, erythromycin,
- e. Quinolones and miscellaneous antibiotics.

**UNIT - III****Chemotherapy of following diseases**

- a. Tuberculosis
- b. Leprosy
- c. Urinary tract infections
- d. Fungal diseases
- e. Viral diseases,

**UNIT - IV**

- a. Antineoplastic agents
- b. Immunopharmacology: Immunosuppressants and Immunostimulants
- c. Antimalarial & Anti-protozoal agents
- d. Anti-filarial agents

**UNIT - V**

**Principles of Toxicology:** Definition of poison, general principles of treatment of poisoning with

particular reference to barbiturates opioids, organ phosphorous and atropine poisoning. Heavy metals and heavy metals antagonists, Diagnostic agents.

**TEXT BOOKS**

1. Tripathi, Textbook of Pharmacology, JAYPEE
2. F.S.K Barar, Essentials of Pharmacotherapeutics.
3. H.P Rang, M. M. dale & J.M. Ritter, Pharmacology, : Churchill Living stone, 4<sup>th</sup> Ed.

**REFERENCES**

1. Sathoskar, Pharmacology and pharmacotherapeutics Vol. 1 & 2, Publ by Popular Prakashan, Mumbai Crossland, Lewis 's Pharmacology, Church living stone
2. Mark A. Simmons, Pharmacology An Illustrated Review

**PS704: MEDICINAL CHEMISTRY – II****B. Pharm IV Year I sem**

<b>L</b>	<b>T</b>	<b>P</b>	<b>C</b>
<b>4</b>	<b>1</b>	<b>0</b>	<b>4</b>

**Course Objectives:** The drug discovery and design with respect to the lead molecules and its optimization is clearly discussed. The concept of CADD is also discussed. Sufficient information about various antibiotics and their chemotherapeutic agents are also studied in depth.

**Course Outcome:** The students would be in a position to participate in the community pharmacy activities with the knowledge they gained through the study of the various topics of the syllabus.

**UNIT - I****(a) Drug discovery and drug design.**

Introduction to discovery of lead molecule, lead optimization, pharmacophore identification, General structure activity relationship studies,

**(b) Computer aided drug design:** Introduction to CADD, Parameters in QSAR, Hansch analysis, Free Wilson analysis

**UNIT - II**

**a. Antibiotics:** Brief historical background, definition, classification of antibiotics.

Penicillins: Historical background and biological sources. Structures of different penicillins.

Reactions: Hydrolysis of penicillin by cold and hot dilute mineral acid, alkali, enzymatic hydrolysis with Pencillinase, amidase.

Classification: Oral and parenteral, based on spectrum of  $\beta$ ,  $\gamma$  – lactamase, as natural, biosynthetic and semi-synthetic.

General method of synthesis of penicillins from 6-APA, SAR, mechanism of action, therapeutic uses, toxicity.  $\beta$  –lactamase inhibitors.

**b. Cephalosporins:** Structures of some important compounds (Cephalosporins, Cephamecins. Cefadroxil, Cefoxitin. Acid hydrolysis of Cephalosporin C. Comparison of 6-APA and 7-ACA, penam and cepham.

Classification: Generations of cephalosporins, Oral and parenteral, SAR and Advantages over penicillins.

**UNIT - III**

**a. Tetracyclins:** Biological sources, structures of the important tetracyclins, important structural units and the three acidity constants in the tetracycline molecule, Amphoteric nature, mechanism of action, spectrum of activity, SAR and toxicity.

**b. Aminoglycosides:** Structure of streptomycin, acid hydrolysis, mechanism of action, therapeutic uses and toxicity. Dihydrostreptomycin and its importance and mention other aminoglycoside antibiotics.

A brief account of chloramphenicol and its synthesis, macrolide and polypeptide antibiotics and rifampicin (Structures not included).

**c. Quinoline type: Ciprofloxacin & norfloxacin**

**UNIT - IV****Chemotherapeutic Agents:**

**a. Sulphadruugs** : Sulphadiazine, Suphasalazine Trimethoprim, Sulphamethoxazole, Sulphameter

**b. Antifungal Agents** : Fluconazole and Itraconazole.

**c. Anti viral Drugs** : Acyclovir, Zidovudine

**d. Anti tubercular agents** : Isonicotinic acid hydrazide and ethambutol

- e. Anti leprotic agents** : Dapsone, clofazemine  
**f. Antiamoebics** : Metronidazole, diloxanide furoate  
**g. Anthelmintics** : Diethylcarbamazine citrate, pyrantel pamoate, mebendazole, Ibandazole  
**h. Antimalarial drugs** : Chloroquine, primaquine and pyrimethamine, norflaxacin and ciprofloxacin

#### UNIT - V

- a. Anticancer Drugs:** Chlorambucil, busulphan, procarbazine, carmustine, 5-fluorouracil, 5-mercaptopurine, methotrexate, vinca alkaloids – vinblastin, vincristine  
**b. Immunosuppressive agents.**  
Brief introduction to therapeutic agents developed from recombinant DNA technology  
**c. Diagnostic agents and radioprotective agents.**

#### TEXT BOOKS

1. William O. Foye, Textbook of Medicinal Chemistry, Lea & Febiger, Philadelphia.
2. JH Block & JM Beale, Wilson & Giswold's Text book of organic Medicinal Chemistry and pharmaceutical chemistry by (Eds), 11<sup>th</sup> Ed, Lipincott, Raven, Philadelphia, 2004.
3. S. N. Pandeya, Textbook of medicinal chemistry, SG Publ. Varanasi, 2003.

#### REFERENCES

1. D. Abraham (Ed), Burger Medicinal chemistry and Drug discovery, Vol. 1 & 2. John Wiley & Sons, New York 2003.
2. Rama Rao Nadendla, Medicinal Chemistry.

**HS705: PHARMACY ADMINISTRATION****B. Pharm IV Year I sem**

L	T	P	C
3	1	0	3

**Course Objectives:**

- To exposes the students, facets of business administration in the new economic environment.
- The manufacturing management.
- Social and behaviour aspects of pharmacy: Pharmaceutical outcomes, Pharmacoeconomics and Pharmacovigilance.

**Course Outcome:** At the end of the course, these students will be familiarized with the above all areas.

**UNIT - I****Features of Business Organisations & 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.

**UNIT - II**

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

**Work Study** –Basic procedure involved in Method Study and Work Measurement-Statistical Quality

Control:  $\bar{X}$  chart, R chart, c chart, p chart, (simple Problems), Acceptance Sampling, Deming's contribution to quality.

**UNIT - III**

**Social Pharmacy:** Social uses of drugs; Abuse of prescription drugs.

**Behavioral Pharmacy:** Compliance / Adherence to medications.

**Introduction to pharmacoeconomics:** Definitions of Efficacy; Comparative cost effectiveness ratios; Comparative Clinical Effectiveness and cost Benefit ratios.

**Pharmaceutical Outcomes (Quality of life concepts)**

History of Pharmaceutical out comes movements in India and abroad.

**Pharmaceovigilence / Pharmacoepidemiology:**

Present status in India; State and Central initiatives; Reporting of Adverse Drug Reactions; Prescribed format for reporting Adverse Drug Reactions; Irrational Drug Combinations, CDSCO: List of Drugs banned by Government of India and other State Governments.

**UNIT - IV**

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

**UNIT - V**

**Pharma Industry:** Growth of pharma industry in India – current status and its role in building national economy 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.



**TEXT BOOK**

1. Aryasri and Subbarao, Pharmaceutical Administration, TMH.
2. Smarta, Strategic Pharma Marketing.
3. Pharmaceutical Industrial Management by G.Vidya Sagar.

**REFERENCES**

1. Subbarao Chaganti, Pharmaceutal Marketing in India – Concepts and Strategy Cases, Pharma Book Syndicate.
2. Pharmacy administration by G. Vidya Sagar.

**PS706: PHARMACEUTICAL ANALYSIS – II LAB****B. Pharm IV Year I sem**

<b>L</b>	<b>T</b>	<b>P</b>	<b>C</b>
<b>0</b>	<b>0</b>	<b>3</b>	<b>2</b>

**List of Experiments**

1. Interpretation of IR Spectra of any two compounds.
2. Determination of  $\lambda_{\max}$  of few bulk drugs.
3. Assay of any two bulk drugs and their formulations by UV-spectro photometry.
4. Assay of any two bulk drugs and their formulations by Colorimetric method.
5. Assay of Quinine Sulphate by Fluorimetry
6. Ascending paper chromatography.
7. Radial paper chromatography.
8. Two dimensional paper chromatography
9. Thin layer chromatography.
10. Column chromatography
11. Determination of amino acids by Paper electrophoresis.
12. Gel electrophoresis (**Demonstration Only**).
13. HPLC (**Demonstration Only**).

**PS707: BIOPHARMACEUTICS AND PHARMACOKINETICS LAB****B. Pharm IV Year I sem**

L	T	P	C
0	0	3	2

**List of Experiments**

1. Estimation of various Pharmacokinetic parameters from the given data
2. Influence of dosage form on dissolution behaviour of same API
3. Influence of Physico-chemical properties (Particle size, salt form, crystalline form) on dissolution rate of drug substances.
4. Approaches to enhance the dissolution rate of drugs  
i.e., i) Cyclodextrin complexation  
ii) Inclusion of Hydrophilic polymers such as PVP, PEG.  
iii) Co-solvency
5. Absorption studies – invitro and invivo
6. Determination of rate of clearance
7. Statistical treatment of Pharmaceutical data i.e.,  
i) test ii) Chi-square test iii) ANOVA

**Reference book**

1. Dr. D. Dhachinamoorthi- Biopharmaceutical and Pharmacokinetic- A Practical Manual

**PS708: MEDICINAL CHEMISTRY – II LAB**

**B. Pharm IV Year I sem**

**L T P C**  
**0 0 3 2**

**Estimations of the following.**

1. Ascorbic acid.
2. Vitamin B1.
3. Penicillin.
4. Alkaloid (by gravimetry).
5. Ibuprofen by volumetric method
6. Aspirin by volumetric method
7. Metronidazole (antiprotozoal)
8. Ibuprofen (analgesic, antiinflammatory)
9. Furosemide (diuretic)
10. Isoniazid (anti tubercular)
11. Compound benzoic acid (anti fungal)

**REFERENCES**

1. Indian Pharmacopoeia.. – 1996, 4<sup>th</sup> Edition.
2. P.D.Sethi – Quantitative Analysis of Drugs and Pharmaceuticals.
3. B.G.Nagavi Lab Hand Book of Instrumental Drug Analysis.
4. Organic chemistry a Lab manual Cengage India Pvt. Ltd. By Pavia

**PS801: NOVEL DRUG DELIVERY SYSTEMS****B. Pharm IV Year II sem**

L	T	P	C
3	1	0	3

**Course Objectives:** This course is designed to impart knowledge on controlled drug delivery systems including oral, transdermal, mucoadhesive, targeted (Liposomes and Nanoparticles). It also helps to know how regulatory agencies (Indian CDSCO, USFDA, Canadian HPFBI and Australian TGA) act on release of NDA & ANDA.

**Course Outcome:** Student shall be able to know the controlled, sustained drug delivery systems, their methods of preparation.

**UNIT - I**

**Oral Control Drug Delivery Systems:** Fundamental study of different types of Oral Controlled drug delivery systems, sustained release concept, design of sustained release dosage form, Zero order release, first order release approximation, multiple dosing.

Dissolution Controlled, Diffusion Controlled, Ion Exchange Resins, Osmotic based systems, pH Independent Systems.

**UNIT - II**

**a. Transdermal Drug Delivery Systems:** Fundamentals, types of TDDS, Materials Employed and Evaluation of TDDS.

**UNIT - III**

**Mucoadhesive Delivery Systems:** Mechanism of bioadhesion, mucoadhesive materials, formulation and development of mucoadhesive-based systems.

**UNIT - IV**

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

**UNIT - V**

Introduction, principle and Fabrication of Intrauterine Devices / injections / implants

**TEXT BOOKS**

1. Novel drug delivery system by Prof. (Dr) A.K. Bandyopadhyay
2. N.K. Jain, Control Drug Delivery Systems by
3. Y.Anjaneyulu & Maraiiah, Quality Assurance & Quality Management in Pharmaceutical Industry.

**REFERENCES**

1. Leon Shargel Isadore Kanfer, Generic Drug Product Development, Solid Oral Dosage Forms, Marcel Dekker.
2. Sagarian & MS Balsam, Cosmetics Sciences & Technology. Vol.1, 2 & 3

**PS802: CLINICAL PHARMACY****B. Pharm IV Year II sem**

L	T	P	C
3	1	0	3

**Course Objectives:** To impart quality use of medicines & their therapeutics of various diseases management. Monitor adverse drug reaction, interpret selected laboratory results of specific disease states, retrieve, analyse, interpret and formulate drug or medicine information.

**Course Outcome:** Know the pathophysiology of selected disease states and the rationale for drug therapy, their therapeutic approach in management of diseases. Understand the needs to identify the patient-specific parameters relevant in initiating drug therapy and its monitoring.

**UNIT - I****Basic concepts of Pharmacotherapy**

- Introduction to Clinical Pharmacy
- Clinical Pharmacokinetics and individualization of Drug Therapy.
- Special precautions in drugs usage during infancy and in the elderly (Pediatrics & Geriatrics).
- Special precautions in drugs usage during pregnancy & lactation
- Adverse Drug Reactions and Pharmacovigilance
- The Basics of Drug Interactions
- Interpretation of Clinical laboratory Tests.

**UNIT - II****Important Disorders of Organ Systems and their Management:**

- Cardiovascular Disorders:** Hypertension, congestive heart failure, angina, acute myocardial infarction, cardiac arrhythmias
- CNS Disorders:** Epilepsy, parkinsonism, schizophrenia depression

**UNIT - III****Important Disorders of Organ Systems and their Management**

- Respiratory Disease:** Asthma, COPD
- Gastrointestinal Disorders:** Peptic Ulcer Disease, Ulcerative Colitis, Hepatitis, and Cirrhosis.
- Infectious Diseases:** Enteric Infections, sexually transmitted diseases, AIDS, Conjunctivitis.

**UNIT IV****Important Disorders of Organ Systems and their Management**

- Endocrine Disorders:** Diabetes mellitus and Thyroid Disorders.
- Neoplastic Diseases:** Leukaemias, Hodgkin's disease, Lymphomas

**UNIT - V**

- Therapeutic Drug Monitoring, Concept of Essential Drugs, Drug and Poison information, Drug induced diseases.
- Community Pharmacy practice, patient counselling, medication review ward round participation, drug utilization review.

**TEXT BOOKS**

- Roger, Walker, Clinical Pharmacy and Therapeutics
- G. Parthasarathi / Karin Nyfort-Hansu A text book of Clinical Pharmacy practice – Universities Press
- Dr. D.R Krishna, V. Klotz, Clinical pharmaco kinetics, Publ Springer Verlab

**REFERENCES**

1. Laurence, DR and Bennet PN. Clinical Pharmacology, Scientific book agency
2. Hamsten, Drug interaction, Kven Stockley.

**PS803: PHARMACEUTICAL BIOTECHNOLOGY****B. Pharm IV Year II sem**

L	T	P	C
3	1	0	3

**Course Objectives:** Pharmaceutical biotechnology is considered to be a logical extension of pharmaceutical microbiology, thus expected to show a dramatic change in the drug product scenario in future. This course is designed to impart knowledge on isolation of industrially interesting microbes, various techniques employed in biotechnology Viz., r-DNA technology, Hybridoma technology, enzyme technology and the products derived using these techniques.

**Course Outcome:** Upon completion of the course, the student shall be able to-

- Know screening of industrially interesting microbes.
- Optimize fermentation process parameters
- Know about preparation, standardization, storage and labelling of biotechnologically derived products
- Know about bioinformatics and its applications in pharmacy.
- Know about the regulatory control of biotechnological products.

**UNIT - I**

**a. Fermentation Technology:** Isolation, Selection and Screening of Industrially important microbes, Strain improvement. Types of fermentations, optimization of fermentation process. Types, design & operation of Bioreactor.

**b. Specific Fermentations:** Selection of organism, fermentation & purification of various antibiotics, vitamins, aminoacids, organic acids, solvents, biomass like penicillin, streptomycin, tetracycline, erythromycin, cyanocobalamin, glutamic acid, citric acid, alcohol, Lactobacillus sporogenes.

**UNIT - II**

**a. 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 r-DNA technology derived therapeutic proteins like humulin, humatrope, intron a, recombivax HB(hepatitis b).

**b. Hybridoma Technology:** Production and applications of Monoclonal Antibodies.

**UNIT - III**

**Immunology & Immunological Preparations:** Principles of Immunity, Humoral immunity, cell mediated immunity, Antigen – Antibody reactions, Hypersensitivity reactions.

Active & passive immunizations preparation of vaccines, standardization & storage of BCG, cholera, smallpox, polio, typhus, tetanus toxoid, immuno serum & diagnostic agents.

**UNIT - IV**

**a. Enzyme Technology:** Methods of immobilization of enzymes and cells and their applications, factors affecting immobilized enzyme kinetics, advantages of immobilized enzymes over isolated enzymes. Study of enzymes such as hyaluronidase, penicillinase, streptokinase & streptodornase, protease.

**b. Blood Products:** Collection processing, storage and control of official blood products, plasma substitutes (dextran) and sutures & ligatures.

**UNIT - V**

**a. Microbial Transformations:** Types, Methods of bioconversions & Application in Pharma Industry, Steroidal transformations.



- b.** An introductory study on bioinformatics and its applications, Regulatory control of Biotechnological products.

**TEXT BOOKS**

1. P. F. Stanbury & A. Whitaker, Principles of fermentation technology, Pergamon Press
2. Sambamurthy. K, Text Book of Pharmaceutical Biotechnology.
3. S. S. Kori, Pharmaceutical biotechnology.

**REFERENCES**

1. Wulf Crueger and Anneliese Crueger, Biotechnology, 2<sup>nd</sup> Ed, Publ- Panima publication cooperation, New Delhi
2. U. Satyanarayana, Text book of Biotechnology

**PS804: PHARMACOGNOSY – III****B. Pharm IV Year II sem**

L	T	P	C
3	1	0	3

**Course Objectives:** To learn about the therapeutically important crude drugs and phytopharmaceuticals under a suitable pharmacognostic scheme and the importance of plant tissue culture in pharmacy. To make the student aware of biologically important molecules from marine sources and neutraceuticals.

**Course Outcome:** Since it is being the last part of Pharmacognosy subject, the student must be enriched with the knowledge on the crude drugs in a systematic way and in the use of crude drugs and phytopharmaceuticals in various systems of medicine for the treatment of different ailments and in various industries.

**UNIT - I**

General introduction to Alkaloids. Systematic pharmacognostic study of the: Cinchona, Tea, Black Pepper, Ergot, Opium, Ipecac, Vinka and Rauwolfia.

Biological source, Chemical constituents. Chemical test and uses of following: Belladonna, Ephedra, Colchicum, Datura, Kurchi, Nux-vomica, Solanum, Tobacco, Withania and Vasaka.

**UNIT - II**

General introduction to Glycosides. Systematic pharmacognostic study of : Aloe, Digitalis ,liquorice and Senna. Biological sources, chemical constituents, tests for identification and uses of following crude drugs: Ammi, , Cascara, Chirata, Dioscoria, Gentian, Ginseng and Strophanthus gratus.

**UNIT - III**

Historical development of plant tissue culture: Types of cultures, nutritional requirements, establishment of cultures, measurement of growth in cultures and their maintenance. Applications of plant tissue culture in production of pharmaceutically important secondary metabolites.

**UNIT - IV**

- A brief introduction to Ayurveda and its preparations like Arishtas, Asavas, Gutickas, Tailas, Churnas, Lehyas and Bhasmas.
- Neutraceuticals : Definition of functional foods and neutraceuticals, classification of neutraceuticals. Source, chemical nature, medicinal uses of Spirulina, Garlic, Soya and Gingko.

**UNIT - V**

- A brief account on standardization parameters of herbal drugs as per WHO guidelines.
- Study of analytical profiles of following medicinal plants using WHO protocols. *Andrographis paniculata*, *Bacopa monneri*, *Boswellia serrata* and *Coleus forshkohlii*.

**TEXT BOOKS**

- J.B.Harbone, Phytochemical Methods: A guide to modern techniques of Plant analysis by
- Kokate C.K, Purohit AP & Gokhale S.B, The Pharmacognosy (Nirali)
- Trease and Evans, Pharmacognosy, Latest Edition.

**REFERENCES**

- Arya Vaidyasala Vol. 1-5, Indian Medicinal Plants – Universities Press
- T.E. Wallis, Text Book of Pharmacognosy.

**PS805: NANO TECHNOLOGY (Open Elective – III)****B. Pharm IV Year II sem**

L	T	P	C
3	1	0	3

**Course Objectives** - To develop expertise regarding suitability and evaluation of nanomaterials, able to apply the properties to the fabrication of nanopharmaceutical and Evaluation

**Course Outcome** – The students should be able to select the right kind of materials, able to develop nano formulations with appropriate technologies, evaluate the product related test and for identified diseases

**UNIT - I – Introduction to Nanotechnology**

- Definition of nanotechnology
- History of nanotechnology
- Unique properties and size of nanomaterials
- Advantages, Disadvantages and Limitations

**UNIT - II – Synthesis of Nanomaterials**

Physical, chemical and biological Methods

**UNIT - III**

Preparation of Nanoemulsions, Nanosuspensions, Liposomes and Niosomes

**UNIT - IV**

Characterisation of Nanoparticles including particle size, morphology, PDI, Zeta sizer and their principles. Analysis of Nanoparticles and release studies.

**UNIT - V**

Applications of Nanotechnology in various areas

**TEXT BOOKS:**

- Nanomedicine and Nanoproducts: Applications, Disposition and Toxicology in the Human body, Eiki Igarashi, CRC press. 2015
- Nanotechnology and Drug Delivery Volume one and two: Nanoplatfoms in Drug Delivery, Jose L.Arias, CRC press
- Nano: The Essentials: Understanding Nanoscience and Nanotechnology, T.Pradeep, Tata McGraw-Hill Publishing Company Limited, New Delhi, 2008.

**RECOMMENDED REFERENCES:**

- Nanocrystals: Synthesis, Properties and Applications, C.N.R.Rao, P.J.Thomas and G.U. Kulakarni, Springer(2007)
- Nanostructures and Nanomaterials: Synthesis, Properties and Application, Guozhong Gao, Imperial College Press(2004)

**PS806: PHARMACOEPIDEMIOLOGY, PHARMACOECONOMICS AND PHARMACOVIGILANCE  
(Open Elective – III)**

**B. Pharm IV Year II sem**

**L T P C  
3 1 0 3**

**Course Objectives:** This course is designed to impart knowledge and skills in vigilance, epidemiology, economics and of various diseases. This will enable the students to understand cost effectiveness in the management of disease and ADRS

**Course Outcome:** At completion of this subject, the students are expected to understand risk of pharmacoepidemiology history and need of pharmacoeconomics and assessment of pharmacovigilance.

**UNIT - I:** Introduction to adverse drug reactions. Definitions and classification of ADRs. Detection and reporting. Causality assessment. Severity and seriousness assessment. Predictability and preventability assessment. Management of adverse drug reactions .Role of pharmacist in management of ADRs.

**UNIT - II:** Pharmacovigilance Scope, definition and aims of Pharmacovigilance .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. Drug dictionaries and coding in pharmacovigilance: WHO adverse reaction terminologies. Med DRA and Standardised Med DRA queries. WHO drug dictionary, EudraVigilance medicinal product dictionary.

**UNIT - III:** Basic terminologies used in pharmacovigilance: Terminologies of adverse medication related events. Regulatory terminologies.

Information resources in pharmacovigilance: Basic drug information resources. Specialised resources forADRs Critical evaluation of medication safety literature

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. Targeted clinical investigations. Vaccine safety surveillance

**UNIT - IV:** Pharmacoepidemiology: Definition and scope: Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications. Measurement of outcomes in pharmacoepidemiology. Pharmacoepidemiological methods: Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods Drug utilization review, case reports, case series, surveys of drug use, cross–sectional studies, cohort studies, case control studies, case–cohort studies, meta–analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

**UNIT - V:** Pharmacoeconomics: Definition, history, need of pharmacoeconomic evaluations Role in formulary management decisions. Pharmacoeconomic evaluation Outcomes assessment and types of evaluation, includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Cost – minimization, cost - benefit, cost – effectiveness, cost utility Applications of Pharmacoeconomics, Softwares used and case studies.

**TEXT BOOKS:**

1. Textbook of Pharmacovigilance: Concept & practice- KG. Revikumar.
2. Textbook of Pharmacovigilance: Concept & practice- Mohanta, Pharmamed press.
3. SK GUPTA Textbook of Pharmacovigilancelcri Institute of Clinical Research, India.

**REFERENCES:**

1. Goodman & Gilman's The Pharmacological basis of Therapeutics Ed. J.G. Hardman, L.E. Limbird, P.B. Molinoff and R. W. Ruddon. International Edition. McGraw Hill.
2. G Katzung, Basic and Clinical Pharmacology. Bertram, 9th edn Lange Publications, 2004.

**PS807: MEDICINAL PLANT BIOTECHNOLOGY (Open Elective – III)****B. Pharm IV Year II sem**

L	T	P	C
3	1	0	3

**Course Objective:** The topics are designed to help the students to get exposed to various techniques of plant tissue culture.

**Course Outcome:** Students will gain the knowledge about various strategies of plant tissue culture.

**UNIT - I**

History of Plant Tissue Culture, Laboratory Organization, Sterilization techniques (Aseptic transfer) Concepts of Totipotency, Physical and Chemical requirements, Media preparation, Explant preparation, establishment of Aseptic cultures (Callus and Suspension), of Plant Tissue Culture, Unorganized and Organized cultures, Measurement of Growth parameters, Biotechnological applications of Plant Tissue culture.

**UNIT - II**

Culture Techniques: Micro propagation of Medicinal and Aromatic plants, Organogenesis, Embryo genesis, Protoplast fusion, Cryopreservation and Synthetic seeds.

**UNIT - III**

Strategies for production of secondary metabolites-

- Elicitation and Precursor feeding
- Immobilization of Plant cells, Technique and its effects on secondary metabolites
- Biotransformation of Plant Cell Culture and its importance in secondary metabolite production
- Transgenic technology- Hairy root cultures, Shooty teratomass and their applications

**UNIT - IV**

Production of Secondary metabolites from callus culture and suspension culture with emphasis on production of biomedicinals like- Ajmalicine, Artemicin, Shikonin; Carotenoids and Rosemaric acid

**UNIT - V**

Metabolic engineering of secondary metabolic pathways, Scale up and commercialization of secondary metabolites . Large scale Cultivation of Plant Cells using Bioreactors: Introduction, Historical developments of bioreactors for Mass culture of plant cells, Types of Bioreactors, Bioreactors for different Plant tissue Cultures.

**TEXT BOOKS:**

- Pharmacognosy and Pharmacobiotechnology by Ashutoshkar
- Introduction to plant tissue culture by M.K.Razadam
- Plant Tissue Culture by Bhojwani

**REFERENCES:**

- Medicinal Plant Biotechnolgy by ciddi veeresham
- Molecular Biology and Biotechnology by J.M.Walker and E.D.Gingo

**PS808: NOVEL DRUG DELIVERY SYSTEMS AND REGULATORY AFFAIRS LAB****B. Pharm IV Year II sem****L T P C**  
**0 0 3 2****List of Experiments**

1. Preparation and Evaluation of Matrix Tablets
2. Formualtion and Evaluation of Film Coated Tablets.
3. Formualtion and Evaluation of Enteric Coated Tablets.
4. Prepartion and Evaluation of Transdermal Drug Delivery Systems.
5. Formulation and Evaluation of Mucoadhesive Delivery Systems.
6. Evaluation of Market SR Formualtions.
7. Preparation and evalution of Nano particles (Minimum two drugs)
8. Preparation and evaluation of Liposomes
9. Preparation and Evaluation of Alginate Beads.
10. Analytical Method Validation.
11. Assignment on Product development and filing to various regulatory agencies , FDA,MCC, EMEA,TGA.Etc (Ref.: [www.fda.gov](http://www.fda.gov))

**PS809: PHARMACOGNOSY - III LAB****B. Pharm IV Year II sem**

<b>L</b>	<b>T</b>	<b>P</b>	<b>C</b>
<b>0</b>	<b>0</b>	<b>3</b>	<b>2</b>

**List of Experiments**

1. Isolation of Caffeine from a marketed formulation
2. Isolation of Piperine from Black Pepper
3. Detection of alkaloids in a powdered crude drug by precipitation tests
4. Extraction and TLC of Nux-vomica/Cinchona alkaloids
5. Detection of Steroidal/Triterpenoidal and Flavonoidal glycosides in powdered crude drugs by test tube reaction method
6. Differentiation of a glycoside and its aglycone by TLC.
7. Identification of powdered crude drugs containing Alkaloids by general chemical test and specific chemical test to identify the particular Alkaloid.
8. Identification of powdered crude drugs containing glycosides by general chemical test and specific chemical test to identify the particular glycosides.
9. Study of Morphology and microscopy of crude drugs by transverse section
  - a. Ephedra            b. Vinca            c. Nux vomica    d. Cinchona    e. Senna
10. Identification of powdered crude drugs by their Microscopical characterization
  - a. Senna    b. Rauwolfia    c. liquorice    d. Nux-vomica    e) Kurchi
11. Identification of powdered crude drugs by their Microscopical characterization
  - a. Cinchona    b. Cinnamon    c. Vasaka    d.Datura            e) Ephedra
12. Isolation of Strychnine and Brucine from Nux vomica seeds.
13. Isolation of Nicotine from Tobacco leaves.
14. Aseptic seed germination for Trigonella fenugrecium.
15. Spotting – Identification of crude drugs mentioned in theory by organoleptic method.

**REFERENCES**

1. Practical Pharmacognosy by C. K. Kokate
2. Plant Drug Analysis by Wagner. H. & Blandt. S.
3. Pharmacognosy of Powdered Crude Drugs by M.A. Iyengar
4. Anatomy of Crude Drugs by M. A. Iyengar and S. C. K. Nayak
5. Study of Crude Drugs by M.A. Iyengar 15<sup>th</sup> Edition
6. Practical Pharmacognosy by T E Wallis 4<sup>th</sup> Edition
7. Practical Pharmacognosy by Dr. G.S. Kumar and Dr. K.N. Jayaveera
8. Practical Pharmacognosy by Saroja Joshi and Vidhu Aeri