**PAAVAI ENGINEERING COLLEGE, NAMAKKAL - 637 018**

(AUTONOMOUS)

**B.Tech PHARMACEUTICAL TECHNOLOGY**

CURRICULUM

**REGULATIONS 2016**

(CHOICE BASED CREDIT SYSTEM)

(For the candidates admitted during the Academic Year **2018 - 2019**)

**SEMESTER VII**

| S. No. | CATEGORY | COURSE CODE | COURSE TITLE | L | T | P | C |
|---|---|---|---|---|---|---|---|
| **THEORY** | | | | | | | |
| **1.** | PC | PT16701 | Pharmacognosy | 3 | 0 | 0 | 3 |
| **2.** | PC | PT16702 | Biopharmaceutics and Pharmacokinetics | 3 | 0 | 0 | 3 |
| **3.** | PC | PT16703 | Computational Biology & Bioinformatics | 3 | 0 | 0 | 3 |
| **4.** | PE | PT1635* | Professional Elective III | 3 | 0 | 0 | 3 |
| **5.** | OE | PT1690* | Open Elective II | 3 | 0 | 0 | 3 |
| **PRACTICALS** | | | | | | | |
| **6.** | PC | PT16704 | Pharmacokinetics & Pharmacognosy Laboratory | 0 | 0 | 4 | 2 |
| **7.** | PC | PT16705 | Computational Biology Laboratory | 0 | 0 | 4 | 2 |
| **8.** | EE | PT16706 | Project Work Phase I | 0 | 0 | 4 | 2 |
| | | | **TOTAL** | **18** | **0** | **12** | **21** |

**SEMESTER VIII**

| S. No. | CATEGORY | COURSE CODE | COURSE TITLE | L | T | P | C |
|---|---|---|---|---|---|---|---|
| **THEORY** | | | | | | | |
| **1.** | PC | PT16801 | Down Stream Processing | 3 | 0 | 0 | 3 |
| **2.** | PE | PT1645* | Professional Elective IV | 3 | 0 | 0 | 3 |
| **3.** | PE | PT1655* | Professional Elective V | 3 | 0 | 0 | 3 |
| **PRACTICALS** | | | | | | | |
| **4.** | EE | PT16802 | Project Work Phase II | 0 | 0 | 12 | 6 |
| | | | **TOTAL** | **9** | **0** | **12** | **15** |

## PROFESSIONAL ELECTIVES (PE)

### PROFESSIONAL ELECTIVE III, SEMESTER VII

| S. No. | COURSE CODE | COURSE TITLE | L | T | P | C |
|---|---|---|---|---|---|---|
| **1.** | PT16351 | Regulatory Toxicology | 3 | 0 | 0 | 3 |
| **2.** | PT16352 | Research Methodology | 3 | 0 | 0 | 3 |
| **3.** | PT16353 | Diagnostics And Therapeutics | 3 | 0 | 0 | 3 |
| **4.** | PT16354 | Fundamentals of Molecular Pathology | 3 | 0 | 0 | 3 |

### PROFESSIONAL ELECTIVE IV, SEMESTER VIII

| S. No. | COURSE CODE | COURSE TITLE | L | T | P | C |
|---|---|---|---|---|---|---|
| **5.** | PT16451 | Vaccine Technology | 3 | 0 | 0 | 3 |
| **6.** | PT16452 | Pharmaceutical Packaging Technology | 3 | 0 | 0 | 3 |
| **7.** | PT16453 | Introduction to Biomaterials & Tissue Engineering | 3 | 0 | 0 | 3 |
| **8.** | PT16454 | Drug Delivery Systems | 3 | 0 | 0 | 3 |

### PROFESSIONAL ELECTIVE V, SEMESTER VIII

| S. No. | COURSE CODE | COURSE TITLE | L | T | P | C |
|---|---|---|---|---|---|---|
| **9.** | PT16551 | Technology of Sterile Products | 3 | 0 | 0 | 3 |
| **10.** | PT16552 | Clinical Trials | 3 | 0 | 0 | 3 |
| **11.** | PT16553 | Pharmacovigilance | 3 | 0 | 0 | 3 |
| **12.** | PT16554 | Pharmacogenomics | 3 | 0 | 0 | 3 |

### OPEN ELECTIVE II (OE)

| S. No. | COURSE CODE | COURSE TITLE | L | T | P | C |
|---|---|---|---|---|---|---|
| **1.** | PT16903 | Plant and Animal Diseases and Their Control | 3 | 0 | 0 | 3 |
| **2.** | PT16904 | Introduction to Pharmaceutical Technology | 3 | 0 | 0 | 3 |

**PT16701** **PHARMACOGNOSY** **3 0 0 3**

**COURSE OBJECTIVES**

To enable students to

- understand the techniques in the cultivation and production of crude drugs
- know the systems of medicine existing in India
- learn the Biosynthesis of metabolites
- understand the basics of tissue culture
- study the applications related to pharmacognosy

**UNIT I BASICS OF PHARMACOGNOSY 9**

History and scope of Pharmacognosy - Crude vegetable and animal drugs. Source of the drug of natural origin; Classification of drug - Organized and unorganized drugs; Different systems of medicine existing in India their basic principles and their relation to pharmacognosy; Salient features of preparation of crude drugs for market.

**UNIT II BIOSYNTHESIS OF SECONDARY METABOLITES 9**

Biosynthesis approach - Building blocks and metabolic pathways for the formation of secondary metabolites such as alkaloids, isoprenoids, coumarins, flavones and glycosides; Study of photosynthesis with special reference to its role in biosynthesis of natural products. Molecular Mechanisms and Gene Regulation for Biosynthesis of Medicinal Plant Active Ingredients.

**UNIT III ISOLATION OF PHYTOPHARMACEUTICALS 9**

Introduction to tissue culture with reference to phytopharmaceuticals; Extraction and isolation of plant drugs - conventional and modern techniques used in extraction and separation of phytoconstituents; Steroids from natural sources; Microbial Transformation of steroids.

**UNIT IV ANALYSIS OF CRUDE DRUGS 9**

Types and significance of standards of crude drugs included in I.P. and B.P, application of spectroscopy and chromatography techniques for isolation, identification, and analysis of phytoconstituents; Principles and methods of Quantitative microscopical analysis - Stomatal index, Stomatal number, Palisade ratio, Vein islet number and vein termination number; Lycopodium Spore method for the evaluation of starches.

**UNIT V PRESERVATION OF DRUGS 9**

Commercial aspects of drug production, preservation and storage of crude drugs; Changes occurring in drying and comminution; Enzyme action in vegetable drugs; Adulteration and evaluation of crude drugs; Deterioration of drugs due to insects and pests.

**TOTAL PERIODS: 45**

**COURSE OUTCOMES**

At the end of this course, the students will be able to

- know the basics of pharmacognosy

- understand the metabolic pathways and biosynthesis of metabolites
- adapt the knowledge on phytopharmaceuticals
- analyze and understand crude drugs
- understand commercial aspects of pharmacognosy

**TEXT BOOKS**


1. W.C.Evans, Trease and Evans "Pharmacognosy", 16th edition, W.B. Sounders & Co., London, 2009.
2. Tyler, V.E., Brady, L.R. and Robbers, J.E., "Pharmacognosy", 9th Edn., Lea and Febiger, Philadelphia, 2011.


**REFERENCES**


1. Dr. SH. Ansari, "Essentials of Pharmacognosy", IInd edition, Birla publications, New Delhi, 2007
2. R.D. Choudhary, "Herbal drug industry", Ist Edn, Eastern Publisher, New Delhi
3. M.A. Iyengar, "Anatomy of Crude Drugs"
4. T.E. Wallis, "Textbook of Pharmacognosy"


**CO/PO MAPPING:**

| **Mapping of Course Outcomes with Programme Outcomes**<br>**(1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak** | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **COs** | **Programmes Outcomes (POs)** | | | | | | | | | | | | | |
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** | **PO6** | **PO7** | **PO8** | **PO9** | **PO10** | **PO11** | **PO12** | **PSO1** | **PSO2** |
| **CO1** | 2 | 2 | 2 | 3 | 2 | 1 | - | - | - | - | 2 | - | 3 | 3 |
| **CO2** | - | 3 | 3 | - | 2 | - | 2 | 2 | - | - | - | - | 2 | 2 |
| **CO3** | 3 | 3 | 2 | 2 | - | - | 1 | - | - | - | - | - | 3 | 3 |
| **CO4** | 3 | 2 | 2 | - | - | 1 | - | - | - | - | 2 | - | 2 | 3 |
| **CO5** | 2 | 3 | 2 | 2 | 1 | 3 | 3 | 2 | - | 1 | 2 | - | 2 | 3 |

**PT16702 BIOPHARMACEUTICS AND PHARMACOKINETICS 3 0 0 3**

**COURSE OBJECTIVES**

To enable students to

- learn important parameters involved in drug disposition and its principles in living systems
- understand how the drug disposition takes place in the in vitro and in vivo conditions.
- understand the concepts of bioavailability and bioequivalence of drug products and their significance
- study the basics of Pharmacokinetics
- acquire knowledge on multiple dosage regimens

**UNIT I DRUG ABSORPTION AND DISTRIBUTION 9**

Introduction to Biopharmaceutics and Pharmacokinetics and their role in formulation development and clinical setting Biopharmaceutics; Passage of drugs across biological barrier (passive diffusion, active transport, facilitated diffusion and pinocytosis); Mechanism of drug absorption through GIT, factors influencing absorption – physiochemical, physiological, and pharmaceutical; Distribution of drugs, Tissue permeability of drugs, binding of drugs.

**UNIT II DRUG ACTION, METABOLISM AND ELIMINATION 9**

Mechanism of drug action; physico-chemical principles of drug metabolism; factors affecting metabolism; renal excretion of drugs; factors affecting renal excretion of drugs; Mechanism of renal clearance; non-renal routes of drug excretion of drugs; Study of drug-membrane interactions.

**UNIT III BIOAVAILABILITY AND BIOEQUIVALENCE 9**

Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, in-vitro drug dissolution models; in-vitro-in-vivo correlations; Design of single dose bioequivalence study and relevant statistics.

**UNIT IV PHARMACOKINETICS 9**

Foundation of pharmacokinetics, Significance of plasma drug concentration measurement; Pharmacokinetic models; One Compartment model - Definition and scope; Pharmacokinetics of drug absorption – Zero order and first order absorption rate constant using Wagner Nelson and Loo-riegelman method; Elimination rate constant and its half-life; AUC, $C_{max}$ and $t_{max}$; Apparent volume of distribution.

**UNIT V MULTIPLE DOSAGE REGIMENS AND NONLINEAR PHARMACOKINETICS 9**

Determination of renal clearance; Calculation of dosage regimen following repetitive IV and oral administration; Nonlinear Pharmacokinetics – Introduction, factors causing Non-linearity, Michaelis-menton method of estimating pharmacokinetic parameters; Detection of non-linearity (Saturation mechanism).

**TOTAL PERIODS: 45**

**COURSE OUTCOMES**

At the end of this course, the students will be able to

- adapt drug dispositions and its principles in living systems
- work on drug action and its metabolism
- inculcate the foundations of Pharmacokinetics
- calculate dosage regimes
- understand applications based on kinetics

**TEXT BOOKS**


1. Rosenbaum, S. E. Basic, "Pharmacokinetics and Pharmacodynamics: An Integrated Textbook and Computer Simulations", 2nd Edition, John Wiley and Sons, 2016.
2. Brahmankar, D.M. and Jaiswal, S.B. "Biopharmaceutics and Pharmacokinetics: a Treatise" ,3rd Edition, Vallabh Prakashan, 2015.


**REFERENCES**


1. Jambhekar, S.S. and Philip, J. B. "Basic Pharmacokinetics" 2nd Edition, Pharmaceutical Press,2012.
2. Gibaldi, M. "Biopharmaceutics and Clinical Pharmacokinetics", 4th Edition, Pharma Book Syndicate, 2016.
3. Shargel,L and Andrew, B.C. Yu. "Applied Biopharmaceutics and Pharmacokinetics",7th Edition, The McGraw-Hill Companies, Inc, 2016.
4. Chatwal, G.R. "Biopharmaceutics and Pharmacokinetics", 2nd Edition, Himalaya Publishing House, 2014.


**CO/PO MAPPING:**

| **Mapping of Course Outcomes with Programme Outcomes (1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak** | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **COs** | **Programmes Outcomes (POs)** | | | | | | | | | | | | | |
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** | **PO6** | **PO7** | **PO8** | **PO9** | **PO10** | **PO11** | **PO12** | **PSO1** | **PSO2** |
| **CO1** | 2 | 2 | 3 | 2 | 3 | 3 | 2 | 3 | 2 | - | 2 | - | 3 | 3 |
| **CO2** | 2 | 2 | 3 | 1 | - | - | 2 | 3 | - | - | - | - | 3 | 3 |
| **CO3** | 3 | 3 | 3 | 3 | 3 | 2 | - | - | - | - | 1 | 2 | 3 | 3 |
| **CO4** | 2 | 3 | 3 | 3 | 2 | 3 | - | - | - | - | - | 2 | 3 | 2 |
| **CO5** | 2 | 2 | 3 | 3 | 3 | 3 | - | 1 | - | - | - | 3 | 2 | 3 |

**PT16703 COMPUTATIONAL BIOLOGY AND BIOINFORMATICS 3 0 0 3**

**COURSE OBJECTIVES**

To enable students to

- understand the principles of analyzing biological data, building models and testing hypotheses using computer science algorithms
- learn basic concept machine learning and its application in the analysis of biological data
- distinguish between gene trees and species trees
- build the foundation of sequence alignment techniques and find evolutionary connections
- understand the basic Bioinformatics and algorithms used in Computational Biology

**UNIT I FUNDAMENTALS OF BIOINFORMATICS 9**

Introduction to bioinformatics; concept of databases; biological databases; integration of databases; Pairwise sequence comparisons by DOT-MATRIX and dynamic programming; Global(Needleman and Wunsch algorithm) and local (Smith and Waterman algorithm) alignments; Measures of sequence similarity (Alignment score, % sequence identity; percentage similarity; statistical scores–E, P and Z); Heuristic approaches for database searching; BLAST and FASTA; multiple sequence alignment; SP scoring; multidimensional dynamic programming.

**UNIT II APPLICATIONS OF BIOINFORMATICS 9**

Gene, ORF of a gene, promoter and regulatory elements prediction; phylogenetic analysis (phylogeny, Phylogenetic tree, construction methods of Phylogenetic tree and Phylogenetic programs); protein structure analysis; protein secondary structure prediction; Homology modelling (principles and procedures); docking; determination of metabolic pathways.

**UNIT III INTRODUCTION TO COMPUTATIONAL BIOLOGY 9**

Protease digestion mapping; sequence motifs identification by Monte Carlo Bayesian approaches, hidden Markov models, computational algorithms, statistical software, high-throughput sequencing data and its application in computational biology

**UNIT IV MODELING AND SIMULATION 9**

Introduction to ab-initio, semi-empirical & molecular mechanical methods, Theory and Practice of Energy minimization, Monte Carlo, and Molecular Dynamics simulations. Theoretical methods to calculate binding free energies and rate constants. Methods to model Nucleic Acids (DNA and RNA).

**UNIT V ARTIFICIAL NEURAL NETWORK 9**

Historic evolution of perceptron; characteristics of neural networks terminology; models of neuron Mc Culloch – Pitts model, Perceptron, Adaline model; Topology of neural network architecture - single layer ANN, multilayer perceptron; Back propagation learning, input - hidden and output layer computation, back propagation algorithm, Applications of ANN

**TOTAL PERIODS: 45**

**COURSE OUTCOMES**

At the end of this course, the students will be able to

- perform computational analyses of biological sequences, genome-wide studies and relate the results to core principles of biology
- use computational methods to help execute a biological research plan
- analyze biological problems and data using the latest machine learning and deep learning techniques.
- learn to align sequences using dot matrices, dynamic programming, and heuristic approach
- understand the notion of similarity, identity, and gaps in the context of sequence alignment and deduce evolutionary relationships among sequences

**TEXT BOOKS**

1. Mount D., "Bioinformatics: Sequence and Genome Analysis",Cold Spring Harbor Laboratory Press, New York. 2004
2. Jonathan Pevsner, "Bioinformatics and Functional Genomics", 2nd Edition.

**REFERENCES**

1. Teresa K. Attwood, David J. Parry-Smith , "Introduction to Bioinformatics" Pearson Education. 1999
2. Jin Xiong, "Essential Bioinformatics", Cambridge University Press; 1st edition 2006.
3. S. C. Rastogi, "Bioinformatics: methods and applications", PHI learning; 4th edition, 2013.
4. Raul Rojas, "Neural Networks: A Systematic Introduction" Springer. 1996

**CO/PO MAPPING:**

| **Mapping of Course Outcomes with Programme Outcomes (1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak** | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **COs** | **Programmes Outcomes (POs)** | | | | | | | | | | | | | |
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** | **PO6** | **PO7** | **PO8** | **PO9** | **PO10** | **PO11** | **PO12** | **PSO1** | **PSO2** |
| **CO1** | 1 | 2 | - | 2 | - | - | - | 1 | - | - | - | 1 | 3 | - |
| **CO2** | - | 1 | 3 | - | 2 | - | - | - | - | - | - | - | - | 1 |
| **CO3** | 2 | 1 | 1 | - | 1 | 2 | - | - | - | - | - | - | - | - |
| **CO4** | - | 1 | - | - | - | 1 | - | 2 | - | - | - | 2 | - | - |
| **CO5** | - | 2 | 1 | 2 | - | 1 | 1 | 2 | - | 2 | 2 | - | - | - |

| PT16704 | PHARMACOKINETICS AND PHARMACOGNOSY LABORATORY | 0 0 4 2 |
|---|---|---|

**COURSE OBJECTIVES**

To enable students to

- impart the knowledge of the rate and extent of drug absorption and distribution
- understand different Pharmacokinetic parameters
- study natural herbs and prepare herbarium photos
- study characteristics of crude drugs

**LIST OF EXPERIMENTS**

1. In-vitro dissolution study of the given sustained release dosage form using various dissolution media.
2. Study the effect of formulation on drug release (Tablet, Solution, suspension etc.).
3. Determination of effect of pH on the partition co-efficient of drug(s)
4. Determination of protein binding of the given drug(s) and the effect of protein binding on drug bioavailability.
5. In-vitro drug absorption study using everted small intestine sac technique.
6. To calculate the various Pharmacokinetic parameters from the given blood data of I.Vbolus injection (one compartment model).
7. Calculation of Ka (absorption rate constant) absorption curve- Wagner nelson method, Loo-Riegel method
8. Collection of natural herbs and preparation of herbariam/laminated photos for five drugs
9. Study of Microscopy, Macroscopy and powder characters of any three to four crude drugs
10. Identification test for two enzymes papain and casein.
11. Chemical tests for Asafoetida, Benzoin, Tannic acid, Pale catechu and Quinine.
12. Determination of proximate values -Moisture content, Ash value, Extractive values

**TOTAL PERIODS: 60**

**COURSE OUTCOMES**

At the end of this course, the students will be able to

- study the effect of different drug formulations
- determine pH and protein binding parameters
- calculate various Pharmacokinetic parameters and absorption rate
- work on Microscopy, Macroscopy and powder characters od drugs
- determine Moisture content, Ash value, Extractive values

**TEXT BOOKS**

1. Andrzej Cybulski, Jacob A. Moulijn, M.M. Sharma, Roger A. Sheldon “Fine Chemicals Manufacture: Technology and Engineering” Elseiver Science B.V, 2001.

2. Gopal Rao, M. and Sittig, M., “Dryden’s Outlines of Chemical Technology”, 3rd Edition, Affiliated East West Press Pvt. Ltd., 2001.

**REFERENCES**

1. Brahmankar, D.M. and Jaiswal, S.B. “Biopharmaceutics and Pharmacokinetics: a Treatise” 3rd Edition, Vallabh Prakashan, 2015.
2. Vijaya Raghavan, C and Judith Justin. “Experimental Biopharmaceutics and Pharmacokinetics”, New century book house (P) Ltd., 2006
3. C.K. Kokate et.al, “Practical Pharmacognosy”.
4. Iyengar, “Practical Pharmacognosy”.
5. Khandelwal, “Practical Pharmacognosy”.

**CO/PO MAPPING:**

| **Mapping of Course Outcomes with Programme Outcomes (1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak** | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **COs** | **Programmes Outcomes (POs)** | | | | | | | | | | | | | |
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** | **PO6** | **PO7** | **PO8** | **PO9** | **PO10** | **PO11** | **PO12** | **PSO1** | **PSO2** |
| **CO1** | 3 | 3 | 2 | 3 | 2 | - | - | - | - | - | - | - | 2 | 3 |
| **CO2** | 1 | - | - | 2 | - | - | - | - | - | - | - | - | 2 | 3 |
| **CO3** | 2 | 2 | 2 | - | 1 | - | - | - | - | - | - | - | 3 | 3 |
| **CO4** | 2 | 2 | 2 | 2 | - | - | - | - | - | - | - | - | 3 | 2 |
| **CO5** | - | 2 | - | 1 | 2 | - | - | - | - | - | - | - | 3 | 2 |

**PT16705** **COMPUTATIONAL BIOLOGY LABORATORY** **0 0 4 2**

**COURSE OBJECTIVES**

To enable students to

- summarize the significance of biological databases
- perform sequence alignment using various sequence alignment tools.
- distinguish the structure and functions of protein molecule using 3D structure of the protein
- construct phylogenetic tree to analysis the evolution
- generate, compare, and analyze 3D structure of ligand and receptor complex.

**LIST OF EXPERIMENTS**

1. Biological Database (DNA) - NCBI-Genbank, EMBL
2. Biological Database (Protein) – Uniprot, Protein Data Bank
3. Sequence Alignment Programs – BLAST, FASTA, Clustal W
4. Protein 3D Structure Prediction Programs – Swissmodel, Rasmol
5. Phylogenetic Analysis Program – Phylip
6. Docking Studies – PatchDock

**TOTAL PERIODS: 60**

**COURSE OUTCOMES**

At the end of this course, the students will be able to

- discuss in detail about impotence of biological databases.
- demonstrate sequence alignment by different opensource software programs
- compare the structure of protein molecule to predict its functions.
- evaluate the phylogenetic tree Construction.
- assemble ligand and receptor complex using Docking programs.

**TEXT BOOKS**


1. Dan Gusfield, “Algorithms on Strings, Trees and Sequences” Cambridge University Press.
2. R.Durbin, S.Eddy, A.Krogh, G.Mitchison, “Biological Sequence Analysis Probabilistic Models of proteins and nucleic acids”


**REFERENCES**


1. David W. Mount, “Bioinformatics Sequence and Genome Analysis” Cold Spring Harbor Laboratory Press.
2. Arthur K. Lesk, “Introduction to Bioinformatics” Oxford University Press.

**CO/PO MAPPING :**

| Mapping of Course Outcomes with Programme Outcomes<br>(1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **COs** | **Programmes Outcomes (POs)** | | | | | | | | | | | | | |
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** | **PO6** | **PO7** | **PO8** | **PO9** | **PO10** | **PO11** | **PO12** | **PSO1** | **PSO2** |
| **CO1** | 3 | 2 | - | 3 | 1 | - | - | - | - | - | - | - | 1 | - |
| **CO2** | 2 | 1 | 2 | 2 | 1 | - | - | - | - | - | - | - | 1 | - |
| **CO3** | 1 | 1 | 1 | 1 | 3 | - | - | - | - | - | - | - | 2 | - |
| **CO4** | 3 | 2 | 1 | 1 | 2 | - | - | - | - | - | - | - | 3 | - |
| **CO5** | 3 | 3 | 1 | 2 | 1 | - | - | - | - | - | - | - | 2 | - |

**PT16706** **PROJECT WORK PHASE I** **0 0 4 2**

## COURSE OBJECTIVES

To enable students to

- develop students' knowledge for solving technical problems through structured project research study in order to produce competent and sound engineers.

The student in a group of 3 to 4 works on a topic approved by the Head of the Department under the guidance of a faculty member and prepares a comprehensive project report after completing the work to the satisfaction of the supervisor. The progress of the project is evaluated based on a minimum of three reviews. The review committee may be constituted by the Head of the Department. A project report is required at the end of the semester. The project work is evaluated based on oral presentation and the project report jointly by external and internal examiners constituted by the Head of the Department.

**TOTAL PERIODS: 60**

## COURSE OUTCOMES

At the end of this course, the students will be able to

- identify and describe the problem and scope of project clearly.
- collect, analyze and present data into meaningful information using relevant tools.
- select, plan and execute a proper methodology in problem solving.
- work independently and ethically.
- identify basic entrepreneurship skills in project management.

## CO/PO MAPPING:

| **Mapping of Course Outcomes with Programme Outcomes (1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak** | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **COs** | **Programmes Outcomes (POs)** | | | | | | | | | | | | | |
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** | **PO6** | **PO7** | **PO8** | **PO9** | **PO10** | **PO11** | **PO12** | **PSO1** | **PSO2** |
| **CO1** | 3 | 2 | 3 | 2 | - | - | - | - | 2 | - | - | - | 2 | 2 |
| **CO2** | - | 3 | 2 | 2 | - | - | - | - | 2 | - | - | 2 | 3 | 2 |
| **CO3** | 2 | 3 | 2 | - | - | 3 | - | 3 | 3 | - | - | - | 3 | 3 |
| **CO4** | - | - | - | - | - | 3 | - | 2 | 2 | 3 | 3 | 2 | 2 | 2 |
| **CO5** | - | - | - | - | - | 2 | - | - | 2 | 2 | 2 | - | - | - |

**PT16351 REGULATORY TOXICOLOGY 3 0 0 3**

**COURSE OBJECTIVES**

To enable students to

- recognize the international, and national regulatory processes concerning chemical risk assessment in humans, biomaterials, and medical devices.
- discuss about how to develop awareness of how toxicology is applied in real world regulatory situations.
- explain the complexities and competing interests that are part of the regulatory decision making.
- classify the methods used to evaluate risk and produce safety guidelines, including laboratory testing, epidemiological studies
- outline the product regulations and produce alternative strategies for challenges in the future.

**UNIT I INTRODUCTION 9**

Regulatory aspects and strategy in medical device and biomaterials safety evaluation. Regulations affecting cosmetic and over-the- counter drug products.

**UNIT II REGULATIONS GOVERNING TOXICOLOGY 9**

Aim and mission, working areas, regulatory process in toxicology, quality assurance in regulatory toxicology, toxicological risk assessment.

**UNIT III TOXICOLOGY AND DRUG PRODUCT REGULATIONS 9**

Introduction, aspects of the IND / NDA process, toxicology and other issues, pediatric drug products, drug combinations, excipients and reformulations, conclusions.

**UNIT IV TOXICOGENEOMICS, GENETIC TOXICOLOGY AND REGULATORY POLICY 9**

Microarrays in toxicology, proteomics and metabolomics, case examples, toxicogenomics in regulatory environment. Initiation of genetic toxicology testing, EPA GENE TOX (Phase I and II), ICPEMC, NTP, Genetic toxicology technologies and concepts. Influence of genetic toxicology research on regulatory policy, future role in safety testing strategies.

**UNIT V ALTERNATIVES IN TOXICOLOGY 9**

Introduction, Societal need for information about toxic chemicals, evolution of alternatives in toxicology, human science, and animal welfare, assessing alternatives, challenges and future.

**TOTAL PERIODS: 45**

**COURSE OUTCOMES**

At the end of this course, the students will be able to

- define the general principles in toxicological risk assessment, both ecotoxicology and human toxicology.
- explain the safety testing strategies, legal regulations, and alternative options in toxicology.

- tell the basic principles of current, cutting-edge knowledge in environmental and human health toxicology.
- demonstrate an understanding of legal, regulatory, and ethical considerations relating totoxicology within the broader societal context.
- categorise different testing strategies and alternatives for societal needs.

**TEXT BOOKS**


1. Shayne C. Gad, "Regulatory Toxicology", Second Edition, CRC Press, 2001.
2. Ian Dewhurst, "Regulatory Toxicology" in the European Union, Royal Society of Chemistry,2017


**REFERENCES**


1. Sidney Green, "Toxicology and Regulatory Process". CRC Press, 2006.
2. Eds. Franz XaverReichl and Michael Schwenk , "Regulatory Toxicology" Springer, 2014.
3. Renuka Sengupta, "Regulatory Toxicology: Essentially Practical Aspects", Narosa Publishing House 2015


**CO/PO MAPPING:**

| **Mapping of Course Outcomes with Programme Outcomes (1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak** | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **COs** | **Programmes Outcomes (POs)** | | | | | | | | | | | | | |
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** | **PO6** | **PO7** | **PO8** | **PO9** | **PO10** | **PO11** | **PO12** | **PSO1** | **PSO2** |
| **CO1** | 1 | 1 | 1 | 1 | - | 1 | 1 | - | - | 1 | - | 1 | 1 | 1 |
| **CO2** | 2 | 2 | 1 | 2 | - | 1 | 1 | 1 | - | - | - | 1 | - | - |
| **CO3** | 1 | 2 | 2 | 3 | - | 1 | - | 1 | - | - | - | - | - | 1 |
| **CO4** | 2 | - | 1 | - | 1 | 1 | - | 1 | - | - | - | - | 2 | |
| **CO5** | 1 | 1 | 1 | - | 1 | 1 | 1 | 3 | - | - | - | - | - | - |

**PT16352 RESEARCH METHODOLOGY 3 0 0 3**

**COURSE OBJECTIVES**

To enable students to

- inculcate research spirit
- Impart in depth understanding of various steps of research
- Formulate of research problem
- Constrict - design, data collection, generation of report
- Develop the skill of scientific writing

**UNIT I OBJECTIVES AND TYPE OF RESEARCH 9**

Motivation and objectives - Research methods vs. Methodology. Types of research – Descriptive vs. Analytical, Applied vs. Fundamental, Quantitative vs. Qualitative, Conceptual vs Empirical.

**UNIT II RESEARCH FORMULATION 9**

Defining and formulating the research problem – Selecting the problem – Necessity of defining the problem – Importance of literature review in defining a problem – Literature review – Primary and secondary sources – reviews, treatise, monographs-patents – web as a source – searching the web – Critical literature review – Identifying gap areas from literature review – Development of working hypothesis.

**UNIT III RESEARCH DESIGN AND METHODS 9**

Research design – Basic Principles – Need of research design – Feature of good design – Observation and facts, Laws and theories, Prediction and explanation, Induction and Deduction, Development of Models. Developing a research plan – Exploration, Description, Diagnosis, Experimentation. Determining experimental and sample designs.

**UNIT IV DATA COLLECETION AND ANALYSIS 9**

Execution of the research – Observation and Collection of data – Methods of data collection – Sampling methods – Data Processing and Analysis strategies – Data Analysis with Statistical Packages – Hypothesis-testing – Generalization and Interpretation.

**UNIT V REPORTING AND THESIS WRITING 9**

Structure and components of scientific reports – Types of report – Technical reports and thesis – Significance – Different Steps in the preparation – Layout, structure and Language of typical reports – Illustrations and tables – Bibliography, reference and footnotes – Oral presentation – Planning – Preparation – Practice – Making presentation – Use of visual aids – Importance of effective communication.

**TOTAL PERIODS: 45**

**COURSE OUTCOMES**

At the end of this course, the students will be able to

- infer the basics of research

- understand various steps and techniques involved in research
- formulate a research problem
- construct and design a project and collect data
- adapt the skill of scientific writing

**TEXT BOOKS**


1. Grag, B.L, Karadia,R Agarwal, F and Agarwal, UK., 2002, "An Introduction to Research Methodology", RBSA Publishers
2. Kothan, C.R., 2004, "Research Methodology Methods and Techniques", New Age International. 418p.


**REFERENCES**


1. Sinha, S.C and Dhiman, A.K., 2002. "Research Methodology", Ess Publications, 2 Vol
2. Trochim, W.M.K., 2005, "Research Methods: the concise knowledge base", Atomic Dog Publishing.
3. Wadehra, B.L, 2011, "Law relating to patents, trademarks, copyright designs and geographical indications", Universal Law Publishing


**CO/PO MAPPING:**

| **Mapping of Course Outcomes with Programme Outcomes (1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak** | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **COs** | | **Programmes Outcomes (POs)** | | | | | | | | | | | | |
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** | **PO6** | **PO7** | **PO8** | **PO9** | **PO10** | **PO11** | **PO12** | **PSO1** | **PSO2** |
| **CO1** | 3 | 3 | 3 | 2 | 3 | 3 | 2 | 3 | 2 | - | 2 | - | 3 | 3 |
| **CO2** | 3 | 2 | 2 | 3 | 1 | - | 2 | 3 | - | - | - | 3 | 3 | 2 |
| **CO3** | 3 | 3 | 3 | 3 | 2 | 2 | - | - | - | - | - | 2 | 3 | 2 |
| **CO4** | 2 | 3 | 3 | 3 | 2 | 3 | - | - | - | - | - | 2 | 3 | 2 |
| **CO5** | 2 | 2 | 2 | 3 | 3 | 3 | - | - | - | 1 | - | 1 | 2 | 2 |

**PT16353 DIAGNOSTICS AND THERAPEUTICS 3 0 0 3**

**COURSE OBJECTIVES**

To enable students to

- list the nature of infection, procedural skills to collect and interpret data.
- classify the cause of infection and the pathogens.
- demonstrate the genetic nature of Human diseases.
- organize current Molecular diagnostics of infectious diseases.
- assess the biosafety aspects involved in molecular diagnosis.

**UNIT I INTRODUCTION TO DIAGNOSTICS AND THERAPEUTICS 9**

Mode of transmissions of infection - Pre-disposing factors of microbial pathogenicity, Normal microbial flora of the human body; Types of infectious diseases - Host - Parasite relationships, Clinical specimens collection, Transport and Processing of samples, Interpretation of results.

**UNIT II MICROBIAL INFECTIONS AND DIAGNOSIS 9**

Pathogenicity and diagnosis of major bacterial infections - Streptococcus, Coliforms, Salmonella, and Mycobacterium; Pathogenicity and diagnosis of major fungal infections - Dermetophytosis, Candidiosis and Aspergillosis; Pathogenicity and diagnosis of major Protozoan infections - Amoebiosis, Malaria, Leishmaniasis; DNA and RNA Viruses - Pox viruses, Hepatitis viruses, Adeno viruses and Retro viruses.

**UNIT III MEDICAL GENETICS 9**

Organization of Human genome - Identifying human disease genes; Genetic disorders - Sickle cell anemia, Duchenne muscular Dystrophy, Retinoblastoma, Cystic Fibrosis, Neonatal and Pre-natal disease diagnostics; Gender identification - Analysis of mitochondrial DNA for maternal inheritance, Genetic counselling.

**UNIT IV METHODS IN MOLECULAR DIAGNOSTICS 9**

Isolation and purification of nucleic acids - Nucleic acid labelling, Hybridization, PCR and types, PCR based molecular typing, Molecular diagnosis of pathogens based on 18S and 16S rRNA sequences, Automated DNA sequencing, Microarrays - types and applications.

**UNIT V BIOSAFETY FOR MOLECULAR DIAGNOSTICS 9**

Good Laboratory Practices - Different levels of biosafety containments for rDNA experiments, Biosafety aspects of tissue / Cell transplantation.

**TOTAL PERIODS: 45**

**COURSE OUTCOMES**

At the end of this course, the students will be able to

- recall about infection, sample collection, transport, and the data.
- explain about the most appropriate infectious agent.
- demonstrate the microorganism have an indispensable role in disease diagnosis

- appraise the genomic knowledge.
- choose the tool for disease diagnosis.

**TEXT BOOKS**


1. Lele Buckingham and Maribeth L. Flaws, 2007. Molecular Diagnostics: Fundamentals, Methods & Clinical Applications.
2. David E. Bruns, Edward R. Ashwood and Carl A. Burtis, 2007. Fundamentals of Molecular Diagnostics.
3. Griffiths, A. J. F., Miller, J. H. and Suzuki, D. T., 2000. An Introduction to Genetic Analysis.


**REFERENCES**


1. Lodish, Berk, Zipursky, Matsudaira, Baltimore Darnell, 2000. Molecular Cell Biology. W.H. Freeman and Company. 4thEdn.
2. Benjamin L., 2008. Genes IX. Jones and Bartlett.
3. Turner, P. C., McLennan, A. G., Bates, A. D. and White, M. R. H., 2003. Instant Notes in Molecular Biology. Viva Books Private Limited
4. Jeremy M. Berg, John L. Tymoczko and LubertStryer, 2002. Biochemistry. W.H. Freeman andCompany.5thEdn


**CO/PO MAPPING:**

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **COs** | **Programmes Outcomes (POs)** | | | | | | | | | | | | | |
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** | **PO6** | **PO7** | **PO8** | **PO9** | **PO10** | **PO11** | **PO12** | **PSO1** | **PSO2** |
| **CO1** | 2 | 1 | - | 2 | - | - | - | - | - | - | - | - | - | - |
| **CO2** | 2 | - | - | - | - | - | 3 | - | - | - | - | - | - | - |
| **CO3** | 2 | 2 | 2 | 2 | - | - | - | - | 1 | - | - | - | 1 | - |
| **CO4** | 3 | 2 | 1 | 1 | - | - | 2 | - | - | - | - | 1 | 1 | - |
| **CO5** | 3 | 2 | 2 | 1 | - | 2 | - | - | -- | - | - | 1 | - | - |

**PT16354 FUNDAMENTALS OF MOLECULAR PATHOLOGY 3 0 0 3**

**COURSE OBJECTIVES**

To enable students to

- impart basic knowledge in microbial pathogenesis
- study the various aspects of host pathogen interactions.
- study the advanced pathogen control techniques and its applications
- know the interactions between host – pathogen Interaction
- know the modern approaches to control pathogens

**UNIT I OVERVIEW 9**

Historical perspective - discovery of microscope, Louis Pasteur's contributions, Robert Koch's postulates, early discoveries of microbial toxins, toxic assays, vaccines, antibiotics and birth of molecular genetics and modern molecular pathogenesis studies, Various pathogen types and modes of entry.

**UNIT II HOST-DEFENSE AGAINST PATHOGENS AND PATHOGENIC STRATEGIES 9**

Attributes and components of microbial pathogenesis, Host defense: skin, mucosa, cilia, secretions, physical movements, limitation of free iron, antimicrobial compounds, mechanism of killing by humoral and cellular defense mechanisms, complements, inflammation process, general disease symptoms, Pathogenic adaptations to overcome the above defenses

**UNIT III MOLECULAR PATHOGENESIS (WITH SPECIFIC EXAMPLES) 9**

Virulence, virulence factors, virulence-associated factors and virulence lifestyle factors, molecular genetics and gene regulation in virulence of pathogens, Vibrio Cholerae: Cholera toxin, co-regulated pili, filamentous phage, survival E.coli pathogens: Enterotoxigenic E.coli (ETEC), labile and stable toxins, Entero- pathogenic E.coli (EPEC), type III secretion, cytoskeletal changes, intimate attachment; Enterohaemerrohogic E.coli (EHEC), mechanism of bloody diarrhoea and Hemolytic Uremic Syndrome, Enteroaggregative E.coli (EAEC). Shigella: Entry, macrophage apoptosis, induction of macropinocytosis, uptake by epithelial cells, intracellular spread, inflammatory response, tissue damage Plasmodium: Life cycle, erythrocyte stages, transport mechanism and processes to support the rapidly growing schizont, parasitiparous vacuoles, and knob protein transport, Antimalarials based on transport processes. Influenza virus: Intracellular stages, Neuraminidase and Haemagglutinin in entry, M1 and M2 proteins in assembly and disassembly, action of amantidine

**UNIT IV EXPERIMENTAL STUDIES ON HOST-PATHOGEN INTERACTIONS 9**

Virulence assays: adherence, invasion, cytopathic, cytotoxic effects. Criteria and tests in identifying virulence factors, attenuated mutants, molecular characterization of virulence factors, signal transduction and host responses

**UNIT V MODERN APPROACHES TO CONTROL PATHOGENS 9**

Classical approaches based on serotyping. Modern diagnosis based on highly conserved virulence factors, immuno and DNA-based techniques. New therapeutic strategies based on recent findings on molecular pathogenesis of a variety of pathogens, Vaccines - DNA, subunit and cocktail vaccines

**TOTAL PERIODS: 45**

**COURSE OUTCOMES**

At the end of this course, the students will be able to

- understand about the overview of microbial pathogenesis.
- understand about various aspects of host pathogen interactions
- understand the advanced pathogen control techniques and its applications
- understand about Host-Pathogen Interactions
- understanding about the modern approaches for controlling pathogens.

**TEXT BOOKS**


1. Chandrasoma, Prakrama and Clive R.Taylor “Concise Pathology”, 3rd Ed., Mc FrawHill, 2001.
2. Stevens, Han and James Lowe “Pathology” 2nd Ed., Moshy 2000.


**REFERENCES**


1. Kumar, vinay, abdul K.Abbas and Nelson Fausto “Robbins and Cotran Pathologic Basis of Disease” 17th Ed., Saunders, 2004.
2. Cook, D.J. “Cellular Pathology” 2nd Ed., Scion, 2006.
3. Iglewski B.H and Clark V.L “Molecular basis of Bacterial Pathogenesis”, Academic Press, 1990.
4. Eduardo A. Groisman, Principles of Bacterial Pathogenesis, Academic Press, 2001.


**CO/PO MAPPING:**

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| **COs** | | **Programmes Outcomes (POs)** | | | | | | | | | | | | |
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| **CO1** | 2 | - | 2 | - | - | 1 | 3 | - | - | - | - | - | 1 | 2 |
| **CO2** | 2 | - | 2 | - | - | 1 | 2 | 1 | - | - | - | - | - | 2 |
| **CO3** | - | 2 | 2 | 1 | - | - | 2 | - | - | - | - | - | - | 3 |
| **CO4** | - | 2 | - | 2 | - | 1 | 3 | - | - | 1 | - | - | - | 3 |
| **CO5** | - | - | 3 | 2 | - | - | 3 | 1 | - | 1 | - | 2 | - | 3 |

**PT16903 PLANT AND ANIMAL DISEASES AND THEIR CONTROL 3 0 0 3**

**COURSE OBJECTIVES**

To enable students to

- recognize the pest morphology and its corresponding pesticides
- describe the pest in agriculture and their control measures.
- choose the appropriate pest control method
- outline the vector plant pathogen interaction and management of vectors for controlling diseases.
- formulate the different sampling methods and monitoring protocol

**UNIT I CLASSIFICATION OF PESTS AND PESTICIDES 9**

Pests – Definition, Morphology and Life cycle; classification of pests – Vertebrate pests, Invertebrate pests and plant pests; Classification of pesticides on chemical nature and according to target species, mode of action.

**UNIT II AGRICULTURAL PESTS AND THEIR CONTROL 9**

Concept of Pest and Types of pests in agricultural products - stored grains, veterinary, forestry and nursery; Major insect pests of agricultural- importance, Marks of identification, life cycle, nature of damage, chestnut blight, potato late blight, downy mildew, Damage economic threshold level and control measures.

**UNIT III PEST CONTROL PRACTICES 9**

Issues - Challenges and Opportunities in the Control of Insects in Vegetable Crops, Control measures Cultural, Physical, Mechanical, Chemical, Herbal and Biological control, Pheromonal and autocidal control.

**UNIT IV EMERGING CONCEPTS AND PRACTICES IN INTEGRATED CONTROL MEASURES 9**

The integrated control/IPM concept - Damage thresholds, Forecasting, Increasing agro-ecosystem resistance, Pesticide selectivity, Eradication versus control; Pests and humans – direct pests and vectors of plant and animal diseases, potential human practices and the occurrence of pests, Prevention of communicable diseases after the disaster

**UNIT V SAMPLING AND MONITORING ARTHROPODS 9**

Methods of sampling and monitoring - Components of a sampling plan, Types of sampling plans, Allocation of Sampling units.

**TOTAL PERIODS: 45**

**COURSE OUTCOMES**

At the end of this course, the students will be able to

- recall the epidemiology of diseases caused by pests in plant and animals
- recall the epidemiology of diseases caused by pests in plant and animals
- classify about the plant and animal disease and integrated control

- examine the diseases in plants and animal and its control
- validate the different samplings methods

**TEXT BOOKS**

1. S.B.Chattopadhyay “Principles and procedures of plant protection” Oxford-IBH. 1993.
2. A. S. Atwal, “Agricultural pests of India and south East Asia” , Kalyani Publishers, 1986.

**REFERENCES**


1. D.S.Hill, S.Pradhan, “Agricultural insect pests of the crops and their control”- Cambridge Univ. Press Insect pest of crops - National Book trust.
2. John Karlik, Mary Louise Flint, and Deborah Golino “Healthy Roses: Environmentally friendly ways to manage pests and disorders in your garden and landscape”, 2nd Edition.
3. Hayes' Handbook of Pesticide Toxicology, Editor-in-Chief: Robert Krieger, University of California, Riverside, U.S.A. Published by January 2010, imprint: Academic Press,
4. Francisco Prieto Garcia, Sandra Y. Cortés Ascencio, John C. Gaytan Oyarzun, Alejandra Ceruelo Hernandez and Patricia Vazquez Alavarado “Pesticides: classification, uses and toxicity. Measures of exposure and genotoxic risks”. Journal of Research in Environmental Science and Toxicology (Vol. 1(11) 2012


**CO/PO MAPPING :**

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| **COs** | **Programmes Outcomes (POs)** | | | | | | | | | | | | | |
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** | **PO6** | **PO7** | **PO8** | **PO9** | **PO10** | **PO11** | **PO12** | **PSO1** | **PSO2** |
| **CO1** | 1 | - | 1 | - | - | 1 | - | - | - | 1 | 1 | 1 | - | - |
| **CO2** | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 1 | - | - | - | 1 | 1 | - |
| **CO3** | 3 | 3 | 3 | - | - | - | - | 3 | - | 2 | - | - | 2 | 1 |
| **CO4** | 2 | - | 2 | - | 2 | 2 | 3 | - | - | - | - | 1 | | 1 |
| **CO5** | 1 | 1 | - | - | 2 | - | - | - | 1 | - | - | 2 | 2 | 1 |

**PT19904 INTRODUCTION TO PHARMACEUTICAL TECHNOLOGY 3 0 0 3**

**COURSE OBJECTIVES**

To enable students to

- understand the microbiology
- know about the medicinal chemistry
- learn about pharmacology
- know about basics of immunology
- learn about unit operations

**UNIT I MICROBIOLOGY 9**

Introduction to microbiology and its significance (beneficial and harmful) in Foods (Dairy including pre and probiotics, cheese, vitamins, beverages etc), Pharmaceuticals (Antibiotics, vaccine production, pathogenic organisms etc), Oils (bioremediation, biodiesel from microorganism etc), and environment (wastewater, nitrification, methanation, green chemicals and biofuels etc)

**UNIT II INTRODUCTION TO MEDICINAL CHEMISTRY 9**

Definitions and explanation of terms used in Medicinal Chemistry (hits, lead, lead development, molecular libraries, toxicity studies, high throughput screening, ADME etc.), nomenclature of drugs, Drug formulation, Fine chemical Manufacturing process.

**UNIT III GENERAL PHARMACOLOGY 9**

Routes of administration-CNS drugs- mechanisum of action (antidepressant,anthi inflammatory, CNS stimulants-cardiovascular drugs- mechanism of action(anti-hypertensive agents, vasodilators),gasointestinal drugs mechanism of action(laxatives,appetite stimulants and suppressants)

**UNIT IV BASICS OF IMMUNOLOGY 9**

Immune system - humoral and cell mediated immunity; Antibodies - antigen-antibody reactions

**UNIT V UNIT OPERATION 9**

Size reduction equipment-crystallizer—theory of filtration-rotary filter-centrifugation

**TOTAL PERIODS: 45**

**COURSE OUTCOMES**

At the end of this course, the students will be able to

- understand the importance of microbiology
- explain the basics of medicinal chemistry
- design, evaluate and to validate the drugs
- apply the knowledge of immunoglobin in manufacturing of drugs
- apply the knowledge of unit operation in drug

**TEXT BOOKS**

1. Girish K.Jjain, “Pharmaceutical Engineering, Unit Operation” I,b.s. Shah Prakasan, India 2006

2. Judith A. Owen, Jenni Punt and Sharon Stranford, “Kuby Immunology”, W.H. Freeman and Company, 7th Edition, 2013

**REFERENCES**

1. Peter J. Delves, Seamus J. Martin, Dennis R. Burton and Ivan M. Roitt, “Roitt’s Essential Immunology” Wiley-Blackwell Publication, 12th Edition, 2011
2. Katzung B G Trevor AJ, “Basic of Clinical Patharmacology”, McGraw-Hill education,13th Edition 2015.
3. Copper and Gunns, “Tutorial Pharmacy”, Edited by s j Carter, CBS Publishers, New Delhi 2005
4. Tripathi. K D, “Essential of Medical Pharmacology”, 7th edition,Jaypee Brothers Medical Publishers, 2015

**CO/PO MAPPING:**

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **COs** | **Programmes Outcomes (POs)** | | | | | | | | | | | | | |
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** | **PO6** | **PO7** | **PO8** | **PO9** | **PO10** | **PO11** | **PO12** | **PSO1** | **PSO2** |
| **CO1** | 3 | 2 | 2 | 1 | 2 | 1 | - | 1 | 2 | - | - | 3 | 2 | 3 |
| **CO2** | 2 | 1 | 3 | - | 2 | 1 | - | 1 | 2 | - | - | 3 | 3 | 2 |
| **CO3** | 2 | 2 | 2 | 1 | 2 | 1 | - | 1 | 2 | - | - | 3 | 3 | 3 |
| **CO4** | 2 | 2 | 2 | 1 | 2 | 1 | - | 1 | 2 | - | - | 3 | 2 | 3 |
| **CO5** | 3 | 3 | 3 | 2 | - | - | - | - | - | - | - | 3 | 3 | 2 |

**PT16801 DOWNSTREAM PROCESSING 3 0 0 3**

**COURSE OBJECTIVES**

To enable students to

- learn about fundamental downstream processes.
- understand the fundamentals of biological product recovery.
- understand the biological product isolation separation.
- understand the biological product purification and formulation.
- acquire in depth knowledge on design and optimization of downstream process operations and equipment.

**UNIT I OVERVIEW OF DOWNSTREAM PROCESSING 9**

Introduction to downstream processing - Principles - Characteristics of biomolecules and bioprocesses; Cell disruption for product release - Mechanical, Enzymatic and Chemical methods; Pretreatment and Stabilization of bio-products.

**UNIT II PHYSICAL METHODS OF SEPARATION 9**

Separation of cells and other insoluble from fermented broth - Sedimentation, Filtration (Pretreatment, Filtration theory, and Continuous rotary filters), Microfiltration, Centrifugation (Batch, Continuous and Basket).

**UNIT III ISOLATION OF PRODUCTS 9**

Liquid-liquid extraction, Aqueous two-phase extraction, Precipitation of proteins by different methods - Salting in and salting out method, Adsorption; Membrane based separation - Ultrafiltration and Microfiltration, Reverse osmosis, Dialysis.

**UNIT IV PRODUCT PURIFICATION 9**

Chromatography - Principles, Instruments and practice; Adsorption, Reverse phase, Ion-exchange, Size exclusion, Hydrophobic interaction, Bio affinity and Pseudo affinity chromatographic techniques.

**UNIT V PRODUCT POLISHING 9**

Crystallization theory - Rate of nucleation, Rate of crystal growth and Equipment for crystallization; Drying of bioproducts - Methods of drying and Equipment for drying; Freeze drying; Effect of thermal processing on food constituents.

**TOTAL PERIODS: 45**

**COURSE OUTCOMES**

At the end of this course, the students will be able to

- understand the physicochemical properties of biotechnological products and economics of downstream processing.
- acquire knowledge about equipment selection and design of mechanical separation process for recovery of biotechnological products.
- identify and optimize the suitable bioproduct isolation process at laboratory and pilot scale.

- understand the chromatographic separation technique and equipment selection during downstream processing.
- understand the various techniques for stability of biotechnology products and will be capable of formulation and stabilization for the enhancement of shelf-life of the biotech products.

**TEXT BOOKS**


1. Belter PA, Cussler E and Hu WS, "Bioseparation – Downstream Processing for Biotechnology", Wiley Interscience (1988)
2. Asenjo, Juan A. "Separation Processes in Biotechnology". Taylor & Francis / CRC,2000.


**REFERENCES**


1. R.O. Jenkins, (Ed.), "Product Recovery In Bioprocess Technology – Biotechnology" By Open Learning Series, Butterworth-Heinemann.
2. J.C. Janson And L. Ryden, (Ed.), "Protein Purification – Principles, High Resolution Methods and Applications", VCH Pub. 2011.
3. R.K. Scopes, "Protein Purification – Principles and Practice", Narosa Pub. 1994.
4. Sivasankar, B. "Bioseparations : Principles and Techniques". PHI, 2005.


**CO/PO MAPPING:**

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **COs** | **Programmes Outcomes (POs)** | | | | | | | | | | | | | |
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** | **PO6** | **PO7** | **PO8** | **PO9** | **PO10** | **PO11** | **PO12** | **PSO1** | **PSO2** |
| **CO1** | 3 | 1 | - | - | - | - | 1 | - | - | - | - | 1 | 1 | 1 |
| **CO2** | 3 | 1 | - | - | - | - | - | - | - | - | - | 1 | 2 | 1 |
| **CO3** | 3 | 1 | - | - | - | 2 | - | - | - | - | - | 1 | 2 | - |
| **CO4** | 3 | 1 | 1 | - | - | 2 | 1 | - | - | - | - | - | 1 | - |
| **CO5** | 3 | 1 | 2 | 2 | 2 | 2 | 2 | 1 | - | - | - | - | 2 | 3 |

**PT16802** **PROJECT WORK PHASE II** **0 0 12 6**

## COURSE OBJECTIVES

To enable students to

- develop students' knowledge for solving technical problems through structured project research study in order to produce competent and sound engineers.

The student in a group of 3 to 4 works on a topic approved by the Head of the Department under the guidance of a faculty member and prepares a comprehensive project report after completing the work to the satisfaction of the supervisor. The progress of the project is evaluated based on a minimum of three reviews. The review committee may be constituted by the Head of the Department. A project report is required at the end of the semester. The project work is evaluated based on oral presentation and the project report jointly by external and internal examiners constituted by the Head of the Department.

**TOTAL PERIODS: 180**

## COURSE OUTCOMES

At the end of this course, the students will be able to

- identify and describe the problem and scope of project clearly.
- collect, analyze and present data into meaningful information using relevant tools.
- select, plan and execute a proper methodology in problem solving.
- work independently and ethically.
- identify basic entrepreneurship skills in project management.

## CO/PO MAPPING:

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **COs** | **Programmes Outcomes (POs)** | | | | | | | | | | | | | |
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| **CO1** | 3 | 2 | 3 | 2 | - | - | - | - | 2 | - | - | - | 2 | 2 |
| **CO2** | - | 3 | 2 | 2 | - | - | - | - | 2 | - | - | 2 | 3 | 2 |
| **CO3** | 2 | 3 | 2 | - | - | 3 | - | 3 | 3 | - | - | - | 3 | 3 |
| **CO4** | - | - | - | - | - | 3 | - | 2 | 2 | 3 | 3 | 2 | 2 | 2 |
| **CO5** | - | - | - | - | - | 2 | - | - | 2 | 2 | 2 | - | - | - |

**PT16451** **VACCINE TECHNOLOGY** **3 0 0 3**

**COURSE OBJECTIVES**

To enable students to

- impart basic knowledge in vaccinology.
- study the various classifications of vaccines and its preparations.
- study the various design and research conducted on vaccine.
- study the various computational tools for vaccine design.
- know the modern approaches to vaccine in animal testing, commercialization, and quality control.

**UNIT I IMMUNOLOGICAL CONCEPTS IN VACCINOLOGY 9**

Short history of vaccination; Requirements for induction of immunity; Epitopes - Linear and Conformational epitopes; Characterization and location of APC, MHC and immunogenicity; Rationale vaccine design based on clinical requirements - Hypersensitivity, Immunity to Infection, Autoimmunity, Transplantation, Tumor immunology, Immunodeficiency; Mechanism of adjuvant action; Scope of future vaccine strategies

**UNIT II CLASSIFICATION OF VACCINES AND ITS PREPARATIONS 9**

Active and passive immunization; Viral/bacterial/parasite vaccine differences; Methods of vaccine preparation - Live, killed, attenuated, sub unit vaccines; Vaccine technology- Role and properties of adjuvants, Recombinant DNA and Protein based vaccines, Plant-based vaccines, Edible vaccines, Reverse vaccinology, Combination vaccines, Therapeutic vaccines, Peptide vaccines, Conjugate vaccines; Antibody genes and Antibody engineering- Chimeric and Hybrid monoclonal antibodies; Catalytic antibodies and generation of immunoglobulin gene libraries; Transfusion of immuno-competent cells; Cell based vaccines

**UNIT III VACCINE RESEARCH AND DESIGN 9**

Fundamental research to rational vaccine design; Antigen identification and delivery; T-Cell expression cloning for identification of vaccine targets for intracellular pathogens; Fundamentals of Immune recognition, Implications for manipulating the T-Cell repertoire, Targeting Dendritic cells; A rational approach for Vaccine development - Cellular basis of T Cell memory , Rational design of new vectors , CpG adjuvant activity, Transcutaneous immunization; Vaccination studies and recent advances in Malaria, Tuberculosis , HIV.

**UNIT IV COMPUTATIONAL TOOLS FOR VACCINE DESIGN 9**

Antigen Sequence analysis; Epitope Mapping; Predictions of Immunogenic peptides of T Cell and B-Cells; Prediction of HLA binding peptides; Comparative Genomics as a tool for vaccine design; Introduction to online epitope databases.

**UNIT V ANIMAL TESTING, COMMERCIALISATION, QUALITY CONTROL 9**

Quality control and regulations in vaccine research - In-vitro experimental validations for predictions of vaccines by software, Animal testing, Rational design to clinical trials, Large scale production, Commercialization, Ethics.

**TOTAL PERIODS: 45**

**COURSE OUTCOMES**

At the end of this course, the students will be able to

- understand about the overview of microbial pathogenesis.
- understand about various aspects of host pathogen interactions.
- understand the advanced pathogen control techniques and its applications.
- understand about Host-Pathogen Interactions.
- understanding about the modern approaches for controlling pathogens.

**TEXT BOOKS**


1. Male, David et al., "Immunology", 7th Edition, Mosby Publication, 2007.
2. Kindt, T.J. etal., "Immunology", 6th Edition, W.H. Freeman, 2007.
3. Janeway, C.A. etal., "Immunology: The Immune Systems in Health and Diseases", 6th Edition, Garland Science, 2005.


**REFERENCES**


1. Coico, R. etal., "Immunology: A Short Course", 5th Edition, Wiley – Liss, 2003.
2. Parham, Peter "The Immune System", 2nd Edition, Garland Science, 2005.
3. Abbas, A.K. etal., "The Cellular and Molecular Immunology", 6th Edition, Sanders / Elsevier, 2007.
4. Lydyard, P.M. "Instant Notes in Immunology", Viva Books Pvt. Ltd., 2000


**CO/PO MAPPING:**

| **Mapping of Course Outcomes with Programme Outcomes (1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak** | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **COs** | **Programmes Outcomes (POs)** | | | | | | | | | | | | | |
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** | **PO6** | **PO7** | **PO8** | **PO9** | **PO10** | **PO11** | **PO12** | **PSO1** | **PSO2** |
| **CO1** | 3 | 3 | 2 | 3 | 2 | 1 | - | 2 | 2 | 1 | - | 2 | 1 | 2 |
| **CO2** | 2 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 3 | 1 | - | 3 | - | 2 |
| **CO3** | 1 | 3 | 3 | 2 | 2 | 3 | 2 | 3 | 3 | 3 | - | 2 | - | 3 |
| **CO4** | 2 | - | 3 | 1 | 1 | 3 | 3 | 3 | 3 | 1 | 1 | - | - | 3 |
| **CO5** | 2 | 2 | 3 | - | 1 | - | 3 | 1 | 2 | 1 | 3 | 2 | - | 3 |

**PT16452** **PHARMACEUTICAL PACKAGING TECHNOLOGY** **3 0 0 3**

**COURSE OBJECTIVES**

To enable students to

- impart the overall concept in pharmaceutical packaging.
- study different types of primary packaging material.
- study the different types of secondary packaging material and its quality control.
- study the different types of process involved in liquid formulation and in method of sterile product packaging.
- know the regulation and stability for packaging material.

**UNIT I PHARMACEUTICAL PACKAGING** **9**

Status - Scope in pharmaceutical industry; Classification of packaging material - Primary and secondary packaging; Functions of packaging.

**UNIT II PRIMARY PACKAGING MATERIAL** **9**

Glass containers, Metal's containers; Fiber and Paper board for bulk; Films and Foils for lamination; Equipment's used in strip and blister packaging.

**UNIT III SECONDARY PACKAGING MATERIALS** **9**

Folding cartons and sets of boxes - Materials of construction, Design, Specifications; Packaging inserts - Specifications – Test methods, Quality control; Cushioning materials - Applications - Tapes and adhesives, Cap threads, Cap liners, Bands, Shrink bands, Stoppers and plugs.

**UNIT IV LIQUID FORMULATION AND STERILE PRODUCT PACKAGING** **9**

Liquid Formulation; Factors influencing selection of liquid filling machinery; Balanced and Unbalanced constant level filling, Volumetric, Gravimetric, Level sensing, Time fill, Peristaltic and Overflow liquid filling machinery; Sterile product packaging- Various types of containers used for sterile products like ampoules – Vials, Bottles for I.V. fluid, etc.; Types of closures used for the sterile products; Sterile product filling and sealing machinery i.e., Ampoule filling and Sealing machine.

**UNIT V STABILITY AND REGULATIONS** **9**

Specifications; Quality control tests - Methods and Evaluation of packaging of materials; Stability of packaging materials; Labels and labeling; Sterilization of containers; Law and Regulations governing packaging.

**TOTAL PERIODS: 45**

**COURSE OUTCOMES**

At the end of this course, the students will be able to

- understand about the scope of pharmaceutical packaging.
- understand about various aspects of primary packaging material.
- understand the various aspects of secondary packaging material and its quality control.

- understand about process involved in liquid formulation and in method of sterile product packaging.
- understanding about the regulation and stability for packaging material.

**TEXT BOOKS**


1. Deak, D.A., Evans, E.R. and Hall, I.H., "Pharmaceutical Packaging Technology", Taylor and Francis, 2000.
2. Harburn, K., "Quality Control of Packaging Materials in the Pharmaceutical Industry", Informa Healthcare, 1990.
3. Edward J. Bauer, "Pharmaceutical Packaging Handbook". CRC Press, 2009.
4. S. Natarajan, M. Govindarajan, B. Kumar, "Fundamental of Packing Technology", PHI Learning Pvt ltd., New Delhi, 2009.


**REFERENCES**


1. Anonymous, "Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials", 2nd Edition, World Health Organization, 2004.
2. Styres, L.K., "Modern Packaging Encyclopedia", Packaging Catalog Corporation Publications, 1969
3. Selke, S.E.M., "Understanding: Plastics Packaging Technology", Hanser Verlag Publications, 1997.
4. U.K. Jain, D.C. Goupale, S. Nayak, "Pharmaceutical Packaging Technology", 2nd ed., Pharma Med Press, Hyderabad, 2008


**CO/PO MAPPING:**

**Mapping of Course Outcomes with Programme Outcomes**

**(1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak**

| COs | Programmes Outcomes (POs) | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** | **PO6** | **PO7** | **PO8** | **PO9** | **PO10** | **PO11** | **PO12** | **PSO1** | **PSO2** |
| **CO1** | - | 2 | - | - | - | 3 | 1 | 1 | - | - | - | 3 | 2 | 2 |
| **CO2** | 2 | 3 | 3 | 2 | - | 3 | 3 | 2 | - | - | - | 3 | 3 | 3 |
| **CO3** | 2 | 3 | 3 | 2 | - | 3 | 3 | 3 | - | - | - | 3 | 3 | 3 |
| **CO4** | 1 | 2 | 3 | 3 | 1 | 3 | 3 | 3 | 1 | - | - | 3 | 3 | 3 |
| **CO5** | - | 3 | 3 | - | - | 3 | 3 | 3 | 2 | 1 | - | - | 3 | 3 |

| PT16453 | INTRODUCTION TO BIOMATERIALS AND TISSUE ENGINEERING | 3 | 0 | 0 | 3 |
|---|---|---|---|---|---|

**COURSE OBJECTIVES**

To enable students to

- understand the basics of biomaterials.
- learn the different types of biomaterials.
- learn about the tissue engineering.
- know about the tissue architecture.
- learn about the clinical application.

**UNIT I INTRODUCTION TO BIOMATERIALS 9**

History of biomaterials; General Properties of Biomaterials; Classes of materials used in medicine; Properties of materials - Bulk and surface properties and their characterization, Mechanical Properties of Biomaterials; Classes of materials used in medicine - Metals, Polymers, Hydrogels Bioresorbable and Biodegradable Materials.

**UNIT II METALIC, CERAMIC AND POLYMERIC BIOMATERIALS 9**

Stainless steel, Titanium, Alloys, Cardiovascular, Orthopedic and Dental applications; Corrosion of Bio-metals; Types of Valve Prostheses - Cardiac Stent; Bio-Ceramics - Bio–inert ceramics, Bio– active ceramics, Biodegradable ceramics, Alumina, Zirconia, Hydroxyapatite; Types of polymers - Sterilization, Structure, Bio-compatibility relationship, Stability, Examples of polymers used in medicine; Hydrogels and Drug delivery systems; Sutures, Adhesives, and Hydro colloids; Super absorbents; Artificial skin and blood.

**UNIT III INTRODUCTION TO TISSUE ENGINEERING 9**

Introduction to tissue engineering- Basic definition; Current scope of development; Use in therapeutics; Cells as therapeutic agents; Cell numbers and Growth rates; Measurement of cell characteristics - Morphology, Number viability, Motility and Functions; Measurement of tissue characteristics - Appearance, Cellular component, Mechanical measurements and Physical properties.

**UNIT IV TISSUE ARCHITECTURE 9**

Tissue types and Tissue components; Tissue repair; Engineering VEGF/angiogenesis; Basic properties - Cell-Matrix and Cell-Cell Interactions, Telomeres and Self renewal; Control of cell migration in tissue engineering Stem cells; Biomaterials in tissue engineering; Tissue culture - Bioreactors and Biomolecular production; Host interactions to biomaterials – Inflammation, Wound healing and The foreign body response, System toxicity and Hypersensitivity, Blood coagulation and Blood-material Interactions, Tumorigenesis, Implant associated infection.

**UNIT V CLINICAL APPLICATION 9**

Stem cell therapy, Molecular therapy, In vitro organogenesis, Neuro degenerative diseases, Spinal cord injury, Heart disease, Diabetes, Burns and Skin ulcers, Muscular dystrophy, Orthopedic applications; Stem cells and Gene therapy physiological models; Issue engineered therapies; Product characterization

- components, safety, efficacy; Preservation -freezing and drying; Patent protection and regulation of tissue-engineered products; Ethical issues.

**TOTAL PERIODS: 45**

**COURSE OUTCOMES**

At the end of this course, the students will be able to

- explain the basics of biomaterials.
- have a knowledge on different types of biomaterials.
- explain about the tissue engineering.
- have a knowledge on tissue architecture.
- have a knowledge about the clinical application.

**TEXT BOOKS**


1. Michael F. Ashby, Hugh Shercliff, David Cebon, “Materials: engineering, science, processing and design”, 2013, 3rd Edition, Elsevier Ltd, Cambridge.
2. Bernhard O.Palsson, Sangeeta N.Bhatia, ”Tissue Engineering” Pearson Publishers 2009.


**REFERENCES**


1. Ratner, Hoffman, Schoen, Lemons, “Biomaterials Science”, 1st Edition, Academic Press, Massachusetts. 2012
2. Steven M. Kurtz, “PEEK Biomaterials Handbook”, 1st Edition, Elsevier, Atlanta. 2011


**CO/PO MAPPING:**

| **Mapping of Course Outcomes with Programme Outcomes (1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak** | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **COs** | **Programmes Outcomes (POs)** | | | | | | | | | | | | | |
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** | **PO6** | **PO7** | **PO8** | **PO9** | **PO10** | **PO11** | **PO12** | **PSO1** | **PSO2** |
| **CO1** | 3 | 2 | 2 | 1 | 2 | 1 | - | 1 | 2 | - | - | 3 | 2 | 3 |
| **CO2** | 2 | 1 | 3 | - | 2 | 1 | - | 1 | 2 | - | - | 3 | 3 | 2 |
| **CO3** | 2 | 2 | 2 | 1 | 2 | 1 | - | 1 | 2 | - | - | 3 | 3 | 3 |
| **CO4** | 2 | 2 | 2 | 1 | 2 | 1 | - | 1 | 2 | - | - | 3 | 2 | 3 |
| **CO5** | 3 | 3 | 3 | 2 | - | - | - | - | - | - | - | 3 | 3 | 2 |

**PT16454** **DRUG DELIVERY SYSTEMS** **3 0 0 3**

**COURSE OBJECTIVES**

To enable students to

- train the students on science and technology of advanced drug delivery systems.
- train the students to design drug delivery systems for passive and active targeting.
- understand various approaches for development of novel drug delivery systems.
- understand the properties of polymer and its significance in drug delivery systems.
- interpret physicochemical properties of the drug with the drug delivery system modules.

**UNIT I INTRODUCTION** **9**

Fundamentals of Controlled Release and target release; Drug Delivery Influence of drug properties; Routes of drug administration on the design of sustained and controlled release systems; Pharmacokinetic/Pharmacodynamic basis of drug delivery; Dosing considerations and bioavailability assessment.

**UNIT II ORAL DRUG DELIVERY SYSTEM** **9**

Design and fabrication of Oral Drug Delivery Systems (DDS), Osmotic DDS, Ion exchange-controlled DDS, Hydrodynamically balanced DDS.

**UNIT III MUCOSAL DRUG DELIVERY SYSTEM** **9**

Design and fabrication of Mucosal DDS - Physiological basis of mucosal delivery; Bio adhesion and Bio adhesive polymers; Design and Fabrication of drug delivery systems of oral and mucosal DDS

**UNIT IV TRANSDERMAL DRUG DELIVERY SYSTEM** **9**

Design, development and evaluation of Transdermal DDS - Percutaneous absorption and Penetration enhancers, Development of transdermal gels, Patches with reference to manufacturing equipment components and Evaluation; Iontophoretic and Sonophoretic DDS.

**UNIT V OCULAR AND DENTAL DRUG DELIVERY SYSTEM** **9**

Design, development, and evaluation of Ocular DDS; Design of CR ophthalmic DDS including gels, inserts, novel DDS and Evaluation; Dental DDS - DDS for oral conditions, Dental care and Therapy

**TOTAL PERIODS: 45**

**COURSE OUTCOMES**

At the end of this course, the students will be able to

- understand design and development of oral drug delivery system.
- understand design and development of mucosal drug delivery system.
- understand design and development of ocular drug delivery system.
- understand design and development of transdermal drug delivery system.
- understand design and development of dental drug delivery system.

**TEXT BOOKS**

1. Binghe wang, Teruna Siahaan and Richard A Soltero “Drug delivery principles and applications” John wiley and Sons Inc, 2005
2. Roseman, T.J, “Controlled Release Drug Delivery Systems”, Marcel Dekker New York

**REFERENCES**

1. Jain, N.K.: “Progress in Controlled and Novel Drug Delivery”, CBS Publisher, New Delhi
2. J. Kost, Florida, “Pulsed and Self-Regulated Drug Delivery”, CRC Press, 1993
3. Raphael M. Ottenbrite and Sung Wan Kim, eds , “Polymeric Drugs and drug Delivery Systems”. Technomic, 2001
4. J. R. Robinson-2nd edition – Marcel Dekker “Controlled Drug Delivery – Foudamentals & applications”

**CO/PO MAPPING:**

| **Mapping of Course Outcomes with Programme Outcomes (1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak** | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **COs** | **Programmes Outcomes (POs)** | | | | | | | | | | | | | |
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** | **PO6** | **PO7** | **PO8** | **PO9** | **PO10** | **PO11** | **PO12** | **PSO1** | **PSO2** |
| **CO1** | 3 | 2 | 2 | 3 | 3 | 1 | 3 | - | - | - | - | - | 3 | 3 |
| **CO2** | - | 3 | 3 | - | 3 | - | 2 | - | - | - | - | - | 3 | 3 |
| **CO3** | 3 | 3 | 3 | 2 | - | - | 2 | - | - | - | - | - | 2 | 3 |
| **CO4** | 3 | 2 | 2 | - | - | 3 | - | - | - | - | 2 | - | 2 | 2 |
| **CO5** | 2 | 3 | 3 | 2 | 1 | 3 | 3 | - | - | 1 | 2 | - | 3 | 2 |

**PT16551** **TECHNOLOGY OF STERILE PRODUCTS** **3 0 0 3**

**COURSE OBJECTIVES**

To enable students to

- describe the principles of parenteral dosage form formulation.
- execute the concepts involved in the manufacture of sterile products.
- solve the difficulties associated with drug delivery to ear, ophthalmic and nasal region.
- differentiate the use of various additives in sterile formulations.
- prepare parenteral based on the guidelines of regulatory bodies.

**UNIT I INTRODUCTION TO PARENTERAL PRODUCTS 9**

Pre-formulation factors; Routes of administration; Water for injection; Pyrogenicity; Non-aqueous vehicles, Isotonicity and Methods of its adjustment; Formulation details - Containers and Closures and their selection, Prefilling treatment - Washing the container and closers, Preparation of solution and suspension, Filling, Closing of ampoules, vials, infusion fluids, Lyophilization, Preparation of sterile powders; Equipment for large scale manufacture and Evaluation of parenteral products.

**UNIT II ASEPTIC TECHNIQUES IN PARENTERALS 9**

Aseptic techniques - Source of contamination, Methods of prevention, Design of aseptic area - laminar flow bench, Air handling units, Services, and Maintenance; Stability evolution of sterile pharmaceutical dosage forms; Special precautions on blood products, Glandular products, Medical sutures, Ligatures.

**UNIT III EAR, NASAL AND OPHTHALMIC DRUG DELIVERY 9**

Nasal and ocular drug delivery overview; Membrane transport processes in the eye, Nasal and Ocular drug transfer following systemic drug administration; Ocular pharmacokinetics and pharmacodynamics ocular penetration enhancers; Corneal collagen shields for ocular drug delivery; The noncorneal route in ocular drug delivery, Ocular iontophoresis; Mucoadhesive polymers in ophthalmic drug delivery; Dendrimers; New experimental therapeutic approaches for degenerative diseases of the retina, Gene, Oligonucleotide and Ribozyme therapy in the eye.

**UNIT IV FORMULATION ADDITIVES 9**

Classifications of various additives in sterile formulations - Buffers, Density modifiers, Isotonicity modifiers, Viscosity enhancers, Preservatives, Irrigations additives.

**UNIT V PARENTERAL REGULATIONS AND VALIDATIONS 9**

cGMP regulations of parenteral drugs; Risk assessment and mitigation in aseptic processing; Development challenges and validation of fill and finish processes for bio-therapeutics; Excipients for parenteral dosage forms - Regulatory considerations and controls, Parenteral product specifications and stability, The management of extractables and leachable in pharmaceutical products, Process analytical technology and rapid microbiological methods, Quality assurance.

**TOTAL PERIODS: 45**

**COURSE OUTCOMES**

At the end of this course, the students will be able to

- describe the principle of manufacturing parenteral products.
- illustrate the various strategies involved in manufacturing of sterile products.
- demonstrate drug delivery to ear, nose and ophthalmic organs.
- examine the role of additives in formulation of sterile products.
- appraise the guidelines formulation, manufacturing, packaging, and marketing of sterile products.

**TEXT BOOKS**


1. Sandeep Nema, John D. Ludwig, "Pharmaceutical Dosage Forms Parenteral Medications", Third Edition Volume 3, Informa Healthcare is a trading division of Informa UK Ltd
2. Aulton, Michael E. "Pharmaceutics: The Science of Dosage Form Design" IInd Ed., Churchill Livingstone, 2002.


**REFERENCES**


1. Ashim K. Mitra, Marcel Dekker "Ophthalmic Drug Delivery Systems" Second Edition, Revised and Expanded, 2003
2. Allen, Loyd V. et al. "Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems"
3. Lachman "Theory and Practice of Industrial Pharmacy".


**CO/PO MAPPING:**

| **Mapping of Course Outcomes with Programme Outcomes (1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak** | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **COs** | **Programmes Outcomes (POs)** | | | | | | | | | | | | | |
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** | **PO6** | **PO7** | **PO8** | **PO9** | **PO10** | **PO11** | **PO12** | **PSO1** | **PSO2** |
| **CO1** | 1 | - | 1 | 1 | - | - | - | - | - | - | - | - | - | - |
| **CO2** | 2 | 2 | 1 | 2 | - | 1 | 1 | 1 | - | - | - | 1 | - | 1 |
| **CO3** | 1 | 3 | 3 | 3 | 1 | 1 | - | 1 | - | - | - | - | - | 1 |
| **CO4** | - | - | - | - | 1 | - | 1 | - | - | - | - | - | 1 | - |
| **CO5** | - | - | - | - | 1 | 3 | 1 | 3 | - | - | - | - | - | 1 |

**PT16552** **CLINICAL TRAILS** **3 0 0 3**

**COURSE OBJECTIVES**

To enable students to

- explain the drug development process and their validation through statistical analysis.
- implement the regulations of various regulatory bodies.
- organize the data obtained from the clinical research.
- organize the data obtained from the clinical research.
- assess the various modules of regulations and safety.

**UNIT I DRUG DEVELOPMENT MODULE 9**

Drug development overview; Phases of clinical research; Pre-clinical (non-clinical) development - Discovery and selection of compounds, Toxicology, Pharmacology Clinical Development programmes; Basics of clinical research statistics.

**UNIT II CLINICAL RESEARCH MODULE 9**

Understanding the evolving role of the Clinical Trial Administrator (CTA)/Clinical Project Assistant (CPA); Good Clinical Practice (GCP) and international harmonization; Case Report Forms; Protocols; Informed Consent; Ethics Committees / Institutional Boards; Role of the Sponsor including the Clinical Research Associate/Monitor.

**UNIT III CLINICAL RESEARCH MODULE II 9**

Clinical trial set up, Trial Master Files and study filling, Data Management; Review of the EU Clinical Trial Directive; How to prepare for Regulatory Inspections or Audit; Fraud in clinical Research.

**UNIT IV ADVANCED CLINICAL RESEARCH MODULE 9**

Project Management; How to develop a proactive approach to supporting clinical trials Building a Successful working relationship with your manager(s) and the rest of the clinical research team; Team effectiveness - Working as an effective clinical research team, Working in partnership with CROs; Legal aspects of clinical research; Laboratory tests Communication skills, Cross-cultural communication with other offices and departments internationally; Time management and optimizing your effectiveness.

**UNIT V REGULATORY AFFAIRS AND SAFETY MODULE 9**

Regulatory requirements for international clinical research; Regulatory requirements for Biotechnology products, medical devices and veterinary products; Health economics; Safety reporting; Responding to drug safety alerts Post marketing surveillance.

**TOTAL PERIODS: 45**

**COURSE OUTCOMES**

At the end of this course, the students will be able to

- demonstrate the steps for developing a drug through various process.

- operate the research based on the requirements of regulatory bodies.
- examine the data from the research modules.
- develop and test the process involved in the research laboratories.
- validate the regulations and safety module of the research.

**TEXT BOOKS**


1. Matoren, Gary M. "The Clinical Research Process in the Pharmaceutical Industry", Marcel Dekker, 2020.
2. Abraham, John "Regulation of the Pharmaceutical Industry", Palgrave, 2003.


**REFERENCES**


1. Blaisdell, Peter, "Twenty – First Century Pharmaceutical Development", Interpharm Press, 2001.
2. Gad, Shayne C. "Drug Safety Evaluation", John – Wiley & Sons, 2002.


**CO/PO MAPPING:**

| **Mapping of Course Outcomes with Programme Outcomes (1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak** | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **COs** | **Programmes Outcomes (POs)** | | | | | | | | | | | | | |
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** | **PO6** | **PO7** | **PO8** | **PO9** | **PO10** | **PO11** | **PO12** | **PSO1** | **PSO2** |
| **CO1** | 2 | - | 1 | - | - | 1 | 1 | - | - | 1 | 1 | 1 | - | - |
| **CO2** | 2 | 1 | 2 | 2 | 1 | 2 | 3 | - | - | - | 1 | 1 | 1 | - |
| **CO3** | 1 | 1 | 1 | - | - | - | 2 | 2 | 2 | - | 1 | 1 | - | 1 |
| **CO4** | 1 | - | 1 | - | 3 | 1 | 3 | 2 | - | 2 | 2 | 2 | 2 | 2 |
| **CO5** | 1 | 1 | - | - | 2 | - | - | - | 2 | - | 3 | 3 | 1 | 2 |

**PT16553** **PHARMACOVIGILANCE** **3 0 0 3**

**COURSE OBJECTIVES**

To enable students to

- compare the development and global scenario of pharmacovigilance and their establishment in an organization.
- develop the skills of classifying drugs, diseases, and adverse drug reactions.
- compare the methods of pharmacovigilance.
- distinguish the statistical methods for the evaluation of drug molecule.
- check and formulate the regulatory aspects of bioactive molecule.

**UNIT I INTRODUCTION TO PHARMACOVIGILANCE 9**

Scope and development of Pharmacovigilance; Importance of safety monitoring of Medicine - WHO international drug monitoring Programme, Pharmacovigilance Program of India (PvPI) - Definitions and classification of adverse drug reactions, Detection and reporting, Methods in Causality assessment, Severity and seriousness assessment, Predictability and preventability assessment; Management of adverse drug reactions; Terminologies used in pharmacovigilance, Adverse medication related events and Regulatory terminologies.

**UNIT II SOURCES OF DATA 9**

Anatomical, therapeutic and chemical classification of drugs; International classification of diseases; Daily defined doses; International Nonproprietary Names for drugs; Drug dictionaries and coding in pharmacovigilance; WHO adverse reaction terminologies; MedDRA and Standardized MedDRA queries; WHO drug dictionary; Eudravigilance medicinal product dictionary Information resources in pharmacovigilance; Basic drug information resources; Specialized resources for ADRs Establishing pharmacovigilance Programme; Pre-clinical studies; Human volunteer studies; Clinical trials; Post marketing surveillance; Systematic reviews and meta-analysis.

**UNIT III PHARMACOVIGILANCE METHODS 9**

Pharmacovigilance methods - Passive surveillance - Spontaneous reports and case series and 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; Communication in pharmacovigilance - Effective communication in Pharmacovigilance, Communication in Drug Safety Crisis management, Communicating with Regulatory Agencies, Business Partners, Healthcare facilities and Media.

**UNIT IV STATISTICAL METHODS FOR EVALUATING MEDICATION SAFETY DATA 9**

Safety data generation - Preclinical phase, Clinical phase, Post approval phase; ICH Guidelines for Pharmacovigilance - Organization and objectives of ICH, Expedited reporting, Individual case safety

reports, Periodic safety update reports, Post approval expedited reporting; Pharmacovigilance planning - Good clinical practice in pharmacovigilance studies.

**UNIT V PHARMACOGENOMICS OF ADVERSE DRUG REACTIONS 9**

Drug safety evaluation in special population – Pediatrics, Pregnancy and lactation, Geriatrics; CIOMS - CIOMS Working Groups, CIOMS Form; CDSCO (India) and Pharmacovigilance - D&C Act and Schedule Y - Differences in Indian and global pharmacovigilance requirements.

**TOTAL PERIODS: 45**

**COURSE OUTCOMES**

At the end of this course, the students will be able to

- explain adverse drug reaction in proper format.
- illustrate the data generated during pharmacovigilance study.
- correlate the regulatory requirements of different countries.
- predict the phases of clinical trials and pharmacovigilance.
- evaluate the pharmacokinetics and pharmacodynamics of the drug.

**TEXT BOOKS**


1. Sumit Verma, S and Gulati, Y, "Fundamentals of Pharmacovigilance", Paras Medical Publishers, 2017
2. Gupta, S. K, "Textbook of Pharmacovigilance", Jaypee Brothers Medical Publishers,2011


**REFERENCES**


1. Waller, P and Harrison Woolrych, M, "An Introduction to Pharmacovigilance", Wiley- Blackwel, 2nd Edition, 2017.
2. Orleans-Lindsay, J, "Pharmacovigilance Medical Writing: A Good Practice Guide", Wiley Blackwell, 2012
3. Mohanta, G.P and Manna, P.K, "A Textbook of Pharmacovigilance: Concept and Practice", Pharma Med Press, 2015.
4. Andrews, E.B and Moore, N. Mann's "Pharmacovigilance", Wiley-Blackwel, 3rd Edition, 2014.


**CO/PO MAPPING:**

| **Mapping of Course Outcomes with Programme Outcomes (1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak** | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **COs** | **Programmes Outcomes (POs)** | | | | | | | | | | | | | |
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** | **PO6** | **PO7** | **PO8** | **PO9** | **PO10** | **PO11** | **PO12** | **PSO1** | **PSO2** |
| **CO1** | 1 | 1 | 1 | 1 | 1 | 1 | - | - | 1 | 1 | 1 | 1 | 1 | - |
| **CO2** | 2 | 1 | 2 | 2 | - | 1 | 1 | 1 | - | - | 1 | - | - | 1 |
| **CO3** | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 2 | 1 | - | - | - | 1 | - |
| **CO4** | - | - | - | - | 1 | - | - | 1 | - | - | - | 1 | 1 | - |
| **CO5** | - | - | - | 1 | - | 2 | - | 3 | - | - | - | 2 | - | 1 |

**PT16554** **PHARMACOGENOMICS** **3 0 0 3**

**COURSE OBJECTIVES**

To enable students to

- understand the basis of pharmacogenomics.
- acquire knowledge on different genetic variations.
- study pharmacogenomic drugs.
- understand metabolism and structural genomics.
- know applications related to pharmacogenomics.

**UNIT I BASICS OF PHARMACOGENOMICS 9**

Introduction - Basic concepts about genetic diseases; Basics of structural pharmacogenomics; Personalized medicine and drug prescription - Introduction and importance; The genetics of therapeutic targets and gene-based targets; Pharmacogenomics necessity in drug designing.

**UNIT II GENETIC VARIATIONS 9**

DNA mutations and their mechanisms; Introduction to Polymorphisms, types and importance in Drug targets; Prediction of structural changes among sequences by the influence of polymorphisms; Single nucleotide polymorphisms and other genetic variations and their potential impact on clinical medicine and related clinical outcomes; The translation of genetic variations to drug selection.

**UNIT III DRUGS 9**

Pharmacological classes of drugs - Antibodies, Antisense RNAs, siRNAs, Aptamers; Pharmacology and pharmacogenomics of cardiovascular system; Pharmacogenomics of monoclonal antibodies; Development of molecularly targeted cancer therapeutics; Cancer pharmacogenomics and biotherapeutics; Examples of drugs related to the pharmacogenomics application in clinical practice such as warfarin dosing in individual patients, and application of tamoxifen in oncology.

**UNIT IV METABOLISM AND STRUCTURAL PHARMACOGENOMICS 9**

Pharmacological and pharmacogenomics approaches to improve drug delivery clinical outcomes; Drug response to patients; Drug metabolism pathways and adverse drug reactions; Tools for pharmacogenomic analysis; Process in Structural Pharmacogenomics - Target Structure optimization, Validation, Lead identification, ADME prediction, Synthesis, Assays and Clinical trials.

**UNIT V COMMERCIAL AND REGULATORY ASPECTS OF PHARMACOGENOMICS 9**

Genetic Counseling; Ethical issues of personal genetic information/ Individualized medicine; Economics of pharmacogenomics testing in clinical practice; Regulatory guidelines involving Pharmacogenomics; Intellectual property and commercial aspects of Pharmacogenomics.

**TOTAL PERIODS: 45**

**COURSE OUTCOMES**

At the end of this course, the students will be able to

- know the basic pharmacogenomic drugs.
- understand different pharmacogenomic drugs.
- work on different metabolic and structural aspects of drugs.
- optimize the lead molecule in drug development.
- understand the regulatory aspects in pharmacogenomics.

**TEXT BOOKS**

1. Laurence L. Brunton, Bruce A. Chabner, Björn C. Knollmann., 2011 Goodman & Gilman's, "The pharmacological basis of therapeutics", (12th ed.) by McGraw Hill education.
2. Guilherme Suarez-Kurtz., 2007, "Pharmacogenomics in Admixed Populations", by Landes Biosciences

**REFERENCES**


1. Sweet, Kevin M., Michaelis, Ron C., "The busy physician's guide to Genetics, Genomics and Personalized Medicine" by Springer Publications, 2011.
2. Daniel A. Brazeau, PhD, and Gayle A. Brazeau. 2006 "A Required Course in Human Genomics, Pharmacogenomics and Bioinformatics", American Journal Pharmaceutical Education, 2006.
3. Rapley, R. & Harbron, S, "Molecular analysis and Genome discovery", John Willey & Sons, Ltd., 2004
4. Alan H.B. Wu. Kiang-Teck J. Yeo., "Pharmacogenomic Testing in Current Clinical Practices" by Humana Press, 2010


**CO/PO MAPPING:**

| **Mapping of Course Outcomes with Programme Outcomes (1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak** | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **COs** | **Programmes Outcomes (POs)** | | | | | | | | | | | | | |
| | **PO1** | **PO2** | **PO3** | **PO4** | **PO5** | **PO6** | **PO7** | **PO8** | **PO9** | **PO10** | **PO11** | **PO12** | **PSO1** | **PSO2** |
| **CO1** | 3 | 3 | 3 | 2 | 3 | 3 | 2 | 3 | 2 | - | 2 | - | 2 | 2 |
| **CO2** | 3 | 2 | 2 | 1 | - | - | 2 | 3 | - | - | - | - | 2 | 3 |
| **CO3** | 3 | 3 | 2 | 3 | 2 | 2 | - | - | - | - | - | - | 3 | 2 |
| **CO4** | 2 | 2 | 3 | 3 | 2 | 3 | - | - | - | - | - | - | 3 | 2 |
| **CO5** | 2 | 2 | 2 | 3 | 3 | 3 | 1 | - | 1 | - | - | 2 | 3 | 2 |