

**UNIVERSITY DEPARTMENTS**  
**ANNA UNIVERSITY : : CHENNAI – 600 025.**  
**REGULATIONS – 2013**  
**I TO IV SEMESTERS CURRICULUM AND SYLLABUS (FULL –TIME)**  
**M. TECH. BIOPHARMACEUTICAL TECHNOLOGY**

**SEMESTER – I**

COURSE CODE	COURSE TITLE	L	T	P	C
<b>THEORY</b>					
BP8101	Biogenerics and Biopharmaceuticals	3	0	0	3
BP8102	Fermentation Technology for Pharmaceutical Industries	3	0	0	3
BP8103	Human Physiology and Drug Metabolism	3	0	0	3
BT8151	Applied Statistics for Biotechnologists	3	1	0	4
	Elective I	3	0	0	3
	Elective II	3	0	0	3
<b>PRACTICAL</b>					
BP8111	Formulation and Analytical Techniques in Biopharmaceutical Technology	0	0	6	3
<b>TOTAL</b>		<b>18</b>	<b>1</b>	<b>6</b>	<b>22</b>

**SEMESTER II**

COURSE CODE	COURSE TITLE	L	T	P	C
<b>THEORY</b>					
BP8201	Computational Methods in Drug design	2	0	2	3
BP8202	High Throughput screening in lead discovery	3	0	0	3
BP8203	Immunopharmacology	3	0	0	3
BP8204	Pharmacokinetics and Biopharmaceuticals	2	0	2	3
BT8251	Advanced Genetic Engineering	3	0	0	3
	Elective III	3	0	0	3
	Elective IV	3	0	0	3
<b>PRACTICAL</b>					
BP8211	Recombinant DNA and Bioprocess Technology lab	0	0	6	3
<b>Total</b>		<b>19</b>	<b>0</b>	<b>10</b>	<b>24</b>

**SEMESTER III**

COURSE CODE	COURSE TITLE	L	T	P	C
<b>THEORY</b>					
BP8301	Drug Discovery Lab	0	0	6	3
BP8302	Immunopharmacology Lab	0	0	6	3
BP8311	Project work Phase –I	0	0	12	6
<b>TOTAL</b>		<b>0</b>	<b>0</b>	<b>24</b>	<b>12</b>

*Attested*

*Sobhan*  
**DIRECTOR**

Centre For Academic Courses  
 Anna University, Chennai-600 025.

## SEMESTER IV

COURSE CODE	COURSE TITLE	L	T	P	C
BP8411	Project Work Phase – II	0	0	24	12
	<b>TOTAL</b>	<b>0</b>	<b>0</b>	<b>24</b>	<b>12</b>

## LIST OF ELECTIVES

### M. TECH. BIO PHARMACEUTICAL TECHNOLOGY

COURSE CODE	COURSE TITLE	L	T	P	C
BP8001	Bioconjugate Technology and Applications	3	0	0	3
BP8002	Chemistry of Natural Products	3	0	0	3
BP8003	Combinatorial Methods for Drug Development	3	0	0	3
BP8004	Drug Dosage Forms and Design	2	0	2	3
BP8005	Drug Regulatory, Quality and Safety evaluation	3	0	0	3
BP8006	Medicinal Chemistry	3	0	0	3
BP8007	Molecular Medicine and Mechanism	3	0	0	3
BP8008	Pharmacogenomics	3	0	0	3
BP8009	Pharmacology	3	0	0	3
BP8010	Protein Engineering and Industrial Applications	3	0	0	3
BP8011	Technologies in Omics Science	3	0	0	3
BT8072	Biocatalysts and Enzyme Technology	3	0	0	3
BP8071	Clinical Trials and Bioethics	3	0	0	3
BT8071	Advances in Molecular Pathogenesis	3	0	0	3
BT8073	Communication Skill Development	2	0	2	3
BT8074	Genomics and Transcriptomics	3	0	0	3
BT8075	Metabolic Process and Engineering	3	0	0	3
BT8076	Nanobiotechnology	2	0	2	3
BT8077	Proteomics and Mass Spectroscopy	3	0	0	3
BT8078	Research and Research Methodology in Biotechnology	3	0	0	3
BT8079	Tissue Engineering and Regenerative Medicine	3	0	0	3
BT8152	Entrepreneurship, IPR and Biosafety	3	0	0	3

PROGRESS THROUGH KNOWLEDGE

Attested

Sobhan  
DIRECTOR

Centre For Academic Courses  
Anna University, Chennai-600 025.

**OBJECTIVES**

To introduce the students about biogenerics and biosimilars and their characterization using analytical methods and presumptions of therapeutic equivalence along with case studies.

**OUTCOME**

The subject will give exposure of fundamental knowledge in biogenerics, biosimilar and biopharmaceuticals for students to make their career in pharmaceutical industries.

**UNIT I BIOGENERICS INTRODUCTION 9**

Definition: Generics and its advantages; Biogenerics and Biosimilars; Why biosimilars are not (bio) generics; The advent of Biosimilars; The role of patents in the drug industry; Protein-based biopharmaceuticals; Manufacturing processes; Global market; International Non-proprietary Names (INN) nomenclature system biosimilars regulation (EU position, US pathways, Government initiatives)

**UNIT II BIOSIMILARS AND ITS SCENARIO 9**

Approved follow-on proteins/Biosimilars; Characteristics of highselling peptides and proteins; Products with expired patents; Challenging originator's patents; Target products for FOB (follow-on biologicals)/Biosimilars development peptides; Recombinant nonglycosylated proteins; Recombinant glycosylated proteins; Industries dealing with biogenerics and its market value; World scenario; Indian scenario.

**UNIT III CHARACTERIZATION OF BIOSIMILARS 9**

Approaches to the characterization of biosimilars; Problems in characterizing biologics (Types of biologic, Peptides, Non-glycosylated proteins, Glycosylated proteins, Monoclonal antibodies); Equivalence issues; Post-translational modifications; Effect of microheterogeneity; Pharmacokinetics; Pharmacodynamics; and Clinical efficacy; Analytical methods for the characterization of biosimilars (Chromatography, Protein sequencing, Mass spectrometry, UV absorption, Circular dichroism, X-ray techniques, Nuclear magnetic resonance, Electrophoresis, Western blotting, Bioassays, ELISA, Immunoprecipitation and other procedures)

**UNIT IV IMMUNOGENECITY OF BIOPHARMACEUTICALS 9**

Immunogenicity of biopharmaceuticals: Immunogenicity; Factors contributing to immunogenicity (product-related factors, host-related factors), Consequence of immunogenicity to biopharmaceuticals; Measurement of immunogenicity

**UNIT V CASE STUDIES 9**

Case studies: Erythropoietin, Insulin, Somatotropin, Interleukin-2, Interferon Granulocyte-macrophage-CSF, DNase, Factor VIIa, Factor IX, Factor VIII, Activated protein C, Tissue plasminogen activator, Monoclonal antibodies etc.

**TOTAL : 45 PERIODS**

**TEXTS/REFERENCES**

1. Niazi, Sarfaraz K. "Handbook of Biogeneric Therapeutic Proteins: Regulatory, Manufacturing, Testing, and Patent Issues". CRC Press, 2006.
2. Ho, Reedney J. Y., MiloGibaldi. "Biotechnology & Biopharmaceuticals Transforming Proteins and Genes into Drugs". Wiley Liss, 2003.

Attested

Sobhan  
DIRECTOR

Centre For Academic Courses  
Anna University, Chennai-600 025.

**BP8102      FERMENTATION TECHNOLOGY FOR PHARMACEUTICAL INDUSTRIES**  
**L T P C**  
**3 0 0 3**

**OBJECTIVE**

The subject provides knowledge involving basic principle of fermentation process, microbial kinetics and recombinant protein production along with case studies, to help the students understand fermentation processes involved in Pharmaceutical Industries.

**OUTCOME**

This course work will provide essential knowledge for the students to make their career in bioprocess Industries.

**UNIT I      INTRODUCTION TO BIOREACTOR DESIGN & CONSTRUCTION      9**

General requirements of fermentation processes, Basic design and construction of CSTR, bioreactor design of agitator/agitator motor, power consumption in aerated bioreactor, design of sparger, mixing time estimation, oxygen mass transfer capability in bioreactor, Removal of Heat in bioreactor, Main parameters to be monitored and controlled in fermentation processes.

**UNIT II      MICROBIAL KINETICS AND DESIGN OF VARIOUS CULTIVATION PROCESSES      9**

Simple unstructured kinetic models for microbial growth of bacterial, fungal, animal and plant systems, kinetics of substrate utilization, biomass growth and product formation in continuous cultures, batch and fed batch cultures, total cell retention cultivation, inhibition on cell growth and product formation.

**UNIT III      MODELING OF RECOMBINANT CULTIVATION SYSTEMS      9**

Structured models of metabolism and growth, models of gene expression and regulation, a generalized model of plasmid replication, Genetic instability, predicting host-vector interactions and genetically instability. Process considerations for utilizing genetically engineered strains.

**UNIT IV      ANIMAL AND PLANT CELL CULTIVATION TECHNOLOGY FOR THERAPEUTIC PROTEINS      9**

Media, aeration in cell culture systems, Bioreactors for plant/animal suspension culture, cell immobilization and organized tissue, bioreactor considerations for animal /plant cell culture for production of pharmaceuticals, Therapeutic proteins and Monoclonal antibodies.

**UNIT V      CASE STUDIES IN FERMENTATION DERIVED PRODUCTS      9**

Case studies on Production of penicillin, recombinant Insulin. Case studies should deal with strain improvement, medium design, reactor design & process optimization etc.

**TOTAL : 45 PERIODS**

**TEXTS BOOKS**

1. Shuler, M.L. and Kargi, F. "Bioprocess Engineering : Basic Concepts". 2<sup>nd</sup> Edition., Prentice- Hall, 2002.
2. Doran, Pauline M, "Bioprocess Engineering Principles". Academic Press, 1995
3. Nielsen, J. and Villadsen, J. "Bioreaction Engineering Principles". Springer, 2007.
4. Blanch, H.W and Clark D.S., "Biochemical Engineering", Marcel Dekker, 1997

**REFERENCES**

1. Bailey, J.E. and Ollis, D.F. "Biochemical Engineering Fundamentals" 2<sup>nd</sup> Edition., McGraw Hill, 1986.
2. Stanbury, Stephen. P. F., Hall, J. and Whitaker, A. "Principles of Fermentation Technology" Elsevier

*Attested*  
*Sobhan*  
**DIRECTOR**  
Centre For Academic Courses  
Anna University, Chennai-600 025.

**OBJECTIVES**

To provide fundamental knowledge of human physiology, drug metabolism and biotransformation of drug in human body.

**OUTCOME**

This course work will provide basic understanding of human physiology and drug metabolism which will enable the student to understand how the body functions and the physiological mechanisms that operate to maintain homeostasis.

**UNIT I FOUNDATIONS OF PHYSIOLOGY AND OVERALL PHYSIOLOGY CONCEPTS 12**

ANS, CNS, Cardiovascular system, Gastrointestinal system, Muscle and skeletal system, excretory system

**UNIT II GROWTH AND METABOLISM 12**

Chemical & Physical Foundations – Homeostatic control – neural & endocrine mechanisms – Transport across cell membranes Endocrine control of organic metabolism and growth – reproduction and its endocrine control.

**UNIT III DRUG ABSORPTION AND METABOLISM 8**

Factors influencing enzyme induction and inhibition; Extraction of drugs; Biliary and fecal excretion; Factors effecting drug metabolism; Drug metabolism in fetus and new born

**UNIT IV BIOTRANSFORMATION CONCEPTS 6**

Biotransformation of drugs; Enzymes responsible for bio-transformations; Microsomal and non-microsomal, mechanisms.

**UNIT V MODEL IN DRUG METABOLISM 7**

Models to study drug metabolism; Dose effect relationships; Adverse drug reactions and drug interactions; Toxic reactions; Allergic reactions; Idiosyncrasy; Acute poisoning and its treatment.

**TOTAL : 45 PERIODS****TEXT BOOKS AND REFERENCES**

1. Ganong W.F., "Review of Medical Physiology", 16<sup>th</sup> Edition, Prentice Hall, 1993.
2. Vander A.J., Sherman, J.H. and Luciano, D.S. "Human Physiology", McGraw-Hill, 1990.
3. Carola, R., Harley, J.P. and Noback, C.R., 'Human Anatomy and Physiology', 2<sup>nd</sup> Edition, McGraw Hill, 1992
4. Guyton, A.C., "Text book of Medical Physiology", 9<sup>th</sup> Edition, Harcourt Brace & Co., 1996.
5. Ross and Wilson, "Human Anatomy and Physiology", ELBS Edition.? 2007
6. Goodman & Gilman, Laurence L Brunton, The Pharmacological Basis of Therapeutics, 11th Edition, McGraw Hill, 2005.
7. Woolf, Thomas F. "Handbook of Drug Metabolism". Marcel Dekker, 1999.

**BT8151 APPLIED STATISTICS FOR BIOTECHNOLOGISTS**L T P C  
3 1 0 4**OBJECTIVES**

This subject will facilitate the students to understand the fundamentals of statistics for biologists.

**OUTCOME**

On the completion of the course the students are expected to have learnt, Understanding and applying Statistical methods of analysis for Biological applications

Attested

Sobhan  
DIRECTORCentre For Academic Courses  
Anna University, Chennai-600 025.

<b>UNIT I</b>	<b>12</b>
Random variable-sample spaces-Events-Axiomatic approach to probability- conditional probability-additional theorem, Multiplication theorem - Baye's theorem problems-continuous and discrete random variables, Distribution function-Expectation with properties-Moments, mean, Variance problems-for continuous and discrete distributions.	
<b>UNIT II</b>	<b>12</b>
Bivariate distribution-conditional and marginal distribution-Discrete distribution-Binomial, Poisson, geometric distribution-Continuous distribution, Normal, exponential and negative exponential, gamma distributions-simple problems-properties	
<b>UNIT III</b>	<b>12</b>
Correlation coefficient, properties-problems-Rank correlation-Regression equations-problems-curve fitting by the method of least squares-fitting curves of the form $ax+b$ , $ax^2+bx+c$ , $ab^x$ and $ax^b$ - Bivariate correlation application to biological problems	
<b>UNIT IV</b>	<b>12</b>
Concept of sampling-Methods of sampling-sampling distributions and Standard Error-Small samples and large samples-Test of hypothesis-Type I, Type II Errors-Critical region-Large sample tests for proportion, mean-Exact test based on normal , t, f and chi-square distribution-problems-Test of goodness of fit.	
<b>UNIT V</b>	<b>12</b>
Basic principles of experimentation-Analysis of variance-one-way, Two-way classifications-Randomised block design, Latin square design-problems.	

**TOTAL : 60 PERIODS**

**TEXT BOOKS**

1. Kapoor, V. C. "Elements of Mathematical statistics".
2. Vittal, P.R. and V.Malini."Statistical and Numerical Methods". Margham Publications.
3. Veerarajan,T. "Probability, Statistics and Random Processes".3<sup>rd</sup> Edition., Tata Mc Graw-Hill, 2008.

**REFERENCES**

1. Johnson, R. A."Miller & Freund's Probability and Statistics for Engineers". 6<sup>th</sup> ed. PHI, 2003.
2. Arora, P. N. Smeet Arora, and Arora, S. "Comprehensive Statistical Methods". S. Chand & Co,
3. Spiegel, Murray R., J.Schiller and R.Alu Srinivasan."Schaum's Outlines Probability and Statistics".2<sup>nd</sup> Edition. Tata Mc Graw-Hill 2000.
4. Kandasamy, P. K. Thilagavathi & K. Gunavathi."Probability Statistics and Queuing Theory". S. Chand & Co., 2004

**BP8111**

**FORMULATION AND ANALYTICAL TECHNIQUES IN  
BIOPHARMACEUTICAL TECHNOLOGY**

**L T P C  
0 0 6 3**

**OBJECTIVES**

This course will provide hands on experience on different forms of drug formulation and the analytical methods available for evaluation of pharmaceuticals.

**OUTCOME**

Hands on experience to make the students competent in drug formulation to taken up challenging industry career.

*Attested*  
*Sobhan*  
**DIRECTOR**  
Centre For Academic Courses  
Anna University, Chennai-600 025.



## PART I: FORMULATION EXPERIMENTS

1. Preparation of solid dosage forms (Eg. Granules, Tablets, Capsules)
2. Preparation of liquid dosage forms ( Eg. True Solutions, mixtures, Elixers)
3. Preparation of biphasic dosage forms (Eg. Emulsion, Suspension)
4. Preparation of semisolid dosage forms (Eg. Ointments, Creams, Gels, lotions)
5. Preparation of Parenteral and ophthalmic formulations
6. Preparation of specialized dosage forms (Eg. Suppositories, Patches)

## PART II: ANALYTICAL METHODS FOR EVALUATION OF PHARMACEUTICALS BASED ON PHARMACOPOEIAS

1. Evaluation of solid dosage forms (Hardness, dissolution etc)
2. Evaluation of liquid dosage forms (Stability tests, pH, odour etc)
3. Evaluation of biphasic dosage forms (Stability tests etc)
4. Evaluation of semisolid dosage forms (pH, spreadability, viscosity etc)
5. Evaluation of Parenteral formulations and evaluation (Microbial Tests etc)
6. Evaluation of specialized dosage forms (Melting tests etc)
7. Preparation of pharmaceutical buffers and determination of buffer capacity, physiological buffers.

## EQUIPMENTS REQUIRED

1. Mortar and Pestle
2. Sieves of all sizes
3. Granulator
4. Punching machine
5. Capsule filler
6. Disintegration, dissolution and friability testing apparatus
7. Formulation reagents (surface acting agents, glidants, diluents etc,)
8. pH meter, physical balances

**TOTAL : 90 PERIODS**

## TEXTS/REFERENCE

1. Lachman, Leon et al., "The Theory and Practice of Industrial Pharmacy", 3rd Edition, Varghese Publishing House, 1986.
2. Ansel, H.C. "Pharmaceutical Dosage Forms and Drug Delivery Systems", 7th Edition, Lippincott Williams & Wilkins, 2000.
3. Lieberman, H.A. et al., "Pharmaceutical Dosage Forms : Tablets" (Vol. I, II & III) 2nd Edition, Marcel Dekkar, 1989.
4. Lieberman, H.A. et al., "Pharmaceutical Dosage Forms: Disperse Systems" (Vol. I, II & III) 2nd Rev. Edition, Marcel Dekker, 1996.
5. Avis, K.E. et al., "Pharmaceutical Dosage Forms: Pareutal Medications", (Vol. I, II & III) 2nd Rev. Edition, Marcek Dekker, 1992.

**BP8201**

**COMPUTATIONAL METHODS IN DRUG DESIGN**

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

## OBJECTIVES

To enable the students to learn the design of drugs using computer programme and the correlate the design generated through computers for laboratory applications.

## OUTCOME

At the end of course work, the students would be expected to learn stereochemistry , structure and activity of the drug , molecular simulations. Principles of Docking and Docking algorithm.

Attested  
Sobhan  
DIRECTOR  
Centre For Academic Courses  
Anna University, Chennai-600 025.

**UNIT I INTRODUCTION TO LIGAND CHEMISTRY 9**

Configuration, conformation, chirality, rational drug design, various approaches in drug discovery, drug targets, lead identification, lead optimization, pharmacophores, bio-isosteres, isosteric replacement.

**UNIT II PARAMETERS FOR LIGAND DESIGN 9**

Physiochemical, geometric, conformational, topological, partitional, steric, stereochemical and electronic properties of drug molecules. To study the SAR and SPR of drugs on modifying size, shape, unsaturation, aromaticity, rigidity, substitutions (alkylation, and halogenation),

**UNIT III PHARMACOKINETIC PARAMETERS OF LIGAND DESIGN 9**

Lipinski "rule of 5", Partition coefficient, Hammett constant, Hansch analysis. Biological, chemical and physical descriptors used in QSAR and QSPR. Statistical methods used for analysing QSAR/ QSPR data.

**UNIT IV INSILICO ANALYSIS OF LIGAND- RECEPTOR INTERACTIONS 9**

Introduction to molecular docking (including methods and scoring functions), de novo pharmacophore elucidation/ drug design for structurally well-defined receptor targets like HIV protease inhibition, ER antagonism, H2 receptor antagonism, Chirase inhibition (quinoline derivative antibiotics) and ACE inhibition, macromolecule-ligand docking, docking algorithms, AUTODOCK

**UNIT V SIMULATIONS OF DRUG/PROTEIN INTERACTIONS 9**

Molecular dynamic simulations, relative energy, energy minimization methods, ligand binding free energy calculations (both simulation and empirical methods), intermolecular interactions, forces related to drug binding, force-field calculation including solvation, role of solubility in drug binding and pKa, Poisson-Boltzmann Surface Area (PBSA), AMBER, GROMOS and GROMACS

**TOTAL : 45 PERIODS**

**TEXTS/REFERENCES**

1. Williams, D.A. and Lemke, T.L., "Foye's Principles for Medicinal Chemistry" 5<sup>th</sup> Edition, Lippincott, Williams & Wilkins, 2002.
2. "Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry". 10<sup>th</sup> Edition, Lippincott-Raven Publisher, 1998.
3. Hinchliffes Alan, "Modelling Molecular Structures", 2<sup>nd</sup> Edition, John Wiley & Sons, 2000.
4. Leach, AR, "Molecular Modeling & Drug Design", 2<sup>nd</sup> Edition, John Wiley, 2000
5. GROMOS and GROMACS Manuals.

**BP8202 HIGH THROUGHPUT SCREENING IN LEAD DISCOVERY**

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

**OBJECTIVES**

This subject will introduce the principle and advanced knowledge involved in High throughput screening using invitro and invivo models. The subject also give exposure to siRNA mediated knock down and advanced microarray techniques.

**OUTCOME**

The course work will provide basic and advanced knowledge in HTS screening, and cutting edge molecular methods help student to absorb advanced techniques in their future industry career.



**UNIT I HTS INTRODUCTION 10**

Classification of HTS: Protein based biochemical screens, methods of analytical biochemistry used in HTS (photometry, purification, electrophoresis, kinetic assay, radioisotopes, immunoassay, Principles of the various detection techniques used in HTS (light absorption, fluorescence, and radioisotope technique). Assay design for HTS and statistical treatment of the results for decision (Descriptive statistics, regression analysis,; Dual-flashlight plot). Introduction to state of the art technologies used in HTS (including automated liquid handling machines (robots), Microfluidic Tools for HTS, Miniaturization)

**UNIT II PRINCIPLES OF SCREENING 12**

Preclinical toxicological studies. Calculation of LD50 & ED50. Acute, subacute and chronic toxicity studies. Therapeutic index General principles of screening; Irwin profile test, Lipinski's rule for drug like molecule; Correlations between various animal models and human situations; Animal ethics. Pharmacological screening models for therapeutic areas such as hypertension, cerebral ischaemia, pain, epilepsy, depression, Parkinson's disease, Alzheimer's disease, diabetic, leishmania etc.

**UNIT III IN-VITRO AND IN-VIVO SCREENS 8**

High throughput screening (*invitro and invivo*) for pre-clinical pharmacokinetic and pharmacodynamic studies; Correlation between in-vitro and in-vivo screens; Special emphasis on cell-based assay, biochemical assay, radio-ligand binding assay; Reporter gene systems - HTS FACS based assays, types of readouts (GFP, luciferase, etc.) Infectious disease screening, Specific use of reference drugs and comparative interpretation of results, knowledge on small molecule repositories (Molecular Libraries Probe Centers Network (MLPCN), Chemical Biology Consortium (CBC) etc).

**UNIT IV GENE SILENCING, SIRNA AND NOVEL TOOLS 6**

Basic of gene silencing, transgenic worms in drug screening; designing SiRNAs, Types of RNAi Screens – Loss of Function screens (LOF), Synthetic Lethal screen, Mini-clonogenic RNAi screen; optimizing, and implementing high-throughput siRNA genomic screening for the discovery of survival genes and novel drug targets, siRNA HTS Screening for identification of targeted pathways in biological systems and compound screening; DNA-encoded chemical libraries and display technologies

**UNIT V MICROARRAYS AND RELATED TECHNOLOGIES 9**

Classification with microarrays and class prediction, Visualization and functional analysis. Bio molecular pathways, gene ontology, genome browsing, Gene expression biology, microarray platforms, design of experiments, file structures and data storage (Eg. Affymetrix); Preprocessing of microarray data for Image analysis, quality control and array normalization, log transformation and collating data together; Screening differential expression of genes. Class comparison with t-tests, permutation tests for rank based tests of differential expression; Synthetic Genetic Array analysis (SGA).

**TOTAL : 45 PERIODS**

**TEXTS/REFERENCES**

1. Skoog, D.A., West, D.M., and Holler, F. "Fundamentals of Analytical Chemistry". 7th Edition. Brooks Cole, 1995.
2. Murray, K.J. "Principles and Practice of High Throughput Screening". Blackwell Scientific Publishers, 2004.
3. Arnold, F.H., and Georgiou, G. "Directed Enzyme Evolution: Screening and Selecting Methods. Humana Press, 2003
4. Janzen W. P. "High Throughput Screening : Methods and protocols". Humana Press. 2002
5. Ye, S., and Day, I.N.M. "Microarrays and Microplates: Applications in Biomedical Sciences". BIOS 2003

Attested

Sobhan  
DIRECTOR

Centre For Academic Courses  
Anna University, Chennai-600 025.

**OBJECTIVES**

To enhance theoretical knowledge in the function of immune system in humans and to understand the applications of immunology and drug response .

**OUTCOME:** On completion of course students will learn advanced knowledge in pharmacology of drugs acting on the immune system, their classification, therapeutic use, mechanism of action; their utility in the treatment of inflammatory disease states and life-style diseases and identification of novel therapeutic targets for their treatments; the relationship of immuno therapeutics with other drugs and their role in the modulation of the body's own natural defenses.

**UNIT I INTRODUCTION TO PHARMACOLOGY AND IMMUNOLOGY 9**

Principles of basic and clinical pharmacokinetics and pharmacodynamics. Adverse drug reactions. Drug interactions, Bioassay of drugs and biological standardisation of immuno-agents, Immuno cell and organ classification, Relationships between immune and neurohumoral regulations, influence of stress, nutrition and environment on immunity; Overview of drug discovery and development of immuno-drugs.

**UNIT II INTRODUCTION TO VACCINOLOGY 9**

Classification, active immunization, vaccines technology, perspective vaccines, means of passive immunization, antibodies in therapy, antibody engineering, monoclonal antibodies, immunoconjugates - specific drug targeting, immunotoxins.

**UNIT III IMMUNO THERAPEUTICS 9**

Cytokines classification, pathways of activation, Therapeutic use of cytokines, immunomodulators classification, thymic hormones and synthetic immunostimulators; compliment pathways diagnostics, development of immuno diagnostics, ELISA, Flow cytometry, ELISPOT, immuno radiology, Basic immunotoxicology - principles of testing of immunomodulating and immunotoxicological properties of drugs and xenobiotics.

**UNIT IV TRANSPLANTATION THERAPEUTICS 9**

Laws of transplantation, host vs graft and graft vs Host reactions; HLA classification immunosuppressants, drugs for immunosuppressive therapy: corticosteroids, antimetabolites and calcineurine inhibitors, Clinical aspects of antiallergic, immunosuppressive, immunostimulating and substitutive therapy.

**UNIT V IMMUNOLOGY OF ALLERGY 9**

Classification of hypersensitivity reactions, Classification of allergens, therapy and prevention of allergic diseases and drug hypersensitivity. Classification of antihistamines, anti-rheumatoid drugs.

**TOTAL : 45 PERIODS****TEXT BOOKS**

1. Janeway, C.A., Travers, P., Walport, M. & Shlomchik, M.J. "Immunobiology", 6<sup>th</sup> Edition, Churchill, Livingstone, 2005.
2. Male, D., Brostoff, J., Roth, D. & Roitt, I. "Immunology" 7<sup>th</sup> Edition, Elsevier.2006
3. Mycek M.J., Gerlmet S.B and Perper M.M. "Lippincott's Illustrated Pharmacology Reviews", Lippincott Company, Philadelphia.

**REFERENCES**

1. Goodman and Gilman's, "The Pharmacological Basis of Therapeutics".
2. Katzung, B.G., "Basic and Clinical Pharmacology", Prentice Hall International.

Attested  
Sobhan  
DIRECTOR  
Centre For Academic Courses  
Anna University, Chennai-600 025.

**OBJECTIVE**

To enhance knowledge in Pharmacokinetic and to correlate theoretical principles with Industrial applications.

**OUTCOME**

At completion of the course, the students would have learnt pharmacokinetic properties of drugs and how to develop pharmacokinetic models, Factors that affect metabolism of drugs and how to improve drug absorption and Biopharmaceuticals.

**UNIT I DRUG ADMINISTRATION AND BIOAVAILABILITY 10**

Definitions, ADME, bioavailability ;Physiology of the absorbing membranes:mechanisms of drug absorption - passive and active transport - Fick's first law - affect of membrane permeability on oral absorption; Factors affecting bioavailability-Physiological, Physicochemical, formulation factors: GI physiology and oral absorption; the physico-chemical factors that affect oral absorption, the pH-partition hypothesis as it applies to drug absorption, drug dissolution; understand formulation factors which affect oral absorption; Routes: oral, sublingual, buccal, parenteral, topical, rectal & inhalation; the pharmacokinetic implications of various routes of administration; the advantages and disadvantage of various routes of administration

**UNIT II DRUG DISTRIBUTION, BIOTRANSFORMATION, DRUG EXCRETION AND BIOAVAILABILITY 8**

The processes by which drugs distribute through the body, volume of distribution, the effect of protein binding on drug distribution processes by which drugs are metabolized, induction and inhibition of metabolism; routes of drug excretion, clearance; Bioequivalence – determination of bioavailability: difference between absolute and relative bioavailability; definition and determination of bioequivalence

**UNIT III PHARMACOKINETICS I 10**

Compartment models: assumptions made in one compartment models, first order kinetics and linear models, differential equations for a simple pharmacokinetic model; To define, use, and calculate the parameters, Half life of Drugs, Volume of Distribution, and bioavailability (AUC)as they apply to a one compartment linear model; Kinetics of IV Bolus administration

**UNIT IV PHARMACOKINETICS II 8**

Oral administration: Diagrams, schemes, and graphs associated with oral administration, relationship between  $t_{max}$  and Plasma Peak Concentration; the Influence of  $k_a$  and  $F$  on  $C_p$  for a given dose; determine  $k_a$  using the; method of Residuals; Wagner-Nelson Method; method of Inspection; Parameters for the evaluation of Drug excretion (Plasma and Urine data)

**UNIT V PHARMACOKINETIC PHARMACODYNAMIC MODELING 9**

Nonlinear pharmacokinetics, Michaelis-Menton kinetics; differential equations associated with nonlinear pharmacokinetic models; the effect of parallel pathways; to estimate the parameters, Michaelis Constant, reaction rate and Kinetics of Drug metabolism, Multiple-dose pharmacokinetics; two-compartment open models; to draw schemes and write differential equations for multicompartment models; to recognize and use integrated equations to calculate pharmacokinetic parameters; metabolite Pharmacokinetics.

**LAB**

- 1.One Compartment Models: - IV Bolus
- 2.One Compartment Models – Zero-Order Input
- 3.One Compartment Models – First-Order Input
- 4.Computer Applications – Single Dose Simulations
- 5.One Compartment Models- Multiple Dosing
- 6.Computer Applications – Multiple Dose
- 7.Computer Applications – Two Compartment
- 8.Computer Applications – Macdope Exercise

**TEXTS/REFERENCES**

1. Schoenwald, R.D., "Pharmacokinetics in Drug Discovery and Development", CRC Press, 2002.
2. Notari, R.E., "Biopharmaceutics and Clinical Pharmacokinetics: An Introduction", 4<sup>th</sup> Edition, Marcell Dekker, 2005
3. Welling, P.G., Francis, L.S. Tse, "Pharmacokinetics Regulatory - Industrial-Academic Perspectives", 2<sup>nd</sup> Edition, Marcell Dekker, 2005
4. Brahmankar, D.M., "Biopharmaceutical and Pharmacokinetics:A Treatise", Vallabh Prakashan, 1995.

**BT8251**

**ADVANCED GENETIC ENGINEERING**

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

**OBJECTIVE**

This subject provides conceptual knowledge in the Cloning & Expression of genes; Construction of DNA libraries & Sequencing; PCR & mutagenesis; Gene transfer & Gene therapy to students.

**OUTCOME**

Students will learn advanced molecular methods to help them design and execute complex molecular Biology experiments.

**UNIT I CLONING AND EXPRESSION OF GENES 10**

Overview of Restriction and Modification system. Cloning vehicles: Plasmids – Host range, Copy number control, Compatibility.  $\lambda$  phage – Insertional and Replacement vectors, *in vitro* packaging. Single strand DNA vector – M13 Phage. Cosmids, Phasmids, PAC, BAC and YAC. Expression vector – Characteristics, RNA probe synthesis, High level expression of proteins, Protein solubilization, purification and export.

**UNIT II CONSTRUCTION OF DNA LIBRARIES 10**

DNA library – Types and importance. cDNA library: Conventional cloning strategies – Oligo dT priming, self priming and its limitations. Full length cDNA cloning – CAPture method and Oligo capping. Strategies for gDNA library construction – Chromosome walking. Differences between gDNA and cDNA library. Screening strategies – Hybridization, PCR, Immunoscreening, South-western and North-Western. Functional cloning – Functional complementation and gain of function. Difference cloning: Differential screening, Subtracted DNA library, differential display by PCR. Overview on microarray and its applications.

**UNIT III DNA SEQUENCING 8**

DNA sequencing – Importance, Chemical & Enzymatic methods, Pyrosequencing, Automated sequence, Genome sequencing methods – top down approach, bottom up approach.

**UNIT IV PCR AND MUTAGENESIS 9**

PCR – Principle and applications. Different types of PCR – Hot start PCR, Touchdown PCR, Multiplex PCR, Inverse PCR, Nested PCR, AFLP-PCR, Allele specific PCR, Assembly PCR, Asymmetric PCR, LATE-PCR, Colony PCR, *in situ* PCR, Long PCR. Real-time PCR – SYBR Green assay, Taqman Probes, Molecular beacons. Mutagenesis and chimeric protein engineering by PCR, RACE, Kuntels' method of mutagenesis.

**UNIT V GENE TRANSFER & GENE THERAPY 8**

Introduction of foreign genes into animal cells – Importance, DNA Microinjection, Retroviral vectors, Transfection of Embryonic stem cells, recombination. Transgenic plants – Importance, Ti Plasmid, Cointegrate and Binary vectors. Overview of Gene therapy.

**TOTAL : 45 PERIODS**

*Attested*  
*Sobhan*  
**DIRECTOR**  
Centre For Academic Courses  
Anna University, Chennai-600 025.

## TEXTS/REFERENCES

1. Primrose S.B., Twyman R.H., and Old R.W. "Principles of Gene Manipulation". 6<sup>th</sup> Edition., Blackwell Science, 2001
2. Winnacker E.L. "From Genes to clones : Introduction to Gene Technology". Panima, 2003
3. Glick B.R. and Pasternak J.J. "Molecular Biotechnology: Principles and applications of recombinant DNA" 3<sup>rd</sup> Edition., ASM Press, 2003
4. Lemonie, N.R. and Cooper, D.N. Gene Therapy, BIOS, 1996.

**BP8211**

**RECOMBINANT DNA AND BIOPROCESS TECHNOLOGY LAB**

**L T P C**

**0 0 6 3**

## OBJECTIVES

Students will get hands-on experience on advanced molecular methods like preparation of DNA, usage of restriction enzymes, gene amplification, molecular cloning, expression of protein and detection by different biochemical methods.

## OUTCOME

Students will be hands on trained in advance molecular methods as per industrial and academic research standards.

- 1.Preparation of plasmid DNA
- 2.Preparation of Genomic DNA
- 3.Restriction Digestion of the vector and Insert
- 4.Ligation and Transformation to *E.coli*
- 5.PCR for confirmation of the gene
- 6.Restriction & gel elution of DNA fragments.
- 7.Induction experiments in *E.coli* using IPTG, salt etc.
- 8.SDS-PAGE analysis of expression
- 9.Enzyme kinetics, inhibition, factors affecting reaction ph, temp.
- 10.Enzyme immobilization studies – Gel entrapment, adsorption and ion exchange immobilisation.
- 11.Optimization techniques – Plackett burman, Response surface methodology.
- 12.Batch cultivation – recombinant *E.coli* – growth rate, substrate utilization kinetics, product analysis after induction.

**TOTAL : 90 PERIODS**

**BP8301**

**DRUG DISCOVERY LAB**

**L T P C**

**0 0 6 3**

## OBJECTIVES

To enable the students to enhance their hands-on experience in learning techniques towards discovery of new drugs and utilize this knowledge for industrial needs.

## OUTCOME

The Students will be able to absorb the principles and practical approach of modern drug discovery including synthetic methods and natural products for drug discovery as per industry standards.

## SYNTHETIC METHODS FOR DRUG DISCOVERY

- 1.Synthesis of selected drugs involving two or more steps of synthesis and study of spectral analysis of drug synthesized (Paracetamol, Aspirin, Fluorscein, acetanilide etc).

Attested

Sobhan  
DIRECTOR



2. Determination of pharmacopoeial standards for the synthesized drugs.
3. Determination of QSAR parameters for drugs (partition co-efficient, dissociation constant, molar refractivity etc)

### DISCOVERY OF DRUGS FROM NATURAL PRODUCTS

1. Extraction Techniques: Cold maceration, Hot Percolation and Soxhalation.
2. Evaluation of extraction Efficiency by yield calculation and TLC.
3. Fractionation : Solvent-solvent
4. Evaluation of fractionation efficiency by TLC fingerprinting.
5. Column chromatography and flash column chromatography.
6. Extraction and determination of alkaloids (caffeine acid from tea leaves).
7. To evaluate the anti oxidant potential of herbal extracts using DPPH free radical scavenging assay.
8. To evaluate the cytotoxic effect of herbal extracts using MTT assay.
9. To evaluate the nitric oxide (NO) modulatory effect of herbal extracts using Griess method.
10. Biotransformation study

**TOTAL : 90 PERIODS**

### TEXTS/REFERENCES

1. Foye's Principles of Medicinal Chemistry. By David A. Williams, Thomas L. Lemke, Thomas L. Lernke, William O. Foye. Lippincott Williams & Wilkins Publishers; 5th edition
2. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry. By Jaime N. Delgado (Editor), Ole Gisvold (Editor), William A. Remers (Editor). Lippincott Williams & Wilkins Publishers; 10th edition (August 1998) ISBN: 0397515839
3. Remington: The Science and Practice of Pharmacy
4. Modern methods of plant analysis – Peech and M. V. Tracey
5. Phytochemistry Vol I & II by Miller, Jan, Nostrant, Rein Hid
6. Recent advances in Phytochemistry Vol. I & IV – Scilicet, Runeckles
7. Natural Product Chemistry "A laboratory guide" by Rapheal Ikan.

**BP8302**

**IMMUNOPHARMACOLOGY LAB**

**L T P C  
0 0 6 3**

### OBJECTIVES

The student will undergo hands on experience on animal handling and various aspects of advanced immunological techniques like Competitive ELISA, Immunoprecipitations and Flow cytometry assays. The students will undergo invitro immuno assays training.

### OUTCOME

Students are expected to absorb the principles and practical approach of modern immunological techniques required for both industry and academic research.

1. Selection and Handling of animals, Preparation of antigens, Immunization and methods of bleeding, Serum separation, Storage.
2. Antibody titre by ELISA method (Direct ELISA)
3. Competitive ELISA – Quantification of antigens
4. Cytokine analysis by Elispot test
5. Immunoprecipitation / Immunoelectrophoresis
6. Isolation and purification of IgG from serum
7. SDS-PAGE, Immunoblotting, Dot blot assays
8. Demonstration of agglutination inhibition by latex beads (Pregnancy test)
9. Direct Agglutination – Widal test Salmonella detection
10. Separation of mononuclear cells by Ficoll-Hypaque

Attested  
Sobhan  
DIRECTOR  
Centre For Academic Courses  
Anna University, Chennai-600 025.



11. Separation and culturing of spleenocytes and demonstration of T cell proliferation
12. Lymphoproliferation by mitogen/antigen and Thymidine uptake assay
13. Demonstration of cell viability by MTT assay
14. Flowcytometry, identification of T cells and their subsets
15. Evaluation of monoclonal antibodies for diagnostic and therapeutic applications
16. Demonstration of Immunodiagnostics using commercial kits (Rapid Dot Blot and Strip Test)

**TOTAL : 90 PERIODS**

**TEXTS/REFERENCES**

1. Goldsby, R.A. et al. "Kuby Immunology". 6<sup>th</sup> Edition, W.H. Freeman, 2002.
2. Turgeon, Mary Louise. "Immunology and Serology in Laboratory Medicine", 2<sup>nd</sup> Edition, Elsevier, 2007.
3. Brostoff J et al., "Clinical Immunology", 6<sup>th</sup> Edition, Gower Medical Publishing, 2002.
4. Coligan, J. E. et al, "Current Protocols in Immunology", 4<sup>th</sup> Edition John Wiley & Sons, 1994
5. Paul, "Fundamental of Immunology", 4<sup>th</sup> Edition, Lippencott Raven, 1999.

**BP8311**

**PROJECT WORK PHASE I**

**L T P C  
0 0 12 6**

**OBJECTIVES**

To provide research training in areas of Biopharmaceutical Technology and to stimulate the students to undertake research in this area.

**OUTCOME**

Students would have developed expertise one or two techniques pertaining to one or two techniques pertaining to research in biopharmaceutical technology and would be able to perform literature survey and make a comprehensive report presentation in a specified area.

**BP8411**

**PROJECT WORK PHASE II**

**L T P C  
0 0 24 12**

**OBJECTIVES**

To provide research training in specific areas of Biopharmaceutical Technology and to develop their skills for academic and industrial research.

**OUTCOME**

The students will be trained to undertake cutting edge research in the area of Biopharmaceutical Technology.

Attested  
Sobhan  
DIRECTOR  
Centre For Academic Courses  
Anna University, Chennai-600 025.

**OBJECTIVES**

The course will provide advanced theoretical knowledge on Bioconjugate technologies in Biopharmaceutical Applications

**OUTCOME**

The students will acquire knowledge in advanced methods to carry out cutting edge academic and industrial research.

**UNIT I FUNCTIONAL TARGETS 9**

Modification of Amino Acids, Peptides and Proteins – Modification of sugars, polysaccharides and glycoconjugates – modification of nucleic acids and oligonucleotides.

**UNIT II CHEMISTRY OF ACTIVE GROUPS 9**

Amine reactive chemical reactions – Thiol reactive chemical reactions – carboxylate reactive chemical reactions – hydroxyl reactive chemical reactions – aldehyde and ketone reactive chemical reactions – Photoreactive chemical reactions.

**UNIT III BIOCONJUGATE REAGENTS 9**

Zero length cross linkers – Homobifunctional cross linkers – Heterobifunctional cross linkers – Trifunctional cross linkers – Cleavable reagent systems – tags and probes.

**UNIT IV ENZYME AND NUCLEIC ACID MODIFICATION AND CONJUGATION 9**

Properties of common enzymes – Activated enzymes for conjugation – biotinylated enzymes – chemical modification of nucleic acids – biotin labeling of DNA- enzyme conjugation to DNA – Fluorescent of DNA.

**UNIT V BIOCONJUGATE APPLICATIONS 9**

Preparation of Hapten-carrier Immunogen conjugates - antibody modification and conjugation – immunotoxin conjugation techniques – liposome conjugated and derivatives- Colloidal – goldlabeled proteins – modification with synthetic polymers.

**TOTAL : 45 PERIODS**

**TEXT/REFERENCE**

1. Hermanson, G.T. "Bioconjugate Techniques". Academic Press,

PROGRESS THROUGH KNOWLEDGE

**OBJECTIVES**

To enhance theoretical knowledge of students in the chemistry of natural products and to explore this knowledge for practical applications

**OUTCOME**

At end of the course work students will appreciate the importance of natural compounds as novel drug entity for the development of newer drugs.

**UNIT I CARBOHYDRATES AND RELATED COMPOUNDS 9**

Sugars and sugar – containing drugs polysaccharides and polysaccharide –containing drugs cellulose gums and mucilages, pectin.

Attested

Sobhan  
DIRECTOR

Centre For Academic Courses  
Anna University, Chennai-600 025.

**UNIT II GLYCOSIDES AND TANNINS 9**

Biosynthesis of glycosides, Phenol and alcohol glycosides, anthraquinone glycosides, cyanophore glycosides, saponin glycosides, cardiac glycosides, isothiocyanate flavonolactone glycosides tannins volatile oils, resins and resin combinations.

**UNIT III ALKALOIDS AND ALICYCLIC COMPOUNDS 9**

Pyridine and piperidine alkaloids, Tropane alkaloids, Quinoline alkaloids, isoquinoline alkaloids, Indole alkaloids, Imidazole alkaloids, Steroidal alkaloids, Alkaloidal amines purine bases. Terpenes, camphor, menthol, carotenes

**UNIT IV VITAMINS, PURINES, FLAVONOIDS 9**

Chemistry, medicinal and pharmaceutical uses of vitamin A, D, E, K, B<sub>1</sub>, B<sub>2</sub>, B<sub>6</sub>, B<sub>12</sub> and Folic acid. Chemistry and structural elucidation of uric acid, interrelation between caffeine, theophylline and theobromine. Classification and application of flavanoids (hesperidine etc)

**UNIT V MOLECULES FROM NATURAL SOURCES 9**

Classification of Drug molecules of Plant/marine/microbial and animal sources-cytotoxic/anti neoplastic agents, cardio vascular drugs -antimicrobial substances – anti-inflammatory and antispasmodic agents

**TOTAL : 45 PERIODS**

**TEXTS/REFERENCES**

1. Evans, W.C., 'Trease and Evans Pharmacognosy', 15<sup>th</sup> Edition, Saunders, 2002
2. Wallis, T.E. "Textbook of Pharmacognosy", 5<sup>th</sup> Edition, CBS Publishers, 2005.
3. Kokate, C.K. "Pharmacognosy", 29<sup>th</sup> Edition, Nirali Prakashan, 2004.

**BP8003 COMBINATORIAL METHODS FOR DRUG DEVELOPMENT L T P C  
3 0 0 3**

**OBJECTIVES**

The objectives of the course will expose students to combinatorial chemistry and theoretical knowledge for peptide synthesis for application in drug development.

**OUTCOME**

Students will learn advanced knowledge in combinatorial chemistry and synthesis of new drug for their academic and industry research in future.

**UNIT I INTRODUCTION 10**

The Original Combinatorial Chemist – Biopolymers constitute natural libraries – Selection and evolution – The expression of genetic information – Combinatorial assembly of antibody genes – Molecular solutions to Combinatorial problems.

**UNIT II SYNTHETIC PEPTIDE LIBRARIES 8**

Solid-Phase peptide synthesis – Peptide on pins – Other iterative deconvolution strategies, Examples of Split/Couple/Mix Peptide Libraries – Positional Scanning

**UNIT III SUPPORTS, LINKERS, AND REAGENTS FOR PEPTIDE AND SMALL MOLECULE SYNTHESIS 10**

Polystyrenes – PEG – Grafted supports – Coupling strategies – New resins and linkers – Ring – forming cleavage – loading.

**UNIT IV SUPPORTED SOLUTION – PHASE SYNTHESIS 7**

Polyethylene glycols – Dendrimers Fluorous synthesis – Solution – Phase parallel synthesis scavenging resins – Ion Exchange resins – Supported reagents – Fluorous reagents – Solid phase extraction – Gas Phase separation.

*A Hested*

*Sobhan*  
**DIRECTOR**

Centre For Academic Courses  
Anna University, Chennai-600 025.

**UNIT V ANALYTICAL METHODS FOR SOLID-PHASE SYNTHESIS 10**  
Product identification – Gel Phase NMR – High resolution magic angle spinning NMR on-bead infrared Spectroscopy – Mass Spectroscopy – Non Spectroscopic Methods

**TOTAL : 45 PERIODS**

**TEXTS/REFERENCES**

1. Fenniri, Hicham, 'Combinatorial Chemistry', Oxford University Press, 2000
2. Block J.H. and Beale, J.M., 'Wilson & Gisvolds Text book of Organic Medicinal and Pharmaceutical Chemistry', 11<sup>th</sup> Edition, Lippincott Williams & Wilkins, 2004
3. Fassina, G. "Combinatorial Chemistry and Technologies: Methods and Applications", 2<sup>nd</sup> Edition, CRC Press, 2005.

**BP8004 DRUG DOSAGE FORMS AND DESIGN LT P C**  
**3 0 0 3**

**OBJECTIVES**

To enable students to acquire theoretical knowledge in pharmaceutical dosage forms and understanding the theoretical principles with application oriented problems.

**OUTCOME**

The students would have learnt various dosage forms of drugs, technological advancements to improve formulations at the completion of course.

**UNIT I INTRODUCTION TO DOSAGE FORMS 5**

History & Evolution; Definitions and Classification of Dosage forms and routes of Administration (Oral, Parenteral, Topical, Rectal and Nasal), Pharmacokinetics/ Pharmacodynamics parameters for Dosage form development

**UNIT II PREFORMULATION AND STABILITY STUDIES 9**

Physical properties of drugs - physical form, polymorphism, particle size, shape, density, wetting, dielectric constant, solubility, dissolution, organoleptic property and their effect on formulation, stability and bioavailability. Study of chemical properties of drugs like hydrolysis, oxidation, reduction, racemisation, polymerization, etc. and their influence on formulation and stability of products. Stabilization and stability testing protocol for various pharmaceutical products.

**UNIT III SOLID DOSAGE FORMS 9**

Capsules: Materials for production of hard/Soft gelatine capsules, size of capsules and method of capsule filling. importance of base absorption, manufacturing, quality control, stability and storage of capsule dosage forms. Micro-encapsulation- Classification, Methods of preparation and Evaluation of microcapsules. Tablets: Classification, tablet excipients, Mixing; Milling; Drying; Compression; Coating; Filling; Sealing; Solubility; Filtration, Clarification, Sieving; granulation technology, tablet compression and machinery, processing problems and evaluation. Coating- Types, materials for coating, formulation, equipments, film defects and evaluation of coated tablets.

**UNIT IV LIQUID, SEMI-SOLID AND AEROSOL DOSAGE FORMS 12**

Liquid Dosage forms: Additives in formulations, vehicles, stabilizers, preservatives, suspending agents, emulsifying agents, solubiliser, colours, flavours, manufacturing, packaging and evaluation of clear liquids, suspensions and emulsions official in pharmacopoeia.

Semisolid Dosage Forms: Mechanisms of drug penetration, factors influencing penetration, semisolid bases and their selection. General formulation of semisolids, clear gels, formulations of semisolids like Cream, Gel, Paste; Suppositories, manufacturing procedure, evaluation and packaging.

Aerosols: Types of propellants, general formulation, manufacturing, packaging methods, pharmaceutical applications and evaluation.

**UNIT V PARENTERALS AND ADVANCED/NOVEL DRUG DELIVERY SYSTEMS****10**

Parenterals; Liquids,(Solutions, Suspensions, Emulsions); Nasal; Ophthalmic and Otic Preparations; Packaging biopharmaceutical dosage design & delivery.

Sustained release and controlled release Pharmaceuticals – Classification and construction of products and evaluation. Novel Drug delivery systems – Transdermal delivery systems, Osmotic drug delivery systems, Liposomes, Nanoparticles.

**TOTAL : 45 PERIODS****TEXTS/REFERENCES**

1. Ansel, H.C. "Pharmaceutical Dosage Forms and Drug Delivery Systems", 7<sup>th</sup> Edition, Lippincott Williams & Wilkins, 2000.
2. Tipnis, H.P. "Bioavailability and Bioequivalence: An Update". New Age International, 1996.
3. Lieberman, H.A. "Pharmaceutical Dosage Forms: Tablets". Vol.1-3, 2<sup>nd</sup> Edition, Marcel Dekker, 2005.
4. Lieberman, H.A. "Pharmaceutical Dosage Forms: Parenteral Medications", Vol.1-3, 2<sup>nd</sup> Edition, Marcel Dekker, 2005.
5. Lieberman, H.A. "Pharmaceutical Dosage Forms: Disperse Systems", Vol.1-3, 2<sup>nd</sup> Edition, Marcel Dekker, 2005.
6. Lippincott, "Remington's The Science and Practice of Pharmacy", Vo.1 & 2, 20<sup>th</sup> Edition, Willaims & Wilkins, 2004.

**BP8005****DRUG REGULATORY, QUALITY & SAFETY EVALUATION****L T P C****3 0 0 3****OBJECTIVES**

To enable students to acquire knowledge in drug regulatory affairs in India and at International level.

**OUTCOME**

After completion of the course, students would have learned the principles of drug regulatory affairs and latest information on drug research, manufacturing, sales and distribution.

**UNIT I INTRODUCTION AND DRUGS & COSMETIC ACT****8**

Definitions, Forms, Licences; Schedules, New Schedule M, Schedule Y

**UNIT II PHARMACOPOEIA****6**

Descriptions & Monographs; Standards & Specifications; Testing of Drugs; Various Countries Pharmacopoeias; Indian, British, U.S, European, Japanese

**UNIT III cGMPs & REGULATORY RECORDS-SITE MASTER FILE, DRUG MASTER FILE, DRUG DOSSIERS****10**

cGMP concepts – Development, Manufacturing Record, Analytical & process Validation, Equipment & utility Qualification and Calibration, Personnel procedures; Regulatory bodies & requirements - Indian FDA, WHO GMP ; U.S. FDA, U.K. MCA, Australian TGA, Japanese PMDA. Drug dossier contents - CTD (CMC section) & data

**UNIT IV CLINICAL STUDIES- PRECLINICAL, PHASE I,II,III,IV****6**

Schedule-Y, pre-clinical study requirements, clinical trial phases, types of trials, bioethics & stakeholders, Bioavailability & Bio equivalence studies,

**UNIT V SAFETY AND ENVIRONMENTAL CONTROL****15**

Patent act- Patent, Trade Mark Regn, I.P.R; Safety & Environmental control; Project (Regulatory Factors).

**TOTAL : 45 PERIODS**



## TEXTS/REFERENCES

1. Abraham, John and Smith, H.W. "Regulation of the Pharmaceutical Industry", Palgrave, Macmillan, 2003.
2. Weinberg, Sandy "Good Laboratory Practice Regulations" 3<sup>rd</sup> Edition, Marcel Dekker, 2003.
3. Gad, Shayne C. "Drug Safety Evaluation", Wiley-Interscience, 2002
4. Malik, Vijay "Drugs and Cosmetics Act, 1940". EBC Publishing Co, 1998.
5. "Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials", Vol.I & II, World Health Organisation and Pharma Syndicate, 2002.
6. Berry, Ira R. and Harpaz, Daniel "Validation of Active Pharmaceutical Ingredients", 2<sup>nd</sup> Edition, CRC Press, 2001
7. British Pharmacopoeia
8. United States Pharmacopoeia.

BP8006

MEDICINAL CHEMISTRY

L T P C  
3 0 0 3

## OBJECTIVES

The students will be learning advanced aspects of medicinal chemistry, biological targets of drugs and their mode of action and will be correlated with structure activity relationship.

## OUTCOME

At end of the course, the students will have a clear understanding of the molecular properties of medicinal compounds and will help design and identification of new drugs and approaches in their academic research.

### UNIT I INTRODUCTION TO MEDICINAL CHEMISTRY 9

Classification of drugs on the basis of sources, structure, site of action and mode of action, drug metabolism, inactive metabolites, biologically active metabolites, phase I and phase II reactions, prodrugs.

### UNIT II HETEROCYCLIC COMPOUNDS 9

Chemistry, Structure property Relationship and properties of drugs having medically important heterocyclic compounds such as pyrrol, furan, thiophene, pyridine, pyrimidine, pyrazine, indole, quinoline and Isoquinoline.

### UNIT III GENERAL PROPERTIES 9

General properties, chemistry, constitution, biosynthesis, biological action and therapeutic applications of the following.

**Alicyclic compounds:** Terpenes, camphor, menthol, carotenes.

**Alkaloids:** Atropine, morphine, codeine, thebaine, reserpine, ephedrine.

**Vitamins (water and fat soluble):** B1, B2, B6, B12, folic acid, nicotinic acid, biotin, pantothenic acid, ascorbic acid. A, D, E and K.

**Hormones:** Testosterone, progesterone, estrogen, aldosterone, cortisol, insulin, glucagon, oxytocin and vasopressin.

### UNIT IV ANTI-MICROBIAL COMPOUNDS 9

To study the chemistry, structure, mechanism of action, SAR and therapeutic applications of the following anti microbial drugs

**Antibiotics:** Penicillins, cephalosporins, streptomycin, chloramphenicol, tetracyclines and erythromycin.

**Antimalarial agents:** 4-aminoquinolines, 8-aminoquinolines, 9-amino acridines, pyrimidine analogues, mefloquine, cinchona alkaloids.

**Anti-Tubercular Agents:** Ethambutol, isonicotinic acid, hydrazid, rifampicin, thioguanine, cytarabine, 5-fluoracil, dicarbazine.

**Antiviral agents:** Acyclovir, tromantadine hydrochloride, ribavirin



**UNIT V           PHYSIOCHEMICAL PRINCIPLES AND STRUCTURE ACTIVITY  
CONCEPTS**

**9**

To study the biological targets and drugs including its chemistry, structure, mechanism of action, and structure activity relationship of the following categories

Anti-histaminics, cholinergic drugs, adrenergic drugs, ACE inhibitors, CNS stimulants, tricyclic antidepressants, anti coagulants, anthelmintics, anti neoplastic agents.

**TOTAL : 45 PERIODS**

**TEXTS/REFERENCES**

1. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry. 10th edition, Lippincott-Raven Publisher, 1998.
2. Nogrady, Thomas, "Medicinal Chemistry: A Biochemical Approach", 2<sup>nd</sup> Edition, Oxford University Press, 2004.
3. William O. Foye, Thomas L. Lemke and David A. William. Principles of Medicinal Chemistry, 4th edition, 1995.
4. Burger's Medicinal Chemistry and Drug Discovery, edited by E. Wolff, 6th edition, Wiley Interscience, New York, 2003.
5. Hansch C, Sammes P.G. Taylor J.B. Comprehensive Medicinal Chemistry, Pergamon Press, Oxford, 1990.
6. Gurdeep Chatwal, "Organic Chemistry of Natural Products", Vol-II, Third edition, Himalaya Publishing House, 1996.

**BP8007**

**MOLECULAR MEDICINE AND MECHANISM**

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

**OBJECTIVES**

The objective of the course is to understand the molecular mechanism of the disease and advanced understanding of drug interactions.

**OUTCOME**

Students will be trained to understand the applications of mechanism of molecular diseases.

**UNIT I           INTRODUCTION TO MOLECULAR MEDICINE**

**9**

Organization of the Human Genome, Chromosomes and Genes – Recombinant DNA and Genetic Techniques – Transcriptional Control of Gene Expression – transmission of Human Genetic Disease – Human Genome Project – Cell Cycle Oncogenes and Tumor suppressor Genes – Molecular Diagnostic Testing – Genetic Counseling – Transgenic Mice as Models of Disease, Introduction to gene therapy.

**UNIT II           CARDIOLOGY**

**9**

Molecular Cardiology – Congenital Heart Disease – Inherited Cardiomyopathies – Coronary Atherosclerosis – Endothelium – Derived Nitric Oxide and Control of Vascular Tone – Hypertension – Cardiac Arrhythmias – Cardiovascular Gene Therapy.

**UNIT III           PULMONOLOGY**

**9**

Asthma – Cystic Fibrosis – Pulmonary Emphysema – Surfactant Deficiency – Lung Cancer: The Role of Tumor Suppressor Genes – Strategies for controlling the diseases.

**UNIT IV           ENDOCRINOLOGY**

**9**

Mechanisms of Hormone Action – Diabetes Mellitus – Pituitary Function and Neoplasia Growth Hormone Deficiency Disorders – Thyroid Disorders – Disorders of the parathyroid Gland – Congenital Adrenal Hyperplasia – Adrenal Disease – Multiple Endocrine Neoplasia Type 2 – Molecular Mechanisms of Hypoglycemia Associated with increased Insulin Production.

*Attested*

*Sobhan*  
**DIRECTOR**

Centre For Academic Courses  
Anna University, Chennai-600 025.

**UNIT V NEPHROLOGY 9**

Renal Development – Mechanisms of Leukocyte Extravasation – Ischemic Acute Renal Failure – Potassium Secretory Channels in the Kidney – Alport Syndrome – Nephrogenic Diabetes Insipidus – Polycystic Kidney Disease – Renal Neoplasms: Wilms' Tumor and Renal-Cell Carcinoma.

**TOTAL : 45 PERIODS**

**TEXTS/REFERENCES**

1. Jameson, J.L., Francis, S.C., "Principles of Molecular Medicine", Humand Press, 1998.
2. Ross, D.W. "Introduction to Molecular Medicine", 3<sup>rd</sup> Edition, Springer, 2002.
3. Ross, D.W. "Introduction to Oncogenes and Molecular Medicine", Springer, 1998.
4. Pasternak, J.J. "An Introduction to Human Molecular Genetics", 2<sup>nd</sup> Edition, Wiley Liss, 2005
5. Strachan, Tom and Andrew P. Read. "Human Molecular Genetics, Bios, 1996.

**BP8008 PHARMACOGENOMICS LT P C  
3 0 0 3**

**OBJECTIVES**

The course intends to provide knowledge about Pharmacogenomics and drug design using genomic applications for drug action and toxicity.

**OUTCOME**

At the completion of course, the student would have learnt advanced pharmacogenomics enabling him for cutting edge academic and industrial research.

**UNIT I INTRODUCTION TO PHARMACOGENOMICS 9**

Pharmacogenetics-The roots of pharmacogenomics, It is not just pharmacogenomics, Genetic drug response profiles, the effect of drugs on Gene expression, pharmacogenomics in drug discovery and drug development.

**UNIT II THE HUMAN GENOME 9**

Expressed sequence Tags (EST) and computational biology, Microbial genomics, computational analysis of whole genomes, computational genome analysis, Genomic differences that affect the outcome of host pathogen interactions: A template for the future of whole genome-based pharmacological science.

**UNIT III ASSOCIATION STUDIES IN PHARMACOGENOMICS 9**

Viability and ADR in drug response: contribution of genetic factor, Multiple inherited genetic factors influence the out come of drug treatments, Plasma binding proteins, Drug targets.

**UNIT IV GENOMICS APPLICATIONS FOR DRUG ACTION AND TOXICITY 9**

Genomics, Proteomics, Bioinformatics, The pharmaceutical process, applications of pharmaceutical industry, Understanding biology and diseases, Target identification and validation, Drug candidate identification and optimization.

**UNIT V PHARMACOGENOMICS AND DRUG DESIGN 9**

The need of protein structure information, protein structure and variation in drug targets-the scale of problem, Mutation of drug targets leading to change in the ligand binding pocket.

**TOTAL : 45 PERIODS**

**TEXTS/REFERENCE**

1. Licinio, Julio and Ma-Li Wong, "Pharmacogenomics: The Search for the Individualized Therapies", Wiley-VCH, 2002
2. Chabrabarth, Chiranjib and Bhattacharyya, Atane, "Pharmacogenomics: An Approach to New Drugs Development", 2004.
3. Othstein, Mark, A. "Pharmacogenomics: Social, Ethical and Clinical Dimensions", Wiley-Liss, 2003

**OBJECTIVES**

The course will provide advanced knowledge in detail the pharmacology of drugs and toxicology

**OUTCOME**

After the completion of course, the systemic effect of drugs action on Human body, chemotherapy and toxicology of drugs for academic and industrial research.

**UNIT I INTRODUCTION TO PHARMACOLOGY 9**

Sources of drugs, dosage forms and routes of drug administration, mechanism of action of drugs. Combined effect of drugs, factors modifying drug action, tolerance and dependence. Absorption, Distribution, Metabolism and Excretion of drugs. Principles of basic and clinical pharmacokinetics. Adverse drug reactions. Drug interactions, Bioassay of drugs and biological standardisation, Overview of drug discovery and development.

**UNIT II DRUGS ACTING ON THE HAEMOPOIETIC SYSTEM 9**

Haematinics, Anticoagulants, vitamin K and haemostatic agents, Fibrinolytic and anti-platelet drugs, Blood plasma volume expanders. Autocoids – Histamine, 5-HT and their antagonists, Prostaglandins, Thromboxanes and Leukotrienes, Pentagastrin, Cholecystokinin, Angiotensin, Bradykinin

**UNIT III PHARMACOLOGY OF GASTROINTESTINAL TRACT AND ENDOCRINE SYSTEM 9**

Antacids, anti-secretory and anti-ulcer drugs, Laxatives and Anti-diarrhoeal drugs, Appetite stimulants and suppressants, Emetics and anti-emetics. Hypothalamic and pituitary hormones, Thyroid hormones and anti-thyroid drugs, Parathormone, Calcitonin and Vitamin D, Insulin, Oral hypoglycaemic agents and glucagon. ACTH and corticosteroids, Androgens and anabolic steroids, Estrogens, progesterone and oral contraceptives, Drugs acting on the uterus

**UNIT IV CHEMOTHERAPY 9**

General principles of chemotherapy, Sulfonamides, Antibiotics – Penicillins, Cephalosporins, Chloramphenicol, macrolides, Quinolones, fluoroquinolones and other antibiotics. Chemotherapy of tuberculosis, leprosy, fungal diseases, viral diseases, urinary tract infections and sexually transmitted diseases. Chemotherapy of malignancy and immuno suppressive agents.

**UNIT V MOLECULAR PHARMACOLOGY AND PRINCIPLES OF TOXICOLOGY 9**

Classification of neurotransmitters and receptors, mechanism of action, receptor activation and signal transduction with special reference to CNS, G-protein coupled receptors, Definition of poison, general principles of treatment of poisoning, Heavy metals and heavy metal antagonists, Definition for acute, sub acute and chronic toxicity, genotoxicity, carcinogenicity, teratogenicity and mutagenicity studies

**TOTAL : 45 PERIODS****TEXT BOOKS**

1. Satoskar, Pharmacology and Therapeutics
2. Tripathi, K.D. Medical Pharmacology
3. Mycek M.J., Gerlnet S.B and Perper M.M. Pharmacology, Lippincott's Illustrated Reviews, Lipincott Company, Philadelphia.

**REFERENCES**

1. Rang, M.P, Dale M.M, Reter J.M-Pharmacology.
2. Goodman and Gilman's, The Pharmacological basis of therapeutics.3. Kulkarni S.K., Hand book of Experimental Pharmacology
3. Katzung, B.G., Basic and Clinical Pharmacology, Prentice Hall International.

**OBJECTIVES**

To provide advanced knowledge of proteins and their structure function relationship, essential for future pharmaceutical technology.

**OUTCOME**

On completion of the course, students will learn the functional characteristics of various types of proteins and engineering of proteins for production of new protein pharmaceuticals.

**UNIT I INTRODUCTION 6**

Amino acids, primary structure of proteins, amino acid composition, industrial significance, primary structure determination by chemical methods including automated sequencing and by gene sequencing, significance of primary structure determination, peptide synthesis, secondary structure and super secondary structures

**UNIT II PROTEIN ARCHITECTURE 6**

Tertiary structure of proteins, types of proteins, domains, quaternary structure, protein complexes, protein-protein interactions

**UNIT III STRUCTURE-FUNCTION RELATIONSHIP 15**

DNA-binding proteins: prokaryotic transcription factors, Helix-turn-Helix motif in DNA binding, Trp repressor, Eucaryotic transcription factors, Zn fingers, helix-turn helix motifs in homeodomain, Leucine zippers, Membrane proteins: General characteristics, Trans-membrane segments, prediction, bacteriorhodopsin and Photosynthetic reaction center, Immunoglobulins: IgG Light chain and heavy chain architecture, abzymes and Enzymes: Serine proteases, understanding catalytic design by engineering trypsin, chymotrypsin and elastase, substrate assisted catalysis other commercial applications.

**UNIT IV PROTEIN ENGINEERING METHODS 9**

Protein engineering methods, amino acid side chain reactions, chemical modification of proteins, site-directed mutagenesis, posttranslational modifications and engineering

**UNIT V INDUSTRIAL APPLICATIONS OF PROTEIN ENGINEERING 9**

Examples of industrial protein engineering applications Engineering of serine proteases, engineering of antibodies, engineering of proteins for thermal stability, engineering of proteins for preventing aggregation, His-tagged proteins in purification, engineering proteins for secretion, de novo protein synthesis.

**TOTAL : 45 PERIODS****TEXT BOOKS**

1. Voet, D. and Voet, G., "Biochemistry". 3rd Edition, John Wiley and Sons, 2001.
2. Branden C. and Tooze J., "Introduction to Protein Structure", 2nd Edition, Garland Publishing, 1999.
3. Creighton, T.E. "Proteins : Structure and Molecular Properties", 2nd Edition, W.H.
4. Freeman, 1993.

**REFERENCES**

1. Whitford, David "Proteins : Structure and Function". John Wiley & Sons, 2005.
2. Holland, I Barry et al., "ABC Proteins : From Bacteria to Man". Academic Press Elsevier, 2003.
3. Alberghina, L. "Protein Engineering in Industrial Biotechnology". Harwood Academic Publications, 2000.
4. Moody P.C.E. and Wilkinson A.J. "Protein Engineering". IRL Press, Oxford, 1990.
5. Rees, A.R., Sternberg, M.J.E. and Wetzel, R. "Protein Engineering: A Practical Approach". IRL Press, 1992.

Attested  
Sobhan  
DIRECTOR  
Centre For Academic Courses  
Anna University, Chennai-600 025.

**OBJECTIVES**

The course intends to give advanced theoretical knowledge on Microarrays, Next Generation DNA sequencing and Protein profiling.

**OUTCOME**

The students will acquire knowledge in advanced molecular methods to carry out cutting edge academic and industrial research.

**UNIT I MICROARRAYS IN GENOMICS 9**

Designing and producing microarrays; types of microarrays; cDNA microarray technology; oligonucleotide arrays; Sample preparation, labeling, hybridization, generation of microarray data. Gene Expression analysis by cDNA and oligonucleotide arrays; ChIP-on-Chip; Bioinformatic analysis of large-scale microarray data for comparative transcriptomics

**UNIT II NEXT GENERATION SEQUENCING TECHNOLOGIES 9**

Introduction to Next Generation Sequencing (NGS) technologies; Principles of NGS by Roche/454, Illumina, Life Technologies, Pacific Biosciences, Ion Torrent technologies; Applications of NGS to disease diagnosis and personalized medicine.

**UNIT III PROTEIN MICROARRAYS 9**

Types of protein arrays; Protein microarray fabrication; Experimental analysis of proteins arrays. Data acquisition and processing; Applications of protein microarray types.

**UNIT IV TWO-DIMENSIONAL GEL ELECTROPHORESIS OF PROTEINS 9**

Sample preparation, First-dimension IEF with IPG; Second dimensional separation of proteins; Image analysis of 2-DE gels; Protein expression profiling and comparative proteomics of complex proteomes using 2-DE.

**UNIT V MASS-SPECTROMETRY 9**

Basics of Mass-spectrometry (MS) and biomolecular analysis; Common ionization methods for peptide/protein analysis (MALDI and ESI); Principles of Time of Flight (TOF), Ion Trap (IT), Quadrupole (Q), Fourier Transform-Ion cyclotron Resonance (FT-ICR), and Orbitrap mass analyzers; Collision-Induced Dissociation (CID) of peptides; Analysis of complex protein mixtures using Nano-liquid chromatography (Nano-LC) coupled to Mass-spectrometry analysis; Analysis of metabolites using Gas-chromatography coupled to Mass-spectrometry; Mass-spectrometry analysis of Post-Translational Modifications of proteins (Phosphorylation and glycosylation). Accurate quantitation of peptides and small molecules using SRM/MRM approach.

**TOTAL : 45 PERIODS**



**OBJECTIVES**

The course intends to give advanced knowledge about Biocatalysts, Enzyme kinetics, immobilization and enzymatic biotransformation of drugs

**OUTCOME**

The students will acquire knowledge in all aspect of Biocatalysis, enzyme kinetics and immobilization. The enzymatic transformation will give theoretical idea about drug biotransformation.

**UNIT I BASICS OF ENZYMES AS BIOCATALYSIS 9**

Introduction to enzymes, Classification, Sources, Mechanism of enzyme action. Strategies of purification of enzymes, criteria of purity, molecular weight determination and characterization of enzymes, Enzymes of biological importance - Acetylcholinesterase, angiotensin converting enzyme (ACE), ACE Inhibitors, HMG Co A reductase inhibitors, pseudocholinesterase, 5 -nucleotidase (5NT), glucose-6-phosphate dehydrogenase (GPD), CKisoforms, immunoreactive trypsinogen (IRT) and chymotrypsin; amylase isoenzymes

**UNIT II KINETICS OF ENZYME ACTION 9**

Methods for investigating the kinetics of Enzyme catalysed reactions – Initial velocity Studies, Estimation of Michaelis Menten parameters, Effect of pH and temperature on enzyme activity, kinetics of inhibition. Modeling of rate equations for single and multiple substrate reactions.

**UNIT III IMMOBILIZED ENZYMES 9**

Techniques of enzyme immobilization; kinetics of immobilized enzymes, effect of solute, partition & diffusion on the kinetics of immobilized enzymes, design and configuration of immobilized enzyme reactors; applications of immobilized enzyme technology, Economic argument for immobilization

**UNIT IV ENZYMES IN FUNCTIONAL GROUP TRANSFORMATION 9**

Functional group interconversion using enzymes (hydrolysis reaction, oxidation/reduction reactions, C-C bond formations), Retrosynthetic biocatalysis, Chemoenzymatic synthesis of natural products. Industrial process using enzymes for production of drugs, fine chemicals and chiral intermediates.

**UNIT V ENZYMATIC TRANSFORMATION 9**

Reaction engineering for enzyme-catalyzed biotransformations. Catalytic antibodies. Biocatalysts from extreme Thermophilic and Hyperthermophilic microorganisms (extremozymes). The design and construction of novel enzymes, artificial enzymes, Biotransformation of drugs (hydroxylation of Steroids), Host Guest Complexation chemistry, enzyme design using steroid templates, enzymes for production of drugs, fine chemicals and chiral intermediates.

**TOTAL : 45 PERIODS****TEXTS/REFERENCES**

1. Blanch, H.W., Clark, D.S. Biochemical Engineering, Marcel Dekker, 1997
2. Lee, James M. Biochemical Engineering, PHI, USA, 1982.
3. Bailey J.E. & Ollis, D.F. Biochemical Engineering Fundamentals, 2<sup>nd</sup> Ed., McGraw Hill, 1986
4. Faber, Kurt "Biotransformations in organic chemistry : A Textbook" 5<sup>th</sup> Edition. Springer 2008.
5. Enzyme catalysis in organic synthesis (Vol I-III); Eds by K.Drauz and H. Waldmann. Willey-VCH (ISBN: 3-527-29949-1)
6. Hydrolases in organic synthesis (regio and stereoselective biotransformations). U. T. Bornscheuer and R. J. Kazlauskas. Willey-VCH. (ISBN: 3-527-30104-6).
7. Stereoselective biocatalysis. Ed. R.N. Patel. Marcel Dekker. (ISBN: 0-8247- 8282-8)

Attested  
Sobhan  
DIRECTOR  
Centre For Academic Courses  
Anna University, Chennai-600 025.



**OBJECTIVES**

The course will provide Fundamental ethical to Advanced clinical trial management including drug development and trial planning; Project management in clinical trials; Consent and data protection; Quality assurance and governance.

**OUTCOME**

The students will acquire knowledge in all aspect of clinical trials, management and ethical standards required to conduct clinical trials.

**UNIT I INTRODUCTION TO CLINICAL TRIALS 9**

Fundamentals of clinical trials; Basic statistics for clinical trials; Clinical trials in practice; Reporting and reviewing clinical trials; Legislation and good clinical practice - overview of the European directives and legislation governing clinical trials in the 21<sup>st</sup> century; International perspectives; Principles of the International Committee on Harmonisation (ICH)-GCP.

**UNIT II REGULATIONS OF CLINICAL TRIALS 9**

Drug development and trial planning - pre-study requirements for clinical trials; Regulatory approvals for clinical trials; Consort statement; Trial responsibilities and protocols - roles and responsibilities of investigators, sponsors and others; Requirements of clinical trials protocols; Legislative requirements for investigational medicinal products.

**UNIT III MANAGEMENT AND ETHICS OF CLINICAL TRIALS 9**

Project management in clinical trials - principles of project management; Application in clinical trial management; Risk assessment; Research ethics and Bioethics - Principles of research ethics; Ethical issues in clinical trials; Use of humans in Scientific Experiments; Ethical committee system including a historical overview; the informed consent; Introduction to ethical codes and conduct; Introduction to animal ethics; Animal rights and use of animals in the advancement of medical technology; Introduction to laws and regulation regarding use of animals in research.

**UNIT IV INFORMED CONSENT 9**

Consent and data protection- the principles of informed consent; Consent processes; Data protection; Legislation and its application; Data management – Introduction to trial master files and essential documents; Data management.

**UNIT V QUALITY CONTROL AND GUIDELINES 9**

Quality assurance and governance - quality control in clinical trials; Monitoring and audit; Inspections; Pharmacovigilance; Research governance; Trial closure and pitfalls-trial closure; Reporting and legal requirements; Common pitfalls in clinical trial management.

**TOTAL : 45 PERIODS****REFERENCES**

1. Lee, Chi-Jen; etal., "Clinical Trials or Drugs and Biopharmaceuticals." CRC / Taylor & Francis, 2011.
2. Matoren, Gary M. "The Clinical Research Process in the Pharmaceutical Industry." Marcel Dekker, 1984.

Attested  
*Sobhan*  
DIRECTOR  
Centre For Academic Courses  
Anna University, Chennai-600 025.

**OBJECTIVES**

The course will provide advanced information on molecular pathogenesis of infectious diseases

**OUTCOME**

The subject will help the student towards understanding the virulence of the pathogen and Host-parasite interactions for advanced academic and industrial research in molecular pathogenesis.

**UNIT I INTRODUCTION 5**

Discovery of microscope, Molecular Koch's postulates, Concepts of disease, Virulence, Pathogenic cycle, Vaccines and its historical perspective, Biofilms, quorum sensing, multidrug resistance.

**UNIT II HOST DEFENSE AGAINST PATHOGENS AND BACTERIAL DEFENSE STRATEGIES 10**

Skin, mucosa, cilia secretions, physical movements, physical and chemical barriers to bacterial colonisation, Mechanism of killing by humoral and cellular defenses, Complement, Inflammatory process, Phagocytosis, Colonization, Adherence, Iron acquisition mechanisms, Bacterial defense strategies.

**UNIT III MOLECULAR MECHANISMS OF VIRULENCE 10**

Virulence, Colonization factors, Microbial toxins, Secretion systems: General secretory pathway, Two-step secretion, Contact dependent secretion, Conjugal transfer system and Autotransporters.

**UNIT IV MECHANISMS UNDERLYING MOLECULAR PATHOGENESIS (COMMON ENTERIC PATHOGENS) 10**

**Shigella:** Entry, Induction of macropinocytosis, Invasion of epithelial cells, Intracellular motility and spread, Apoptotic killing of macrophages, Virulence factors involved. **E.coli:** Enterotoxigenic *E.coli* (ETEC), labile & stable toxins, Entero-pathogenic *E.coli* (EPEC), type III secretion, Cytoskeletal changes, intimate attachment; Enterohaemorrhagic *E.coli* (EHEC), Mechanism of bloody diarrhea and Hemolytic Uremic Syndrome, Enteroaggregative *E.coli* (EAEC). **Vibrio Cholerae:** Cholera toxin, Co-regulated pili, filamentous phage, survival.

**UNIT V MECHANISMS UNDERLYING MOLECULAR PATHOGENESIS (COMMON NON-ENTERIC PATHOGENS) 10**

**Mycobacterium tuberculosis:** The Mycobacterial cell envelope, Route of entry, Uptake by macrophages, Latency and persistence, Entry into and survival in phagocytes, Immune response against MTB, MTB virulence factors, Emergence of resistance. **Influenza virus:** Intracellular stages, Neuraminidase and Haemagglutinin in entry, M1 & M2 proteins in assembly and disassembly, action of amantadine. **Plasmodium:** Lifecycle, erythrocyte stages, transport mechanism and processes to support the rapidly growing schizont, parasitinous vacuoles and knob protein transport, Antimalarials based on transport processes.

**TOTAL : 45 PERIODS****TEXTS/REFERENCES**

1. Salyers, Abigail A. "Bacterial Pathogenesis: A Molecular Approach"
2. Groisman, "Principles of Bacterial Pathogenesis".
3. Waksman, Gabriel and Michael Caparon "Structural Biology of Bacterial Pathogenesis".
4. Clark, Virginia L. "Bacterial Pathogenesis"
5. Williams, Peter "Bacterial Pathogenesis" (Methods in Microbiology)
6. Mc Clane, Bruce A. "Microbial Pathogenesis"
7. Madigan, Michael T. "Biology of Microorganisms"
8. Stanley, "Genetic analysis of Pathogenic Bacteria".
9. Hacker, Jorg "Molecular Infection Biology"

Attested  
Sobhan  
DIRECTOR  
Centre For Academic Courses  
Anna University, Chennai-600 025.

**OBJECTIVES**

To enhance the overall capability of students and to equip them with the necessary communication and soft skills to enable them to excel in their profession

**OUTCOME**

The course will enhance soft skills and interpersonal skills, which will make their transition from college to work place smoother and help them excel in their job.

**UNIT I PROCESS OF COMMUNICATION 9**

Concept of effective communication- Setting clear goals for communication; Determining outcomes and results; Initiating communication; Avoiding breakdowns while communicating; Creating value in conversation; Barriers to effective communication; Non verbal communication- Interpreting non verbal cues; Importance of body language, Power of effective listening; recognizing cultural differences

**UNIT II PRESENTATION SKILLS 9**

Formal presentation skills; Preparing and presenting using Over Head Projector, Power Point; Defending Interrogation; Scientific poster preparation & presentation; Participating in group discussions

**UNIT III TECHNICAL WRITING SKILLS 9**

Types of reports; Layout of a formal report; Scientific writing skills: Importance of communicating Science; Problems while writing a scientific document; Plagiarism; Scientific Publication Writing: Elements of a Scientific paper including Abstract, Introduction, Materials & Methods, Results, Discussion, References; Drafting titles and framing abstracts

**UNIT IV COMPUTING SKILLS FOR SCIENTIFIC RESEARCH 9**

Web browsing for information search; search engines and their mechanism of searching; Hidden Web and its importance in Scientific research; Internet as a medium of interaction between scientists; Effective email strategy using the right tone and conciseness

**UNIT V RESUME / REPORT PREPARATION / LETTER WRITING 9**

Students prepare their own resume and report, Presentation- Students make presentations on given topics, Group Discussion- Students participate in group discussions, and Interview Skills- Students participate in Mock Interviews

**TOTAL : 45 PERIODS****TEXTS/REFERENCES**

1. Mohan Krishna and N.P. Singh, Speaking English effectively, Macmillan, 2003.

**OBJECTIVES**

The course intends to give advanced theoretical knowledge on genomic organization and Genomic methods like microarray and transcriptome analysis

**OUTCOME**

The students will acquire knowledge in advanced molecular methods to carry out cutting edge academic and industrial research.

Attested  
Sobhan  
DIRECTOR  
Centre For Academic Courses  
Anna University, Chennai-600 025.

**UNIT I ORGANIZATION AND STRUCTURE OF GENOMES 9**

General organization and structure of genomes of viruses, prokaryotes, eukaryotes, and organelles (chloroplast, mitochondrion)

**UNIT II GENOME MAPPING AND SEQUENCING 9**

Isolation and cloning of genomic DNA, Genome mapping (genetic and physical), STS assembly, ESTs, RAPDs, RFLPs, AFLPs, SSLPs, SNPs, linkage analysis, Restriction mapping, FISH, Chromosome painting, microsatellites, Gene finding, annotation, ORF and functional prediction, Chain termination and chemical degradation sequencing methods, Whole genome shot-gun sequencing.

**UNIT III LARGE SCALE GENOMICS/ FUNCTIONAL GENOMICS ANALYSES 9**

Genome-wide association (GWA) analysis; Comparative Genomic Hybridization (CGH); Serial Analysis of Gene Expression (SAGE); Massively parallel Signature Sequencing (MPSS); Analysis of alteration in gene expression by Differential Display and Suppression Subtractive Hybridization. Introduction to Next Generation Sequencing (NGS) technologies for genome sequencing.

**UNIT IV MICROARRAY TECHNOLOGY AND ANALYSIS 9**

Designing and producing microarrays; cDNA microarray technology; oligonucleotide arrays and designs; Sample preparation, labeling, hybridization, generation and analysis of microarray data.

**UNIT V HIGH-THROUGHPUT TRANSCRIPTOMICS ANALYSES 9**

Gene Expression analysis by cDNA and oligonucleotide arrays; Methylome analysis using microarray; ChIP-on-Chip; Bioinformatic analysis of large-scale microarray data for comparative transcriptomics: Data normalization; Cluster analysis; Significance Analysis of Microarrays (SAM); Gene Ontology and Pathway analysis.

**TOTAL : 45 PERIODS**

**TEXTS/REFERENCES**

1. S.P. Hunt and F. J. Livesey, (2000) Functional Genomics
2. S. B. Primose (1998) Principles of Genome Analysis
3. C. R. Cantor and C. L. Smith (1999) Genomics\_ The Science and Technology behind the Human Genome Project
4. N. K. Spur, B. D. Young, and S. P. Bryant (1998) ICRF Handbook of Genome Analysis Volume 1 & 2.
5. G. Gibson and S. V. Muse (2002) A primer of Genome Science
6. R. J. Reece (2004) Analysis of Genes and Genomes
7. S. Suhai (2002) Genomics and Proteomics\_Functional and computational aspects. Kluwer Academic
8. Hans Joac and Thomas Roeder (2005) Microarrays
9. Steve Russell, Lisa A. Meadows and Roslin R. Russell (2009) Microarray Technology in Practice
10. . Allison D. B., Page G. P., Beasley T. M., and Edwards J. W. (2006) DNA microarrays and related genomics techniques – Design, Analysis, and Interpretation of Experiments. Chapman & Hall/CRC
11. Pevsner J. (2009) Bioinformatics and Functional Geneomics. Wiley-Balckwell
12. Rinaldis E. D. and Lahm A (2007)DNA Microarrays. Horizon bioscience.
13. Stekel D. (2003) Microarray Bioinformatics. Cambridge University Press.

Attested

Sobhan  
DIRECTOR

Centre For Academic Courses  
Anna University, Chennai-600 025.

**OBJECTIVES**

To familiarize the student with quantitative approaches for analyzing cellular metabolism and the use of theoretical and experimental tools that can give insights into the structure and regulation of metabolic networks. A central aspect of the course is to identify the optimal strategy for introducing directed genetic changes in the microorganisms with the aim of obtaining better production strains. Case studies will be taken up on metabolically-engineered products and processes in various expression systems.

**OUTCOME**

This course work will provide essential knowledge for the students to make their career in bioprocess Industries.

**UNIT I METABOLIC FLUX ANALYSIS 9**

Introduction to metabolic engineering, comprehensive models of cellular reactions with stoichiometry and reaction rates; metabolic flux analysis of exactly/over/under determined systems. Shadow price, sensitivity analysis.

**UNIT II TOOLS FOR EXPERIMENTALLY DETERMINING FLUX THROUGH PATHWAYS 9**

Monitoring and measuring the metabolome, Methods for the experimental determination of metabolic fluxes by isotope labeling metabolic fluxes using various separation-analytical techniques. GC-MS for metabolic flux analysis, genome wide technologies: DNA /phenotypic microarrays and proteomics.

**UNIT III CONSTRAINT BASED GENOMIC SCALE METABOLIC MODEL 9**

Development of Genomic scale metabolic model, Insilico Cells:studying genotype-phenotype relationships using constraint-based models, case studies in *E. coli*, *S.cerevisiae* metabolic network reconstruction methods, optimization of metabolic network, Identification of targets for metabolic engineering; software and databases for genome scale modeling

**UNIT IV METABOLIC CONTROL ANALYSIS AND KINETIC MODELING 9**

Fundamental of Metabolic Control Analysis, control coefficients and the summation theorems, Determination of flux control coefficients. Multi-substrate enzyme kinetics, engineering multifunctional enzyme systems for optimal conversion, and a multi scale approach for the predictive modeling of metabolic regulation.

**UNIT V CASE STUDIES IN METABOLIC ENGINEERING 9**

Metabolic engineering examples for bio-fuel, bio-plastic and green chemical synthesis. Study of genome scale model in various systems for the production of green chemicals using software tools. Validation of the model with experimental parameters.

**TOTAL : 45 PERIODS****TEXT BOOKS**

1. Stephanopoulos, G.N. "Metabolic Engineering: Principles and Methodologies". Academic Press / Elsevier, 1998.
2. Lee, S.Y. and Papoutsakis, E.T. "Metabolic Engineering". Marcel Dekker, 1998.
3. Nielsen, J. and Villadsen, J. "Bioreaction Engineering Principles". Springer, 2007.
4. Smolke, Christiana D., "The Metabolic Pathway Engineering Handbook Fundamentals", CRC Press Taylor & Francis, 2010.

**REFERENCES**

1. Voit, E.O. "Computational Analysis of Biochemical Systems : A Practical Guide for Biochemists and Molecular Biologists". Cambridge University Press, 2000.
2. Scheper, T. "Metabolic Engineering" Vol 73 (Advances in Biochemical Engineering Biotechnology) Springer, 2001.
3. Cortassa, S. et al, " An Introduction to Metabolic and Cellular Engineering", World Scientific Publishing, 2002.
4. Kholodenko, Boris N and H. V. Westerhoff "Metabolic Engineering in the Post Genomic Era", Horizon Bioscience, 2004.



**OBJECTIVES**

The 'Nanobiotechnology' course aims to provide fundamental concepts of nanotechnology and advanced knowledge on the application of nanotechnology to biological sciences including nanomedicine.

**OUTCOMES**

The students would have learned the physicochemical properties of nanomaterials; the unique changes that happen at nanoscale; nanoscale view of the natural biomolecular processes; synthesis, modification, and characterization of nanomaterials; and application of nanomaterials to biological problems including nanomedicine.

**UNIT I NANOSCALE AND NANOBIOTECHNOLOGY 6**

Introduction to Nanoscience and Nanotechnology; Milestones in Nanotechnology; Overview of Nanobiotechnology and Nanoscale processes; Physicochemical properties of materials in Nanoscales.

**UNIT II FABRICATION AND CHARACTERIZATION OF NANOMATERIALS 10**

Types of Nanomaterials (Quantum dots, Nanoparticles, Nanocrystals, Dendrimers, Buckyballs, Nanotubes); Gas, liquid, and solid –phase synthesis of nanomaterials; Lithography techniques (Photolithography, Dip-pen and Electron beam lithography); Thin film deposition; Electrospinning. Bio-synthesis of nanomaterials.

**UNIT III PROPERTIES AND MEASUREMENT OF NANOMATERIALS 9**

Optical Properties: Absorption, Fluorescence, and Resonance; Methods for the measurement of nanomaterials; Microscopy measurements: SEM, TEM, AFM and STM. Confocal and TIRF imaging.

**UNIT IV NANOBIOLOGY AND BIOCONJUGATION OF NANOMATERIALS 10**

Properties of DNA and motor proteins; Lessons from nature on making nanodevices; Reactive groups on biomolecules (DNA & Proteins); Surface modification and conjugation to nanomaterials. Fabrication and application of DNA nanowires; Nanofluidics to solve biological problems.

**UNIT V NANO DRUG DELIVERY AND NANOMEDICINE 10**

Properties of nanocarriers; drug delivery systems used in nanomedicine; Enhanced Permeability and Retention effect; Blood-brain barrier; Active and passive targeting of diseased cells; Health and environmental impacts of nanotechnology.

**TOTAL : 45 PERIODS****REFERENCES**

1. Nanobiotechnology: Concepts, Applications and Perspectives, Christof M. Niemeyer (Editor), Chad A. Mirkin (Editor), Wiley-VCH; 1 edition, 2004.
2. NanoBioTechnology: BioInspired Devices and Materials of the Future by Oded Shoseyov and Ilan Levy, Humana Press; 1 edition 2007.
3. NanoBiotechnology Protocols (Methods in Molecular Biology) by Sandra J Rosenthal and David W. Wright, Humana Press; 1 edition, 2005.
4. Bio-Nanotechnology\_ Concepts and applications. Madhuri Sharon, Maheshwar Sharon, Sunil Pandey and Goldie Oza, Ane Books Pvt Ltd, 1 edition 2012
5. Microscopy Techniques for Material Science. A. R. Clarke and C. N. Eberhardt (Editors) CRC Press. 1<sup>st</sup> Edition, 2002.

Attested

Sobhan  
DIRECTORCentre For Academic Courses  
Anna University, Chennai-600 025.

**OBJECTIVES**

The course intends to give advanced theoretical knowledge on advanced proteomics and Mass spectroscopy analysis.

**OUTCOME**

The students will acquire knowledge in advanced Protein methods to carry out cutting edge academic and industrial research.

**UNIT I            PROTEOMICS AND BIOLOGICAL MASS-SPECTROMETRY            9**

Over-view of strategies used for the identification and analysis of proteins; Basics of Mass-spectrometry (MS) and bimolecular analysis; One-dimensional (1-D) polyacrylamide gel electrophoresis (PAGE) of proteins; Enzymatic cleavage of proteins in solution; In-gel digestion of protein bands; Electrophoretic transfer of proteins on to membranes (PVDF).

**UNIT II            MASS-SPECTROMETRY IN PROTEOMICS            9**

Common ionization methods for peptide/protein analysis (MALDI and ESI); Principles of Time of Flight (TOF), Ion Trap (IT), Quadrupole (Q), Fourier Transform-Ion cyclotron Resonance (FT-ICR), and Orbitrap mass analyzers; Collision-Induced Dissociation (CID) of peptides; Introduction to Ion detectors.

**UNIT III            SEPARATION AND PROCESSING OF PROTEINS FOR PROTEOMICS ANALYSIS            9**

Protein extraction from biological samples (Mammalian Tissues, Yeast, Bacteria, and Plant Tissues); 2-DE of proteins for proteome analysis; Difference in-gel electrophoresis (DIGE); Liquid chromatography separations in proteomics (Affinity, Ion Exchange, Reversed-phase, and size exclusion); Strategies for multidimensional liquid chromatography in proteomics; Analysis of complex protein mixtures using Nano-liquid chromatography (Nano-LC) coupled to Mass-spectrometry analysis.

**UNIT IV            COMPARATIVE AND QUANTITATIVE PROTEOMICS            9**

Rapid identification of Bacteria based on spectral patterns using MALDI-TOF- MS. Comparative proteomics based on global in-vitro and in-vivo labeling of proteins/peptides followed by Mass-spectrometry analysis: ICAT, iTRAQ, SILAC. Analysis of Post-translational modification (PTM) of proteins; Enrichment and analysis of phospho- and glyco-proteins; Characterization of protein interactions using yeast two-hybrid system, Co-immunoprecipitation followed by MS, and Protein microarrays.

**UNIT V            PROTEOMICS INFORMATICS            9**

Identification of proteins by PMF and MS/MS data; Database search engines for MS data analysis (Mascot, Sequest, and others); Proteomics informatics strategies for biomarker discovery, analysis of protein functions and pathways. Applications of proteomics (Disease diagnosis, drug development, and plant biotechnology).

**TOTAL : 45 PERIODS****TEXTS/REFERENCES**

1. Simpson R. J. "Proteins and Proteomics - A Laboratory Manual". Cold Spring Harbour Laboratory Press, 2002.
2. Pennington S. R. and Dunn M. J. "Proteomics - From Protein Sequence to Function. Viva Books, 2002.
3. Twyman R. M. "Principles of Proteomics". Taylor & Francis. 2004
4. O'Connor C. D. and Hames B. D. "Proteomics". Scion, 2008.
5. Dassanayake R. S. and Gunawardene Y.I.N. S. "Genomic and Proteomic Techniques". Narosa, 2011.
6. Siuzdak G. "Mass Spectrometry for Biotechnology". Academic Press. 1996.
7. Hoffman E. D. and Stroobant V. "Mass Spectrometry – Principles and Applications", John Wiley & Sons, 2007
8. Chapman J. R. "Mass Spectrometry of Proteins and Peptides" (Methods in Molecular Biology – Vol 146) Humana Press. 2000.

9. Rosenberg I. M. "Protein analysis and Purification – Benchtop Techniques". Springer, 2005.
10. Scopes R. K. "Protein Purification – Principles and Practice". Springer, 1994.
11. Schena M. "Protein Microarrays". Jones and Bartlett, 2005.
12. Smejkal G. B. and Lazarev A. V. "Separation methods in Proteomics". CRC Press, 2006.

**BT8078 RESEARCH AND RESEARCH METHODOLOGY IN BIOTECHNOLOGY**

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

**OBJECTIVES**

The course will provide knowledge about the objectives to perform research and for interpretation of data from experimental results and presenting technical publications.

**OUTCOME**

After the completion of course, students will able to design, conduct, and interpret research outcomes for academic and industrial research needs.

**UNIT I RESEARCH AND ITS METHODOLOGIES (WITH EXAMPLES) 9**

Objectives of research; research process – observation, analysis, inference, hypothesis, axiom, theory, experimentation; Types of research (basic, applied, qualitative, quantitative, analytical etc); Features of translational research, the concept of laboratory to market (bench to public) and Industrial R&D.

**UNIT II RESEARCH IN BIOTECHNOLOGY – AN OVERVIEW 9**

Biological systems and their characteristics that influence the type and outcome of research; Exploratory and product-oriented research in various fields of biotechnology (health, agri, food, industrial etc). Types of expertise and facilities required; Interdisciplinary nature of biotech research; Sources of literature for biotech research

**UNIT III EXPERIMENTAL RESEARCH: BASIC CONCEPTS IN DESIGN AND METHODOLOGY 9**

Precision, accuracy, sensitivity and specificity; major experimental variables, biochemical measurements, types of measurements, enzymes and enzymatic analysis, antibodies and immunoassays, instrumental methods, bioinformatics and computation, experimental planning – general guidelines

**UNIT IV RESULTS AND ANALYSIS 9**

Importance and scientific methodology in recording results, importance of negative results, different ways of recording, industrial requirement, artifacts versus true results, types of analysis (analytical, objective, subjective) and cross verification, correlation with published results, discussion, outcome as new idea, hypothesis, concept, theory, model etc.

**UNIT V SCIENTIFIC AND TECHNICAL PUBLICATION 9**

Different types of scientific and technical publications in the area of biotechnology, and their specifications, Ways to protect intellectual property – Patents, technical writing skills, definition and importance of impact factor and citation index; Assignment in technical writing

**TOTAL : 45 PERIODS**

**TEXT/REFERENCES**

1. Essentials of Research Design and Methodology Geoffrey R. Marczyk, David DeMatteo, David Festinger, 2005 John Wiley & Sons Publishers, Inc
2. Biochemical Calculations: How to Solve Mathematical Problems in General Biochemistry, 2nd Edition, Irwin H. Segel, 1976 John Wiley & Sons Publishers, Inc
3. Guide to Publishing a Scientific paper, Ann M. Korner, 2004, Bioscript Press.

*Attested*

*Sobhan*  
**DIRECTOR**

Centre For Academic Courses  
Anna University, Chennai-600 025.

**OBJECTIVES**

The course intends to give advanced theoretical knowledge on tissue engineering, Stem cells and its biological applications

**OUTCOME**

The students will acquire knowledge in advanced methods to carry out cutting edge academic and industrial research.

**UNIT I INTRODUCTION 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, ECM component, mechanical measurements and physical properties.

**UNIT II TISSUE ARCHITECTURE 9**

Tissue types and Tissue components, Tissue repair, Basic wound healing events, Applications of growth factors: Role of VEGF. Angiogenesis, Basic properties, Cell-Matrix & Cell-Cell Interactions, Control of cell migration in tissue engineering.

**UNIT III BIOMATERIALS 9**

Biomaterials: Properties of Biomaterials, Surface, bulk, mechanical and biological properties. Scaffolds & tissue engineering, Types of Biomaterials, biological and synthetic materials, Biopolymers, Applications of biomaterials, Modifications of Biomaterials, Role of Nanotechnology.

**UNIT IV BASIC BIOLOGY OF STEM CELLS 9**

Stem Cells : Introduction, Types & sources of stem cell with characteristics: hematopoietic differentiation pathway, Potency and plasticity of stem cells, sources, embryonic stem cells, hematopoietic and mesenchymal stem cells, Stem Cell markers, FACS analysis, Differentiation, Stem cell systems- Liver, neuronal stem cells, cancer stem cells, induced pluripotent stem cells.

**UNIT V CLINICAL APPLICATIONS 9**

Stem cell therapy, Molecular therapy, In vitro organogenesis, Neurodegenerative diseases, spinal cord injury, heart disease, diabetes, burns and skin ulcers, muscular dystrophy, orthopedic applications, Stem cells and Gene therapy, Physiological models, tissue engineering therapies, product characterization, components, safety, efficacy. Preservation – freezing and drying. Patent protection and regulation of tissue-engineered products, ethical issues.

**TOTAL : 45 PERIODS****TEXTS/REFERENCES**

1. Bernhard O. Palsson, Sangeeta N. Bhatia, "Tissue Engineering" Pearson Publishers 2009.
2. Meyer, U.; Meyer, Th.; Handschel, J.; Wiesmann, H.P. .Fundamentals of Tissue Engineering and Regenerative Medicine. 2009.
3. Bernard N. Kennedy (editor). New York : Nova Science Publishers, c2008. Stem cell transplantation, tissue engineering, and cancer applications
4. Raphael Gorodetsky, Richard Schäfer. Cambridge : RSC Publishing, c2011. Stem cell-based tissue repair.
5. R. Lanza, I. Weissman, J. Thomson, and R. Pedersen, Handbook of Stem Cells, Two-Volume, Volume 1-2: Volume 1-Embryonic Stem Cells; Volume 2-Adult & Fetal Stem Cells, 2004, Academic Press.
6. R. Lanza, J. Gearhart et al (Eds), Essential of Stem Cell Biology, 2006, Elsevier Academic press.
7. J. J. Mao, G. Vunjak-Novakovic et al (Eds), Translational Approaches In Tissue Engineering & Regenerative Medicine" 2008, Artech House, INC Publications Naggy N. Habib, M.Y. Levicar, , L. G. Jiao, , , and N. Fisk, Stem Cell
8. Repair and Regeneration, volume-2, 2007, Imperial College Press.

**UNIT I ENTREPRENEURSHIP 10**

Definition, functions and kinds of entrepreneurs, intrapreneur-entrepreneurship and economic development, entrepreneurial competencies-traits, developing competencies, project identification, selection and financing. Project report- content and significance, Planning Commission's guidelines for formulating project reports-methods of project appraisals.

**UNIT II INTRODUCTION TO INTELLECTUAL PROPERTY 10**

Types of Intellectual property (IP): Patents, Trademarks, Copyright & Related Rights, Industrial Design, Traditional Knowledge, Geographical Indications, Protection of GMOs IP as a factor in R&D; IPs of relevance to Biotechnology Agreements and Treaties History of GATT & TRIPS Agreement; Madrid Agreement; Hague Agreement; WIPO Treaties; Budapest Treaty; PCT; Indian Patent Act 1970 & recent amendments Case Studies

**UNIT III BASICS OF PATENTS AND CONCEPT OF PRIOR ART 8**

Introduction to Patents; Types of patent applications: Ordinary, PCT, Conventional, Divisional and Patent of Addition; Specifications: Provisional and complete; Forms and fees Invention in context of "prior art"; Patent databases; Searching International Databases; Country-wise patent searches (USPTO, esp@cenet(EPO), PATENTScope(WIPO), IPO, etc.)

**UNIT IV PATENTING PROCEDURES 7**

National & PCT filing procedure; Time frame and cost; Status of the patent applications filed; Precautions while patenting – disclosure/non-disclosure; Financial assistance for patenting - introduction to existing schemes Patent licensing and agreement Patent infringement-meaning, scope, litigation, case studies

**UNIT V BIOSAFETY 10**

Introduction; Historical Background; Introduction to Biological Safety Cabinets; Primary Containment for Biohazards; Biosafety Levels; Biosafety Levels of Specific Microorganisms; Recommended Biosafety Levels for Infectious Agents and Infected Animals; Biosafety guidelines - Government of India; Definition of GMOs & LMOs; Roles of Institutional Biosafety Committee, RCGM, GEAC etc. for GMO applications in food and agriculture; Environmental release of GMOs; Risk Analysis; Risk Assessment; Risk management and communication; Overview of National Regulations and relevant International Agreements including Cartagena Protocol.

**TOTAL : 45 PERIODS****TEXTS/REFERENCES**

1. BAREACT, Indian Patent Act 1970 Acts & Rules, Universal Law Publishing Co. Pvt. Ltd., 2007
2. Kankanala C., Genetic Patent Law & Strategy, 1st Edition, Manupatra Information Solution Pvt. Ltd., 2007
3. S.S.Kanka Entrepreneurship Development, S.Chand and Co, New Delhi 1997

Attested  
  
 DIRECTOR  
 Centre For Academic Courses  
 Anna University, Chennai-600 025.