M. TECH. BIO PHARMACEUTICAL TECHNOLOGY

AIM:
The aim of this programme is to enable the students to learn Basic and advanced facts in BioPharmaceutical technology and to develop an understanding of the biological-efficacy of drugs.

OBJECTIVES:

1. This programme will help students to understand the chemical combinations, molecular mechanism, pharmacology and medicinal properties of Biopharmaceuticals and drug molecules. It will also help gain insights into latest and advanced techniques such as Genomics and transcriptomics, Proteomics, Mass spectroscopy, Tissue Engineering and Regenerative medicine.

2. The programme will enable students to acquire knowledge in the area of drug discovery and their critical use towards drug development by modifying drug formulation strategies at an industrial scale. It will also help the students to learn sophisticated biotechnological aspects of Enzyme fermentation and Bioprocess technology and their use in relevant biopharmaceutical applications.

3. This programme will facilitate the students to acquire wide knowledge in fields such as genetic engineering, protein engineering and recombinant DNA technology enabling their application through pharmacogenomic approaches. It will also empower the students to have advanced focus on the molecular pathogenesis of infectious diseases and necessary pharmacological approach towards drug discovery.

4. This programme will aid the students to know the significance of Bioethical standards and an extensive understanding of the regulatory guidelines of Drugs and its dosage forms aided by the advantages and risks in the statistical evaluation of Drugs through Clinical trials. It also helps the students to know about the pharmacokinetics of drug, its metabolism and its immunopharmacological response through in-depth understanding about the Physiology of Human

5. This programme will give knowledge about the use of High throughput screening of Biomolecules using applied statistical approach in Drug designing with computational methods and introduce to interdisciplinary fields such as Nanotechnology, Bioconjugate technology, Omics sciences. Additionally, it will assist students to gain expertise presentation and communication skills along with a creative scientific perspective.
### Semester I

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**LIST OF ELECTIVES**

**M. TECH. BIOPHARMACEUTICAL TECHNOLOGY**

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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

UNIT I
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.

UNIT II
Bivariate distribution-conditional and marginal distribution-Discrete distribution-Binomial, Poisson, geometric distribution-Continuous distribution, Normal, exponential and negative exponential, gamma distributions-simple problems-properties

UNIT III
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 \( ax^\delta \) - Bivariate correlation application to biological problems

UNIT IV
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.

UNIT V
Basic principles of experimentation-Analysiss 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”.

REFERENCES
2. Arora, P. N. Smeet Arora, and Arora, S. “Comprehensive Statistical Methods”. S. Chand & Co,
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

REFERENCES
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
Definition: Generics and its advantages; Biogenerics and Biosimilars; Why biosimilars are not (bio) generics; 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
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
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
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

TOTAL : 45 PERIODS

TEXTS/REFERENCES
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

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
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


BO7201 COMPUTATIONAL METHODS IN DRUG DESIGN

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.
UNIT I INTRODUCTION TO LIGAND CHEMISTRY
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
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 haloginition).

UNIT III PHARMACOKINETIC PARAMETERS OF LIGAND DESIGN
Lipinski “rule of 5”, Partition coefficient, Hammet contant, Hansch analysis. Biological, chemical and physical descriptors used in QSAR and QSPR. Statistical methods used for analysing QSAR/ QSPR datas.

UNIT IV INSILICO ANALYSIS OF LIGAND-RECEPTOR INTERACTIONS
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
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
5. GROMOS and GROMACS Manuals.

BO7202 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
Classification of HTS: Protein based biochemical screens, methods of analytical biochemistry used in HTS (photometry, purification, electrophoresis, kinetic assay, radioisotopes, immunoassay. Principals 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
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, leishmaniasis etc.

UNIT III  IN-VITRO AND IN-VIVO SCREENS
High throughput screening (in vitro and in vivo) 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
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
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
5. Ye, S., and Day, I.N.M. “Microarrays and Microplates: Applications in Biomedical Sciences”. BIOS 2003
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 lifestyle 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 immunogens, 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 IMMUNOTHERAPEUTICS
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, immununo 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

REFERENCES
1. Goodman and Gilman’s, “The Pharmacological Basis of Therapeutics”.
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
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 physicochemical 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
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
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
Oral administration: Diagrams, schemes, and graphs associated with oral administration, relationship between tmax and Plasma Peak Concentration; the Influence of ka and F on Cp for a given dose; determine ka 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
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
5. One Compartment Models- Multiple Dosing
6. Computer Applications – Multiple Dose
7. Computer Applications – Two Compartment
8. Computer Applications – Macdope Exercise
TEXTS/REFERENCES

BO7205 ADVANCED GENETIC ENGINEERING

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

UNIT II CONSTRUCTION OF DNA LIBRARIES

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

UNIT IV PCR AND MUTAGENESIS

UNIT V GENE TRANSFER & GENE THERAPY

TOTAL : 45 PERIODS
TEXTS/REFERENCES

BO7211 RECOMBINANT DNA AND BIOPROCESS TECHNOLOGY LABORATORY

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
10. Enzyme immobilization studies – Gel entrapment, adsorption and ion exchange immobilisation.

TOTAL : 90 PERIODS

BO7311 DRUG DISCOVERY LABORATORY

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).
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 antioxidant 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
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.

BO7312 IMMUNOPHARMACOLOGY LABORATORY

OBJECTIVES
The student will undergo hands on experience on animal handing 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
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 Immunodiagnosics using commercial kits (Rapid Dot Blot and Strip Test)

TOTAL : 90 PERIODS

TEXTS/REFERENCES

BO7313 PROJECT WORK PHASE I

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.

TOTAL : 90 PERIODS

BO7411 PROJECT WORK PHASE II

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

UNIT III GENERAL PROPERTIES
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, panthenic acid, ascorbic acid. A, D, E and K.
- Hormones: Testosterone, progesterone, estrogen, aldosteron, cortisol, insulin, glucagon, oxytocin and vassopressin.

UNIT IV ANTI-MICROBIAL COMPOUNDS
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 acidines, pyrimidine analogues, mefloquine, cinchona alkaloids.
- AntiTubercular Agents: Ethambutol,isonicotinic acid, hydrazid, rifempacin, thioguanine, cytarabine, 5-fluoracil, dicarbazine.
- Antiviral agents: Acyclovir, tromantadine hydrochloride, ribavirin

UNIT V PHYSIOCHEMICAL PRINCIPLES AND STRUCTURE ACTIVITY CONCEPTS
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
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 pharmaceutics.

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

UNIT III  STRUCTURE-FUNCTION RELATIONSHIP
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, Transmembrane 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
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
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
REFERENCES

BO7003 DRUG DOSAGE FORMS AND DESIGN L T P C 20 2 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.
Aerosols: Types of propellants, general formulation, manufacturing, packaging methods, pharmaceutical applications and evaluation.
UNIT V  PARENTERALS AND ADVANCED/NOVEL DRUG DELIVERY SYSTEMS  

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

TOTAL : 45 PERIODS

TEXTS/REFERENCES

BO7004  DRUG REGULATORY, QUALITY AND SAFETY EVALUATION  

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

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

UNIT V  SAFETY AND ENVIRONMENTAL CONTROL  
Patent act- Patent, Trade Mark Regn, I.P.R; Safety & Environmental control; Project (Regulatory Factors).

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
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

UNIT III  IMMOBILIZED ENZYMES
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
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
(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

BO7006 COMMUNICATION SKILLS DEVELOPMENT

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
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
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
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
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
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
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 Backround; 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 Cartegana Protocol.

TEXTS/REFERENCES
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 21st 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.
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
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
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
Viability and ADR in drug response: contribution of genetic factor, Multiple inherited genetic factors influence the outcome of drug treatments, Plasma binding proteins, Drug targets.

UNIT IV GENOMICS APPLICATIONS FOR DRUG ACTION AND TOXICITY
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
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

BO7010 ADVANCES IN MOLECULAR PATHOGENESIS

OBJECTIVES
The course will proved 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
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

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

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)


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

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, parastiparous vacuoles and knob protein transport, Antimalarials based on transport processes.

TOTAL : 45 PERIODS

TEXTS/REFERENCES
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”

BO7011 CHEMISTRY OF NATURAL PRODUCTS

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.

UNIT II  GLYCOSIDES AND TANNINS  9
Biosynthesis of glycosides, Phenol and alcohol glycosides, anthraquinone glycosides, cyanophore glycosides, sapoin glycosides, cardiac glycosides, isothiocyanate flavonol lactone 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, B₁, B₂, B₆, B₁₂ and Folic acid. Chemistry and structural elucidation of uric acid, interrelation between caffeine, theophyline and theobromine. Classification and application of flavanoids (hespiridine 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

TEXTS/REFERENCES

TOTAL : 45 PERIODS

BO7012  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

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
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.

UNIT V  NEPHROLOGY
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

BO7013  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
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
Solid-Phase peptide synthesis – Peptide on pins – Other iterative disconvolution strategies,
Examples of Split/Couple/Mix Peptide Libraries – Positional Scanning

UNIT III  SUPPORTS, LINKERS, AND REAGENTS FOR PEPTIDE AND SMALL
MOLECULE SYNTHESIS
Polystyrenes – PEG – Grafted supports – Coupling strategies – New resins and linkers –
Ring – forming cleavage – loading.

UNIT IV  SUPPORTED SOLUTION – PHASE SYNTHESIS
Polyethylene glycols – Dendrimers Fluorous synthesis – Solution – Phase parallel synthesis
scavenging resins – Ion Exchange resins – Supported reagents – Flourous reagents – Solid
phase extraction – Gas Phase separation.

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

TOTAL : 45 PERIODS
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 NANOBIO TECHNOLOGY
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
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
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
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
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
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

UNIT II DRUGS ACTING ON THE HAEMOPOIETIC SYSTEM

UNIT III PHARMACOLOGY OF GASTROINTESTINAL TRACT AND ENDOCRINE SYSTEM
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
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
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

REFERENCES
2. Goodman and Gilman’s, The Pharmacological basis of therapeutics

BO7016 RESEARCH AND RESEARCH METHODOLOGY IN BIOTECHNOLOGY

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)
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
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
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
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
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
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
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
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
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
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
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.

TEXT BOOKS

REFERENCES

BO7018 TECHNOLOGIES IN OMICS SCIENCE L T P C 3 0 0 3

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
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
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
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
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
Basics of Mass-spectrometry (MS) and bimolecular 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
REFERENCES

BO7019 TISSUE ENGINEERING AND REGENERATIVE MEDICINE L T P C 3 0 0 3

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
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
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
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
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
BO7020 BIOCONJUGATE TECHNOLOGY AND APPLICATIONS  L T P C  
3 0 0 3

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

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

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
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.

UNIT I ORGANIZATION AND STRUCTURE OF GENOMES
General organization and structure of genomes of viruses, prokaryotes, eukaryotes, and organelles (chloroplast, mitochondrion)

UNIT II GENOME MAPPING AND SEQUENCING
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 GENOMIC ANALYSES
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
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
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.

TEXTS/REFERENCES
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
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
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
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
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
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).

**TEXTS/REFERENCES**