ANNA UNIVERSITY, CHENNAI  
NON-AUTONOMOUS COLLEGES AFFILIATED TO ANNA UNIVERSITY 
M.TECH BIOPHARMACEUTICAL TECHNOLOGY 
REGULATIONS - 2021 
CHOICE BASED CREDIT SYSTEM 
I TO IV SEMESTERS CURRICULA AND SEMESTER SYLLABUS

PROGRAM EDUCATIONAL OBJECTIVES (PEOs)

<table>
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<tr>
<th>I.</th>
<th>To provide students with adequate scientific information regarding basic principles of Pharmaceutics with good scientific and technical knowledge so as to comprehend, analyze, design, and create novel products and solutions for developing novel therapeutics, drugs and enzymes.</th>
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<td>II.</td>
<td>To prepare students to excel and succeed in biopharmaceutical research or industry through the latest state-of-art post graduate education and to demonstrate an adaptable, flexible and effective approach towards organizational development</td>
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<td>III.</td>
<td>To sensitize students about scientific temper and the necessity of bioethics, social responsibility and awareness of the environment and to demonstrate knowledge of professional and ethical responsibilities as per pharmaceutical jurisprudence. They will be able to demonstrate knowledge and skills in all disciplines of pharmaceutical sciences and develop a sound pharmaceutical care plan to manage medication-related problems</td>
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<td>IV.</td>
<td>To enable the student to develop good communication and leadership skills, respect for authority, loyalty and the life-long learning needed for a successful scientific and professional career and to develop an ability to communicate scientific knowledge in non-expert/lay term by adopting various modes of scientific communications</td>
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PROGRAM OUTCOMES (POs)

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<td>On successful completion of the Masters in Biopharmaceutical technology graduates will be able to</td>
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<td>1.</td>
<td><strong>Pharmaceutical Sciences knowledge:</strong> Apply the knowledge of mathematics, science, pharmaceutical fundamentals, and a Pharmacy specialization to the solution of complex pharmaceutical problems.</td>
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<td>2.</td>
<td><strong>Unit Operations:</strong> Technology renders knowledge about the basic unit operations that are taking place in pharmaceutical industry and the different factors associated with it. This information is useful for both pharmaceutics and pharmaceutical technology.</td>
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<td>3.</td>
<td><strong>Entrepreneurship:</strong> The knowledge on different pharmaceutical dosage forms are imparted on students. This knowledge comes while handling a pharmacy or a</td>
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manufacturing unit in the further courses.

4. **Design/Development of solutions:** The information on solid dosage forms like tablets and capsules, their formulation and quality control serve as an important perquisite for dosage form design.

5. **Application oriented Knowledge:** The knowledge of biopharmaceutics enables the students to visualize the effect of pharmacokinetic (ADMET) parameters on the biological effect of the drug. The correlation of pharmacokinetics and pharmacodynamics is thus introduced and is experimentally explained to them.

6. **Conduct investigations of complex problems:** To understand biopharmaceutical principles and pharmacokinetic principles through different compartment models, multiple dosage regimens, non-linear pharmacokinetics, and assessment of bioavailability and bioequivalence.

PEO / PO Mapping:

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<th>Code No.</th>
<th>Course Title</th>
<th>Periods per week</th>
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<th>Semester</th>
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<tr>
<td>1.</td>
<td>BO4101</td>
<td>Drug Regulatory, Quality and Safety Management</td>
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<td>Formulation and Quality Control Methods for Pharmaceuticals Laboratory</td>
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<td>BO4202</td>
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<td>7.</td>
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<td>Conventional and Rational Drug Discovery Strategies</td>
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<td>8.</td>
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<td>9.</td>
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<td>Modern Methods of Pharmaceutical Analysis Laboratory</td>
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<td>Computational Methods in Pharmaceuticals Laboratory</td>
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## RESEARCH METHODOLOGY AND IPR COURSES (RMC)

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### EMPLOYABILITY ENHANCEMENT COURSES (EEC)

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<td>Project Work II</td>
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**Total Credits:** 20

### AUDIT COURSES (AC)

Registration for any of these courses is optional to students

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<td>தமிழ் இலக்கியம்</td>
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## SUMMARY

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<tr>
<th>S.NO.</th>
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<td>Audit courses (Non Credit)</td>
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</table>
UNIT I  INTRODUCTION TO DRUG REGULATORY LAWS

UNIT II  PHARMACOPOEIA
Descriptions & Monographs; Standards and Specifications; Testing of Drugs; Various Countries Pharmacopoeias; Indian, British, U.S, European, Japanese and International pharmacopoeia.

UNIT III  cGMPs& REGULATORY RECORDS
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  DRUG DEVELOPMENT APPROVAL PROCESS/CLINICAL TRIALS
Drug development stages, FDA guidelines on IND, NDA, ANDA approvals. European regulatory agency: types of filing process (Centralized, decentralized, RMS countries), Regulation of preclinical studies, Schedule-Y, pre-clinical study; Introduction to animal ethics; Animal rights and use of animals in the advancement of medical technology; Introduction to laws and regulations regarding the use of animals in research.

UNIT V  PRODUCT MANAGEMENT AND QUALITY ASSURANCE
GLP, ISO 9000, TQM, Quality Review and Quality Documentation, Regulatory control, regulatory drug analysis, interpretation of analytical data, Basic requirements - design of product, facility, equipment selection and personnel. Industrial hazards due to fire, accident, mechanical, electrical equipment, monitoring and preventive system (Safety measures including insurance). Effluent testing, treatment and waste management. Safety and Environmental Control; ISO 14000.

TOTAL: 45 PERIODS

REFERENCES:
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 – hydrolysis, oxidation, reduction, polymorphisms racemization, polymerization and their influence on formulation and stability of products. Stabilization and stability testing protocol for various pharmaceutical products.

UNIT III                SOLID DOSAGE FORMS 9

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

UNIT V                PARENTERALS AND DRUG DELIVERY OF LARGE MOLECULES 10
Parenteral; Liquids, (Solutions, Suspensions and Emulsions); Nasal; Ophthalmic and Optic Preparations; Packaging dosage design & delivery. Delivery systems for Peptides and Proteins – Delivery of Nucleic acids, Antibodies and siRNA.

TOTAL : 45 PERIODS

REFERENCES:

BO4103 MOLECULAR PHARMACOLOGY

UNIT I MOLECULAR MECHANISM OF DRUG ACTION
Basic concepts in molecular pharmacology: agonists, antagonists and inverse agonists; potency, intrinsic activity and efficacy; Transducer mechanisms of receptors; Receptor occupancy theory and cellular signalling systems such as G-proteins, cyclic nucleotides, calcium and calcium binding proteins, phosphatidylinositol. Ion channels and their modulators: measurement of binding and response, Voltage-gated ion channels. G protein-coupled receptors, G proteins and effectors, Mechanism of G protein-mediated signalling: - Wnt, hedgehog and notch; Signal transduction through tyrosine kinases; Receptors regulating gene expression.

UNIT II RECEPTORS AND THEIR MODE OF ACTION
Angiotensin receptors Excitatory amino acid receptors Kinin receptor, Adrenoceptors, Low molecular weight heparins, hirudins and GP IIB/IIIa receptor antagonists, Cholinergic receptors, Dopamine receptors, Serotonin receptors, Hormone receptors, GABA and Benzodiazepine receptors, Opioid receptors, Purinergic receptors, Glutamate receptors.

UNIT III BIOACTIVE MOLECULES
Endogenous bioactive molecules: Cytokines, neuropeptides and their modulators, neurosteroids, nitric oxide, phosphodiesterase enzyme and protein kinase C, arachidonic acid metabolites, COX-2 regulators and their role in inflammation, endothelium derived vascular substances (NO, endothelins) and their modulators.

UNIT IV OVERVIEW OF DRUGS ACTING ON VARIOUS SYSTEMS
Central nervous system, Autonomic nervous system, Autacoids, Analgesic, Antipyretic, and Anti-inflammatory Agents, Renal and cardiovascular system, Anti Infective agents, Hormones, Hematopoietic agents.

UNIT V TOXICOLOGY
Principles of toxicology, Physicochemical, Biochemical and genetic basis of toxicity, principles of toxicokinetics, mutagenesis and carcinogenesis, Acute, sub-acute and chronic toxicity studies according to guidelines. Guidelines and regulatory agencies – CPCSEA, OECD, FDA, ICH, FHSA, EPA, EEC, WHO.

TOTAL: 45 PERIODS
REFERENCES:

RM4151 RESEARCH METHODOLOGY AND IPR L T P C 2 0 0 2

UNIT I RESEARCH DESIGN 6
Overview of research process and design, Use of Secondary and exploratory data to answer the research question, Qualitative research, Observation studies, Experiments and Surveys.

UNIT II DATA COLLECTION AND SOURCES 6
Measurements, Measurement Scales, Questionnaires and Instruments, Sampling and methods. Data - Preparing, Exploring, examining and displaying.

UNIT III DATA ANALYSIS AND REPORTING 6
Overview of Multivariate analysis, Hypotheses testing and Measures of Association. Presenting Insights and findings using written reports and oral presentation.

UNIT IV INTELLECTUAL PROPERTY RIGHTS 6

UNIT V PATENTS 6

TOTAL: 30 PERIODS

REFERENCES:

BO4111 FORMULATION AND QUALITY CONTROL METHODS FOR PHARMACEUTICALS LABORATORY

PART I: FORMULATION EXPERIMENTS
1. Preparation of Nano Emulsions.
2. Preparation of Lyophilised powder
3. Preparation of solid dosage forms (Eg. Granules, Tablets, Capsules)
4. Preparation of liquid dosage forms (Eg. True Solutions, mixtures, Elixirs)
5. Preparation of biphasic dosage forms (Eg. Emulsion, Suspension)
6. Preparation of semisolid dosage forms (Eg. Ointments, Creams, Gels, lotions)
7. Preparation of Parenteral and ophthalmic formulations
8. Preparation of specialized dosage forms (Eg. Suppositories, Patches)

PART II: QUALITY CONTROL METHODS FOR PHARMACEUTICALS
1. Disintegration test, weight variation.
3. pH, Dissolution, Sedimentation volume, Rheological method, Zeta potential measurement,
4. Particle size distribution, In-vitro release testing,
5. Leakage test, Pyrogen test, Sterility, Particulate matter, Preservative efficacy test.
8. Stability testing for all dosage forms.

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: 60 PERIODS
REFERENCES:

BO4201 PHARMACOKINETICS AND PHARMACODYNAMICS L T P C 3 0 0 3

UNIT I FUNDAMENTALS ON DRUG ABSORPTION AND DISTRIBUTION 9 Definitions, various routes of administration with advantages/disadvantages, bioavailability concepts in drug absorption and distribution, theories of drug dissolution, drug partition hypothesis, permeability and distribution of drugs, perfusion rate and volume of distribution, protein binding of drugs, kinetics of drug binding, various factors that affect drug absorption and distribution, drug interactions in the level of drug absorption and distribution.

UNIT II FUNDAMENTALS ON DRUG METABOLISM AND EXCRETION 9 Biotransformation of drugs, pathways and enzymes of drug metabolism, Phase I and Phase II, drugs excretion – renal and non-renal routes, various factors that affect drug metabolism and excretion, prodrugs, drug interactions in the level of drug metabolism and excretion, bioavailability concepts in drug metabolism and excretion.

UNIT III PHARMACOKINETIC INVESTIGATION AND EVALUATION 9 Concept of therapeutic concentration, time-profile, rates and various order of reactions (first, zero, mixed), Michaelis-Menton kinetics, differential equations for a simple pharmacokinetic models, compartment models (one, two, multi, open models), definition and calculation of parameters such as drug half-life, of Drugs, Volume of Distribution, and bioavailability(AUC) and their application to compartment models and kinetics of IV Bolus administration, comparison between bioavailability and bioequivalence.

UNIT V APPLICATION OF PK/PD PRINCIPLES IN DOSAGE FORM DEVELOPMENT
Regimens for dosage form design, concentration response relationships, individualization therapeutics, controlled release formulations and novel drug delivery (oral, parenteral, transdermal, ophthalmic and intrauterine) systems, bioavailability testing of novel release formulations.

TOTAL : 45 PERIODS

REFERENCES

BO4202 IMMUNOPHARMACOLOGY

UNIT I BASICS OF PHARMACOLOGY AND IMMUNOLOGY
Principles of basic and clinical pharmacokinetics and pharmacodynamics of immune drugs; Overview of discovery and development of immuno-drugs and various therapeutic pathways and targets of immune system, immune cell and organ classification, Innate and adaptive immunity, Immunity to virus, bacteria and fungi; neuro humoral regulation of immune responses, complement pathways, cytokine classification and activation, T-cell and B-cell development, bioassay and animal models for immune drug validation.

UNIT II VACCINOLOGY AND IMMUNODIAGNOSTICS
T and B epitopes classification, adjuvant and hapten classification, immuno-screening of antigens, vaccine formulation technology, vaccine production and validation, recombinant vaccines, peptide vaccines, therapeutic vaccines. Concept of reverse vaccinology, Monoclonal antibody production and applications, antibody engineering, scFv Antibodies, immunoconjugates, immunotoxins. Immunodiagnostics— ELISA types, Flow cytometry principle, instrumentation and diagnostic applications, principle/development of Rapid immuno diagnostic tests.
UNIT III IMMUNOTHERAPEUTICS AND CANCER IMMUNOTHERAPY

(WHO) Anatomical Therapeutic Chemical (ATC) Classification and pharmacology of drugs affecting the immune system (L, L01, L02, L03, L04), therapeutic use of cytokines, therapeutic Mabs classification and formulation. Cancer vaccines, CAR T-cell therapy, immune check-point inhibitors.

UNIT IV TRANSPLANTATION

Laws of transplantation, host vs graft and graft versus host reactions; Role of T cell in allograft rejection, HLA Classification, HLA typing and transplantation, general immunosuppressive therapy – Corticosteroids, mitotic inhibitors, fungal metabolites, lymphoid irradiation; Specific immunosuppressive therapy – Mabs, Co stimulatory signal blockers and adjuvant therapies.

UNIT V IMMUNOLOGY OF ALLERGY

Classification of hypersensitivity reactions, Classification of allergens, Drug Hypersensitivity – pharmacologic perspective, immunologic perspective, Off-target toxicity, Cellular Basis, Chemical Basis – The Hapten/pro hapten hypothesis, The Danger theory, The pi concept, therapy and prevention of allergies; Pharmacology of antihistamines, mast cell stabilizers, anti-inflammatory agents and anti-rheumatoid drugs

TOTAL :45 PERIODS

REFERENCES

UNIT I DRUG DESIGN STRATEGIES
Various approaches in drug discovery process– conventional versus rational, drug targets, lead identification; Principles of ligand chemistry– lead optimization, pharmacophores, bioisosteres, principles of ligand chemistry such as configuration, conformation, chirality, isosteric replacement; Parameters of ligand design such as– Phytochemical, geometric, conformational, topological, partitional, steric, stereochemical and electronic properties of drug molecules; Pharmacokinetic parameters of ligand design such as- Lipinski “rule of 5”, partition coefficient, Hammet constant, Hansch analysis. Biological, chemical and physical descriptors used in QSAR and QSPR. Statistical methods used for analysing QSAR/ QSPR data.

UNIT II IN-SILICO METHODS FOR DRUG DISCOVERY
Introduction to molecular docking, Principles of macromolecule-ligand docking, docking algorithms, AUTODOCK; de novopharmacophore elucidation/ drug design for structurally well-defined receptor targets from casestudies (Eg. HIV protease inhibition, ACE inhibition); 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 calculations including solution, role of solubility in drug binding and pKa, PoissonBoltzmann Surface Area (PBSA), AMBER,GROMOS and GROMACS.

UNIT III COMBINATORIAL CHEMISTRY FOR DRUG DISCOVERY
Combinatorial Chemistry in drug development, Biopolymers as natural libraries, Selection and evolution of expression genetic libraries, Combinatorial assembly of antibody genes, Molecular solutions to Combinatorial problems, Solid-Phase peptide synthesis, Peptide on pins, Other iterative deconvolution strategies, Examples of Split/Couple/Mix Peptide Libraries, Positional Scanning., Polystyrenes, Grafted supports, Coupling strategies, linkers, Supported Solution and Phase Synthesis, analytical methods for solid-phase.

UNIT IV HIGH THROUGHPUT SCREENING IN DRUG DISCOVERY
Classification of HTS: Protein based biochemical screens, methods of analytical biochemistry used in HTS (photometry, purification, electrophoresis, kinetic assay, radioisotopes, immunoassay, HTS FACS based assays). Assay design for HTS and statistical treatment of the results for decision. Introduction to state of the art technologies used in HTS (including automated liquid handling machines (robots), Microfluidic Tools for HTS, Miniaturization); preclinical toxicological studies, Correlation between in-vitro and in-vivo screens.

UNIT V GENETIC BASED TOOLS IN DRUG DISCOVERY PROCESS
Basics of gene silencing, transgenic worms in drug screening; designing SiRNAs, Types ofRNAi 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. Microarray technologies- Classification with microarrays and class prediction, Visualization and functional analysis. Bio molecular pathways, gene ontology, genome browsing, Gene expression biology, microarray platforms (Eg.Affymetrix); Preprocessing of microarray data for Image analysis, quality control and array normalization.

TOTAL :45 PERIODS

REFERENCES
BO4211 IMMUNOPHARMACOLOGY LABORATORY L T P C 0 0 6 3

OBJECTIVES

The course aims to,
- provide hands-on experience on handling animals for research and various relevant immunological techniques like ELISA, Flow cytometry etc.
- provide practical experience on performing and understanding immunoassays for evaluating drugs and vaccines.
- To provide practical exposure in the clinical diagnosis.
- To provide laboratory training for different immunotechnological techniques.
- To give hands on training in cell staining, separation and identification.

LIST OF EXPERIMENTS

1. Selection and Handling of animals used in immunopharmacological assays (Eg. Mice, Rat, Rabbit, Zebra fish, Caenorhabditis elegans etc.).
2. Preparation of antigens and immunization procedures for raising anti-sera.
3. Demonstration of various methods of bleeding, serum separation and storage. 4. Antibody titre by ELISA method (Indirect ELISA).
5. Sandwich ELISA – Quantification of antigens.
6. Immunoprecipitation/Immunoelectrophoresis. 7. Isolation and purification of IgG from serum (Ammonium sulphate method/Protein A).
8. Studies for characterisation of antigens - SDS -PAGE, Immunoblotting, Dot blot assays.
9. Assay for immunostimulants (Erythropoietin assay etc., ).
10. Direct Agglutination-Widal test, Salmonella detection.
12. Separation and culturing of splenocytes and demonstration of T cell proliferation.

TOTAL : 90 PERIODS
REFERENCES


BO4212 MINI PROJECT WITH SEMINAR

OBJECTIVES

The course aims to

- encourage the students to get connected with relevant industries/laboratory/research institutes.
- acquire knowledge on solving practical problems, gaining work experience and skills.
- learn the basics of research methodologies in academic/industrial/research environment.
- To train students in reputed companies/research institutes/organizations for the specified duration.

TOTAL : 45 PERIODS

COURSE OUTCOMES

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

CO1 learn methods and procedures from industrial/academic/research institute
CO2 gain experience to work as an member in industrial or research team for
CO3 acquire practical knowledge and enhance skills
LIST OF EXPERIMENTS

1. Calibration of volumetric glasswares.
2. Establishing standard operating procedure (SOP) and Calibration records for analytical balance, pH meter and UV/Vis spectroscopy.
3. Determination of \( \lambda_{\text{max}} \).
4. Effect of change in physio-chemical parameters on absorbance spectrum of a drug molecule.
5. Quantitative and qualitative analysis of drug molecule using standard comparison method by UV/Vis spectroscopy and HPLC.
6. Quantitative analysis of drug molecule using E1%1cm method by UV/Vis spectroscopy.
7. Quantitative analysis of drug molecule using calibration graph method by UV/Vis spectroscopy and HPLC.
8. Separation and identification of mixtures of drugs by TLC.
10. Identification of functional group of a drug molecule by IR spectroscopy.
11. Determination of impurities by limit test.
12. Quantitative analysis by titrimetric methods.

TOTAL: 90 PERIODS

LIST OF EQUIPMENT FOR BATCH OF 30 STUDENTS

1. Digital weighing balance
2. Digital pH meter
3. UV chamber
4. TLC chamber
5. UV/Vis spectroscopy
6. HPLC
7. IR spectroscopy

REFERENCES:

LIST OF EXPERIMENTS

1. Introduction to Multiuser Operating System Linux. 2. Databases : Biological and Pharma related.
3. Computing molecular properties of drugs / compounds.
4. Molecular modeling of small molecules : obtaining 3D structures, understanding data formats.
5. Drug targets, Data resources and PDB structures.
6. Homology modeling of Protein Targets and Model evaluation.
9. Drug like property evaluation of compounds and ADME (Lipinski’s rule of five).
10. Methodology of building and refining protein drug targets structure models from X-ray crystallographic data using CCP4i.
11. Molecular docking : Protein – Protein, Protein-Small Molecule.

REFERENCES

1. Introduction to Bioinformatics by Arthur K. Lesk, Oxford University Press.2014
2. Algorithms on Strings, Trees and Sequences by Dan Gusfield, Cambridge University Press.2004
4. Bioinformatics Sequence and Genome Analysis by David W. Mount, Cold Spring Harbor Laboratory Press. 2004

TOTAL :90 PERIODS
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 pharmacopoeia 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 freeRadicals 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: 75 PERIODS

Required Equipments:

Soxhlet apparatus, rotary flash evaporator, Hot air oven, sonicator, mortar and pestle, TLC chamber, Fume hood, purification columns, micro-plate reader, UV spectrometer, centrifuge, required strains & consumables.

REFERENCES

5. Recent advances in Phytochemistry Vol. I & IV – Scilicet, Runeckles.
OBJECTIVES

The course aims to enable the students to
- identify the problem/process relevant to their field of interest that can be carried out
- search databases and journals to collect and analyze relevant data
- plan, learn and perform experiments to find the solution
- prepare project report

TOTAL: 180 PERIODS

Individual students will identify a problem relevant to his/her field of study, collect and analyze literature, design, and carryout experiment, collect data, interpret the result and prepare the project report.

OUTCOMES:
At the end of the course the students will be able to

- CO1 Identify the research/industrial problems
- CO2 Collect and analyze the relevant literature
- CO3 Design, conduct experiment and analyse the data
- CO4 Prepare project report

TOTAL: 360 PERIODS

Individual students will identify a problem relevant to his/her field of study, collect and analyze literature, design, and carryout experiment, collect data, interpret the result and prepare the project report.
COURSE OUTCOMES
At the end of the project the student will be able to
CO1 Formulate and analyze problems for developing new methods/solutions/processes.
CO2 Plan and conduct experiments to find solutions in a logical manner
CO3 Analyze the results, interpret and prepare project report/know the strategies for commercialization

BO4001 CLINICAL TRIALS AND BIOETHICS L T P C
3 0 0 3

UNIT I INTRODUCTION TO CLINICAL TRIALS 8

UNIT II REGULATIONS OF CLINICAL TRIALS 9

UNIT III STUDY DESIGN AND POPULATION 12

UNIT IV ETHICAL ISSUES 8

UNIT V QUALITY CONTROL AND ASSURANCE & DATA ANALYSIS 8
Quality control and assurance procedures – Performance monitoring – Training procedures – Assurances and certifications – Site visiting procedures – Audit procedures; Analysis datasets – Frequentist vs Bayesian analysis – Final analysis – Subgroup analysis; Pharma c ovigilance; Research governance; Trial closure and pitfalls-trial closure; Reporting and legal requirements; Common pitfalls in clinical trial management.

TOTAL: 45 PERIODS
REFERENCES:
4. Lee, Chi-Jen et. al, “Clinical Trials or Drugs and Biopharmaceuticals.” CRC/Taylor & Francis, 2011.

BO4002 BIOCONJUGATE TECHNOLOGY AND APPLICATIONS

UNIT I MODIFICATION OF FUNCTIONAL TARGETS
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
Amine reactive chemical reactions – Thiol reactive chemical reactions – carboxyl reactive chemical reactions – hydroxyl reactive chemical reactions – aldehyde and ketone reactive chemical reactions - Photoreactive chemical reactions.

UNIT III BIOCONJUGATE REAGENTS

UNIT IV ENZYME AND NUCLEIC ACID MODIFICATION AND CONJUGATION
Properties of common enzymes – Activated enzymes for conjugation – biotinylated enzymes– chemical modification of nucleic acids – biotin labeling of DNA- enzyme conjugation toDNA – Fluorescent of DNA.

UNIT V BIOCONJUGATE APPLICATIONS

TOTAL : 45 PERIODS

REFERENCES:
1. Chemistry of bioconjugates : synthesis, characterization, and biomedical applications / edited by Dr. Ravin Narain, Department of Chemical and Materials Engineering, University of Alberta, Edmonton, Alberta, Canada.
UNIT I BIOGENERICS INTRODUCTION
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
Approved follow-on proteins/Biosimilars; Characteristics of high selling peptides and proteins; Products with expired patents; Challenging originator’s patents; Target products for FOB (follow-on biologics)/Biosimilars development peptides; Recombinant Non Glycosylated 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 IMMUNOGENICITY OF BIOPHARMACEUTICALS
Immunogenicity of biopharmaceuticals: Immunogenicity; Factors contributing to immunogenicity, (product-related factors and host-related factors), consequence of immunogenicity to biopharmaceuticals; Measurement of immunogenicity.

UNIT V CASE STUDIES

TOTAL : 45 PERIODS

REFERENCES:
UNIT I  VECTOR SYSTEMS
Overview of tools in recombinant DNA technology. Artificial chromosomes – YACs and BACs. Principles for maximizing gene expression – expression vectors, pMal, GST, pET-based vectors. Protein purification – His-tag, GST-tag and MBP-tag. Intein-based vectors; Inclusion bodies; methodologies to reduce formation of inclusion bodies; mammalian expression and replicating vectors; Baculovirus and Pichia vectors system, plant based vectors, Ti and Ri plasmids as vectors, yeast vectors and shuttle vectors.

UNIT II  ASSAY TECHNIQUES IN MOLECULAR BIOLOGY
Nuclease protection assays, Nuclease S1 mapping, Reporter assays – Mono and dual reporter assays, Electrophoretic mobility shift assay (EMSA) / Gel shift assay, Run-off transcription assay, Phage display, Ribosome display, Gene silencing – siRNAs and Morpholinos.

UNIT III  HIGH-THROUGHPUT DNA SEQUENCING

UNIT IV  GENE EXPRESSION ANALYSIS

UNIT V  GENOME EDITING TECHNOLOGIES
Basics and applications of genome editing methods - Zinc-finger nuclease (ZFN), Transcription activator-like effector nucleases (TALEN), Mega nucleases, CRISPR-Cas systems – Types and applications, Homing endonucleases, Transposons and Cre/lox P systems. Gene delivery systems – Physicochemical methods and viral vectors.

TOTAL: 45 PERIODS

REFERENCES:
UNIT I  MICROARRAYS IN GENOMICS  
Microarrays, types, Designing and production of microarrays; cDNA microarray technology; Oligonucleotide arrays; Sample preparation, labeling, hybridization, generation of microarray data. Transcriptomics using cDNA and oligonucleotide arrays.

UNIT II  NEXT GENERATION SEQUENCING TECHNOLOGIES  
Overview of 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 AND YEAST TWO-HYBRID SYSTEM  
Types of protein arrays; Protein microarray fabrication; Experimental analysis of proteins arrays. Data acquisition and processing; Applications of protein microarray types. Principles and methods in yeast two-hybrid system, Advances in yeast two hybrid system and its applications.

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; DIGE, 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; Principles of Time of Flight (TOF), Ion Trap (IT), and Orbitrap mass analyzers; Mass spectrometry based proteomics: MALDI-TOF, Nano-LC-MS; Gas chromatography coupled to Mass spectrometry; Mass-spectrometry analysis of Post-Translational Modifications of proteins.

REFERENCES:
UNIT I CELLULAR METABOLISM

UNIT II REGULATION, MANIPULATION AND SYNTHESIS OF METABOLIC PATHWAY

UNIT III ANALYSIS AND METHODS FOR THE METABOLIC FLUX
Metabolic flux map – Fluxes through the catabolic pathways in microbes– Metabolic flux analysis for determined, over-determined and under-determined systems –Sensitivity analysis – Direct flux determination from fractional label enrichment – Applications involving complete enumeration of metabolite isotopomers – Carbon metabolite balances-GC-MS for metabolic flux analysis – genome wide technologies

UNIT IV GENOME BASED METABOLIC MODEL DEVELOPMENT
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 V ANALYSIS OF METABOLIC CONTROL AND INDUSTRIAL CASE STUDIES
Fundamental of Metabolic Control Analysis (MCA), MFA, and MPA and their application, Multi-substrate enzyme kinetics, 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

REFERENCES


BO4006 CHEMISTRY OF NATURAL PRODUCTS L T P C 3 0 0 3

UNIT I CARBOHYDRATES AND RELATED COMPOUNDS 7
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, saponin glycosides, cardiac glycosides, isothiocyanate flavonol lactone glycosides, tannins, volatile oils, resins and resin combinations.

UNIT III ALKALOIDS AND PURINES 10
Pyridine and piperidine alkaloids, Tropane alkaloids, Quinoline Alkaloids, isouquinoline alkaloids, Indole alkaloids, Imidazole alkaloids, Steroidal alkaloids, Alkaloidal amines and purine bases. Chemistry and structural elucidation of uric acid, interrelation between caffeine, theophylline and theobromine.

UNIT IV VITAMINS, TERPENOIDS AND FLAVONOIDS 10

UNIT V MOLECULES FROM NATURAL SOURCES 9

TOTAL : 45 PERIODS

REFERENCES:
UNIT I UV-VISIBLE SPECTROSCOPY

UNIT II IR SPECTROSCOPY AND THERMAL METHODS OF ANALYSIS
Infrared radiation, theory of IR absorption by a molecule, vibrational frequency and factors influencing vibrational frequency, rotational degrees of freedoms, transmission/absorption modes, types of bands, instrumentation and sampling techniques, interpretation of spectra, applications in pharmaceuticals. FT-IR-theory and applications, Attenuated Total Reflectance (ATR). Instrumentation and applications of thermal methods - Thermo Gravimetric Analysis (TGA), Differential Scanning Calorimetry (DSC), Differential Thermal Analysis (DTA) and Thermo Mechanical Analysis (TMA).

UNIT III NUCLEAR MAGNETIC RESONANCE PECTROSCOPY
Basic theory of NMR/PMR, excitation/emission process and instrumentation. solvents, reference compound, scale of measurement, shielding/deshielding; chemical shift, and factors affecting chemical shift, spin-spin coupling, coupling constant, and factors influencing the value of coupling constant, spin-spin decoupling and shift reagents, proton exchange reactions, FT- NMR, 2D -NMR, NMDR, NOE, NOESY, COSY and applications in pharmaceuticals, spectral interpretations, $^{13}$C NMR, Natural abundance and applications.

UNIT IV MASS SPECTROMETRY
Basic principles, instrumentation and ionization methods; precursor ion/product ion production and fragmentation pattern; atmospheric pressure ionization (API), Chemical ionization (CI), Field Ionization (FI), Fast Atom Bombardment (FAB), Matrix assisted laser desorption ionization (MALDI), Time of Flight (TOF), hybridization with other techniques, and interpretation of mass spectrum and applications in pharmaceuticals.

UNIT IV CHROMATOGRAPHIC METHODS
Classification of chromatographic methods on mechanism of separation: High Performance Liquid Chromatography: Principle, instrumentation, solvents, packing materials and applications in pharmaceuticals; Gas Chromatography: principle, theory, column operations, instrumentation, derivatisation methods and applications in pharmaceuticals; HPTLC and Super Critical Fluid Chromatography (SFC): Theory, instrumentation, elution techniques and pharmaceutical applications; Principles, classifications, instrumentation, moving boundary electrophoresis, Zone Electrophoresis (ZE), Iso-electric focusing (IEF) and applications.

TOTAL: 45 PERIODS

REFERENCES

**BO4008**  PROTEIN ENGINEERING AND INDUSTRIAL APPLICATIONS  
**LT P C**  
3 0 0 3

**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, 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**  
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

REFERENCES:
UNIT V  BIOCATALYST TECHNOLOGY
Advantages and disadvantages of biocatalysis over chemical catalysis; Different types of biocatalysis: Microbial, enzymatic and immobilized system of biocatalysis; Current industrial biocatalysis; Biocatalysis with different enzymes: Lipase, amidase/ aminopeptidase, Acylase, Hydantoinase, lyases, Oxidoreductase, Nitrilase, Epoxide hydrolase, Hydroxylase, Aldolases, Decarboxylase;

REFERENCES:

TOTAL : 45 PERIODS
REFERENCES:

BO4011 APPLIED STATISTICS FOR BIOLOGISTS L T P C A
2 1 0 3

UNIT I PROBABILITY
Random variable-sample spaces-Events-Axiomatic approach to probability-conditional probability-
additional theorem, Multiplication theorem -Bayes theorem problems-continuous and discrete random
variables, Distribution function-Expectation with properties-Moments, mean, Variance problems-for
continuous and discrete distributions.

UNIT II DISTRIBUTION
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 METHODS OF CORRELATION
Correlation coefficient, properties-problems-Rank correlation-Regression equations problems- curve
fitting by the method of least squares-fitting curves of the form ax^2+bx+c, ab^x and ax^b-Bivariate
correlation application to biological problems.

UNIT IV SAMPLING
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 DESIGN OF EXPERIMENT
Basic principles of experimentation - Analysis of variance-one-way, Two-way Classifications -
Randomized block design, Latin square design - problems.

REFERENCES:
   2008.
5. Arora, P. N. SmeetArora, and Arora, S. “Comprehensive Statistical Methods”. S. Chand &
   Chand & Co., 2004. 61 61 Course Articulation Matrix Course Outcome Statements rogramme
   Outcome (PO) 1 2 3 4 5
UNIT I  FUNDAMENTAL OF TISSUE ENGINEERING  9
Cell cycle – Stem cells – Types, factors influencing stem cells – Mechanical properties of cells and
tissues, cell adhesion – Extracellular matrix – Glycans, laminin, fibronectin, collagen, elastin,
extracellular matrix functions – Signalling – Mechanics and receptors – Ligand diffusion and
binding, trafficking and signal transduction – In vitro cell proliferation.

UNIT II  BIOMATERIALS FOR TISSUE ENGINEERING  9
Introduction to Biomaterials - classification- significance.in tissue engineering based therapies,
Modifications of Biomaterials, Measurement of protein adsorption – Direct and indirect methods,
fibrinogen adsorption – Displaceable and non-displaceable – Changes in protein conformation upon
adsorption – Vroman effect principle to maximize the amount of fibrinogen adsorption – Devices for
tissue engineering transplant cells.

UNIT III  DELIVERY OF MOLECULAR AGENTS AND CELL INTERACTIONS WITH
POLYMERS  9
Molecular agents in tissue engineering – Controlled released of agents – Methods, in time and space
– Future applications of controlled delivery – Microfluidic systems – Microfluidics and microfluidic
devices – Cell interactions – Factors influencing cell interactions – Cell interactions with polymer
surfaces and suspension – Cell interactions with three-dimensional polymer.

UNIT IV  BIOMATERIALS AND CONTROLLED DRUG DELIVERY  9
Biomaterials: Properties of biomaterials ,Surface, bulk, mechanical and biological properties .Natural
and synthetic biodegradable Polymers – Engineered tissues – Skin regeneration – Nerve
regeneration – Liver, cartilage, bone – Biodegradable polymers in drug delivery –Polymeric drug
delivery systems – Applications of biodegradable polymers, Recent advancements of Nanotechnology
based biomaterials in targeted and controlled drug delivery.

UNIT V  BIOPOLYMER- BASED BIOMATERIALS AS SCAFFOLDS AND STEM CELLS  9
Natural polymers – Structural and chemical properties, scaffold processing, mechanical properties
and biodegradability – Biocompatibility and host response – Application of scaffolds in tissue
engineering. Use of stem cells in tissue engineering – Embryonic stem cells, mesenchymal stem cells
(MSC), adult stem cells, markers for detection of stem cells – Risks with the use of stem cells.
Applications of macro, micro and nano sized commercially available biomaterials for stem cell
therapy.

TOTAL: 45 PERIODS

REFERENCES
2003.
UNIT I       INTRODUCTION TO NETWORKS

UNIT II      KINETIC MODELING
Kinetic modelling of biochemical reactions, describing dynamics with ODEs, rate equations, deriving a rate equation, incorporating regulation of enzyme activity by effectors, E-cell platform and erythrocyte modeling

UNIT III     FLUX BALANCE ANALYSIS

UNIT IV      NETWORK MOTIFS AND MODELS
Network motifs, Feed forward loop network motif. Gene circuits, robustness of models, Chemotaxis model, Integration of data from multiple sources: Building genome scale models.

UNIT V       RESOURCES AND SBML
Tools and databases for modeling: Pathway databases KEGG, EMP, Metacyc, Enzyme kinetics database BRENDA, Gene expression databases, Biomodels database, Basics of Systems Biology Markup Language (SBML), SBML editors.

TOTAL: 45 PERIODS

REFERENCES
UNIT I POLYMERS
Polymers used in controlled drug delivery modules – Classification – Advantages and disadvantages of polymers – Polymer Characterisation - Various classes of controlled release systems.

UNIT II SUSTAINED RELEASE FORMULATIONS
Introduction, concept, advantages and disadvantages. Physicochemical and biological properties of drugs relevant to sustained release formulations.

UNIT III TRANSDERMAL DRUG DELIVERY SYSTEMS

UNIT IV TARGETED DRUG DELIVERY SYSTEMS

UNIT V DRUG DELIVERY LARGE MOLECULES
Delivery system for Peptides and Proteins – Delivery of nucleic acids – Antibodies and siRNA.

REFERENCES:
2. Junginger H.E “Drug Targeting and Delivery- concepts in dosage form design” EllisHarwood series in Pharmaceutical Technology

UNIT I NANOSCALE AND NANOBIOTECHNOLOGY
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 III PROPERTIES AND MEASUREMENT 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 nano carriers; 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. COURSE OUTCOMES:

TOTAL: 45 PERIODS

REFERENCES
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

REFERENCES


UNIT I  CLONING AND EXPRESSION OF GENES  

UNIT II  CONSTRUCTION OF DNA LIBRARIES  
UNIT III DNA SEQUENCING
DNA sequencing – Importance, methodology, Chemical & Enzymatic methods, Pyrosequencing, How to sequence a genome? , Short gun sequencing and clone contig approach, Automated sequence, Genome sequencing methods – top down approach, bottom up approach.

UNIT IV PCR AND MUTAGENESIS

UNIT V GENE TRANSFER AND GENE THERAPY

TOTAL : 45 PERIODS

REFERENCES
UNIT I FOUNDATIONS OF PHYSIOLOGY

UNIT II PHYSIOLOGICAL CONCEPTS
Nervous system-Sensory nervous system, Motor nervous system, Higher functions of the nervous system, Synapse, Reflexes, Cerebrospinal fluid, Blood brain and blood CSF barrier. Properties of cardiac muscles, Conducting system of the heart, Pressure changes during cardiac cycles, Capillary circulation, Arterial and venous blood pressure. Gastro intestinal system - General structure of alimentary canal, Gastric secretion, Pancreatic secretion, Gastric motility-digestive peristalsis Gastrointestinal hormones

UNIT III PHYSIOLOGICAL CONCEPTS

UNIT IV DRUG ABSORPTION AND BIOTRANSFORMATION CONCEPTS
Factors influencing enzyme induction and inhibition; Extraction of drugs; Biliary and fecal excretion; Factors effecting drug metabolism; Drug metabolism in fetus and new born. Biotransformation of drugs; Enzymes responsible for bio-transformations; Microsomal and non-microsomal, mechanisms.

UNIT V DRUG METABOLISM - STUDY MODELS
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

REFERENCES
UNIT I  INTRODUCTION TO BIOREACTOR DESIGN AND CONSTRUCTION  9
General requirements Basics of fermentation processes- range and component parts, functions of a fermenter. 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, achievement of aseptic conditions, 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
Overview of batch, continuous and fed batch cultures and comparison between the underlying concepts. 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 ANIMAL AND PLANT CELL CULTIVATION SYSTEMS FOR THERAPEUTIC PROTEINS  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. 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. Industrial applications of the bioreactors as cell cultivation systems.

UNIT IV  DOWNSTREAM PROCESSING AND SEPARATION TECHNIQUES  9
Characteristics of biological materials: Recovery and purification of fermentation products; pretreatment methods; Separation of cell mass: centrifugation, clarification and filtration; Different methods of cell disruption; Solid shear method and liquid shear method; Different concentration methods: evaporation, distillation, crystallization, evaporation, SCFE, solvent extraction, phase separation, drying etc., whole broth extraction, protein precipitation, SCP, extraction; adsorption; Modern techniques: Electrophoresis; Chromatographic methods; Membrane processes- Ultrafiltration; Reverse osmosis; Cross flow filtration; Microfiltration; Isoelectric focusing; Affinity based separations. Advantages and disadvantages of the above methods.

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 and process optimization etc.

TOTAL: 45 PERIODS

REFERENCES
AUDIT COURSES

AX4091 ENGLISH FOR RESEARCH PAPER WRITING L T P C 2 0 0 0

COURSE OBJECTIVES
- Teach how to improve writing skills and level of readability
- Tell about what to write in each section
- Summarize the skills needed when writing a Title
- Infer the skills needed when writing the Conclusion
- Ensure the quality of paper at very first-time submission

UNIT I INTRODUCTION TO RESEARCH PAPER WRITING 6
Planning and Preparation, Word Order, Breaking up long sentences, Structuring Paragraphs and Sentences, Being Concise and Removing Redundancy, Avoiding Ambiguity and Vagueness

UNIT II PRESENTATION SKILLS 6

UNIT III TITLE WRITING SKILLS 6
Key skills are needed when writing a Title, key skills are needed when writing an Abstract, key skills are needed when writing an Introduction, skills needed when writing a Review of the Literature, Methods, Results, Discussion, Conclusions, The Final Check

UNIT IV RESULT WRITING SKILLS 6
Skills are needed when writing the Methods, skills needed when writing the Results, skills are needed when writing the Discussion, skills are needed when writing the Conclusions

UNIT V VERIFICATION SKILLS 6
Useful phrases, checking Plagiarism, how to ensure paper is as good as it could possibly be the first-time submission

TOTAL: 30 PERIODS

COURSE OUTCOMES:
At the end of the course, students will be able to
CO1 – Understand that how to improve your writing skills and level of readability
CO2 – Learn about what to write in each section
CO3 – Understand the skills needed when writing a Title
CO4 – Understand the skills needed when writing the Conclusion
CO5 – Ensure the good quality of paper at very first-time submission

REFERENCES:
COURSE OBJECTIVES:
- Summarize basics of disaster
- Explain a critical understanding of key concepts in disaster risk reduction and humanitarian response.
- Illustrate disaster risk reduction and humanitarian response policy and practice from multiple perspectives.
- Describe an understanding of standards of humanitarian response and practical relevance in specific types of disasters and conflict situations.
- Develop the strengths and weaknesses of disaster management approaches

UNIT I INTRODUCTION
Disaster: Definition, Factors and Significance; Difference between Hazard And Disaster; Natural and Manmade Disasters: Difference, Nature, Types and Magnitude.

UNIT II REPERCUSSIONS OF DISASTERS AND HAZARDS

UNIT III DISASTER PRONE AREAS IN INDIA
Study of Seismic Zones; Areas Prone To Floods and Droughts, Landslides And Avalanches; Areas Prone To Cyclonic and Coastal Hazards with Special Reference To Tsunami; Post-Disaster Diseases and Epidemics.

UNIT IV DISASTER PREPAREDNESS AND MANAGEMENT
Preparedness: Monitoring Of Phenomena Triggering a Disaster or Hazard; Evaluation of Risk: Application of Remote Sensing, Data from Meteorological And Other Agencies, Media Reports: Governmental and Community Preparedness.

UNIT V RISK ASSESSMENT

COURSE OUTCOMES:
At the end of the course, students will be able to
CO1 Ability to summarize basics of disaster
CO2 Ability to explain a critical understanding of key concepts in disaster risk reduction and humanitarian response.
CO3 Ability to illustrate disaster risk reduction and humanitarian response policy and practice from multiple perspectives.
CO4 Ability to describe an understanding of standards of humanitarian response and practical relevance in specific types of disasters and conflict situations.

CO5 Ability to develop the strengths and weaknesses of disaster management approaches

REFERENCES:

AX4093 CONSTITUTION OF INDIA

COURSE OBJECTIVES:
Students will be able to:
- Understand the premises informing the twin themes of liberty and freedom from a civil rights perspective.
- To address the growth of Indian opinion regarding modern Indian intellectuals’ constitutional role and entitlement to civil and economic rights as well as the emergence of Indian nationalism.
- To address the role of socialism in India after the commencement of the Bolshevik Revolution in 1917 and its impact on the initial drafting of the Indian Constitution.

UNIT I HISTORY OF MAKING OF THE INDIAN CONSTITUTION
History, Drafting Committee, (Composition & Working)

UNIT II PHILOSOPHY OF THE INDIAN CONSTITUTION
Preamble, Salient Features

UNIT III CONTOURS OF CONSTITUTIONAL RIGHTS AND DUTIES

UNIT IV ORGANS OF GOVERNANCE
Parliament, Composition, Qualifications and Disqualifications, Powers and Functions, Executive, President, Governor, Council of Ministers, Judiciary, Appointment and Transfer of Judges, Qualifications, Powers and Functions.

UNIT V LOCAL ADMINISTRATION
UNIT VI ELECTION COMMISSION
Election Commission: Role and Functioning, Chief Election Commissioner and Election Commissioners - Institute and Bodies for the welfare of SC/ST/OBC and women.

TOTAL: 30 PERIODS

COURSE OUTCOMES:
Students will be able to:
- Discuss the growth of the demand for civil rights in India for the bulk of Indians before the arrival of Gandhi in Indian politics.
- Discuss the intellectual origins of the framework of argument that informed the conceptualization of social reforms leading to revolution in India.
- Discuss the circumstances surrounding the foundation of the Congress Socialist Party[CSP] under the leadership of Jawaharlal Nehru and the eventual failure of the proposal of direct elections through adult suffrage in the Indian Constitution.
- Discuss the passage of the Hindu Code Bill of 1956.

SUGGESTED READING
1. The Constitution of India, 1950(Bare Act), Government Publication.

AX4094 தொடர்புத் தொகுப்பு

UNIT I கருத்துக்கட்டம்
1. கருத்துக்கட்டம் தொடர்புத் தொகுப்பு
   - சுருக்கல், தொகுதி, பராமரிப்பு
2. ஆக்குதற்போல(82)
   - விஷயக்குறிச்சி ஆராய்ச்சி
3. பொருளாயின் தொடர்புபத்தால்
4. புது மாணவர்(95,195)
   - பொருளாயின் தொடர்புபத்தால்

UNIT II அறநூல்கள்
1. அறநூல்களின் தொடர்புபத்தால்
   - முதல் பக்தநூல், தமிழ், தமிழ் வருத்தம்
2. பாதுகாப்பியங்கள் - தொடர்புபத்தால்
   - தக்காடி, தொடர்புபத்தால், திருக்காடி, அரங்கத்தால்
   (சமசுமதி தொடர்புபத்தால் போன்றால்)

UNIT III பிரசுராதா பண்புத் தொகுதிகள்
1. குறிப்பிட்டு பொருளாயின்
UNIT IV
அருள்நநறித்தமிழ்
1. தமிழ்மரவர்புப்பலம்
2. தமிழ்மூகப் கவில்லக்கியம்மணிபமககல
3. நற்றிகண
4. திருமந்திரம் (617, 618)
5. தர்மதொகலயநிறுவியவள்ளலொர்
6. புறநொனூறு -சிறுவபனவள்ளலொனொன்

UNIT V
நவீனதமிழ்இலக்கியம்
1. உகரநகடத்தமிழ்
2. முதொயவிடுதகலயும்
3. தமிழ்இகணயகல்விக்கழகம் (Tamil Virtual University)
4. தமிழ்விக்கிப்பீடியொ
5. தமிழ்ககலக்களஞ்சியம் -தமிழ்வளர்சித்துகற( thamilvalarchithurai.com)
6. அறிவியல்களஞ்சியம் -தமிழ்ப்பல்ககலக்கழகம்,தஞ் ஊவூர்

TOTAL: 30 PERIODS